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DID THE EMERGENCY USE AUTHORIZATION APPROVAL PROCESS FOR COVID-19 TESTING UNDER THE FOOD, DRUG & COSMETIC ACT ADEQUATELY ADDRESS THE PANDEMIC DURING THE 1ST QUARTER OF 2020?

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ABSTRACT

The SARS-CoV-2/COVID-19 pandemic has led to 4.55 million deaths worldwide and 219 million cases. The USA has approximately 673,000 total fatalities and approximately 42 million total cases with 165,000 cases per day. In the first quarter of the year in 2020 which was the beginning stages of the pandemic, the uncertainty regarding testing and diagnosis of COVID-19 was disorganized and confusing. The use of the Emergency Use Act ("EUA") allowed immediate access to testing with the use of the only CDC-approved real-time polymerase chain reaction nasopharyngeal ("RT-PCR") testing for COVID 19. At the end of the 1st quarter in 2020 less than 50 organizations had EUA approval for COVID 19 testing and there were approximately 936 deaths and 503 cases in the USA with 3299 deaths worldwide and 2882 daily new cases. To date, there are over 600,000 deaths in the USA. The inadequate use of private Clinical Laboratory Improvement Amendments ("CLIA") certified state and government lab testing centers in the 1st quarter of the pandemic in 2020 led to the following: inability to test and collect data, inability to identify and treat COVID positive patients, extreme unmanageable number of hospitalizations nationwide with countless deaths. The inability to meet the supply and demand led to the following deficiencies: inadequate testing, supplies with ventilators, PPE, staffing, poorly regulated hospitals, lack of statesmanship and governing of states, inadequate treatment of ill and underserved patients, testing patients without informed consent, inability to retrieve and report test results ultimately producing a quarantine with global economic disaster. The ability of the Federal Government to enact statutes such as the Food, Drug & Cosmetic Act ("FD&C") and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 ("PAHPRA") amendment within the pharmaceutical healthcare sector to protect the public is paramount for our medical and financial survival. The lack of executive leadership and anticipation of a public health emergency ("PHE") on all levels of government led to a quagmire. The COVID 19 pandemic has revealed serious issues and deficiencies in how the USA diagnoses, treats and evaluates patients. The first quarter of 2020 revealed that we were not prepared for a Global Pandemic and as a result, there were catastrophic fatalities. The current policy analysis details the complexity in obtaining an EUA, and the detailed policy required to address this issue. The detailed recommendations included in this policy analysis are a starting point to produce an in-depth evaluation of Emergency Preparedness which may assist in the treatment of the next pandemic.

INTRODUCTION

On January 31st 2020, the Dept. of HHS ("Health and Human Services") declared a PHE pursuant to 21 U.S.C. §564, 564A, 564B of the FD&C[1] as amended or added by the PAHPRA[2] due to COVID-19/SARS CoV-2. As a result of this pandemic, policies were being developed for testing of this lethal virus and on March 13th, 2020, the President of the USA declared the pandemic to be a National Emergency. These policies for diagnostic testing of COVID 19 were developed hastily and emergently which allowed for immediate testing of the virus but lead to confusion regarding the interpretation, validation, distribution, and efficiency of testing with possible exposure and fatalities. The FDA's primary responsibility is to protect public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. These medical products are referred to as "medical countermeasures" ("MCM") which include vaccines, blood products, biological therapeutics, and devices such as in vitro diagnostic and personal protective equipment. This guidance finalizes the draft guidance, *Emergency Use Authorization of Medical Products and Related Authorities (April 2016)*, and replaces the following two guidance documents, *Emergency Use Authorization of Medical Products* (July 2007) and *Emergency Use Authorization Questions and Answers* (April 2009). Id. 1. The FDA has policies that prevent laboratories from developing and utilizing tests for COVID 19 testing without prior EUA. Under sections 564, 564A, and 564B the Secretary of HHS acting under the FD&C Act has delegated EUA approval process to the FDA Commissioner pursuant to section 564A(e) was delegated to the Director of the CDC for EUA approval. Id. The EUA requires the submission of a well-organized study with complete analysis and assessment, with statistical data regarding safety and effectiveness, along with the interpretation of the findings including interim reports with source data for clinical and nonclinical laboratories, and any animal studies that may contribute to assessing the effectiveness of the product to treat the underlying disease[3] (COVID 19). The EUA also requires that studies were conducted with Good Laboratory Practice for Nonclinical Laboratory Studies regulation ("GLP"),[4] and in compliance with applicable Good Clinical Practices and standards.[5] The FDA EUA approval process involves multiple stakeholders, such as industry and government sponsors (Federal, State, local, Tribal or territorial entities), public health entities involved with the public health emergencies/responses, military, county entities with the ability to deliver, distribute, hold or dispense medical products during an

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[1] This guidance was prepared by the Office of Counterterrorism and Emerging Threats (OCET) in cooperation with the Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), and Center for Drug Evaluation and Research (CDER).

[2] Public Law 113-5, Section 3088 of the 21st Century Cures Act, signed into law by the President on December 13, 2016, amends sections564, 564A, and 564B of the FD&C Act to add new authorities to: (1)authorize emergency use of unapproved animal drugs, (2) make applicable other emergency use authorities(e.g., to issue emergency dispensing orders, waive compliance with current good manufacturing practices(CGMPs), make available Centers for Disease Control and Prevention (CDC) emergency use instructions, and extend expiration dates) to approved animal drugs, and (3) allow unapproved animal drugs to be held for emergency use. While much of what is described in this guidance will apply to these new authorities, this guidance does not by its terms reference them; FDA asks anyone interested in utilizing these authorities to contact FDA directly to discuss how to proceed. FDA plans to review these new authorities and address any new procedural issues raised as we develop more experience with these new authorities.

[3] 21 CFR 314.600 (drugs) or 21 CFR 601.90 (biological products); see also Product Development Under the Animal Rule–Guidance for Industry (October 27, 2015), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM399217.pdf.

[4] 21 CFR Part 58.

[5] http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.

emergency, and most importantly, American citizens. Id. As of 11/29/21, COVID 19 led to the death of 762,000 Americans, with 47 million cases domestically and 5.1 million/253 million worldwide[6] respectively. The development of a material threat to the health and security of the United States citizens, territories, and those living abroad requires expertise from diverse stakeholders that may have had an effect on the dispensing and development of COVID 19 testing in the first quarter of the pandemic in 2020. This document will analyze the controversy with the pros and cons associated with the FDA EUA process of laboratory diagnostic testing ("LDT") of COVID 19 during the 1st quarter of the 2020 COVID 19 pandemic beginning with the stakeholders. The stakeholders involved have political, economic, social, legal, and practical reasons for adequate evaluation and diagnosis/testing of COVID 19 such as is represented in the following table:

Stakeholders	**Executive Branch/Agencies of the Federal Govt.**	**Industry Vendors/Lab Testing Centers**	**States/Local Govt.**	**American Citizens**
Political	During the first quarter of the 2020 Pandemic, the Trump administration's Job rating approval was 43%[7]; 93% job approval of Trump by Republicans in the first quarter 2020 COVID pandemic. The possibility of losing political support by not acknowledging the severity and global magnitude of the COVID 19 Virus led to nationwide confusion.	CARES Act, March 27, 2020, required commercial health insurance plans to cover COVID 19 tests without cost-sharing but does not prevent out-of-network balance billing and increased costs to consumers[8] with political consequences.	The FD&C Act preempted state and local govt. management, diagnosis, and testing of the COVID 19 Pandemic; states were relying on the Federal Govt. to provide guidance for diagnosis and treatment of COVID 19 thus producing contradictory GOP and Democratic Emergency responses across the states with an inability to provide adequate testing supplies or centers.	Development of state and national instability due to the inability of elected leaders to develop Emergency Preparedness Plans to manage the pandemic leading to political violence, conflict, city/county curfews, unemployment, and confusion regarding the treatment and testing of COVID 19.

[6] https://www.nytimes.com/interactive/2021/us/covid-cases.html
[7] https://news.gallup.com/poll/208778/trump-job-approval-first-quarter-lowest-points.aspx
[8] https://www.congress.gov/bill/116th-congress/house

Stakeholders	Executive Branch/Agencies of the Federal Govt.	Industry Vendors/Lab Testing Centers	States/Local Govt.	American Citizens
Legal	The executive team developed a panel of experts to provide leading experts (CDC, NIH, world-renowned clinicians, and policy experts) guidance for COVID 19 testing and transmission thus producing contradictory, misleading information to the public daily.	Limited Authorized testing only by large national chains (LabCorp®, Quest Diagnostics, small facilities to perform only CDC RT-PCR not Serology/Antibody or Antigen testing during first quarter 2020.[9]	Inadequate crisis management and policy responses produce economic, social, and fiscal disarray with many economies not recovering until 2022.[10]	Rapidly changing CDC guidelines led to uncertainty regarding appropriate mode of testing with RT-PCR, Serology (antibody), or Antigen testing for COVID with implications for quarantine, return to work, or hospitalization impacting first responders (e.g., MD, RN, Correctional Officers, Fire Fighters, etc.
Social	As a result of the high number of GOP supporters, the inadequate messaging regarding the severity of and policies related to the COVID 19 pandemic, it did not undergo requisite intense bipartisan scrutiny with failure of anticipation of the required testing nationally.	Insufficient tests for citizens with extremely long waiting times for testing, results and increased risk of exposure due to crowded testing centers and confusion regarding wearing masks, drawing blood, physical, social distancing for testing due to risk of exposure or transmission of COVID 19.	Large disparities in HC, housing, education, public services, job loss affecting poor, less educated, non-skilled workers, and the need for govt. subsidies to support the local economy.	Extreme social isolation from family, friends, co-workers, loss of recreational activities, and employment, depression, anxiety, domestic violence and anger, food shortages, confusion regarding - wearing, travel, mode of transmission (resp. v. airborne).

[9] https://www.brookings.edu/blog/usc-brookings-schae

[10] OECD (2020), *OECD Economic Outlook, Interim Report September 2020*, OECD Publishing, Paris, https://dx.doi.org/10.1787/34ffc900-en.

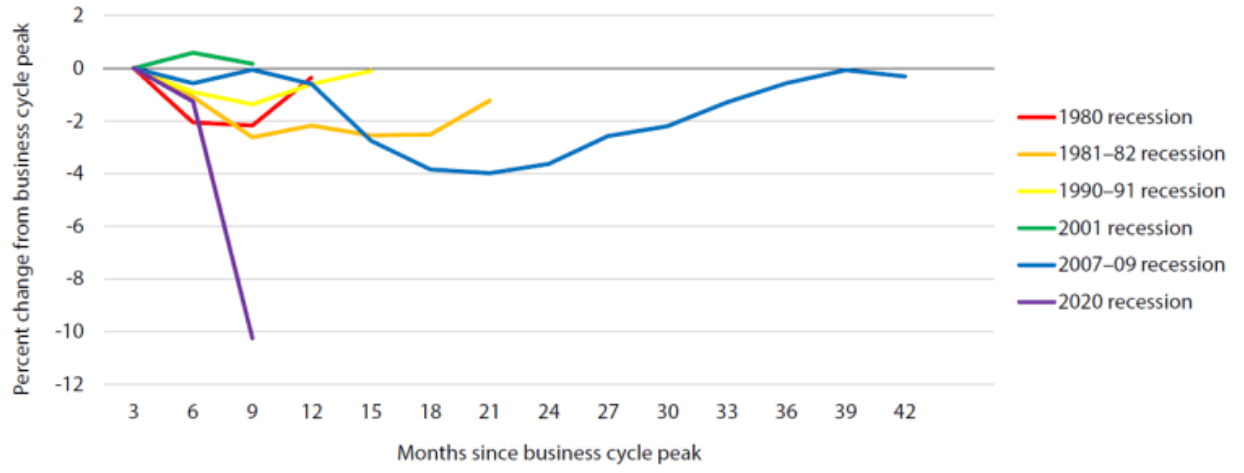
Stakeholders	Executive Branch/Agencies of the Federal Govt.	Industry Vendors/Lab Testing Centers	States/Local Govt.	American Citizens
Economic	President Trump's approval rating among small business owners hits an all-time high of 64%, for the first quarter of 2020[11]; thus, national discussions regarding the possibility of unemployment, recession, quarantine or actual costs to produce and dispense COVID 19 were not prioritized.	COVID-19–related job losses wiped out 113 straight months of job growth, with total nonfarm employment falling by 20.5 million jobs in April (BLS 2020b; authors' calculations). The COVID-19 pandemic and associated economic shutdown created a crisis for all workers, but the impact was greater for women, non-white workers, lower-wage earners, and those with less education (Stevenson 2020).[12]	Small business revenue fell 20%, Chapter 11 Bankruptcies increased nationally, reducing new businesses. Layoffs and shutdowns accounted for the majority of hours worked. The number of labor force participants not at work quadrupled. The personal savings rate reached its highest record. The number of people not in the labor force who wanted a job increased by 4.5 million. Twenty-six states had greater than 1 out of 5 households behind in their rent, and the rate of food insecurity doubled for households with children.[13]	GDP fell at an annualized rate of 4.8% first quarter of 2020[14] concentrated in personal consumption of durable goods and services, exports, and business investments with greater than 20% reductions spending for automobiles, clothing, recreational services, transportation, and food services, the unemployment rate rose to 14%, unemployment claims exceeded 3 million per week since March 21 and peaked at 6.9 million by March 28, 2020. Id.

[11] https://www.cnbc.com/2020/02/20/trumps-approval
[12] https://www.brookings.edu/research/ten-facts-about-covid-19-and-the-u-s-economy/
[13] OECD (2020), *OECD Economic Outlook, Interim Report September 2020*, OECD Publishing, Paris, https://dx.doi.org/10.1787/34ffc900-en.
[14] https://crsreports.congress.gov/product/pdf/IN/IN11388

Stakeholders	Executive Branch/Agencies of the Federal Govt.	Industry Vendors/Lab Testing Centers	States/Local Govt.	American Citizens
Practical	These positive responses led to decisions to downplay the severity of the pandemic to maintain political support	The economic losses due to insufficient testing and diagnosis lead to a severe recession (see graph below); Historically GDP had never experienced a drop greater than 3% quarterly since record-keeping began in 1947[15] with its steepest GDP drop of 9.1% by the second quarter of 2020.[16]	High unemployment, inadequate contradictory messaging of PHE, treatment, and testing COVID 19 with national uncertainty of life outcomes.	The effect of the pandemic led to a national recession with high unemployment and inadequate messaging regarding testing, diagnosing, treating, quarantining of individuals who test positive or contract the disease with uncertain financial, political, and health outcomes.

FIGURE C.

Percent Change in GDP Relative to Business Cycle Peak, by Business Cycle



Source: U.S. Bureau of Economic Analysis (BEA) 1980–2020; NBER n.d.; authors' calculations.
Note: The figure shows the quarterly percent change in real Gross Domestic Product (GDP) from the peak of a business cycle until GDP returns to the level of the previous business cycle peak. GDP is in billions of chained 2012 dollars.

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[15] Routley 2020
[16] https://www.brookings.edu/research/ten-facts-about-covid-19-and-the-u-s-econ

Pros:

- The [new] CDC EUA approval process begins after, the HHS Secretary determines the following circumstances: either the DOD (Department of Defense), DHS (Department of Homeland Security), DHHS (Department of Health and Human Services) issues a determination of either a military emergency, domestic emergency, public health emergency, or a material threat, respectively, in order to declare an emergency by the FDA under section §564 (b)(1) (c) of the Federal Food, Drug and Cosmetic Act (FD&C)[17]. This process allows multidisciplinary subject matter experts to immediately initiate the EUA (Director of CDC, Director of NIH, ASPR (Assistant Secretary for Preparedness and Response and **emergent** use of an unapproved or approved product provided statutory criteria are met.

- FD&C Act allows the Secretary of HHS to grant EUA of unapproved medical products or uses of products in an emergency to prevent life-threatening diseases caused by Chemical, Biological, Radiation, Nuclear ("CBRN") agents **when there are no adequate or approved alternatives**.

- In 2016, the President of the USA under sections §564, 564A and 564B of the FD&C Act amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) enhanced the FDA's authority to support emergency preparedness, allowed the government pre-positioning of MCMs (medical countermeasures) without FDA approval for availability in a PHE, development and dispensing of medical products for use in Emergencies such as: drugs, antivirals, antidotes, vaccines and devices (PPE, in-vitro testing) and allowed the CDC to create EUI (emergency use of instructions) concerning FDA approved conditions of use for eligible products with use of interstate commerce for transport or stockpiling without violation of the FD&C Act.

- EUA approval of products or testing occurs when there is a **serious or life-threatening disease, or a product "may be effective"** to prevent or treat life-threatening illness, potential benefits outweigh the risks (Risks/Benefits Analysis), and there are no adequate or approved alternatives.

- FDA requirement of the pre-EUA sponsor (private business, government) submission to facilitate more complete evaluation prior to implementation in addition to **clinical trials** conducted during the EUA period to ensure quality data collection and evaluation prior to use of the product.

- §564, 564B of the FD&C Act allows issuance of an EUA before a CBRN emergency (**including if the emergency is occurring in another country** but not yet in the U.S.).

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[17] U.S. Department of Health and Human Services, Delegation of Authority of section 564A(e) of the Federal Food, Drug, and Cosmetic Act, December 16, 2013, see http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/UCM510446.pdf.H

- FDA may issue EUAs expeditiously (e.g., **within hours or days**) when circumstances warrant, and adequate information has been made available for prior review through the pre-EUA process.

- The FDA recommends that a request for an EUA include a "Fact Sheet"[18] for recipients that includes essential information about the product, dosing, contraindications/warnings, contact **information for reporting adverse events, risks, and benefits**[19] with an option to accept or refuse the EUA written for the most basic level of training and languages for HCP.

- FDA and CDC have a Memorandum of Understanding ("MOU") stating the CDC may create, issue, and disseminate special emergency use instructions (EUI) concerning an eligible MCMs approved, licensed, or cleared conditions of use (section 564A(e)).[20]

- 02/04/2020 CDC received the only EUA with FDA approval to test for COVID-19 with RT-PCR.

Cons:

- EUA evaluation approval process failure with limited LDT's by only allowing/granting the CDC to perform EUA testing for COVID 19 on February 4th, 2020 for the entire country (USA).

- The FDA's published document "Emergency Use Authorization of Medical Products and Related Authorities", http://fda.gov/medicalcountermeasures [21], for EUA approval does not establish legally enforceable responsibilities but offer the agency's current thinking on a topic and should be viewed only as recommendations unless specific regulatory or statutory requirements are cited.

- EUA tort liability from claims involving testing, distribution, and administration protections afforded under the Public Readiness and Emergency Preparedness ("PREPARE") Act, 42 U.S.C. 247d-6d which may lead to the urgent release of poorly validated diagnostic tests by manufacturers due to federal relief/immunity.

- FDA acceptance of data for EUA approval in the developmental stages, controlled clinical trials but also bench testing with inconclusive results and possible public safety issues.

- Informed consent is not required for use of or administration of an EUA product 21 U.S.C.§ 564(e)(1)(A)(ii)) but the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstance which may lead to patients giving consent for poorly validated tests as a result of the PHE and possibility of death.

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[18]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM399217.pdf.
[19] 21 USC §564(e)(1)(A)(iii)),
[20]http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current
[21]http://fda.gov/medicalcountermeasures

- Pre-EUA Activities and Submissions for investigational new drugs/investigational device exemption (IND/IDE") of the Center for Drug Evaluation and Research/Center for Biologic Evaluation ("CDER/CBER")[22] and Research by licensed prescribers (CDC acting solely as nation's doctor in recommending unapproved products) is a series of preliminary actions evaluated on a case by case analysis that may take up 30 days and cost from tens of thousands to even millions of dollars with average cost of $40,000,[23] thus limiting rapid use of diverse Centers for Medicare and Medicaid Services ("CMS") CLIA certified diagnostic laboratories applicant opinions for product evaluation, development and dispensing during the COVID pandemic.

- Inadequately prepared pre-existing official government response plans led to distribution failures and the use of the CGMP Waiver[24] Section 564A(c) of the FD&C Act (Current Good Manufacturing Practice) which allows use of products without an EUA due to exigencies and demands of CBRN (e.g., COVID 19) after consultation with the CDC, govt. officials in adjacent jurisdictions thus producing an extreme number of fatalities.

- The FDA delayed publishing and approval of EUA in the Federal Register leading to stakeholder (industry vendors/laboratories) uncertainty regarding approval for testing and product production/scalability for demand.

- Failure of early initiation of Section 564 (m) of the FD&C Act allowing EUA for a diagnostic device (Nasal PCR/Serology Antibody testing) to be performed at Point of Care or LDT of complex tests which are certified via CLIA during a PHE when the benefits outweigh the risks thus leading to further delays in diagnostic testing.

- Inadequate use of Section 564A(d) of the FD&C Act allowing states provisions to facilitate emergency dispensing of eligible MCM's to: Assistant Secretary of Preparedness Response ("ASPR"), CDC, DHS, DOD, regional authorities during the PHE and receive protection under the Act.

- Insufficient use of the States' Attorney General to interpret states' law regarding stockpiling, dispensing, and local stakeholders' responsibility during a PHE.

- The FDA believes the terms and conditions for issuance of EUA under section 564 FD&C Act preempts state, local and common-laws requirements imposed for medical products in which the EUA was issued notwithstanding the states continued to have uncertainty regarding which test to use Serology (antibody testing) v. RT-PCR due to repeated

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[22] The Pre-Submission Program and Meetings with Food and Drug Administration Staff(February 2014) at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.

[23] https://repository.upenn.edu/cgi/viewcontent

[24] http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#doxyhttp://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#cipro.

changing of federal policies by CDC and inconsistencies with product (COVID test) availability.

The result of the FD&C Act amendments led to nationwide controversy regarding the diagnosis, treatment, and deployment of COVID 19 testing during the first quarter of the pandemic in 2020 thus several **options** should be considered for corrective actions such as amendment of the current FD&C Act, obtaining stakeholders opinions' with development of a multidisciplinary subcommittee with specific elected officials, Healthcare industry representatives/leaders for LDTs, public representatives, or no changes to the Act. The results of this subcommittee should be presented to the Secretary of HHS to adequately inform the CDC of possible alternatives during the PHE. Options are listed below with comparisons for Cost/Benefit, Timeliness, Targeted Impact, and Political Feasibility:

Options	**Amend the FD&C Act**	**Obtain Multi-discipline stakeholder opinion**	**No changes to the FD&C Act**	**Pros**	**Cons**	**Cost/ Benefit**	**Timeliness**	**Targeted impact**	**Political Feasibility**
[new] CDC EUA approval process begins after, the HHS Secretary determines either a military emergency, domestic emergency, public health emergency, or a material threat.			No change	Rapid declaration of PHE with the issuance of EUA to identify the CBRN threat by multiple stakeholder involvement such as DHS, DOD, DHHS, and CDC.	Requires one of several agency stakeholders to identify and present the PHE to the HHS Secretary thus may lead to a delayed identification and agreement on the CBRN Threat and hastily approval of EUA.	Low	Yes	Yes	High
EUA of unapproved medical products or uses of products in an emergency to prevent life-threatening diseases caused by CBRN agents **when there are no adequate or approved alternatives.**			No change	Rapid deployment when no other alternatives are available.	Potentially leading to incomplete peer review of medical products with legal exposure and adverse effects.	High	High	Yes	Yes

Options	**Amend the FD&C Act**	**Obtain Multi-discipline stakeholder opinion**	**No changes to the FD&C Act**	**Pros**	**Cons**	**Cost/ Benefit**	**Timeliness**	**Targeted impact**	**Political Feasibility**
PAHPRA enhanced FDA authority to support emergency preparedness, allowed government pre-positioning of MCMs without FDA approval for availability in a PHE, development and dispensing of medical products for use in Emergencies.			No change	Allows Federal Govt. to obtain MCMs' for stockpile and use during PHE.	Inadequate supply and extremely high demand for testing nationally.	High	No	Yes	Yes
EUA approval of products or testing when there is a **serious or life-threatening disease, or a product "may be effective**			No changes	Allows for the immediate release of effective products when the benefits outweigh the risks.	Inadequate long-term data and peer review with possible legal exposure.	Low	Yes	Yes	Yes

Options	**Amend the FD&C Act**	**Obtain Multi-discipline stakeholder opinion**	**No changes to the FD&C Act**	**Pros**	**Cons**	**Cost/ Benefit**	**Timeliness**	**Targeted impact**	**Political Feasibility**
FDA requirement of pre-EUA sponsor (private business, government) submission to facilitate more complete evaluation prior to implementation in addition to **clinical trials.**			No changes	Facilitates a safe screening process with a sponsor to ensure quality data collection during the EUA submission process.	Identification of a sponsor in the industry with local/state stakeholders possibly producing competition and elimination of qualified applicants.	High	No	Yes	Yes
§564, 564B of the FD&C Act allows issuance of an EUA before a CBRN emergency (**including if the emergency is occurring in another country** but not yet in the U.S.			No change	Early Identification of the CBRN threat (COVID 19) in the USA or another country allows for the rapid deployment of Emergency Preparedness, and allocation of resources for a potential outbreak.	Foreign countries may delay or not cooperate and release data; insufficient domestic resources for early identification of CBRN.	Low	Yes	Yes	Yes

Options	Amend the FD&C Act	Obtain Multi-discipline stakeholder opinion	No changes to the FD&C Act	Pros	Cons	Cost/ Benefit	Timeliness	Targeted impact	Political Feasibility
FDA may issue EUAs expeditiously (e.g., **within hours or days**) when circumstances warrant.			No change	Immediate use of EUA after identification of CBRN threat with ability to potentially save lives.	Only requires one agency (e.g., DOD, DHS, DHHS) to determine a CBRN threat with possible hastily release of EUA.	Low	Yes	Yes	Yes
EUA "Fact Sheet"[25] for recipients that includes essential information about the product, dosing, contraindications, warnings, contact **information for reporting adverse events, risks, and benefits.**			No change	Informs recipients of risk of adverse events in various basic languages thus reducing risk and giving the option to refuse.	Educational level and language may be barriers to understanding the product warnings and contraindication.	Low	Yes	Yes	Yes

[25]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM399217.pdf.

Options	Amend the FD&C Act	Obtain Multi-discipline stakeholder opinion	No changes to the FD&C Act	Pros	Cons	Cost/ Benefit	Timeliness	Targeted impact	Political Feasibility
FDA and CDC MOU stating the CDC may create, issue, and disseminate special EUIs concerning eligible MCMs.		Refer to subcommittee for opinion for appropriate dissemination to states.		Allows CDC to create large-scale documents and immediately issue them to states for guidance and treatment.	Incomplete data collection may produce conflicting testing and treatment protocols with an increased risk of exposure to CNRN threats.	Low	Yes	Yes	Yes
Allowing **only** the CDC to perform EUA testing for COVID 19 on February 4th, 2020 for the entire country (USA).		Refer to subcommittee for appropriate industry involvement.		The FD&C Amendment allows CDC (The nation's doctor) under the direction of Secretary HHS is allowed to immediately address CBRN Threats (COVID 19) and provide testing for US citizens.	The scope and magnitude of the COVID Pandemic were unclear thus leading to an insufficient number of tests and possible disease transmission and exposure.	High	Yes	Yes	Yes

Options	Amend the FD&C Act	Obtain Multi-discipline stakeholder opinion	No changes to the FD&C Act	Pros	Cons	Cost/ Benefit	Timeliness	Targeted impact	Political Feasibility
EUA approval does not establish legally enforceable responsibilities but offers the agency's current thinking on a topic and should be viewed only as recommendations unless specific regulatory or statutory requirements are cited.	Requires amendment to establish clearly defined legal responsibilities of a federal agency (FDA).			The FDA provides recommendations regarding the regulatory process for guidance as statutory requirements are evolving during the pandemic.	Insufficient explanations of recommendations for testing thus leading to states/local govt. using various MCMs such as Antibody, Antigen, and RT-PCR to treat local citizens.	Low	High	Yes	No
EUA tort liability from claims involving testing, distribution and administration protections afforded under the PREP Act, 42 U.S.C. 247d-6d.		Refer to subcommittee for development of appropriate-ness for statutory limits to damages related to vendor relief under the EUA.		Encourages the Federal Govt. with CDC and Industry vendors to perform research and release a product (COVID 19) test) in the peak of the pandemic.	May lead to the release of poorly validated tests with long-term adverse consequences with limited liability.	High	Yes	Yes	Yes

Options	Amend the FD&C Act	Obtain Multi-discipline stakeholder opinion	No changes to the FD&C Act	Pros	Cons	Cost/ Benefit	Timeliness	Targeted impact	Political Feasibility
FDA acceptance of data for EUA approval in the developmental stages controlled clinical trials but also bench testing with inconclusive results and possible public safety issues.		Refer to subcommittee for industry opinions and data evaluation.		Allows release of potentially lifesaving tests in the early stages.	Inconclusive results could be harmful with long-term effects.	Low	Yes	Yes	Yes
Informed consent is not required for use of or administration of an EUA product 21 U.S.C.§ 564(e)(1)(A)(ii)) but the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstance.			No change	Immediate use of an approved EUA after evaluation thru the Pre-EUA submission.	Language and educational barriers may discourage the extent to which practicable discussions can occur regarding the EUA testing.	Low	Yes	Yes	Yes

Options	Amend the FD&C Act	Obtain Multi-discipline stakeholder opinion	No changes to the FD&C Act	Pros	Cons	Cost/ Benefit	Timeliness	Targeted impact	Political Feasibility
Pre-EUA Activities and Submissions for IND/IDE of CDER/CBER[26] evaluated on a case-by-case analysis that may take up 30 days and cost from tens of thousands to even millions of dollars with an average cost of $40,000.[27]		Refer to sub-committee for appropriate-ness and cost evaluation including both positive and negative externalities.		Evaluation on a case-by-case analysis allows thorough evaluation of the request for the IND/IDE and protects the public from poorly designed and potentially hazardous products.	The case-by-case analysis may be insufficient in a Global Pandemic thus requiring multiple industry leaders to produce and request EUA approval; High costs may limit competition and discourage potential LDT's from pursuing EUA approval.	High	Yes	Yes	Yes

[26] The Pre-Submission Program and Meetings with Food and Drug Administration Staff(February 2014) at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.

[27] https://repository.upenn.edu/cgi/viewcontent

Options	Amend the FD&C Act	Obtain Multi-discipline stakeholder opinion	No changes to the FD&C Act	Pros	Cons	Cost/ Benefit	Timeliness	Targeted impact	Political Feasibility
CGMP Waiver[28] Section 564A(c) of the FD&C Act (CGMP) allows use of products without an EUA due to exigencies and of CBRN.	demands		No change	Allows for use of CGMP without EUA approval in urgent/ emergent scenarios after consultation with CDC, govt. officials providing immediate treatment and testing of US citizens. .	Inadequate evaluation of CGMP by stakeholders may lead to a high number of fatalities if poorly validated products are used without undergoing the formal EUA screening process.	High	Yes	Yes	Yes
FDA publishing and approval of EUA in the Federal Register	Requires amendment with statutory time for reporting for product availability.			Allows public and vendor notification of approved EUA approved producers.	Timeliness of publishing posting and enactment of the EUA may take 30 to 90 days.[29]	Low	No	Yes	No

[28] http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#doxyhttp://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#cipro.

[29] https: //www.federalregister.gov/documents/2020/06/02/2020-11898/process-for-publishing-emergency-use-authorizations-for-medical-devices-during-coronavirus-disease

Options	Amend the FD&C Act	Obtain Multi-discipline stakeholder opinion	No changes to the FD&C Act	Pros	Cons	Cost/ Benefit	Timeliness	Targeted impact	Political Feasibility
Early initiation of Section 564 (m) of the FD&C Act allowing EUA for diagnostic device (Nasal PCR/Serology Antibody) testing to be performed at Point of Care or LDT of complex tests.	Requires amendment with statutory time for initiation in PHE.	Subcommittee involvement with Industry leaders to expedite large-scale testing centers and product availability.		The use of diverse CLIA certified labs and Healthcare industry leaders in LDT to begin Point of Care testing would contribute to the identification of the COVID 19 endemic areas and risk stratification with treatment.	Identification of labs capable of managing large volumes of patients and obtaining quality data, with adequate supplies.	High	No	Yes	Yes
Section 564A(d) of the FD&C Act allows states provisions to facilitate emergency dispensing of eligible MCMs.		Refer to sub-committee to advise states' attorney to interpret statutory language during a PHE/ Pandemic.		The provision of eligible MCMs by States allows them the capacity to diagnose treat and quarantine citizens to prevent a statewide outbreak.	Inadequate use by state officials may produce bottlenecks with insufficient supplies as demands rise.	High	No	Yes	Yes

Options	Amend the FD&C Act	Obtain Multi-discipline stakeholder opinion	No changes to the FD&C Act	Pros	Cons	Cost/ Benefit	Timeliness	Targeted impact	Political Feasibility
EUA under section 564 FD&C Act preempts state, local and common-laws requirements imposed for medical products in which the EUA was issued.		Refer to sub-committee evaluation of states' rights for medical products testing and use of alternative testing (e.g., Serology/ Antibody testing) during pandemic.		The preemption of state and local laws allows appropriately validated EUA products to be safely dispensed to the public with Federal Guidance and accountability.	Non-diverse use of industry leaders in healthcare and LDT may limit supplies and reduce diverse expert opinions.	Low	Yes	Yes	Yes

SUMMARIZED RECOMMENDATIONS:

- Develop a multidisciplinary collaborative subcommittee for policy review and reporting to the Secretary of Health and Human Services.

- Maintain CDC EUA approval process enacted by the Secretary HHS for PHE.

- Maintain the EUA use of unapproved products when there are no adequate or approved alternatives.

- Maintain Govt. pre-positioning of an MCM in a PHE for availability without FDA approval.

- Maintain EUA approval of products or testing in a PHE when the product is considered effective for treating life-threating illness.

- Maintain the pre-EUA sponsor and IND/IDE submission of data from vendors and labs to assure the quality of the data and accountability with the use of subcommittee evaluation of costs and appropriateness.

- Early issuance of EUA before CBRN threat occurs domestic or foreign.

- Statutory reporting of timeliness of issuance of EUA (hours/days) from Federal Register reporting and enactment.

- FDA and CDC MOU expansion with multidisciplinary subcommittee reporting.

- Eliminating the requirement of only allowing the CDC to issue initial EUA and allow industry experts on the subcommittee to advise.

- Tort liability refers to the subcommittee for opinion.

- Maintain CGMP waiver.

- Amend Section 564(m) of the Act with statutory timeliness initiation of Point of Care testing and data reporting.

- Maintain Section 564A(d) allowing states to facilitate emergency dispensing of eligible MCM.

- Subcommittee evaluation of preemption of state, local and common laws requirements for use of approved EUA product.

- Amend the Act and establish statutory requirements and responsibilities for FDA reporting on EUA approval.