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TOO IMPORTANT FOR THE BUREAUCRATS: RETHINKING RISK AND REGULATORY PRESUMPTIONS IN TIMES OF CRISIS

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INTRODUCTION

The posture of American regulation of medicine is negative—we assume that a new drug is unsafe and ineffective until it is proven safe and effective.[1] This regulatory posture is a heuristic normative principle, a specific instance of the so-called precautionary principle in public health law.[2] It is defensible, if debatable, in many ordinary circumstances.[3] But like many normative heuristics, this negative posture may compel suboptimal decision-making in emergencies, where context-specific decisions must be made and a range of unique values may apply.

It is not hard for us to imagine, for instance, a deadly epidemic raging across the country.[4] Drug-makers have developed vaccine candidates—it's very plausible they'll work, very unlikely they'll cause substantial harm.[5] While we wait for three phases of clinical trial results, hundreds of

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[1] *See* 21 U.S.C. § 355(a).

[2] *See* LAWRENCE O. GOSTIN & LINDSAY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 68-69 (3d ed. 2016).

[3] *See* PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD & DRUG LAW: CASES & MATERIALS 642-644 (4th ed. 2014) (describing the development of the negative presumption in American drug law); *see also* Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1003 (arguing that "[t]he salutary moral and political goals of the precautionary principle should be promoted through other, more effective methods").

[4] *See generally* NICHOLAS CHRISTAKIS, APOLLO'S ARROW: THE PROFOUND AND ENDURING IMPACT OF CORONAVIRUS ON THE WAY WE LIVE (2020) (describing the 2020 COVID-19 pandemic).

[5] *See* Anne Trafton, *Explained: Why RNA vaccines for Covid-19 raced to the front of the pack*, MIT NEWS (Dec. 11, 2020), https://news.mit.edu/2020/rna-vaccines-explained-covid-19-1211 (explaining how mRNA vaccines "stimulate the immune system to mount a response, without posing any risk of infection").

thousands will die.[6] It's conceivable that the best thing to do is begin vaccination campaigns immediately, or at least earlier than full Phase III trial results. But under American drug law, with its negative posture and inadequate emergency provisions, that would not be on the table.[7]

This Article considers the challenge of emergency normative decision-making—a fundamental challenge of democratic legal design—in the context of authorization of new drugs or vaccines in public health emergencies. I conclude, for the same reasons of political theory that apply in the analogous context of emergency military decision-making, that the President ought to have the authority to deviate from the normative heuristics of our drug law in emergencies. This is so for two reasons. First, because emergency decision-making must happen quickly and decisively, it is best situated in one person. Second, normative decisions are political decisions, and in democracies we make political decisions through electoral processes. If we are to situate emergency decision-making in one person, it ought to be the most broadly democratically responsive federal official—the President.

Because, however (and unlike the military context), the President's constitutional authority in public health emergencies is debatable, and the current emergency provisions in our drug laws are inadequate, the federal drug laws should be amended to grant the President clear statutory authority to deviate from the ordinary process of premarket approval where necessary to combat public health emergencies. In short, just as we recognize that war is too important to be left to the generals, notwithstanding their military expertise, we ought to recognize that balancing risk and reward in public health emergencies is too important to be left to the scientists, and value Presidential control over the Food and Drug Administration just as we value civilian control of the Pentagon.

The argument proceeds in four parts. First, I summarize the negative posture of U.S. drug law, and explain the inadequacies of the current emergency provisions. In Part II, I argue that the decision to authorize or not authorize a new drug is fundamentally a normative one, though of course one that takes account of descriptive predicates. Part III argues that a

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[6] *See* Tommy Beer, *November's Grim Covid-19 Totals: More Than 4.3 Million Infections And 37,000 Americans Killed*, Forbes (Dec. 1, 2020), https://www.forbes.com/sites/tommybeer/2020/12/01/novembers-grim-covid-19-totals-more-than-43-million-infections-and-37000-americans-killed/?sh=285772e16acb (reporting that 268,000 Americans had died of COVID-19 before widespread vaccinations began).

[7] *See, e.g.*, Robert Kuznia, *The timetable for a coronavirus vaccine is 18 months. Experts say that's risky*, CNN (Apr. 1, 2020), https://www.cnn.com/2020/03/31/us/coronavirus-vaccine-timetable-concerns-experts-invs/index.html.

statutory grant of authority to the President to deviate from the negative presumption is the best move, if necessarily an imperfect one. Finally, I address the two most powerful counterarguments to this conclusion—that it politicizes science and that it prevents us from learning about medical treatments through complete clinical testing.

I. THE NEGATIVE POSTURE OF DRUG LAW IN THE UNITED STATES

The negative posture of federal regulation of drugs and medicine is established in the Food, Drug and Cosmetic Act (FDCA), which states that "[n]o person shall introduce or deliver into interstate commerce any new drug, unless an approval . . . is effective with respect to such drug."[8] And the Food and Drug Administration (FDA)—the agency charged with enforcing the FDCA—may only issue an approval upon "substantial evidence" of the drug's safety and efficacy.[9] This "substantial evidence" standard has been codified by regulation into the standard three-phases of clinical testing.[10] Thus, new drugs are assumed unsafe and ineffective until robustly proven otherwise; their use is prohibited in the same way if there is incomplete evidence of their safety and efficacy just as if there were proof that they were unsafe and ineffective. As many scholars have noted, this regulatory posture is a particular instance of the "precautionary principle" of public health and international environmental law, which conservatively favors government regulation to maintain the status quo in conditions of uncertainty.[11]

The FDCA provides for a limited emergency exception to this presumption (the Emergency Use Authorization, or EUA, provisions). The Act authorizes the Secretary of Health and Human Services (HHS) (who has delegated the authority to the Commissioner of the FDA)[12] to determine "that there is a public health emergency . . . that affects . . . national security

[8] 21 U.S.C. § 355(a). Vaccines and other biologics are regulated by the Public Health Service Act, which adopts "a regulatory regime similarly rigorous to that for drugs, including premarket review by FDA for safety and effectiveness." HUTT, MERRILL & GROSSMAN, *supra* note 3, at 135; *see also* 42 U.S.C. § 201 *et seq.* This Article is focused on the drug and biologic approval process, which is distinct from that for medical devices. *See generally* 21 U.S.C. § 360e (providing premarket approval procedures for medical devices).

[9] *Id.* at § 355(d).

[10] *See* 21 C.F.R. Title 21.

[11] *See* Noah M. Sachs, *Rescuing the Strong Precautionary Principle from Its Critics*, 2011 U. ILL. L. REV. 1285, 1290 (2011) (describing "the Food and Drug Administration's review process for new drugs as just one of myriad examples" of "Strong Precaution" in U.S. law"); *see also* WILEY & GOSTIN, *supra* note 2, at 68-69.

[12] *See* CONGRESSIONAL RESEARCH SERVICE, EMERGENCY USE AUTHORIZATION AND FDA'S RELATED ACTIVITIES (2018).

. . . and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents."[13] Under these circumstances, the Secretary may authorize an unapproved new drug where three conditions are met: (1) the public health threat "can cause a serious or life-threatening disease or condition;" (2) "based on the totality of scientific evidence available to the Secretary . . . *it is reasonable to believe* that . . . the product may be effective . . . ; or . . . the known and potential benefits of the product . . . outweigh the known and potential risks of the product;" (3) "there is no adequate, approved, and available alternative to the product . . . ."[14] In an emergency, then, the FDCA lowers the evidentiary burden from "substantial evidence" to "reasonable belief."

The EUA provisions suffer from three essential shortcomings that prevent them from adequately addressing the challenges of emergency normative decision-making. First, the text and the context of these provisions suggest that they were primarily designed for terrorist attacks against the United States,[15] and some commentators have argued that the FDA's reliance on EUAs in the 2020 coronavirus pandemic has been inappropriate for that reason.[16] Second, although the EUA provisions

[13] 21 U.S.C. 360bbb-3(b)(1)(C).

[14] 21 U.S.C. § 360bbb-3(c)(1)-(3).

[15] This can be seen in the provisions' emphasis on emergencies implicating national security. For instance, the EUA provisions have four potentially triggering emergencies—(1) "a domestic emergency . . . involving a heightened risk of attack" (2) "a military emergency" (3) "a public health emergency . . . that affects . . . national security or the health and security of United States citizens living abroad" and (4) "the identification of a material threat . . . sufficient to affect national security or the health and security of United States citizens living abroad." 21 U.S.C. § 360bbb-3(b)(1)(A)-(D). Moreover, the provisions were originally enacted as part of a counterterrorism package "[i]n response to the September 11, 2001 terrorist attacks, and subsequent anthrax attacks." Elizabeth Y. McCuskey, *FDA in the Time of COVID-19*, 45-SPG ADMIN. & REG. L. NEWS 7, 7 (2020); *see also* Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-Testing Debacle*, 130 YALE L. J. FORUM 78, 80 (2020). As a textual matter, however, pandemics would seem to meet the triggering condition, and the FDA has interpreted the provisions that way in prior pandemics. *See* FDA, *Emergency Use Authorizations for Medical Devices* (last visited Feb. 26, 2021), https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#:~:text=Since%20February%2026%2C%202016%2C%20when,Use%20Authorization%20(EUA)%20for%20a (listing EUAs issued to combat Zika and Ebola epidemics).

[16] *See* Matthew W. McCarthy, David Oshinsky & Arthur Caplan, *Make pre-approval Covid-19 vaccines available through expanded access, not an EUA*, STAT (Nov. 9, 2020), https://www.statnews.com/2020/11/09/expanded-access-not-eua-for-distributing-preapproval-covid-19-vaccines/ (noting that "the intent of emergency use authorization" was "designed for counterterrorism measures to address chemical, biological, radiological, and nuclear hazards—not necessarily a pandemic").

mention a number of executive officials, including the Secretary of Defense and the Secretary of Homeland Security, they do not refer to the President. This diffusion of responsibility facilitates buck-passing and diminishes political accountability. We saw this happen in the 2020 coronavirus pandemic, where it was unclear to the public who was responsible for issuing more controversial EUAs for hydroxychloroquine and convalescent plasma and on the basis of what evidence.[17]

Finally, while the EUA provisions lower the evidentiary threshold from "substantial evidence" to "reasonable belief," they do not account for the possibility that we may want our normative decision-making in an emergency to account for values other than a narrow cost-benefit analysis.[18] In other words, the EUA provisions make approval less burdensome within the essentially utilitarian framework of the FDCA, but do not contemplate deviating from that framework. In making specific, case-by-case normative decisions in emergencies, however, we may want our decision-makers to be free to consider a broader range of values.[19]

II. THE NORMATIVITY OF AUTHORIZING NEW DRUGS

Philosophers distinguish between two kinds of claims—"descriptive" claims and "normative" ones.[20] Descriptive claims "address the way the world is, was, or will be."[21] They are empirically verifiable statements about facts in the world—or probabilistic, predictive claims about future facts about the world.[22] We resolve descriptive questions primarily through the scientific method, a tool for clarifying and crystalizing facts of reality.[23] In contrast, normative claims "speak to how the world ought to be."[24] They are ethical claims about what we should do.[25] We resolve normative questions, in contrast to descriptive ones, through philosophy and politics.[26]

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[17] *See* Marisa Taylor & Aram Roston, *Exclusive: Pressed by Trump, U.S. pushed unproven coronavirus treatment guidance*, REUTERS (Apr. 4, 2020), https://www.reuters.com/article/us-health-coronavirus-usa-guidance-exclu/exclusive-pressed-by-trump-u-s-pushed-unproven-coronavirus-treatment-guidance-idUSKBN21M0R2.

[18] *See* Sachs, *supra* note 11, at 1314.

[19] *Id.*

[20] *See* Bart Streumer, *Are normative properties descriptive properties?*, 154 PHILOSOPHY STUDIES 325, 326 (2011).

[21] Adam J. Kolber, *How to Fix Legal Scholarmush*, 95 IND. L. J. 1191, 1196 (2020).

[22] *Id.*

[23] *See* Deborah M. Hussey Freeland, *Law & Science: Toward a Unified Field*, 47 CONN. L. REV. 529, 238 (2014).

[24] Kolber, *supra* note 18, at 1196-1197.

[25] *Id.*

[26] *See* David L. Faigman, et al., 1 MOD. SCI. EVIDENCE § 4.4 (2021) (noting that

The question of the conditions under which a new drug ought to be authorized is a normative question, not a descriptive one.[27] It is a claim about how our government *ought* to behave—what levels of risk are tolerable, whether and how much the government should protect individuals from themselves, and the extent to which harms caused or prevented by drugs are similar to or different from other harms. To be sure, this normative analysis must take account of descriptive predicates. Science can, and must, tell us what the potential risks and rewards of the product are and estimate their probabilities based on studies that have been conducted and our understanding of the way the world works.[28] But it cannot tell us what to *do* with that information—whether to demand further studies and greater confidence or to authorize the drug on the basis of what we have. To do so requires us to consider a range of values, balancing the value of potentially saving lives now against risks to lives in the future,[29] our commitments to libertarianism or paternalism,[30] the value of information in itself or instrumentally,[31] and many others. Thus, the decision to *authorize* or *not authorize* a new drug—in contrast to determinations about the physical properties of a drug—is irreducibly normative.[32]

From this perspective, the negative posture of American drug regulation is a *normative* presumption—a conservative posture based on the ethical premise that it is *ethically better* for the government to forcibly maintain the status quo until an alternative to it is definitively proven better than to gamble on the risks concomitant with novel technologies.[33] Moreover, it is a normative *heuristic*, justified *in general* rather than with reference to particular cases. Some *particular* drugs may, of course, have relatively low

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"philosophers, theologians and literary scholars" address "normative questions").

[27] *See* Sachs, *supra* note 11, at 1321 (noting that decisions about thresholds for acceptable levels of risk are "fundamental value choices").

[28] *Id.* (observing that "[l]egislatures should consider knowable tradeoffs where they can be quantified, but they should also view their role as more than utility maximizers, summing up individual preferences").

[29] *See* DEREK PARFIT, REASONS & PERSONS 351-441 (1986) (philosophically analyzing how to weigh the effects of current decisions on future lives).

[30] *Compare* ROBERT NOZICK, ANARCHY, STATE, AND UTOPIA (1974) *with* RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS (2008).

[31] *See generally* DUNCAN PRITCHARD, ALAN MILLER & ADRIAN HADDOCK, THE NATURE AND VALUE OF KNOWLEDGE: THREE INVESTIGATIONS (2010).

[32] *Cf., e.g.*, I. Glenn Cohen, *What (If Anything) Is Wrong with Human Enhancement? What (If Anything) Is Right With It?*, 49 TULSA L. REV. 645, 677 (2014) (describing the "FDA's premarket approval regime" as one normative solution to questions regarding "the scope of justified paternalism . . . and of parens patriae state interventions").

[33] *See* GOSTIN & WILEY, *supra* note 2, at 68-69; Sachs, *supra* note 11, at 1303 (noting that default rules regulating risk are not "value neutral").

risk and a higher probability of success than others.[34] In our general design of an administrative state, however, normative heuristics like this are entirely justifiable and even necessary—after all, basic financial and logistic constraints make it effectively impossible to conduct an individualized normative assessment for every drug proffered for approval to the FDA.[35]

To the extent that we are justified in adopting normative heuristics to guide the decision whether to authorize drugs in general, the negative presumption we have settled on is defensible, if certainly not the only conceivable one.[36] Its descriptive premises are plausible—most hypothesized new drugs turn out not to be effective,[37] and history is replete with examples of new substances causing substantial harm, including death, to human bodies.[38] Its normative assumption that harm caused by active deviation from the status quo is worse than the harms endemic to the status quo is not implausible and widely believed,[39] albeit not without controversy.[40] In other words, the negative posture of American drug law is a defensible heuristic normative principle for the background design of a regulatory regime.

But this conservative stance can misfire in a public health emergency,

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[34] For example, in the COVID-19 pandemic, vaccines based on more traditional designs were initially seen as more promising than unproven mRNA technologies. *See* Jennifer Abbasi, *COVID-19 and mRNA Vaccines—First Large Test for a New Approach*, 324 JAMA 1125 (2020); *see also* Jenny Strasburg & Joseph Walker, *AstraZeneca-Oxford Covid-19 Vaccine Up to 90% Effective in Late-Stage Trials*, WALL ST. J. (Nov. 23, 2020), https://www.wsj.com/articles/astrazeneca-oxford-covid-19-vaccine-up-to-90-effective-in-late-stage-trials-11606116047.

[35] *See* Sachs, *supra* note 11, at 1320 ("In federal toxics policy, the legislative task is not to perform a utilitarian calculus on the costs and benefits of banning or restricting specific chemicals. It is to determine the best legislative architecture for assessing and managing the risks of the universe of 84,000 chemicals that have been introduced into commerce."); STILLWELL V. OFFICE OF THRIFT SUPERVISION, 569 F.3d 514, 519 (D.C. Cir. 2009 ("An agency need not suffer the flood before building the levee.").

[36] *See supra* note 3.

[37] *See* Attila A. Seyhan, *Lost in translation: the valley of death across preclinical and clinical divide—identification of problems and overcoming obstacles*, 4 TRANS. MED. COMMS. (2019) ("80 to 90% of research projects fail before they ever get tested in humans and for every drug that gains FDA approval, more than 1000 were developed but failed. Almost 50% of all experimental drugs fail in Phase III trials.").

[38] *See* Barbara Sibbald, *Death but one unintended consequence of gene-therapy trial*, 164 CMAJ 1612 (2001) (discussing the death of Jesse Gelsinger four days after injection of an experimental gene therapy).

[39] *See generally* EDMUND BURKE, REFLECTIONS ON THE REVOLUTION IN FRANCE (1790); *see also See* Rep. of the U.N. Conf. on Envir. & Dev., at 3, U.N. Doc. A/CONF.151/26 (Vol. I) (1992) ("Rio Declaration").

[40] *See* Cass R. Sunstein, *The Laws of Fear*, 115 HARV. L. REV. 1119 (2002); Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 1285 (1996).

requiring the government to make normative decisions that are suboptimal under a variety of ethical frameworks. An emergency is a set of circumstances that in their nature justify addressing that set of circumstances before anything else. This is because the emergency threatens the fundamentals of the economic, social, and political order without which other aspirations would be meaningless.[41] What is at stake in an emergency is, in Lincoln's words, whether society itself will "go to pieces," after which other societal goals would seem futile—reducing income inequality doesn't mean much in a war of all against all.[42] This prioritization of addressing the emergency makes available resources for case-by-case decision-making where we might otherwise rely on heuristics.[43] And because the emergency is by definition an unanticipated set of circumstances, it is characterized by its *specificity*—by the need to address its particular challenges in a bespoke and context-specific way.[44]

The long and the short of all this is that in an emergency, the government ought to consider whether to authorize specific hypothesized treatments *on the merits of the specific question* rather than deferring to heuristic generalizations.[45] The negative posture of our drug law may plainly fail when the decision to authorize a particular drug is considered on its own merits.[46] Through the lens of the utilitarian moral framework that

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[41] *See* CARL SCHMITT, POLITICAL THEOLOGY 6 (George Schwab, trans., 2005) ("The exception . . . can at best be characterized as a case of extreme peril, a danger to the existence of the state, or the like."); The Federalist No. 23, at 121 (Alexander Hamilton) ("[I]t is impossible to foresee or define the extent and variety of national exigencies, or the correspondent extent and variety of the means which may be necessary to satisfy them. The circumstances that endanger the safety of nations are infinite . . . ."); BAGHAT SINGH V. KING EMPEROR, (1931) 58 IA 169 (defining "emergency" as "a state of matters calling for drastic action"), *see also* Karin Loevy, *What is an Emergency? The Legal Politics of Defining the 'Un-definable'*, 22 ILSA J. INT'L & COMP. L. 155, 160-175 (2015) (summarizing theories of the emergency).

[42] *See* Abraham Lincoln, Speech, July 4th Message to Congress (1861), available at https://millercenter.org/the-presidency/presidential-speeches/july-4-1861-july-4th-message-congress.

[43] Federalist 23, *supra* note 36 (noting that in emergency decision-making "the means ought to be proportioned to the end").

[44] *Id.* ("The circumstances that endanger the safety of nations are infinite . . . ."); *see also* Oren Gross, *Once More unto the Breach: The Systemic Failure of Applying the European Convention on Human Rights to Entrenched Emergencies*, 23 YALE J. INT'L L. 437, 439 n. 8 (1998) (quoting the International Law Association as stating that "each [emergency] case has to be judged on its own merits taking into account the overriding concern for the continuance of a democratic society").

[45] *Cf.* SCHMITT, *supra* note 36, at 7 (noting that in emergency situations "[t]he most guidance the constitution can provide is to indicate who can act in such a case")

[46] *See* Sachs, *supra* note 11, at 1325 (observing that "the spread of contagious disease" may be an instance in which the Precautionary Principle ought not apply).

animates the administrative state in general,[47] for instance, it may be that a *particular* hypothesized treatment has a strong probability of success and relatively low stakes for failure. Vaccines for COVID-19 may have been an example of this, even the novel mRNA ones—their mechanism of action was plausible and hotly anticipated.[48] Moreover, historically, the *only* deaths caused by vaccines have been caused by *contamination*, a risk the premarket approval requirements of the FDCA are not designed to mitigate anyway.[49] Moreover, under utilitarian moral frameworks, use of a vaccine could be justified *even if* it caused death in some fraction of those inoculated, so long as it was less deadly than the virus[50]—in the case of SARS-CoV-2, killing fewer than 0.5% of people to whom it was administered.[51] If indeed a vaccine were deadlier than that, we would know relatively quickly, and could prohibit its further use.[52]

More generally, however, in making specific normative evaluations in an emergency, we may want to consider values beyond the utilitarian background of the administrative state.[53] Some of these considerations might be general values that we think of differently in emergencies—individual freedom against governmental compulsion, allocating risks of harm across different segments of society, weighing the present against the future. It may be much easier, for example, for those of us who can work

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[47] *See* Mark D. Steedman, *Taming Leviathan*, 52 TULSA L. REV. 621, 630-31 (2017).

[48] *See* Mark Terry, *Moderna Therapeutics Sets Record for Biggest Biotech IPO*, BIOSPACE (Dec. 7, 2018), https://www.biospace.com/article/moderna-therapeutics-biggest-ipo-in-biotech-history/ (observing that Moderna set the record for the biggest biotech IPO ever on optimism of its "focus[] on messenger RNA (mRNA) therapeutics" including vaccines).

[49] *See* CDC, Vaccine Safety: Historical Vaccine Safety Concerns (last visited Nov. 23, 2020), https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html (listing the "Cutter incident" with the novel polio vaccine, which killed 10, as the only incident where vaccination has been robustly linked to death).

[50] *See* J.S. MILL, UTILITARIANISM 55 (Roger Crisp, ed., 1998) ("The creed which accepts as the foundation of morals, Utility, or the Greatest Happiness Principle, holds that actions are right in proportion as they tend to promote happiness, wrong as they tend to produce the reverse of happiness.").

[51] *See* CDC, COVID-19 Pandemic Planning Scenarios (Sept. 10, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.

[52] *Cf.* Harvey Miller & Gregory Conko, *The Science of Biotechnology Meets the Politics of Global Regulation*, ISSUES IN SCI. & TECH. ONLINE (2000), http://www.nap.edu/issues/17.1/miller.htm ("If the precautionary principle had been applied decades ago to innovations such as polio vaccines and antibiotics, . . . that precaution would have come at the expense of millions of lives lost to infectious diseases.").

[53] *See* Sachs, *supra* note 11, at 1314 ("Utilitarian welfare maximization need not be the driving goal of every regulatory regime, and the Strong Precautionary Principle can incorporate a wider variety of goals and values.").

from home to wait for a robustly tested vaccine than for those who must interact with others, and perhaps our decision-makers ought to take that into account. Some values may be unique to emergency contexts—whether there's a deontological value in the preservation or continuity of the legal order, for instance[54]—or even may be unique to *specific* emergencies—how do we weigh the less tangible harms of social distancing against the intangible benefit of robust scientific knowledge, for example?

The answers to these questions are not obvious, nor can they be planned for definitively in advance. They are normative questions. And they are normative questions so context-specific that pre-existing heuristics cannot answer them. Simply relying on the negative presumption of the FDCA to govern the decision whether to authorize a hypothesized new treatment in an emergency can result in indefensible decision-making—under utilitarianism or a variety of plausible ethical frameworks.

In sum, decisions to authorize or not authorize new drugs—though they necessarily accommodate descriptive predicates—are normative. By their nature, emergencies justify case-by-case normative decision-making. And when analyzed on a case-by-case basis, the negative presumption embedded in the FDCA may fail to plausibly resolve that normative question—in certain emergencies, with respect to certain hypothesized drugs, under certain circumstances. With these conclusions, the question of how such case-by-case normative decisions should be made is one of institutional design, to which we now turn.

III. PRESIDENTIAL EMERGENCY DECISION-MAKING

In democracies, we answer normative questions through majoritarian political processes[55]—although in a *liberal* democracy this principle only applies to most normative questions, most of the time.[56] Therefore, normative decisions about the threshold of proof required for new drug authorization should be allocated to a politically responsive entity. If the decision-maker makes a normative decision that most people disagree

[54] *See* OREN GROSS & FIONNUALA NI AOLAIN, LAW IN TIMES OF CRISES: EMERGENCY POWERS IN THEORY AND PRACTICE 4-10 (2006)

[55] *See* Fabienne Peter, *Democratic legitimacy and proceduralist social epistemology*, 6 POL., PHIL. & ECON. 329 (2007) (discussing justifications in political philosophy for the democratic principle that majorities generally resolve value judgments); *see also* Sachs, *supra* note 11 at 1291 (arguing that "[l]egislators may opt for a Strong Precautionary framework" for a variety of normative reasons).

[56] *See* UNITED STATES V. CAROLENE PRODUCTS, 304 U.S. 144, 153 n. 4 (1938) (noting that majorities may be restrained by the Constitution where "prejudice against discrete and insular minorities" "seriously curtail[s] the operation of those political processes ordinarily to be relied upon to protect minorities").

with—recklessly authorizes a drug or vaccine that causes more harm than good, for example—we want to be able to replace them with someone who will make a decision with which more people will agree.

The United States Constitution establishes two branches intended to be responsive to electoral majorities in different ways—Congress and the President.[57] At a high level of abstraction, Congress, through its legislative power, resolves normative questions in the generality,[58] while the President resolves these questions in the particular application[59] and the emergency.[60] Congress declares war and the President commands its conduct;[61] Congress passes criminal laws and the President exercises prosecutorial discretion.[62]

On the normative question of whether new drugs should be authorized for the treatment of a disease, our government has followed this prescription in part—Congress has legislated in the generality, establishing a negative presumption that places a burden of "substantial evidence" on the proponent of the new drug.[63] But it has not recognized particular authority in the President to authorize new drugs in emergency situations. It should.

There are two essential reasons that the President is the best office in which to situate normative emergency decision-making, in public health crises as in war. The first is that because emergencies require *immediate* response, decision-making authority should be situated in *one person*, who can respond more quickly and decisively than a collective group like Congress, or even the various committees of the Food and Drug Administration.[64] The second is that because normative questions are

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[57] *See* U.S. Const., Art I. (vesting the legislative power in an elected bicameral Congress); U.S. Const. Art. II (vesting the executive power in the elected President).

[58] *See* Zachary S. Price, *Enforcement Discretion and Executive Duty*, 67 VAND. L. REV. 671, 676 (2014) ("[T]he central legislative task is to formulate general laws and policies for the executive and judicial branches to implement."); *see also* Sachs, *supra* note 11, 1320 ("Congress must determine what decision-making procedures as default rules should be put in place for *all* chemical substances subject to the statute.").

[59] *See id.*, at 675 ("[S]ome degree of enforcement discretion is a natural incident of the core executive function of applying general rules to particular cases.").

[60] *See* Leslie E. Gerwin, *Planning for a Pandemic: A New Model for Governing Public Health Emergencies*, 37 AM. J. L. & MED. 128, 142 (2011) ("The Constitution's silence on the government's authority during a national emergency does not mean that the President must await congressional permission before acting.").

[61] *See* U.S. Const. Art. I sec. 8 (granting Congress the power to declare war); U.S. Const. Art. II sec. 2 (providing that the President is Commander-in-Chief "of the Army and Navy of the United States").

[62] *See generally* Zachary S. Price, *Enforcement Discretion and Executive Duty*, 67 VAND. L. REV. 671 (2014) (discussing the historical relationship between executive enforcement discretion and Congress's prerogative to prescribe general laws).

[63] 21 U.S.C. § 335(a); 21 U.S.C. § 355(d)

[64] *See* BAGHAT SINGH V. KING EMPEROR, (1931) 58 IA 169, PC ("A state of emergency . . . connotes a state of matters calling for drastic action which is to be judged as

political, and political questions in democracies are resolved through electoral processes, the one person in whom we situate this power should be the *most politically accountable*—and the President is the only federal official elected by the country as a whole.[65] Of course the President—elected for four-year terms by the Electoral College—is not *perfectly* politically accountable.[66] But he is the *most*, and to the extent that the need for immediacy justifies situating emergency decision-making in one individual, the President is the *best*.

Moreover, the same reasons of political theory that justify granting the President command of the military forces, authority over the conduct of war, and the capacity to respond swiftly to military threats to national security justify similarly granting him emergency decision-making in public health emergencies.[67] The conduct of war, like the conduct of a pandemic, involves countless normative decisions, particularly decisions that balance risks and rewards, determine how bad the risks are and what sorts of things qualify as rewards. Indeed, throughout the 2020 coronavirus pandemic, decision-makers have leaned heavily on rhetorical comparisons to war.[68] In war, we recognize that the President will make decisions based on limited information. We accept that a particular strike, say, may not work, may kill more people than it saves, may ultimately have been a bad idea. But we recognize this kind of decision-making as a necessity in military emergencies. And we are comfortable vesting it in the President, the only *individual* elected by the *country as a whole*.

In a public health crisis, as in war, decision-makers are making choices on the basis of limited—and sometimes deeply flawed—information.[69]

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such by some*one*. . . . Emergency demands immediate action . . . ." (emphasis added)); Schmitt, *supra* note 36, at 5 ("Sovereign is *he* who decides on the exception." (emphasis added)); CLINTON L. ROSSITER, CONSTITUTIONAL DICTATORSHIP: CRISIS GOVERNMENT IN THE MODERN DEMOCRACIES (1979).

[65] *See* Steven G. Calabresi, *Some Normative Arguments for the Unitary Executive*, 48 ARK. L. REV. 23, 38 (1989) ("Energy in the executive is defended here as being essential for both foreign policy reasons and to protect the polity as a whole from factional strife."); Jack H. McCall Jr. & Brannon P. Denning, *Mission Im-posse-ble: The Posse Comitatus Act and Use of the Military in Domestic Law Enforcement*, 39 TENN. B. J. 26, 27 (2003) ("From its founding, this nation has largely viewed civilian control over the military as a critical and distinguishing feature of American democracy.").

[66] *See, e.g.*, SANFORD V. LEVINSON, OUR UNDEMOCRATIC CONSTITUTION: WHERE THE CONSTITUTION GOES WRONG (AND HOW WE THE PEOPLE CAN CORRECT IT) (2006).

[67] *See* U.S. Const. Art. II, Sec. 2 ("The President shall be Commander in Chief of the Army and Navy of the United States.").

[68] *See* Joseph Guzman, *Fauci: 'The cavalry is coming' with coronavirus vaccine, but public health measures are still needed'*, THE HILL (Nov. 12, 2020), https://thehill.com/changing-america/well-being/prevention-cures/525714-fauci-the-cavalry-is-coming-with-coronavirus.

[69] *See* Daniela Hernandez, Sarah Toy & Caitlin McCabe, *New Playbook for Covid-19*

They are weighing risks to blood, treasure, prestige, ethics, morale and values against potential good outcomes measured in the same. For the same reasons that we feel the President ought to have emergency decision-making authority to defend against military threats to national security, similar standards should govern the President's ability to make decisions in a public health emergency. Just as we recognize that, in the famous words of Georges Clemenceau, war is too important to be left to the generals,[70] pandemic response is too important to be left to the scientist-bureaucrats.

As discussed above, the FDCA vests limited emergency powers in the Secretary of HHS.[71] Under the "unitary executive" theory, some may see this as tantamount to a vesting of power to the president.[72] As a practical matter, however, the Secretary of HHS has delegated EUA authority to the FDA, and it is FDA making EUA determinations, not the Secretary, and certainly not the President.[73] Moreover, the Supreme Court has never recognized plenary presidential authority over executive officials,[74] and the notion that the President as a constitutional matter has the power to direct executive agents is contestable and contested.[75] Moreover, the EUA provisions purport to render the determination of whether a particular drug should be authorized an empirical rather than a normative question—altering the evidentiary threshold, but not the broader regulatory posture. From this perspective, the EUA provisions are analogous to Congress's purporting to give the Secretary of Defense a comprehensive playbook for directing the conduct of war—a bad idea, even if it could be constitutional.[76]

Therefore, the FDCA should be amended to expressly authorize the

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Protection Emerges After Year of Study, Missteps, WALL ST. J. (Jan. 26, 2021), https://www.wsj.com/articles/new-playbook-for-covid-19-protection-emerges-after-year-of-study-missteps-11611680950.

[70] *See* Sanford Levinson, *Identifying "Independence*," 86 B.U. L. REV. 1297, 1307 (2006).

[71] 21 U.S.C. § 360bbb-3.

[72] *See* Steven G. Calabresi & Kevin H. Rhodes, *The Structural Constitution: Unitary Executive, Plural Judiciary*, 105 HARV. L. REV. 1153 (1992).

[73] *See* Sheila Kaplan, *In 'Power Grab,' Health Secretary Azar Asserts Authority Over F.D.A.*, N.Y. Times (Sept. 19, 2020), https://www.nytimes.com/2020/09/19/health/azar-hhs-fda.html (criticizing an assertion of authority by Secretary of HHS Alex Azar over FDA).

[74] *See* MORRISON V. OLSON, 487 U.S. 654 (1988) (affirming Congressional limits on the President's authority to remove an executive officer).

[75] *See* Lawrence Lessig & Cass R. Sunstein, *The President and the Administration*, 94 COLUM. L. REV. 1 (1994).

[76] *See* Michael Stokes Paulsen, *Drone On: The Commander in Chief Power to Target and Kill Americans*, 38 HARV. J. L. & PUB. POL'Y 43, 55 (2015) ("The buck stops with the President.").

President to override the FDA's new drug approval—or EUA—process on an individualized level in emergencies. Doing so would comport with the general structure of our government, accord with the analogy between normative decision-making in public health emergencies and war, resolve the limitations of the current emergency decision-making structure, and sidestep the constitutional question of whether the President would possess the authority anyway.

More generally, the reasoning behind this change would not necessarily require altering the relationship between the President and independent federal agencies such as the Federal Reserve Board.[77] The reason for this is straightforward—emergency decision-making in public health crises like pandemics is *more like* emergency decision-making in war than the kinds of decisions encountered by independent agencies—decisions of monetary policy, say.[78] As in war, pandemics threaten the short-term loss of human life. At stake in war and pandemics is widespread political and economic disruption. These decisions are quintessentially executive and necessarily immediate.[79] In contrast, decisions of monetary policy—no matter how controversial or consequential—are made over the course of months or years.[80] Where decisions do not need to be made immediately and do not require the exercise of substantial executive authority, legislatures may be justified in adopting heuristic normative principles—with the FDA or the Federal Reserve—and delegating their execution to specified multimember committees.[81] It is only when decisions must be made *immediately*—when emergencies threaten the fundamentals—that they must be vested in one person, who ought not be anyone other than the President.[82]

As with any presidential emergency power, the constraints on the exercise of the power to authorize particular drugs in public health

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[77] *See generally* Peter Conti-Brown, *The Institutions of Federal Reserve Independence*, 32 YALE J. ON REG. 257 (2015).

[78] *See* SEILA LAW LLC v. CONSUMER FINANCIAL PROTECTION BUREAU, 140 S. Ct. 2183, 2199-2200 (2020) (suggesting that independent agencies may only be constitutional where they "do not wield substantial executive power"). For the reasons discussed in Part II, *supra*, the decision to authorize a drug in an emergency is substantial executive power.

[79] *Id.* at 2200 (noting that "quintessentially executive power" may not be constitutionally exercised by independent agencies).

[80] *See* Christine Kexel Chabot, *Is the Federal Reserve Constitutional? An Originalist Argument for Independent Agencies*, 96 NOTRE DAME L. REV. 1, 7-14 (2020) (discussing the deliberative process of decision-making of the Federal Reserve's most independent "Open Market Committee").

[81] *Cf.* Sachs, *supra* note 11, at 1320; *see also* SEILA LAW, 140 S. Ct. at 2197 ("We hold that the CFPB's leadership by a single individual removable only for inefficiency, neglect, or malfeasance violates the separation of powers.").

[82] SIELA LAW, 140 S. Ct. at 2197.

emergencies will be fundamentally political.[83] This entails a familiar suite of risks. It is possible that in future pandemics we will happen to have—as we did in this one—a President singularly unequipped to meet the demands of the moment.[84] But there are good reasons to believe that political constraints will be enough, or at least the best we could hope for. President Trump *lost* his bid for re-election and it is plausible that but for his handling of the pandemic, he would have won.[85] Similarly, a President who recklessly authorizes a dangerous drug, fails to monitor and adjust as evidence of its danger is revealed, and ultimately makes a crisis worse rather than better will, no doubt, pay at the polls. On the other hand, a President who acts decisively, based on sound scientific guesswork and a willingness to take limited risks for potentially powerful rewards, quickly launching a vaccination plan that *works* will be hailed a hero, and would be one.

IV. COUNTERARGUMENTS

A. The Politicization of Science

Perhaps the most significant concern with granting the President authority to authorize new drugs in emergencies—made all the more acute by President Trump's egregious mishandling of the COVID pandemic—is that doing so risks the "politicization of science."[86] Politicization of science—which we might define as making descriptive claims purportedly backed by the scientific method in fact driven by *exogenous normative commitments* rather than a commitment to descriptive truth—is a serious concern.[87] To make informed decisions under any normative framework, we

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[83] *See* ERIC A. POSNER & ADRIAN VERMEULE, TERROR IN THE BALANCE: SECURITY, LIBERTY, AND THE COURTS 54-55 (2007) (discussing political constraints on the abuse of presidential power in emergencies).

[84] *See* Lori Aratani, *Oversight report says Trump coronavirus response a 'failure'*, Wash. Post (Oct. 30, 2020), https://www.google.com/search?q=president+trumps+mishandling+of+coronavirus&rlz=1C1CHBF_enUS723US723&oq=president+trumps+mishandling+of+coronavirus&aqs=chrome..69i57.5247j0j4&sourceid=chrome&ie=UTF-8.

[85] *See* Ashley Parker, Josh Dawley, Matt Viser & Michael Scherer, *How Trump's erratic behavior and failure on coronavirus doomed his reelection*, WASH. POST (Nov. 7, 2020), https://www.washingtonpost.com/elections/interactive/2020/trump-pandemic-coronavirus-election/.

[86] *See* Robert M. Califf, et al., *Seven Former FDA Commissioners: The FDA Should be an Independent Federal Agency*, 38 HEALTH AFFS. (2019).

[87] *See* Genevieve P. Kanter, *Science journal editors shouldn't contribute to politicizing science*, STATNEWS (Oct. 23, 2020), https://www.statnews.com/2020/10/23/science-journal-editors-shouldnt-contribute-to-politicizing-science/.

must understand descriptive facts about the world, and the scientific method—which gives no credence to what we *want* to be true—is the best method we have for establishing those facts.[88] We ought to design institutions to limit normative interference in scientific processes. But this principle does not preclude situating emergency drug-authorization authority in the President.

Indeed, the argument that the FDA's drug-authorization decision should be insulated from President commits the very sin it hopes to avoid—it conflates descriptive questions about the potential risks and rewards of a particular drug with normative questions of what to do with that information. As discussed above, the decision to *authorize or not authorize* a drug is *always* normative. The *authorization decision*—as opposed to inquiries into the physical nature of a substance and its interaction with human biology—is *supposed* to be political. And it always has been—the negative posture of the FDCA is a normative, political choice just as much as deviating from it would be, though because it applies in general it has appropriately been made by Congress rather than the President.[89]

From this perspective, the FDA's theoretical role, as an administrative agency composed of scientific experts, has always been simply to answer scientific questions about how proffered drugs affect humans.[90] The decision of what to do with that information is a normative one that Congress has already answered in general and, I argue, the President ought to answer in emergencies. The best way to avoid the politicization of science is to ensure a clear-headed conceptual distinction between the questions science can answer and those it cannot. By suggesting that the decision to authorize a new drug is one scientists are competent to answer, this counterargument in fact risks public confusion about the distinction between normative and descriptive claims and could *further* rather than inhibit the politicization of science.

Indeed, the coronavirus pandemic offered ample evidence that lack of clarity about the limits of science to resolve normative questions can contribute to the rejection of descriptive claims because of exogenous normative commitments. For example, it seems that one of the reasons for politicization of issues such as mask-wearing during the 2020 pandemic was the perception by a substantial portion of the population that the experts urging mask-wearing were politically biased—that is, that public health

[88] *See generally, e.g.*, KARL POPPER, OBJECTIVE KNOWLEDGE: AN EVOLUTIONARY APPROACH (1972) (defending falsification as a method of discerning descriptive truth).

[89] *See* Sachs, *supra* note 11, at 1303, 1320.

[90] *See* Shelby Baird, *Don't Try This At Home: The FDA's Restrictive Regulation of Home-Testing Devices*, 67 DUKE L. J. 383, 388 (2017) (arguing that the FDA's regulatory authority is grounded in its scientific expertise).

experts were promoting mask-wearing for *normative* reasons that only *purported* to be descriptive.[91] In this situation, the outcome that concerned us (disbelief in the descriptive scientific evidence of mask-efficacy) may have been the result of a perception of the mingling of scientific and normative recommendations *from scientists*, not (as the politicization-of-science counterargument would assume) from the interference of the President in the normative aspects of a public-health decision-making process.[92]

Finally, it is true that President Trump made knowingly false descriptive claims during the COVID pandemic.[93] But it is unclear the extent to which this phenomenon either arose from or contributed to broader concerns about the politicization of science as distinct from more narrow concerns about a particular mendacious President. President Trump made knowingly false descriptive claims about all sorts of things.[94] Our entire constitutional order assumes that the President will fulfill his duties in good faith.[95] Where he doesn't, the appropriate remedies are impeachment or voting him out, the latter of which appears to have operated effectively in the case of President Trump. To the extent that a President ignores that constitutional duty, we have far larger problems, and far more powerful remedies, than anything as narrow as the President's statutory relationship with the FDA.

B. Compromising Clinical Trials

Finally, some commentators have argued against deviating from the "substantial evidence" standard in emergency situations on the ground that

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[91] *See* Bryan Walsh & Alison Snyder, *Scientists caught between pandemic and protests*, AXIOS (June 10, 2020), https://www.axios.com/black-lives-matter-protests-coronavirus-science-15acc619-633d-47c2-9c76-df91f826a73c.html (attributing differences in trusts of scientists among republicans and democrats to the endorsement by public health officials of widespread protests following the death of George Floyd).

[92] *See* David Wallace-Wells, *People Don't Trust Public-Health Experts Because Public-Health Experts Don't Trust People*, N.Y. MAG. (June 20, 2020), https://nymag.com/intelligencer/2020/06/american-public-health-experts-coronavirus-masks.html (attributing skepticism of public health expertise to normative public health decision-making early in the pandemic).

[93] *See* Christian Paz, *All the President's Lies About the Coronavirus*, THE ATLANTIC (Nov. 2, 2020), https://www.theatlantic.com/politics/archive/2020/11/trumps-lies-about-coronavirus/608647/ (compiling President Trump's lies during the COVID pandemic).

[94] *See, e.g.*, Daniel Dale, *The 15 most notable lies of Donald Trump's Presidency*, CNN (Jan. 16, 2021), https://www.cnn.com/2021/01/16/politics/fact-check-dale-top-15-donald-trump-lies/index.html.

[95] *See* U.S. Const. Art. II Sec. 3 (providing that the President "take care that the laws be faithfully executed"); Alexander Bickel, 1573 *War Powers Hearings*, at 185 (noting that the War Powers Resolution rests on "the assumption that in the future Presidents will act in good faith to discharge their duty to execute the law.").

doing so would compromise clinical trials, and result in it taking longer for us to learn about the safety and efficacy of the treatment.[96] It is true that if we were to authorize a vaccine prior to the completion of Phase III trials, we may lose the opportunity to ever conduct a large-scale, randomized, double-blinded, placebo-controlled study of safety and efficacy.[97] These are important informational costs to early authorization. Moreover, early authorization could diminish public confidence in vaccines in both the short and longer terms. But the question of how much those costs matter is a normative one. And as a normative one, it should be answered by the President rather than the scientists.

It is plausible that, in a pandemic, the value of information determined to the gold standard of scientific confidence is at its lowest ebb. That is, it may be that what matters is whether we can actually *lower the death rate* or *limit transmission*, not whether we understand how we are doing so, nor whether we know for sure that the result is not attributable to the placebo effect or some exogenous behavioral variable. What matters could be whether healthcare workers are continuing to be infected with SARS-CoV-2 or not and whether our hospitals are overflowing with dying patients or not. These things can be measured whether or not their cause can be robustly determined. Similarly, it's conceivable that permitting people who *want* to vaccinate themselves to do so is more important than ensuring general confidence in vaccination.

Of course, many would disagree, and argue that knowledge matters in this context as much as elsewhere, that it is only by knowing how the virus works that we can devise better long-term strategies to limit its spread, and that conceding any uncertainty about safety to the anti-vaccine movement is a defeat.[98] This argument is at least as plausible. But distinguishing between these alternatives is a normative determination. It may well be that in some circumstances, it makes sense to try everything immediately (we could imagine this not being particularly controversial if a novel pathogen had the

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[96] *See* David Cranoski, *Why emergency COVID-vaccine approvals pose a dilemma for scientists*, Nature News (Nov. 23, 2020), https://www.nature.com/articles/d41586-020-03219-y?utm_medium=tr_social&utm_campaign=site_visitor.unpaid.engagement&utm_source=Facebook&fbclid=IwAR09GS-vBc2CRpWNIrxN8O4MNh82E-NVJig8euOfDbXCjPMA6tkZOfavAzg#Echobox=1606240872 (discussing concern among scientists that early approval compromises the ability to learn about the safety and efficacy of the vaccine).

[97] *See* Matthew McCarthy, David Oshinsky & Arthur Caplan, *Make pre-approval Covid-19 vaccines available through expanded access, not EUA*, STATNEWS (Nov. 9, 2020), https://www.statnews.com/2020/11/09/expanded-access-not-eua-for-distributing-preapproval-covid-19-vaccines/.

[98] *See id.*

contagiousness of measles and the lethality of Ebola), and other situations (perhaps the SARS-CoV-2 pandemic itself) where we can credibly anticipate that containment will never work and that the virus's lethality is simply not enough to deviate from our ordinary standards of knowledge-acquisition.[99] But weighing which kind of situation we are in is precisely the normative balancing the political process is designed to accomplish.

In a democracy, the people ought to have a say in the tradeoffs we make between the acquisition of scientific knowledge and the risky but tangible prospect of ending a pandemic sooner rather than later.

CONCLUSION

Extraordinary times—including public health emergencies—call for extraordinary measures. But one of the unquestioned assumptions in the 2020 coronavirus pandemic was that the United States would have to wait for at least preliminary data from three phases of clinical trials to use vaccines that we knew from the beginning were very unlikely to be as harmful as the virus and which quite plausibly could work. Maybe that was right in these particular circumstances. But this Article argued that it did not have to be so. Instead, to prepare for future pandemics, the FDCA should be amended to recognize the President's authority to modify the FDA approval process—or, alternatively, the EUA process—in an emergency.

[99] *See* CHRISTAKIS, *supra* note 41.