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À PROPOS DU PROJET DE LOI SUR LA SANTÉ

## Du 11 septembre au COVID-19 : un bref historique de l'autorisation d'utilisation d'urgence de la FDA 🛗 28 janvier 2021 🙎 L'équipe du Centre Petrie-Flom 🕞 COVID et la loi , FDA , Politique en matière de droit de la santé, Recherche sur des sujets humains, Soins aux patients, Produits pharmaceutiques, Santé publique, Preuves scientifiques,

Publié à partir de COVID-19 et de The Law , où il a été initialement publié le 14 janvier 2021. Par Jonathan Iwry La lutte en cours contre le COVID-19 a mis en lumière la Food and Drug

Administration (FDA) et son pouvoir d'accorder des autorisations d'utilisation d'urgence (EUA). L'autorité EUA autorise la FDA à autoriser des produits formellement non approuvés pour une utilisation temporaire comme contre-

## mesures d'urgence contre les menaces pour la santé et la sécurité publiques.

Vaccins

En vertu de l'article 564 de la loi sur les aliments, les médicaments et les cosmétiques (FD&C Act), l'utilisation de l'autorité EUA de la FDA nécessite une détermination de l'existence d'une urgence par les secrétaires du ministère de la Sécurité intérieure, du ministère de la Défense ou du ministère de la Santé et des Affaires humaines. Services (HHS), ainsi qu'une déclaration du secrétaire du HHS selon laquelle des circonstances d'urgence existent justifiant la

délivrance d'EUA. Chaque délivrance d'un EUA exige que la FDA conclue que :

• il est raisonnable de croire qu'un produit donné « peut être efficace » comme contre-mesure d'urgence, • les avantages connus et potentiels de l'autorisation l'emportent sur les risques connus et potentiels, et • aucune alternative formellement approuvée n'est disponible à l'heure actuelle.

Le message d'Annie Kapnick sur le COVID-19 et l'autorité EUA de la FDA fournit un aperçu utile des pouvoirs d'urgence de la FDA et de leur utilisation en réponse à la pandémie. Un bref aperçu de l'histoire des pouvoirs d'urgence

la situation à laquelle est confrontée la FDA aujourd'hui et ses implications

contre le COVID-19 soulève des questions fondamentales sur le rôle des

pour l'avenir. L'histoire de l'EUA illustre comment son utilisation aujourd'hui

- de la FDA, y compris des événements clés qui ont conduit à leur promulgation - thalidomide, grippe porcine, sida et 11 septembre - offre une perspective sur
- agents publics, l'expertise scientifique et les normes administratives en temps de crise. La préhistoire de l'EUA The first event to foreshadow the major themes surrounding FDA's EUA power was the Thalidomide tragedy of the mid-20th century. In the 1950s, a new drug called Thalidomide was put into circulation in West Germany and other countries as a treatment for morning sickness. The next decade would reveal that the drug resulted in severe birth defects, with known cases numbering in

the tens of thousands. The drug's introduction to market is remembered as

one of the worst public health disasters in recent times. It underscored the

### importance of strict standards of clinical review in approving new food and drug products, and remains a key reference point for FDA regulators,

emphasizing the importance of the agency's extensive and thorough formal approval process. Fast forward to 1976, when reports of cases involving a new strain of influenza A (the same family of flu viruses that caused the flu pandemic of 1918) prompted fears of a possible "swine flu" pandemic. President Gerald Ford pushed for a first-ever national vaccination program — shortly before starting his reelection campaign. After millions had been vaccinated, the public was alarmed by reports that the vaccine might be causing Guillain-Barré syndrome. And ultimately, a pandemic never materialized. In their post-mortem study, Richard Neustadt and Harvey Fineberg described the swine flu episode as a policymaking disaster; yet they also expressed concern that the American public and policymakers would wrongly

oversimplify the event in their memory as a case of government overreaction

responding too swiftly to fears of a pandemic. (Some would argue that this

Next, the AIDS crisis gave rise to an early precursor to EUA authority. In the

and overstepping, and that they would thus over-learn the dangers of

concern did not bear out, as nothing was learned at all.)

need.

late 1980s, public health experts suggested that an investigational drug called DDI might prove useful for AIDS patients unable to tolerate other medications. Many objected that DDI lacked formal approval and was not guaranteed to be safe and effective; others countered that the risks of breaking protocol by issuing a drug lacking formal approval paled in comparison to the number of lives that could be saved. Impatient with FDA regulators' conservative approach, Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, proposed a new "parallel track" system to administer DDI to eligible patients while continuing to study the drug. Other measures for

circumventing FDA's formal approval process already existed at the time, but

support encouraged FDA to adopt the process and administer DDI to those in

this proposal attracted the attention of President George H.W. Bush, whose

The enactment and early years of EUA Ultimately, it was the War on Terror that would give rise to emergency use authorization. After the events of September 11, 2001 and subsequent anthrax mail attacks, Congress enacted the Project Bioshield Act of 2004. The act called for billions of dollars in appropriations for purchasing vaccines in preparation for a bioterror attack, and for stockpiling of emergency countermeasures. To be able to act rapidly in an emergency, Congress allowed FDA to authorize formally unapproved products for emergency use against a threat to public health and safety (subject to a declaration of emergency by HHS). The record indicates that Congress was focused on the threat of bioterror specifically, not on preparing for a naturally-occurring pandemic. FDA's newfound EUA authority would be used relatively sparingly for the first

16 years following its enactment. During that time, its most extensive use was

equipment and existing influenza drugs. Health policy experts would look back

in combating the H1N1 swine flu pandemic of 2009 by authorizing medical

on the use of EUA against H1N1 as an overall success. It would also be used

occasional countermeasures in anticipation of MERS, Ebola, Zika, and other

Then came COVID-19. In February 2020, HHS Secretary Alex Azar declared the

(pursuant to an amendment allowing for preemptive EUAs) to authorize

epidemics, none of which ultimately materialized in the United States.

pandemic a national health emergency warranting emergency use of in

400 EUAs for personal protective equipment, medical equipment, in

vitro diagnostics, followed by subsequent declarations in March warranting

emergency use of other countermeasures. Since then, FDA has issued nearly

**EUAs against COVID-19** 

on December 18, 2020.

was not authorized by end of day.

*vitro* diagnostic products, drug products, and, most notably, vaccines (compared to 22 EUAs issued in response to H1N1 in 2009). An EUA had never been granted for a brand-new vaccine before; the only vaccine ever to have received an EUA prior to the current pandemic was AVA, an anthrax vaccine that had already been formally approved for other purposes when it was granted an EUA in 2005. This, combined with the stakes of administering a vaccine to people who are otherwise healthy, led FDA to commit itself to heightened standards of review, or "EUA plus," in evaluating a COVID-19 vaccine for emergency authorization. Two vaccines have been authorized thus far: one by Pfizer-BioNTech on December 11, 2020, and another by Moderna

and the politicization of the pandemic by President Donald Trump has added a political dimension to FDA's decision making as an administrative agency run by a presidential appointee. Many have criticized the White House for encroaching on FDA's independence and failing to uphold basic standards of respect for scientific evidence and decision-making autonomy by technical experts. Trump notoriously pressured FDA officials into authorizing chloroquine and hydroxychloroquine, anti-malarial drugs that many believed might pose substantial risks for COVID-19 patients. The EUA came only days after Trump publicly endorsed the drugs; FDA revoked it months later. Public health experts were similarly concerned by FDA's decision to authorize SARS-CoV-2 convalescent plasma on the eve of the Republican

National Convention. Even FDA's decision to grant its first vaccine

authorization to Pfizer-BioNTech was somewhat controversial: White House

Chief of Staff Mark Meadows allegedly contacted FDA Commissioner Stephen

Hahn the day the vaccine would be authorized, demanding his resignation if it

Yet even when making decisions free of overt political interference, FDA has

confronted difficult decisions in exercising its discretion to grant EUAs. In the

shortages by issuing "umbrella" EUAs for entire categories of diagnostic and

antibody tests (as well as masks and other protective equipment) ex ante —

allowing those tests to come to market before reviewing them on a case-by-

spring of 2020, for instance, FDA decided to address widespread testing

FDA's exercise of discretion in issuing EUAs has not been without controversy,

case basis. In doing so, FDA essentially made a value judgment that the risk of allowing unreliable tests to come to market — and thus the risk of contributing to inaccurate data about the pandemic — was outweighed by the value of having more testing data at all. **Historical reflections** Looking back through the history of EUA, two key themes emerge. The first concerns the influence of the President on FDA decision making: sometimes in ways that seem motivated by the public interest, other times by political or personal interest. As the swine flu affair of 1976 demonstrates, President Trump is not the first president to have pressed for a speedy vaccination effort while running for reelection. As long as health regulators are answerable to political officials, there will always be some possibility of political influence.

This reflects a deep and fundamental tension between respecting technical

officials (and, ultimately, to the public will).

expertise and ensuring that technical experts are held accountable to elected

Second, this history points up an inherent ethical dilemma between protecting

individuals and benefiting the collective in times of crisis — between cautious

restraint and urgent pragmatism. How should FDA weigh the costs to individuals posed by unapproved and potentially harmful products against the benefit to society in addressing a public health emergency quickly? What degree of risk are health regulators justified in imposing on individuals for the sake of a promising but uncertain solution to a pandemic? Even when a drug or vaccine might seem to carry a low risk of serious side effects, the decision to authorize that product takes a stance on this dilemma, rather than finding a way around it. There will always be some tension between those who are willing to depart from ordinary protocol to save lives quickly (as in the case of the AIDS crisis) and those whose primary goal is to avoid authorizing the next Thalidomide. **Beyond COVID-19** 

Lawmakers and policymakers place great value in precedent, whether written

or historical. There is almost no precedent to guide FDA's use of this relatively

ever faced. On the contrary, the history of EUAs points up essential dilemmas

that aren't going away, and that will have to be grappled with in emergencies

administrative state. Others have discussed the myriad violations of norms of

democratic governance by the Trump administration (arguably the defining

legacy of the Trump years). These issues cannot be resolved by looking to the

These questions are not unique to FDA. Much has been written generally

about the role of agency norms and institutional dynamics in the

new power, let alone during the greatest public health crisis the agency has

law; they will inevitably require hard judgments about how to balance deference to scientific expertise with public accountability, how to integrate empirical analysis and value judgments, and how to weigh our competing values in times of crisis. FDA's emergency powers underscore the impact these questions have on the public welfare — and demonstrate that the way we answer them can literally be a matter of life and death. Share this:

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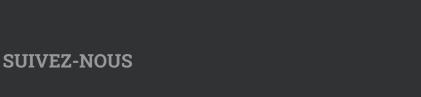
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