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Opioid Prescribing and the Ethical Duty to *Do No Harm*

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Doctors have two ethical duties: to cure disease or ease suffering and, also, to do no harm. The ethical duty to "Do No Harm" has been used to justify two sides of a pendulum swing in the philosophy of opioid prescribing for pain. In the 1990s, it was invoked to expand prescribing, and more recently to justify dramatic reductions in prescription opioid use. In this Article, we explore whether prescribing opioids for pain presents challenges that differ from the ordinary mandate physicians face as they balance the call for action with the imperative to do no harm [DNH].

We argue that the treatment of pain differs in three important ways. First, the fact that pain is present and occurrent reduces uncertainty about the need for action, and thus strengthens the reasons to act. Second, while DNH applies to both physicians and policymakers, each has distinct duties: physicians have a duty to the individual patient; policymakers have a duty to society. As a result, harm from drug diversion should weigh little when clinicians decide how to treat individual patients. Public health officials, by contrast, rightly consider societal effects. However, in doing so, they must adopt policies that mitigate the ethical burdens placed on physicians, respect the testimony of patients in pain, and pay particular attention to how policy guidance is likely to be implemented by others. Finally, we address what duties are owed to patients who are currently taking opioid medication, given evidence that they are experiencing significant barriers in receiving healthcare. We argue that once treatment has been initiated, there are special duties to these patients.

> It's 1997, and I'm sprawled on the waiting room floor of a hospital, as bright lights glare down at me. A recent attempt to repair a previous surgical injury to my spinal cord has failed, and I remain unable to sit or stand and in severe pain. When my name is called, my husband gathers me in his arms like a sleepy six-year-old child and carries me to a treatment room. An entire treatment team crowds into the small room, as my primary physician begins, "The thing is— we've put you through painful procedure after painful procedure. We've tried dozens of medications, blocks, infusions. I have a duty to do no further harm. It's time for you to consider prescription opioids."[1]

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INTRODUCTION

The ethical duty to "Do No Harm" is as deeply embedded in modern medicine as any. It is usually attributed to a phrase in the Hippocratic Corpus, from *Of the Epidemics*: "The physician must be able to tell the antecedents, know the present, and foretell the future—must mediate these things and have two special objects in view with regard to the disease, namely, to do good or to do no harm."[2]

To "Do No Harm" ("DNH") translates to the idea that, in certain situations, inaction is better than action: that is, it is preferable to do nothing than to intervene if there is potential to cause more harm than good. In each physician-patient interaction, this duty must be balanced with the physician's obligation to "do good:" to cure disease where possible and, if not, to prolong life, ease suffering, and improve function.

In the context of what has been dubbed the opioid crisis, DNH has proven an elusive precept that has been used to justify opposite sides of the pendulum swing on opioid prescribing.[3] In the past, it was used to justify the rejection of invasive procedures and in favor of palliation using opioids.[4] Beginning in the 1990s, physicians, like the doctor in the quote at the start of the Article, who were concerned about undertreated pain, weighed the calculus in favor of expanded prescribing.[5] Today, DNH is as often a rationale for discouraging doctors from prescribing.[6]

Given this use of the DNH principle to justify opposing positions on opioid prescribing, we set out to examine whether treating pain with opioids raises issues that are distinct when balancing the call for action (to cure disease or ease suffering) with the counsel of inaction (to do no harm). In so doing, we consider opioid prescribing for both acute and chronic pain, but focus on prescribing for chronic pain, as it has garnered the most attention and raises thornier ethical issues. This paper thus contributes to the substantial literature on the opioid crisis by identifying ways in which opioid prescribing differs from the perennial issues clinicians face.

We make three arguments. First, we argue that the fact of pain's contemporaneousness reduces uncertainty about the need for action over inaction, and thus strengthens the reasons to act. Second, we note that while the DNH principle applies to both physicians and policymakers, each has distinct duties: physicians have

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[2] HIPPOCRATES, OF THE EPIDEMICS 360 (Francis Adams trans., 1849).

[3] "Opioid crisis" is a misnomer because most overdose deaths involve multiple substances used in combination and because the crisis is evolving to include non-opioid drugs. *See, e.g.,* Haylea A. Hannah et. al., *Using Local Toxicology Data for Drug Overdose Mortality Surveillance*, INTERNATIONAL SOCIETY FOR DISEASE AND SURVEILLANCE (2016) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5462295 [https://perma.cc/ENV3-B357] (average number of substances involved in overdose deaths was six); MASS DEP'T OF PUB. HEALTH, DATA BRIEF: STIMULANTS, HEALTH DISPARITIES, AND THE IMPACT OF THE OPIOID EPIDEMIC ON MATERNAL HEALTH AND HIGH RISK POPULATIONS (2019) https://www.mass.gov/files/documents/2019/03/13/PHD-1.0-Combined-Data-Brief.pdf [https://perma.cc/28GE-23LF] (fewer than 1 in 5 overdose deaths involved only opioids (and primarily illicit)); *see generally*, Centers for Disease Control and Prevention [hereinafter "CDC"], *Opioid Overdose: Other Drugs* (Aug. 12, 2019), https://www.cdc.gov/drugoverdose/data/otherdrugs.html [https://perma.cc/GR5R-L59G] (showing data on non-opioid drugs and use in combination). Thus, "polypharmacy" or "polysubstance" crisis is a more apt label. The authors recognize that co-prescribing (especially of opioids with benzodiazepines or other CNS depressants) places patients at higher overdose risks but have confined our discussion to opioid prescribing because it has garnered the most attention and has been the focus of changing prescribing practices.

[4] RICHARD J. BONNIE ET AL., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC 62–63 (2017).

[5] *Id.*

[6] *See, e.g.,* NATIONAL ACADEMY OF MEDICINE, FIRST DO NO HARM: MARSHALING CLINICIAN LEADERSHIP TO COUNTER THE OPIOID EPIDEMIC (2017); Roger A. Rosenblatt & Mary Catlin, *Opioids for Chronic Pain: First Do No Harm*, 10 ANNALS FAM. MED. 300, 300–01 (2012).

a duty to the individual patient, while policymakers have a duty to society. We argue that harm to society should weigh little, if at all, in the treating physician's assessment of whether action or inaction is best, whereas policymakers appropriately consider societal harm. We offer guidance to inform policymakers' impulses toward action or inaction aimed at mitigating the ethical burdens placed on physicians and respecting the testimony of patients in pain. In addition, we offer cautions to public health officials gleaned from the context of opioid prescribing about eschewing decisions based on the status of those affected, avoiding policy cycling, and considering how their recommendations are likely to be implemented by subsequent actors. Finally, we address what duties are owed to patients who are currently taking opioid medication. We argue that once treatment has been initiated, health professionals have special duties to these patients.

OPIOID PRESCRIBING IN THE CURRENT ENVIRONMENT

Hippocrates' advice to physicians to heed the antecedents, know the present, and foretell the future is prescient—even chilling—when we consider the medical establishment's failure to anticipate the societal effects of increased opioid prescribing. The gravity of these consequences cannot be overstated: in 2017, over 70,000 people died from a drug overdose.[7] Although deaths in 2019 seem to be leveling off, in 2018, for the third year in a row, life expectancy in the United States fell, due primarily to overdose deaths and suicide.[8] Nearly 2.1 million Americans currently have an opioid use disorder related to prescription or illicit opioids.[9]

The question of what constitutes appropriate opioid prescribing stands to affect many people with considerations weighing on both sides. Weighing on one side is the persistence of pain. Relief from suffering is a central duty of physicians, and by all measures, pain remains undertreated.[10] Some 50 million Americans suffer from persistent, daily, or near daily pain; 40 million report severe pain, and nearly 20 million have pain that is effectively disabling.[11] Pain is a chief cause of disability,[12]

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[7]National Institute on Drug Abuse, *Overdose Death Rates*, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates [https://perma.cc/Q9UJ-JX4Z]. In about two-thirds of those cases (47,600), the decedents tested positive for opioids, with about three-quarters related to illicit drugs such as heroin and fentanyl. Of those involving prescription opioids, the vast majority involved multiple substances (legal and illicit) used in combination.

[8]Lenny Bernstein, *U.S. life expectancy declines again, a dismal trend not seen since World War I*, WASHINGTON POST (Nov. 29, 2018), https://www.washingtonpost.com/national/health-science/us-life-expectancy-declines-again-a-dismal-trend-not-seen-since-world-war-i/2018/11/28/ae58bc8c-f28c-11e8-bc79-68604ed88993_story.html [https://perma.cc/2TB9-PZV8]. *See generally,* CDC, *Life Expectancy* (Mar. 17, 2017), https://www.cdc.gov/nchs/fastats/life-expectancy.htm [https://perma.cc/BMG8-RJ7Z].

[9]*See* National Institute on Drug Abuse, *Medications to Treat Opioids Use Disorder* (June 2018), https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview [https://perma.cc/P4RA-8FN6].

[10]*See* DEPARTMENT OF HEALTH AND HUMAN SERVICES, PAIN MANAGEMENT BEST PRACTICES INTERAGENCY TASK FORCE REPORT (May 2019); NATIONAL INSTITUTES OF HEALTH, NATIONAL PAIN STRATEGY: A COMPREHENSIVE POPULATION HEALTH-LEVEL STRATEGY FOR PAIN (2016); INSTITUTE OF MEDICINE, RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION AND RESEARCH 1–4 (2011).

[11]James Dahlhamer et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults – United States, 2016*, 67 MORBIDITY MORTALITY WKLY. REP. 1001 (2018).

[12]THE INSTITUTE FOR HEALTH METRICS AND EVALUATION, GLOBAL BURDEN OF DISEASE STUDY, TOP TEN CAUSES OF YEARS LIVED WITH DISABILITY (YLD) (2017); George E. Ehrlich, *Low Back Pain*, 81 BULL. WORLD HEALTH ORG. 671, 671 (2003).

and the most commonly reported reason for misusing a prescription opioid (62.3%) is to relieve physical pain.[13]

Weighing on the other side are the risks of prescribing opioids for pain. We now know that these risks are higher than once believed and that they increase when opioids are used long-term.[14] A small but significant portion of people who are prescribed an opioid for pain may develop an opioid use disorder, with risks ranging from .07%[15] to 8%.[16] While this danger is important, the substantial majority of people who take opioids do not become addicted to them.[17] The problem is that, beyond careful practices like using screening tools, providing patient education, and performing ongoing monitoring, we really don't know enough to distinguish in any definitive way for whom the benefits are likely to outweigh the risks.

Whatever the risk-benefit calculus may be for individual patients, however, the public health consequences of opioid prescribing have increased substantially in recent years. Beginning in the 1990s, we saw a significant increase in non-medical use of prescription opioids and the developing public health crisis that arose partly from unduly discounting the risks of addiction.[18] The largest risk of increased opioid prescribing is diversion—meaning the use of a prescription opioids by someone other than the person to whom it was prescribed.[19] The overwhelming weight of the data suggests that the vast majority of people who misuse prescription opioids did not receive them from a doctor but from a family member, friend, or on the street.[20] Among those who misuse—either not using them as prescribed or using opioids prescribed to another—an estimated 8 to 12% may develop a use disorder.[21]

Presently, the efficacy of opioids for relieving long-term pain is being re-evaluated,[22] and the U.S. Food and Drug Administration ("FDA") and the National Academies of Science, Engineering and Medicine[23] are in the process of providing guidance on prescribing for acute pain. While prescribing medication is but one aspect

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[13]Rebecca Ahrnsbrak et al., *Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health* (Sept. 2017), https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm [https://perma.cc/Q6JW-R5S6].

[14]Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16 EXPERIMENTAL CLINICAL PSYCHOPHARMACOLOGY 405, 408 (2008).

[15]Deborah Dowell et al., *Guidelines for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 MORBIDITY MORTALITY WKLY. REP. 1 (2016) (showing a range from 0.7–6%).

[16]Nora D. Volkow & A. Thomas McLellan, O*pioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies,* 374 N. ENG. J. MED. 1253 (2016).

[17]*Id.*

[18]BONNIE, *supra* note 4, at 24.

[19]Volkow, *supra* note 16, at 1254.

[20]*See Id.* at 1258.

[21]National Institute on Drug Abuse*, Opioid Overdose Crisis* (Feb. 2020), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis [https://perma.cc/V294-2YZX].

[22]*See generally,* P. Bialas et al., *Efficacy and Harms of Long-Term Opioid Therapy in Chronic Non-Cancer Pain*, EUR. J. PAIN 266, 266 (2019). There are studies showing efficacy for a subset of patients up to one year and others suggesting that opioids are not significantly more efficacious than other medications. *See* M. Noble et al., *Long-Term Opioid Management for Chronic Noncancer Pain*, COCHRANE SYSTEMATIC REV. (2010); *see also* E.E. Krebs, et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial*, 319 JAMA 872, 872–82 (2018). It is difficult to assess the efficacy of opioids for long-term pain from available studies because of the variety of conditions causing chronic pain, the fact that FDA drug approval requires only a short time frame for studies, and the ethical problems of designing long, placebo-controlled trials with suffering people.

[23]*See* NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, FRAMING OPIOID PRESCRIBING GUIDELINES FOR ACUTE PAIN (2020) (describing how the FDA asked NAESM to develop a framework for new evidence-based guidelines).

of effective pain management, *all* current guidelines continue to provide a role for prescribed opioids in both acute and chronic pain management.[24] Thus, assessing the ethical obligations of prescribing remains a pressing concern.

Below, we examine the DNH principle in the general case, before turning to distinct ethical problems posed by pain treatment.

THE PHYSICIAN'S TWIN AIMS: THE GENERAL CASE

The correct balance between the twin duties of action and inaction in medicine is not easy to determine. First, despite Hippocrates' wise counsel, the physician rarely knows for certain what the effects of her action or inaction will be. Instead, she operates under conditions of uncertainty, making evidence-based predictions about the likelihood that various outcomes will occur.[25] This first challenge leads to another: how to combine the physician's degrees of confidence regarding each outcome with a principle for balancing the twin duties.

Suppose Jane is ill with a disease that has a 20% chance of killing her, a 30% chance of significantly reducing her quality of life and a 50% chance of causing no harm. A therapy is available, but both its efficacy and its side-effects come with uncertainty. Perhaps it cures the disease 80% of the time, fails to work in 15% of cases, and leads to significant long-term harm for the patient 5% of the time. To say that the injunction to "do good or to do no harm" will be complicated to operationalize is an understatement.

In addition, the DNH mandate appears to rest on an empirical supposition about clinicians themselves. The DNH principle speaks in a cautionary voice and is offered as a corrective for the physician's assumed tendency to respond to the patient's distress with action. It counsels restraint when the desire to "do something" is insistent. A further complication, then, arises from the fact that it is hard to know how large this bias is in order to appropriately calibrate a principle to correct for it.

With this general background in view, we pose a new question: when doctors treat pain, is anything different? In our view, it is.

HOW PAIN AND OPIOID PRESCRIBING COMPLICATE THE ANALYSIS

Opioid prescribing for pain differs from the standard case in two important respects. First, unlike the standard case in which patient prognosis, treatment effectiveness, and occurrence of side-effects are *future* events, the presence of patient pain is occurrent. This fact about pain matters because it affects the need for action. Second, in the standard case, the harms to be avoided by the caution underlying DNH are harms *to the patient*. With opioid prescribing for pain, these harms include harms to third parties and to society as a whole.

PAIN'S PRESENCE

A clinician applying the DNH principle must weigh the costs of action versus those of inaction, discounted by the probability that each cost will materialize. For the

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[24]Jason Busse, et al., *The Canadian Guideline for Opioid Therapy and Chronic Noncancer Pain*, CMAJ (2017); U.S. DEPTARTMENT OF VETERANS AFFAIRS, VA/DoD CLINICAL PRACTICE GUIDELINES FOR OPIOID THERAPY FOR CHRONIC PAIN V. 3.0 (2017). *See also* Dowell et al., *supra* note 15.

[25]Benjamin Djulbegovic, Iztok Hozo & Sander Greenland, *Uncertainty in Clinical Medicine*, *in* PHILOSOPHY OF MEDICINE 299, 335-36 (Fred Gifford ed., 2011).

physician treating a patient for a condition other than pain, many of the outcomes she considers will occur in the future. What distinguishes the patient in pain is that a patient in pain is currently in pain. The pain is present, certain, occurring. For this reason, the doctor treating a patient in pain has more reason to act than does a doctor treating a condition whose harm to the patient is largely in the future and is thus uncertain. This is our first claim.

We must be careful not to overstate this claim. Non-pain patients also seek treatment for presently occurring conditions: loss of function, depression, etc. And when doctors treat pain, they must also make predictions about the future. Is the pain likely to lessen or worsen if untreated? Will untreated pain cause other problems, both physiological and psychological? Still, in the case of the patient in pain the greatest part of why she seeks treatment relates to a presently occurring state for which no prediction is necessary. This matters.

Pain's presence thus functions as a thumb on the scale in favor of action. This counsel for action does not suggest any specific treatment, however. The clinician should make treatment decisions guided by the evidence and clinical experience and consider opioid prescribing to the extent that both support its use.[26] Our point is simply that the presence of pain reduces uncertainty about the need for action and so alters the calculus in the clinician's assessment of the twin aims of medicine.

A critic of this point might object that the presence of pain is not certain from the perspective of the doctor. Only the patient knows whether the pain is currently present. Because pain is not objectively verifiable, the doctor might worry that the patient is exaggerating, or even lying in order to get drugs.[27] One might think that the doctor should discount the harm of the patient's current pain by her certainty that the patient is reporting accurately and honestly. We disagree. Discounting the weight accorded to a future harm by its predictive likelihood of occurring is morally different than discounting the weight accorded to a current harm by the doctor's assessment that the patient is reporting correctly. The first involves a prediction about the future, which the doctor cannot be expected to know. The second involves an assessment about the patient's reliability, which— we suggest—the doctor is not entitled to doubt, unless doing so would benefit the patient.

In order to treat the patient with the respect she is owed, we believe that the doctor must trust her patient and accept her testimony about her pain.[28] This duty is grounded in two ways. First, distrusting the patient may have negative consequences for the patient. Second, distrusting the patient itself violates the duties inherent in that relationship irrespective of its consequences.

Dismissing patients' accounts harms patients because pain can be a signal that something else is wrong. A physician may miss a serious disease. Also, where trust is

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[26]In the case of treating chronic pain, there is a lack of high-quality evidence on the efficacy of opioids beyond twelve weeks, although that is also the case for most other medications and treatments approved to treat pain. *See* Baraa Tayeb et al., *Durations of Opioid, Nonopioid Drug, and Behavioral Clinical Trials for Chronic Pain: Adequate or Inadequate?* 17 PAIN MED. 2036, 2042-43 (Nov. 2016). This owes partly to the duration of the FDA approval processes, practical and ethical difficulties of doing long-term, placebo-controlled studies with suffering human beings, and to the fact that chronic pain represents a large umbrella category representing pain of different types and etiologies.

[27]*See* Diane Hoffmann & Anita Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: the Role of State Medical Boards*, J. L. MED. ETHICS, 21, 21–40 (2003). Commonly-used practices that lean toward surveillance mitigate against uncertainty regarding malingering or drug seeking, including Prescription Drug Monitoring Programs, pain contracts, urine drug testing, and pill counts.

[28]One of us has developed the argument for this claim elsewhere. *See* Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701, 711 (2009).

absent, patients may experience fear or shame, which may lead them not to share symptoms out of fear of being disbelieved or to cease seeking medical attention altogether.[29] Lastly, the experience of being distrusted itself causes humiliation and distress.[30]

Even if distrust did not cause negative consequences for the patient, the doctor's duty of loyalty to the patient includes an obligation to show her respect as an agent to be believed. To ask doctors to adopt skeptical attitudes toward their patients undermines that relationship in a way that is inherently morally troubling. There is one exception to this principle. If the doctor thinks the patient may be misusing the drugs and is likely to harm herself by doing so, the doctor must balance her concern for her patient's interests against her obligation to treat the patient respectfully by believing her. But in cases where this exception does not apply, the doctor wrongs the patient by adopting a skeptical attitude toward her report.

One further consideration counts in favor of clinicians trusting patient reports of pain. If the testimony or reports of some groups—people of color, women, individuals with disabilities, and others who are marginalized—are discounted or challenged more often than are the accounts of others, this tendency to disbelieve these groups wrongs these patients and amounts to what the philosopher Miranda Fricker terms "testimonial injustice."[31] The "Me Too" movement aims to confront precisely this phenomenon of testimonial injustice and it is for this reason that their slogan is "Believe Women."[32] To the extent that chronic pain patients are disproportionately from groups who tend to be disbelieved,[33] the physician has an additional reason, both epistemic and moral, to correct this injustice and "Believe Pain."[34]

In sum, in balancing the conflicting calls to action and inaction, the fact that a patient reports current pain weighs distinctively in favor of action. The presence of the pain obviates the need for future prediction about the imperative to treat.

HARM TO THIRD PARTIES AND TO SOCIETY

Opioid prescribing for chronic pain differs from the standard medical context in another important respect, one that has garnered significantly more attention than the contemporaneousness of pain. Communities around the country have been devasted by the "opioid epidemic," words that convey the scope of the problem.[35] In

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[29] *Id.*

[30] *See* Daniel Goldberg, *Pain, Objectivity and History: Understanding Pain Stigma*, 43 MED. HUMANITIES 238–43 (2017).

[31] MIRANDA FRICKER, EPISTEMIC INJUSTICE: POWER AND THE ETHICS OF KNOWING 630 (2007). *See generally* Daniel Z. Buchman, Anita Ho & Daniel S. Goldberg, *Investigating Trust, Expertise, and Epistemic Injustice in Chronic Pain*, 2017 J. BIOETHICAL INQUIRY 31–42 (applying Fricker's concept of testimonial injustice to chronic pain patients as a disbelieved group and arguing clinicians should adopt an attitude of "epistemic humility").

[32] Kimberly Kessler Ferzan, *#BelieveWomen and the Presumption of Innocence: Clarifying the Questions for Law and Life*, NOMOS (forthcoming 2019) (on file with author).

[33] *See* Dahlhamer, et al ., *supra* note 11 (age-adjusted prevalence of both chronic pain and high-impact chronic pain significantly higher among women); Kelly M. Hoffman et al., *Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs About Biological Differences Between Blacks and Whites*, 113 PNAS 4296 (2016) (people of color have their pain disbelieved more often than do white people).

[34] Recently, a video posted to Twitter showing a nurse distrusting and mocking patients went viral and elicited an indignant response from people in pain under the hashtag #patientsarenotfaking. *See* #patientsarenotfaking, TWITTER, https://twitter.com/hashtag/patientsarenotfaking?lang=en [https://perma.cc/GAA4-L6K8].

[35] *Impact of the Opioid Epidemic: Shared Stories*, CDC (Sep. 25, 2019), https://www.cdc.gov/injury/features/opioid-epidemic-stories/index.html [https://perma.cc/2FYJ-4VWN].

what follows, we argue that while this problem is real, serious, and warrants governmental attention, the individual doctor treating an individual patient ought not to consider broader societal effects when making a treatment recommendation.

Doctors treating individual patients, like lawyers with individual clients, have obligations that run directly to the patients and that prohibit the sort of divided loyalties that give rise to conflicts of interest.[36] It is for this reason that ethical issues arise when physicians gain financially by prescribing the drugs made by particular companies,[37] or when physicians are financially rewarded for offering less care.[38]

While the doctor is not prohibited from ever considering how her treatment of her patient affects others, it is important to minimize conflicting loyalties as much as is practicable. Ethical tension is lessened when the obligation to consider others does not compromise the medical care provided to the patient. For example, the law requires that doctors report suspected child abuse and wounds that appear to be caused by gun violence.[39] While such reporting is justified by the interests of others, it does not impair the medical care provided. Were a doctor to decline to prescribe opioid medication because she worries that unused drugs may be stolen or sold, the doctor compromises patient care on behalf of community welfare. Instead, she should mitigate potential harms by educating the patient regarding the risk to others if medication falls into the wrong hands, urging safe medication storage and disposal practices and providing the smallest effective supply of medication for her patient.

This analysis implies that the public health official has different obligations that may yield a different recommendation about how best to balance the twin goals of medical practice. We address the public health perspective in the next section.

THE PUBLIC HEALTH PERSPECTIVE

The public health perspective is different. The official charged with developing recommendations for the use of opioid medication must ask herself what is best for everyone. For her, it is appropriate to balance patients' need for treatment against the harm to others that may be caused by the diversion of prescribed drugs. We offer two recommendations and two warnings to guide the public health official.

Before doing so, we first address whether the DNH principle applies to the public health official at all, as the directive in the Hippocratic Corpus focuses on the treating physician. While this is accurate, we argue that the public health official faces analogous ethical imperatives to do good and to avoid harm. As a result, she too must

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[36]*See e.g.* MODEL RULES OF PROF'L CONDUCT r. 1.7 (AM. BAR ASS'N 2018) ("a lawyer shall not represent a client if the representation involves a concurrent conflict of interest"); AM. MED. ASS'N , CODE OF MED. ETHICS Opinion 9.6.2, https://www.ama-assn.org/delivering-care/ethics/gifts-physicians-industry [https://perma.cc/4P8J-RUYH] ("addressing gifts to physicians from pharmaceutical, biotechnology, and medical device companies").

[37]*See* ELDO E. FREZZA, MEDICAL ETHICS: A REFERENCE GUIDE FOR GUARANTEEING PRINCIPLED CARE AND QUALITY 69–70 (2019); Joseph S. Ross et al., *Pharmaceutical Company Payments to Physicians: Early experiences with Disclosure Laws in Vermont and Minnesota*, 297 JAMA 1216, 1222 (2007); Howard Brody, *The Company We Keep: Why Physicians Should Refuse to See Pharmaceutical Representatives* 3 ANNALS FAM. MED. 82–83 (2005).

[38]George J. Agich & Heidi Forster, *Conflicts of Interest and Management in Managed Care*, 9 CAMBRIDGE Q. HEALTHCARE ETHICS 189 (2000).

[39]States have their own laws governing what doctors must report. *See e.g.* CAL. PENAL CODE § 11166 (DEERING 2019) (requiring mandated reporters, which includes doctors and nurses, to report child abuse within 36 hours of "receiving information concerning the incident"); N.Y. PENAL LAW § 265.25 (MCKINNEY 2000) (physicians must report "every case of a bullet wound, gunshot wound . . . or any other injury arising from or caused by the discharge of a gun or firearm, and every case of a wound which is likely to or may result in death . . . inflicted by a knife").

grapple with how best to balance these twin aims. Indeed, the number of people potentially affected by action and inaction is far greater in the case of the public health official, a fact that complicates rather than obviates the balancing the public health official must consider.

First, the policies adopted by the public health official should minimize as far as possible the ethical strain they place on clinicians treating pain patients. Second, public health officials should also keep in mind the issue of testimonial injustice and calibrate their recommendations in light of the fact that disbelieving pain patients may exacerbate these injustices.

We now turn to the warnings. In the context of the individual patient and her provider, the DNH principle served as a counterweight to the supposed physician bias toward action. In the public health context, there is no uniform bias toward either action or inaction.[40] Instead, what we see are two important dynamics that public health officials must be aware of and accommodate.

First, whether there is a bias toward action or inaction may depend upon who it is that is suffering. When the group suffering enjoys high social status, there is likely to be a bias toward action. When the group suffering lacks social status, there is likely a bias toward inaction. The argument has been made that drug overdose deaths were ignored for far too long owing to the low social status of people who use drugs or have addiction, and that policymakers became responsive to the opioid crisis and began to treat addiction as a public health matter because of the perception of its impact on white Americans.[41]

Second, officials should recognize that policy is often responsive. We see one problem, react; another develops, react. Public health officials should be cautious not to over-react in addressing one problem lest they create a different problem in the policy's wake.

Indeed, each of these dynamics can be seen in our policy on opioid prescribing. As noted earlier, the problem of addiction likely attracted more sympathy when the affected population was perceived to be largely white.[42] Regarding cycling, we have whipsawed from over-emphasizing the benefits of opioid medication and focusing narrowly on treating pain to caring dramatically more about the risks of addiction.[43] Our first warning to public health officials is to be attentive to these two dynamics: the tendency of action or inaction to track status and the dangers of cycling.

Our second warning relates to the manner in which classic trade-offs between rules and standards are complicated in the context of opioid prescribing. As lawyers know well, there are benefits and drawbacks to each approach.[44] Consider two examples. We have speed limits to ensure that motorists drive at a safe speed. We could simply say, "Drive safely," but we don't, because we believe that we will achieve more safety by telling drivers that they cannot exceed 65 mph. Of course, that rule sometimes produces errors. Some drivers could drive safely at 75 mph and some drivers should be driving 50 mph (given their skill, the weather, or other factors). But the choice of a rule (65mph) versus a standard (drive safely) reflects the judgment that there will be fewer errors with the rule. In other contexts, the standard is the better

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[40]MARY ANNE BOBINSKI ET AL., BIOETHICS AND PUBLIC HEALTH LAW 266 (3d ed. 2013).

[41]*See, e.g.,* Maia Szalavitz, *What the Media Gets Wrong about Opioids*, COLUMBIA J. REV. (Aug. 15, 2018) https://www.cjr.org/covering_the_health_care_fight/what-the-media-gets-wrong-about-opioids.php, [https://perma.cc/WNA6-3AHC].

[42]*Id.*

[43]*See* Rosenblum, *supra* note 14.

[44]*See generally*, FREDERICK SCHAUER, PLAYING BY THE RULES: A PHILOSOPHICAL EXAMINATION OF RULE-BASED DECISION-MAKING IN LAW AND IN LIFE 13, 104 (1991).

choice. We direct family court judges to make custody determinations in accordance with "best interests of the child" because we believe these judges will reach better decisions guided by this goal than they would if constrained by a rule that limits discretion and sets specific criteria.[45] The point to stress is that rules and standards each produce errors. The choice between them requires we ask: will there be more errors with a rule or more errors with a standard, in the particular context?

This is familiar terrain. What is sometimes neglected is the manner in which the structures and systems involved in the enforcement of a policy affect how rule-like or standard-like a policy actually turns out to be. Our second warning to public health officials is to be aware of how a standard can be transformed into a rule by the actors who play a role in its implementation.

Prescribing guidelines for opioid-based medication provide an apt example of this phenomenon. In 2016, the Centers for Disease Control and Prevention ("CDC") issued its "Guideline for Prescribing Opioids for Chronic Pain" ("Guideline") designed to inform primary care physicians about safer opioid prescribing.[46] This Guideline encourages doctors first to use alternative medications or treatments for chronic pain as opposed to opioids, and, when opioids are used, to prescribe at the lowest effective dose for the shortest effective duration.[47] The Guideline provides a standard that is non-mandatory guidance, though coming from the CDC, it carries significant weight.[48]

Nevertheless, two of the more concrete provisions in the Guideline have been widely adopted into laws and policies by state legislatures, major insurance companies, major pharmacy chains, pharmacy benefit managers, and others in ways that have had reverberating implications throughout the healthcare system.[49] These progeny of the CDC's Guideline take a stricter, more rule-like form. One provision that is included in the laws enacted in over half the states limits the number of days for which a physician may prescribe opioids for acute pain.[50] Another uses dosage guidance that was designed to assist physicians when starting a new patient on opioids but has become, in effect, a benchmark for safe prescribing.[51]

A final actor involved in implementation of the Guideline is law enforcement, which is using the dosage guidance in the CDC's Guideline to make decisions about who to watch.[52] Prescribing over the dosage suggested in the Guideline may subject a clinician to oversight.[53] This development has had downstream effects on patients. A

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[45]Frederick Schauer, *The Generality of Law*, 107 W.VA. L. REV. 217, 220-22 (2004).

[46]Dowell et al., *supra* note 15.

[47]*Id.* at 16.

[48]*See* Kate M. Nicholson, Diane E. Hoffman & Chad D. Kollas, *Overzealous use of the CDC's opioid prescribing guideline is harming pain patients*, STAT (Dec. 6, 2018), https://www.statnews.com/2018/12/06/overzealous-use-cdc-opioid-prescribing-guideline [https://perma.cc/8LCS-KXN6].

[49]*Id.*

[50]*See Opioid prescription limits and policies by state*, BALLOTPEDIA (Oct. 4, 2019), https://ballotpedia.org/Opioid_prescription_limits_and_policies_by_state#Alaska [https://perma.cc/P3Y5-YREH].

[51]*See* Kurt Kroenke et al., *Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report*, 20 PAIN MED. 724, 726 (2019).

[52]*See* Nicholson, Hoffman & Kollas, *supra* note 48.

[53]*See* Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. KAN. L REV. 961, 962–67 (2019) (arguing that the lack of a definition of improper prescribing makes reliance on proxies like dosage more likely); *see also* Jessica Schneider, *Justice Department reveals its number crunching methods to catch over-prescribers*, CNN (Sept. 24, 2019), https://www.cnn.com/2019/09/24/politics/opioid-doctors-arrests/index.html [https://perma.cc/S8SN-667R] (noting factor of doctor's prescribing above the dosages recommended by the CDC).

landmark report issued by the international watchdog group, Human Rights Watch, for example, found that doctors were tapering patients off of opioids or denying them care —and doing so even against their medical judgment—in an effort to protect their licenses or stay under the radar of law enforcement.[54]

Each of the subsequent actors—pharmacists, insurers, law enforcement officers, and physicians themselves—have, in effect, treated a guideline as a rule. Public health officials who draft policies must take account of these predictable dynamics. While guidelines may be written in a manner that leaves discretion to clinicians, other actors may react in ways that subtly but powerfully transform the policy into more of a rule.

To be fair, the CDC this year addressed concerns that the proliferation of laws and policies stemming from its Guideline risked harm to patients.[55] The CDC issued clarifications that its guideline was being misapplied by policymakers, and underscored the danger of misapplication in view of the limitations of available evidence.[56] In a coordinated effort, the FDA issued a warning and announced a label change for opioid medication that cautions against abrupt cessation of opioids, advising that doing so can result in withdrawal symptoms, uncontrolled pain, and suicide.[57] This is a positive step but one that may not be as effective as hoped: the response has been so wide-reaching that course correction of the previous directive may be hard to dislodge.[58]

At least with respect to one group of people, the between 8 and 13 million[59] Americans who currently take opioids for pain, there is reason for concern. We turn to the special obligations to these patients in the next section.

SPECIAL OBLIGATIONS TO PATIENTS ALREADY ON OPIOID TREATMENT

Opioid prescribing policy should also consider what duty is owed to those who already take opioids long-term for chronic pain. Some of these patients have functioned on opioids for years or even decades.[60] Some, though certainly not all, are on higher dosages than is now considered ideal, and may do better at lower doses.[61]

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[54]*See* HUMAN RIGHTS WATCH, NOT ALLOWED TO BE COMPASSIONATE, 65 (2018).

[55]*See* Deborah Dowell, Tamara Haegerich & Roger Chou, *No Shortcuts to Safer Opioid Prescribing*, 380 NEW ENG. J. MED. 2285, 2287 (2019)

[56]*See Id.* at 2285–86. In its guideline, the CDC had rated the quality of the evidence it used for each recommendation. These two provisions that were translated into law and mandates were based on poor and low-quality evidence.

[57]*FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering*, U.S. FOOD AND DRUG ADMINISTRATION (Apr. 9, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes [https://perma.cc/T87C-KBNU].

[58]*See* Nicholson, Hoffman & Kollas, *supra* 48.

[59]*See* Kroenke et al., *supra* note 51, at 725; Ramin Mojtabai, *National Trends in Long-term Use of Prescription Opioids*, 27 PHARMACOEPIDEMIOLOGY AND DRUG SAFETY (2018) (finding 5.4% of adults in the United States had long-term opioid prescriptions in 2013–2014).

[60]*See* Ajay Manhapra et al., *The Conundrum of Opioid Tapering in Long-Term Opioid Therapy for Chronic Pain: A Commentary*, SUBSTANCE ABUSE 153, 157 (2018) (includes case studies of patients on opioid for long duration); *see generally,* Judith Parsells et al., *Prevalence and characteristics of opioid use in the US adult population*, PAIN 507, 511 (2008).

[61] Jane Ballantyne & Jianren Mao, *Opioid therapy for chronic pain*, NEW ENG. J. MED. 1943, 1944-45 (2003).

Yet, while risks rise with higher doses, there is no set dosage threshold that will be appropriate for all patients.[62]

Recently, there has been an uptick in reports of long-term pain patients being abruptly tapered off their medication or abandoned in care altogether.[63] As a result, patients report damage to their mental and physical health.[64] Some are no longer able to work or function and have suffered financial devastation as a result.[65] Others have resorted to the illegal market and even suicide when their medication or care is denied.[66] The studies that have emerged just this year are harrowing. One study of Medicaid patients who had been on high dosages for more than 90 days found that the average time to discontinuation of opioids was 24 hours, and that it was often followed by an opioid-related hospital or emergency room visit as a result.[67] Another showed a three-fold increase of overdose death, just from destabilizing dosage.[68] Yet another showed that opioid tapering was associated with dissolution in care relationships between providers and patients.[69] And a recent study found that tapering was happening too abruptly and disproportionately to women and people of color.[70]

Moreover, additional studies suggest that chronic pain patients who use opioids to manage pain are facing increasing barriers to getting access to health care, with one study finding that approximately 40% of primary care physicians are unwilling to take on a new patient who uses opioids to manage pain, [71] and another concluding that 81% are reluctant to.[72]

Some of these issues are practical in nature and require attention and resources. For example, 70% of physicians report that they need help understanding how tapering can be done in a safe manner.[73] This data suggests a need for better education. But in an imperfect world in which optimal physician training is unlikely to permeate to all clinicians and thus one in which we can predict that some number of patients may be abandoned or inappropriately titrated by their physicians, what public policy response is appropriate?

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[62]*See* PAIN MANAGEMENT BEST PRACTICES, *supra* note 10 at 26.

[63]*See* U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 57; HUMAN RIGHTS WATCH, *supra* note 54, at 3–4.

[64]*See* HUMAN RIGHTS WATCH, *supra* note 54, at 39.

[65]*See generally id.* (reporting on eighty-six interviews with chronic pain patients, healthcare providers, and officials to highlight the struggles of these patients).

[66]*See id.* at 39, 48.

[67]Tami L. Mark & William Parish, *Opioid Medication Discontinuation and Risk of Adverse Opioid-Related Health Care Events*, 103 J. SUBSTANCE ABUSE TREATMENT 58, 60–61 (2019). Anyone who has taken opioids long-term is likely to develop physical dependence, requiring that opioids be tapered slowly to avoid side effects. Dependence is distinct from addiction, because it lacks the behavioral component that characterizes a use disorder. *See e.g.,* NATIONAL INSTITUTE ON DRUG ABUSE, MEDIA GUIDE: THE SCIENCE OF DRUG USE AND ADDICTION 3 (2018), https://www.drugabuse.gov/publications/media-guide/science-drug-use-addiction-basics [https://perma.cc/35D7-8BTZ].

[68]Jason M. Glanz et al., *Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy*, 2 JAMA NETWORK OPEN (2019); *see also* Jocelyn R. James et al., *Mortality after Discontinuation of Primary Care–Based Chronic Opioid Therapy for Pain: A Retrospective Cohort Study*, 34 J. GEN. INTERNAL MED. 2749, 2755 (2019) (increased mortality risk).

[69]Hector R. Perez et al., *Opioid Taper Is Associated with Subsequent Termination of Care: A Retrospective Cohort Study*, 35 J. GEN. INTERNAL MED. 36, 40 (2019).

[70]Joshua J. Fenton et al., *Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-Term Opioid Therapy, 2008–2017*, 2 JAMA NETWORK OPEN (2019).

[71]Pooja A. Lagisetty et al., *Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids,* JAMA NETWORK OPEN, JULY 2019.

[72]JAY WOHLGEMUTH ET AL., QUEST DIAGNOSTICS, HEALTH TRENDS: DRUG MISUSE IN AMERICA 2019, at 6 (2019).

[73]*See id*. at 9.

Given that public health agencies allowed doctors to prescribe opioids, even at high doses, we believe that society and physicians have special duties to these patients. This contention draws support from the existence of a similar duty in other contexts. For example, although a person has no legal duty to rescue a person in need, if a good Samaritan attempts a rescue, she incurs duties to continue and to carry out the rescue competently.[74] In a similar vein, Henry Richardson argues that medical researchers incur obligations to research subjects to provide ancillary care and that these duties arise from the fact that the researcher has involved himself in the treatment of the research subject.[75]

Indeed, we already apply these principles to the one in three cancer patients who no longer have active disease but continue to experience chronic pain either as a consequence of the disease or its treatment.[76] The CDC has stated that its guideline was not intended to apply to anyone who has ever had cancer.[77] This recognition of the duty to on-going patients supports our contention.

Along these lines, we posit that physicians and society have special obligations that add extra normative heft to the claims of patients currently on opioid-based drugs. These patients did not put themselves on opioids. The duty of the physician who initiated opioid prescribing is the clearer case. But we argue that given the recalibration in views of the medical and public health community on opioid prescribing, this duty extends to the broader medical and public health community. As a result, the harm to existing patients who are inappropriately treated in the wake of more restrictive prescribing policies is not merely a cost to be weighed alongside other costs and benefits, but is instead a wrong that society inflicts on these patients.

One possible solution that retains the benefits of current policy choices, while mitigating harms, might be to provide legal amnesty to clinicians who are willing to take on medication management of patients on long-term opioid therapy a sort of safe haven from heightened oversight. Given misapplication of the CDC's dosage guidance, clinicians who are willing to care for patients on higher doses face elevated oversight risk, and this creates an incentive to discard or fail to treat some of the most vulnerable patients. Any such provision must be drawn carefully and narrowly to avoid backsliding into liberal prescribing. Guidance that is just now emerging from public health authorities might provide sufficient guardrails against such concerns,[78] while enabling the protection and care of this vulnerable and not insubstantial group of patients.

CONCLUSION

[74]*See* 2 DAN B. DOBBS ET AL., THE LAW OF TORTS § 312 (2d ed. 2019).

[75]*See* HENRY S. RICHARDSON, MORAL ENTANGLEMENTS: THE ANCILLARY-CARE OBLIGATIONS OF MEDICAL RESEARCHERS (2012) (adopting a nuanced view regarding when ancillary care obligations are incurred that begins with the moral entanglement of the researcher and research subject).

[76]*See* Helen Leask, *1 in 3 Survivors Still in Pain Years After Cancer Treatment*, MEDSCAPE (June 24, 2019), https://www.medscape.com/viewarticle/914817.

[77]*See* CDC, GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN, https://www.cdc.gov/drugoverdose/pdf/prescribing/Guidelines_Factsheet-a.pdf [https://perma.cc/8D3R-JHGB]. The complication arises because once the disease is in remission, it becomes a much harder to come up with a principled distinction between this pain and chronic non-cancer pain.

[78]*See* DEPARTMENT OF HEALTH AND HUMAN SERVICES, HHS GUIDE FOR CLINICIANS ON THE APPROPRIATE DOSE REDUCTION OR DISCONTINUATION OF LONG-TERM OPIOID ANALGESICS (2019) (underscoring the risks of rapid taper in providing guidance on when tapering is and is not appropriate and how taper appropriately affects patients).

We have highlighted the factors that should inform physician and policy decisions regarding opioid prescribing for pain, examining how both the dangers of opioids and the presence of pain complicate the delicate balance between the twin goals of medicine. We conclude with a final, more general, concern.

At least with respect to patients presently taking opioids, current policy may be turning the ordinary ethical and legal obligations of clinicians on their head. Physicians have an ethical duty to relieve suffering and both an ethical and legal duty not to abandon their patients, especially where serious harm might result from such abandonment.[79] Refusing to see a patient on the basis of her medical condition[80] or the medication she takes for that condition[81] also violates that patient's civil rights. To the extent that current policies may be encouraging physicians to do so, these are serious considerations, which raise deeper concerns about undermining both trust in the doctor-patient relationship and the helping nature of the profession.

[79]*See* AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS OPINIONS, CHAPTER 1: OPINIONS ON PATIENT-PHYSICIAN RELATIONSHIPS (discussing ethical obligation not to decline patients whom they've accepted into care); Helen Lippman & John Davenport, *Patient Dismissal: The Right Way to Do It*, 60 J. FAM. PRAC. 135, 136 (2011) (discussing legal obligation against abandonment).

[80]Physicians have these responsibilities under Title III of the Americans with Disabilities Act of 1990, 42 U.S.C. § 12181-9, 28 C.F.R. pt. 36 (title III); *see* Bragdon v. Abbott, 524 U.S. 624 (1998) (refusal of dentist to treat patient on the basis of HIV disease violates ADA).

[81]Press Release, U.S. Dep't of Justice, Justice Department Reaches Settlement with Selma Medical Associates Inc. to Resolve ADA Violations (Jan. 31, 2019), https://www.justice.gov/opa/pr/justice-department-reaches-settlement-selma-medical-associates-inc-resolve-ada-violations [https://perma.cc/66G6-PEWB] (resolving violations of the ADA related to the refusal to accept a prospective new patient on the basis that he takes Suboxone).