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BEN

BIO QUARTERLY

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Investigational, Authorized, Approved, Off-Label: Definitions and Ethical Considerations

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Introduction

The Covid-19 pandemic has made terms like "EUA" (emergency use authorization) and "clinical trial" commonplace not only in medical centers, but in many households, on the news, and in conversations with friends and family. The novelty, and impact, of Covid-19 required clinicians and researchers to quickly innovate by repurposing and investigating treatments for other diseases to treat Covid-19 symptoms, as well as to identify new pharmaceutical interventions, and launch efforts to develop vaccinations against Covid-19.

With all these drugs and vaccines being used through clinical trials, off-label use, and emergencyuse authorization, we aim to summarize what these terms mean, and specific ethical questions that arise in the context of individual patient decision-making or hospital policy development. Although the Covid-19 pandemic placed these terms in the spotlight, they apply to research and clinical care beyond Covid-19. For this reason, familiarizing ourselves with the relevant ethical issues may be useful for those involved with their hospital ethics committees, ethics consult services, or in hospital policy development.

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President's Greetings

With this letter of greetings, I am reminded of the many things we have to look forward to at this time of year. Longer (and hopefully sunnier) days, hopefully permanent waning of COVID infections and hospitalizations, professional conferences where we once again may be able to see each other in person, and finding—or making—time for ourselves, our families, and our friends.

On the topic of conferences, it is my pleasure to confirm that the annual BENO conference will take place April 21-22, 2022. Although we will not be meeting in person this year, over the last several months conference planners have secured presenters who will cover a robust range of topics related to the conference theme: Moral Courage in the Changing Healthcare Landscape. We are particularly excited to welcome Dr. Amy Acton as one of our plenary speakers!

The content will be rich and practical to issues we all face in our daily ethics work. Registration this year is deeply discounted (see the BENO website for additional details). I encourage those of you who have attended previous conferences will share with your colleagues the value of this opportunity and the many benefits of BENO membership more generally.

Finally, I hope you enjoy the content of this issue of BioQuarterly. As an organization, we continue to endeavor to provide helpful information through this publication and to support healthcare ethics work across Ohio. In this issue, topics include treatment with investigational, authorized, approved, and off-label products; rights related to health care; television and book reviews; and visual art with commentary related to the burdens of being a healthcare professional during COVID. If you have topics you'd like to see addressed in future issues or ideas about a piece you might submit, please reach out to BioQuarterly editors.

My Best,

Josh

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Investigational

Before drugs and medical devices can be used in everyday clinical care, they must go through a rigorous process of investigation to ensure their safety and efficacy. This process involves a series of clinical trials that occur after laboratory testing and animal modeling has shown promise for benefit in people. Clinical trials occur across four phases (sometimes five): Phase 1, whether the drug is safe (and at what doses); Phase 2, whether the drug works; Phase 3, whether the drug works better, or at least as well with fewer side effects, than the current treatment (or placebo); Phase 4, whether there are longer-term side effects after the drug has been approved. Clinical trials prior to a drug's full approval can sometimes take several years.

Medical care is provided when an approved treatment is believed likely to benefit an individual patient and when such treatment is consistent with that patient's preferences and values. Investigational interventions—those that are part of clinical trials—are part of a pre-defined protocol to maximize information gathered about that intervention. In other words, providing investigational interventions is based on the goal of developing or contributing to generalizable knowledge and may or may not benefit the individual patient research subject. Researchers must minimize harms to research subjects, but direct benefit to (adult) research subjects is not the primary aim of the intervention.

Because the goals of research are different than the goals of clinical care, particular ethical considerations can arise. Here we will mention just a few. To avoid using people merely as means to gaining knowledge, and to avoid exploitation, there are considerations of fair subject selection (including recruitment practices and reimbursement for participation). Research studies also must be scientifically rigorous so that the information gained is more likely to result in useful knowledge. Of course, research studies are reviewed by an independent body, usually an Institutional Review Board, to ensure compliance with Federal Regulations and local policy [1].

At the patient and research subject level, one concern is that research subjects mistake the goals of research and the goals of clinical treatment (therapeutic misconception). This can be addressed through good informed consent processes. Addressing concerns about "equipoise," the notion that there should be genuine uncertainty during later phases of research whether the investigational intervention is better or worse than the current best treatment, also help ensure that research subjects are not unnecessarily put at risk of harm.

One particular phenomenon during Covid-19 was the acceleration and prioritization of research related to treatment and prevention of Covid-19. This makes sense, of course, given the novelty and severity of the SARS-CoV-2 virus but also raises ethical concerns at a systems level related to the deprioritization of research for other diseases and conditions.

Emergency Use Authorization (EUA)

Most closely associated with vaccines over the past couple years, this mechanism was also used to authorize temporary use of other drugs and biological products that were not vaccines, including certain monoclonal antibodies, convalescent plasma, certain antivirals, and certain medicines used for sedation or during continuous renal replacement therapy. Several medical devices were authorized under an EUA, including certain blood purification devices, certain personal protective equipment, and certain ventilators and ventilator accessories.

An EUA is issued by the U.S. Food & Drug Administration (FDA), and authorizes "unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN [chemical, biological, radiological, and nuclear] threat agents [including diseases]" [2] Importantly, it is not enough for an emergency to exist. During the current pandemic, the Secretary of the U.S Department of Health & Human Services (HHS) declared the use of EUAs justified based on the prior determination of a public health emergency that threatens national security or the health and security of U.S. citizens living abroad. [3]

Once authorized to issue EUAs the FDA must evaluate interventions and devices according to four criteria: 1) the CBRN agent(s) can cause a serious or life-threatening disease or condition, 2) there is evidence that the intervention or device may be effective, 3) there is a favorable balance of risk and benefits, and 4) there are no adequate, approved, and available options. It is important to note that the "may be effective" criterion is a lower standard than what is required when the FDA is considering an intervention or device for full approval (see next section), but is

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still based on rigorous research. This research is also necessary for engaging in a risk benefit analysis, which considers evidence from laboratory data, animal studies, and clinical trials with humans.

Ethical issues associated with EUA range from concerns about the adequacy of evidence justifying authorization to broader concerns such as whether vaccines authorized for emergency use only could be mandated. When EUAs are issued, there is corresponding guidance for how to determine who may receive the intervention. During the current pandemic, however, such guidance often had to be further interpreted to help hospitals determine how to prioritize distribution of interventions available under an EUA that had severely limited supply.

To identify just one example of how EUAs involve corresponding ethical considerations: administering certain monoclonal antibody therapies requires a visit to an infusion center, and it is widely known that such therapies are more likely to be beneficial the closer to onset of illness they are given. Processes needed to be developed locally to increase access both to testing, which was affected by supply chain issues, and to infusion centers, which require travel and where appointments were limited because of hospital staffing shortages. Addressing these various ethical concerns requires in some instances applying the ethical frameworks suitable during crisis conditions of a pandemic, and should involve collaboration between ethicists, various clinical specialties, hospital administration, and state and federal authorities.

FDA Approved

Using FDA-approved pharmaceuticals or vaccines in clinical care does not mean there are no ethical considerations that arise, but certain of those considerations are mitigated by the fact that the FDA has cleared the product through its rigorous approval process. Approval by the FDA, what we often now hear as something being "fully approved," means that the FDA granted a pharmaceutical company's biologics license application, or BLA [4]. The approved BLA is what allows a pharmaceutical manufacturer to introduce their product to the commercial market. It only occurs following multiphase clinical trials (as described above) that demonstrate both safety and efficacy of the product for use in a specific population, for a specific clinical indication, and at a specific dosing.

As noted, many steps along the way to full FDA approval involve various ethical considerations related to clinical trial study design, recruitment and enrollment, and research conduct. Once a product is FDA-approved, however, the ethical questions primarily occur at the level of individual patient care: is a particular product the right treatment for the patient in question after weighing the risks and benefits of the intervention as they apply to this patient's care? Further, FDA approval does not guarantee that new information won't come to light that leads to a revised evaluation of risks and benefits. Some drugs are recalled by the manufacturer or at the request of the FDA [5], and this is a possibility that prescribing physicians and pharmacists should be aware of to ensure they are providing accurate treatment recommendations, and safely filling prescriptions or orders for treatment.

Off-Label Use

Typically, once a product has been fully approved by the FDA, it can be used "off-label." Off-label use refers to using the drug, treatment, or vaccine outside of the population in which it was approved, at a different dosage, or for a different indication than for which it was approved.While it might sound risky or unusual to use a product "off-label," it is incredibly common in healthcare for multiple reasons. Bringing a product through development all the way to FDA approval is time and cost intensive for both researchers and clinical trial participants. If an FDA- approved product, one that is already proven to be reasonably safe (it wouldn't have FDA approval otherwise), is found to be useful to treat a condition other than the one for which it was approved, then off-label use allows it to be used in this new way without moving through another full FDA approval process. Off-label use also can be common where research regulations make conducting clinical trials in some populations, such as pregnant people and children, even more challenging. While some studies suggest approximately 20% of all pre-

scriptions written in the United States are off-label [6], this figure can be much higher in pediatrics and during pregnancy. The FDA maintains registries to track outcomes and side-effects reported by individuals who use medications off-label during pregnancy to try to address the gap in medications being studied in formal trials [7]. Various drugs were administered off-label during the Covid-19 pandemic [8] to attempt to treat symptoms as providers began to understand the disease, while others were used within clinical trials and have since received FDA authorization or approval for use to treat Covid-19 specifically (as described in the above sections).

Because the FDA regulates the products, but not the practice of medicine, off-label use is outside the purview of the FDA. It is instead a clinical decision guided by clinical, not research, ethics. For this reason, off-label use is always first and foremost about the individual patient and the decision to go off-label is made within the context of their individual clinical care. Providers recommending or prescribing off-label are generally not at heightened risk of malpractice or other liability so long as they are prescribing off-label based on an individualized assessment of clinical risk and benefit to the patient, and not for investigational purposes [9]. Yet like many novel things about the Covid-19 pandemic, the pandemic created novel situations for off-label use. Some treatments using FDA-approved products off-label have proven controversial within the medical profession, and society at large. And Covid-19 vaccines have departed from typical norms regarding off-label use. While other vaccines can and are used off-label (especially during disease outbreaks), there are specific prohibitions built into the Covid-19 vaccine provider agreement the CDC has with facilities administering Covid-19 vaccines purchased and supplied by the federal government (currently all Covid-19 vaccines in the United States) against administering Covid-19 vaccine outside the ages for which they are authorized or approved [10].

Although individual patient care considerations ought to guide ethical off-label use, examples of prescribing controversial treatments – or wishing to vaccinate a young child – off-label because an individual physician believes it to be in their patient's best interest demonstrates how an individual exercising clinical judgement in a specific patient's care can have implications on health systems, a practice group, or those in other departments such as nursing or pharmacy who are tasked with fulfilling the requested off-label prescription or vaccine administration.

Final Thoughts

We, like others, are hopeful that the threat of Covid-19 continues to diminish. Yet understanding drug and device development and use will enhance ethicists' abilities now, and in the future, to engage with caregivers at the bedside, leaders in the boardroom, patients in the hospital, and as members of the broader community. To invoke a common mantra in clinical ethics: "good facts make good ethics." It is important that ethics practitioners base their engagement with stakeholders on factual information and solid ethical reasoning. Although just a peek into a much broader body of literature, the foregoing may provide a foundation for further investigation and deeper understanding to aid in providing ethical guidance to patients, healthcare professionals, and the general public.

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Vaccine Mandates: Not New, Not Unconstitutional, Not Unethical

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Addressing the COVID-19 pandemic required a coordinated effort between Federal, State, and local governments. Central to the response were government mandates such as wearing a mask in certain situations, lockdowns, and the use of vaccines. As would be expected from a pluralistic society, some viewed the mandates as justified, even if they were burdensome. Others, however, viewed those mandates as governmental overreach, and even a violation of Constitutional rights. Herein we review prior instances when, in the name of societal benefit, the government felt compelled to set limits on individual freedoms.

While the first ten amendments to the Constitution of the United States – known as the Bill of Rights – might be the most well-known of all securities against government intrusion, it is the Due Process Clause of the Fourteenth Amendment which provides much of the protection afforded to the American citizen today. The Due Process Clause of the Fourteenth Amendment states that the government shall not "deprive any person of life, liberty, or property, without due process of law..."[1] In this manner, the Fourteenth Amendment protects rights unenumerated in the Constitution – but held fundamental nonetheless. As Justice Stevens wrote, "[All] men were endowed by their Creator with liberty as one of the cardinal unalienable rights. It is that basic freedom which the Due Process Clause protects, rather than the particular rights or privileges conferred by specific laws or regulations."[2]

Even then, the government may impose regulations impacting liberties guaranteed by the Fourteenth Amendment when they meet one of three legal tests.[3] Under the most stringent one, the government's action can be deemed legal under the "strict scrutiny test" if the government can prove it has a compelling interest, and the action is narrowly tailored.[3] Establishing regulations vital to the protection of the public's health and safety meets the standard of a "compelling interest" because the government has a responsibility to protect the public.[4] Limiting the regulation to certain locations – airports, government buildings, indoor public gatherings – or a well-defined group of individuals – workers at facilities that participate in Medicare and Medicaid – meets the requirement that the regulation be "narrowly tailored."[4, 5, 6] Thus, while some COVID-19 related mandates were cumbersome, they were not a governmental overreach.

Since 2020, there have been a slew of cases brought forth regarding the legality of directives implemented to combat the COVID-19 epidemic – namely mask and vaccine mandates. However, government regulations impacting Fourteenth Amendment liberties as they relate to public health are not a new concept. While one could consider the 2015 Second Circuit Court of Appeals ruling that vaccination requirements for schoolchildren were in fact Constitutional, in examining these COVID-19 related legal challenges, no court decision parallels the debate about COVID-19 and the Fourteenth Amendment more than Jacobson v. Massachusetts, 197 U.S. 11 (1905).[7, 8]

In May of 1901, there was an outbreak of smallpox in various neighborhoods of Boston.[9] Between 1901 and 1903, Boston recorded nearly 1600 cases of smallpox, with 270 deaths – 3 cases per 1000 persons, and a fatality rate of 17 percent.[9] In an effort to control the spread of the disease, the Boston Board of Health took several steps including: patient isolation, contact tracing, contact quarantine, and vaccinations. Initially, the vaccination program was voluntary and free. Physicians dispersed across the city to inoculate people at vaccination stations and at places of work. In spite of these efforts, the outbreak of smallpox continued to worsen – especially among the unvaccinated.[10] Facing this public health emergency, the city of Cambridge, Massachusetts ordered that all of the city's inhabitants be vaccinated or revaccinated, and those who refused would have to

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MINISERIES & BOOK REVIEW

Miniseries: Dopesick
Book: American Overdose:
The Opioid Tragedy in Three Acts

Kelli Schweitzer, MSN, RN, NPD-BC

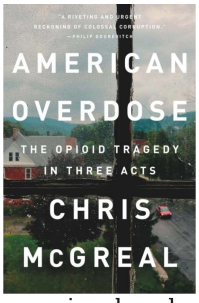
Dopesick, an eight-part drama series distributed by Hulu, analyzes the opioid epidemic from three points of view including the Sackler family, an Appalachian community, and the justice system. Each episode provides detail and historic examination into the problem that has been a part of almost every family in America beginning with the rise of a small relatively unknown company to the travesty that happened in many small Appalachian towns.

High quality dramatization by a team of actors, directors and producers presents facts corroborated through court proceedings and investigative journalism regarding the opioid epidemic. It also provides dramatic insight into how one small town changed within a few short years; changes that are mirrored in many Appalachian communities.

The show explores the processes used by Purdue to increase prescribing of its drug OxyContin. A physician working with a small group of inpatients described no evidence of addiction in a letter to the editor of a medical journal. The miniseries revealed that this letter to the editor was used repeatedly as evidence that OxyContin is not addictive. After attending a conference sponsored by Purdue encouraging physicians to prescribe the drug, a rural physician unknowingly starts the downfall of his own community and himself into opioid addiction. While the character played by Michael Keaton is not an actual person, the dramatization is an examination of what occurred little by little over the decades since OxyContin first appeared.

A weakness of the series is the shifting timelines that are often hard to follow. Most episodes have events that occur in the past followed by references before and after, which can cause confusion. Also, the portrayal of the conversations of individual Sackler family member is at times speculative at best.

After watching the series, I searched for books and articles to learn if other sources corroborate information included in Dopesick. I am currently reading the book **Dopesick (2018) by Beth Macy (376 pages).** But I wanted to read something else first to see if what the author and co-creator of Dopesick portrayed was supported by other authors. I read **American Overdose: The Opioid Tragedy in Three Acts, 2018, author Chris McGreal (336 pages).**



Chris McGreal authors a well written non-fiction account that provides facts and details substantiating the events of the book and miniseries Dopesick. McGreal analyzes what he calls Congressional neglect and corporate greed that led to the tragedy seen in small towns throughout Appalachia. He offers a compelling analysis of the transformation of a small town in West Virginia from poor to devastated in a few short years. Describing events in a town (population less than 10,000), culminating in filling opioid prescriptions in the millions, he details how many are to blame for the extreme rise in use of a drug at unsafe doses that has resulted in the deaths of hundreds of thousands.

The timeline presented in this book is easier to follow than that of Dopesick. The book introduces people and events not explored in the miniseries. It largely focuses on the events that led to large amounts of opioid prescribing in small towns. The book also provides evidence corroborating the story of those who worked to bring the issue to justice. Some of the shocking accounts shown in Dopesick including how Purdue enticed physicians to prescribe large quantities of OxyContin and how warning signs by physicians, the justice system, and patient advocacy groups were largely ignored for decades are verified in this book.

One potential weakness of this book is the challenge of following the extreme level of detail regarding many characters. For some this may seem tedious and unnecessary.

Through miniseries and books such as these, those of us in the medical community can assess how thiswas allowed to happen and hopefully learn ways we can speak up to prevent such occurrences in the future. While the opioid epidemic is a multi-faceted problem, both **Dopesick** and **American Overdose: The Opioid Tragedy in Three Acts**, show how a few people willing to speak up and bring attention to a problem that few were recognizing has resulted in change. It causes one to wonder what would have occurred if more were willing to act sooner.

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UPCOMING EDUCATIONAL OPPORTUNITIES

Bioethics Intensive 2022
In person, Baylor University, Houston, Texas
Date: March 18-22, 2022

BENO Annual Conference : Moral Courage in the Changing Healthcare Landscape
Bioethics Network of Ohio: Virtual only
Date: April 21-22, 2022
https://www.benoethics.org/events/beno-2022-conference-10414

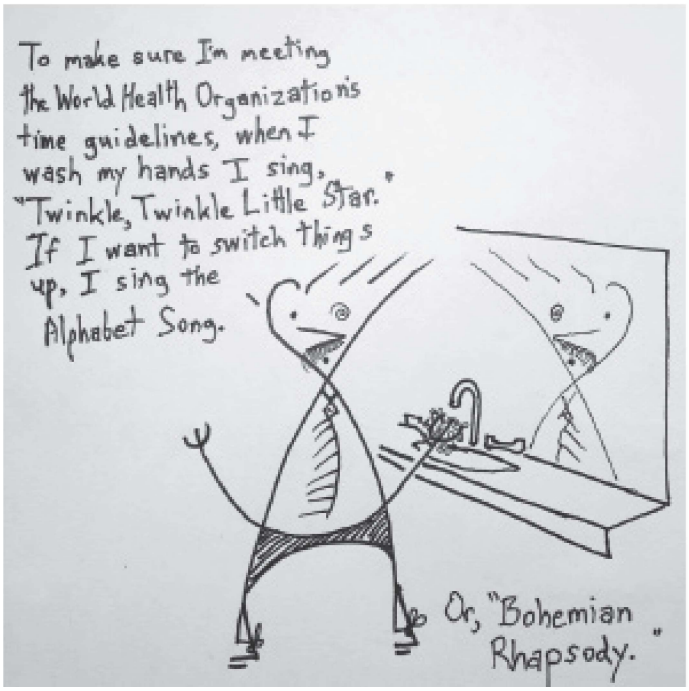
Propelling Clinical Ethics Forward: A Working Unconference
Wellstar Ethics Development Center, Atlanta, Ga.
In person only.
Date: April 28-29, 2022
https://www.wellstar.org/event-calendar/propelling-clinical-ethics-forward-a-working-unconference-e1001

Intensive Bioethics Course
Georgetown University Kennedy Center for Ethics | Georgetown University in-person
Date: June 9-11, 2022
https://ibc.georgetown.edu/

Intensive Course in Managing Inappropriate Communications in Medical Practice
Live or Virtual, Cleveland, OH
Date: Wednesday, May 11, 2022, 7:45 AM - Friday, May 13, 2022, 2:30 PM EST
https://cwru.cloud-cme.com/course/listing?p=1000
Additional offerings at this link

Intensive Course in Medical Ethics, Boundaries and Professionalism
George S. Dively Conference Center, Cleveland, OH
Dates: *Thursday, September 15, 2022, 8:00 AM EST & Friday, September 16, 2022, 3:30 PM EST*
https://cwru.cloud-cme.com/course/listing?p=1000
Additional offerings at this link

Ongoing Lecture Series
1-2 per week, on a variety of ethics issues
University of Pittsburg Center for Bioethics and Health Law
https://bioethics.pitt.edu/events
Many virtual, some in-person lectures, from several universities



Cartoon by Craig Dove

***Mandates** continued from page 6...*
pay a $5.00 fine (roughly $163.46 today).[9]

At the time of the smallpox epidemic, Henning Jacobson (1856 - 1931) was the pastor of the Swedish Evangelical Lutheran Augustana Church of Cambridge. In 1902, Jacobson refused both to be vaccinated and to pay the $5.00 fine claiming that the law requiring compulsory vaccination violated his rights of Due Process and Equal Protection as guaranteed by the Fourteenth Amendment to the Constitution.[8] In July of 1902, the Chairman of the Cambridge Board of Health, Dr. E. Edwin Spencer, filed a suit against Jacobson – Massachusetts v. Jacobson, 183 Mass. 242 (1903).[11] Jacobson lost and was fined. He then took his case to the Massachusetts Supreme Court where he lost again. In 1905, Jacobson brought suit against the Commonwealth of Massachusetts in Jacobson v. Massachusetts, 197 U.S. 11 (1905).[8]

On February 20, 1905, in a split decision – 7 to 2 – the Supreme Court ruled in favor of Massachusetts.[8] Writing for the majority, Justice John Marshal Harlan opined that the Massachusetts law did not violate Jacobson's rights as guaranteed by the Fourteenth Amendment because the police power of the state may be allowed to constrain individual liberties through reasonable regulations when required to protect public safety.[8] In the opinion, Harlan wrote:

"The liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members. Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy. Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others. This court has more than once recognized it as a fundamental principle that persons and property are subjected to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state; of the perfect right of the legislature to do which no question ever was, or upon acknowledged general principles ever can be, made, so far as natural persons are concerned. The possession and enjoyment of all rights are subject to such reasonable conditions as may be deemed by the governing authority of the country essential to the safety, health, peace, good order, and morals of the community. Even liberty itself, the greatest of all rights, is not unrestricted license to act according to one's own will. It is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others. It is, then, liberty regulated by law."[8]

Setting for a moment, the Supreme Court's opinion on the aforementioned matter aside, is there an ethical imperative to give public health ethics equal footing with clinical ethics?

Healthcare workers have the duty to promote the wellbeing of all patients, staff, and the public. Because of their profession, healthcare workers are at increased risk of contracting infectious diseases and transmitting them to their coworkers and vulnerable populations. An immunized healthcare worker can act as a barrier against the spread of infections. [12] For those reasons, healthcare organizations may need to establish infection control protocols which can include compulsory vaccinations.[13] Furthermore, because vaccines may prevent hospitalizations, their wide use in healthcare settings may reduce worker shortages. Thus, a healthcare worker who chooses to remain unvaccinated fails to contribute to their end of the collective responsibility.[1]

In public health ethics, the approach often differs from that of clinical ethics. For example, autonomy is a key principle in clinical ethics, but not in public health ethics. Controlling the spread of infection is a top priority in public health. Hence, when the choice is to be made between safety and liberty, limits on liberty may be justified, as the right of the community to protection seem to outweigh some individual rights. Public health ethics supports vaccine mandates because they may help prevent adverse health outcomes for a community at a minimal cost to the individual. Because as Justice Harlan indicated *"Even liberty itself, the greatest of all rights, is not unrestricted license to act according to one's own will. It is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others. It is, then, liberty regulated by law."*[8]

The opinions presented herein are those of the two authors. They do not represent those of the United States Air Force.

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ART SPOTLIGHT

Maeve Pascoe, Beneath the Waves

So often in medicine we feel out of our depth. In this season of life, fighting from beneath the waves of COVID-19, sometimes it feels as though we may never surface. But it is our love for our fellow humans that keeps us going. Even as case numbers rise and fall, we look to the light, the light in each other, to keep fighting. Nurses, pharmacists, physicians, therapists, environmental services workers...everyone is fighting their own battles, but we fight to keep our patients and each other alive together. It is this indomitable spirit that inspired this piece; the empathy for our patients and for each other that urges us to keep swimming upward. For even when we feel alone, there's always someone there striving to take our hands and pull us out from the deep. For even when our colleagues or patients feel alone, we strive to pull them to the surface so that they may breathe again.