OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports were presented by Rebecca Brendel, MD, Chair:

1. CONTRACTS TO DELIVER HEALTH CARE SERVICES

CEJA Opinion; No reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2025 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 05-A-25, "Protecting Physicians Who Engage in Contracts to Deliver Health Care Services." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-11.2.3 – Contracts to Deliver Health Care Services

Prioritizing profits over patients is incompatible with physicians' ethical obligations. No part of the health care system that supports or delivers patient care should place profits over such care. Physicians have a fundamental ethical obligation to put the welfare of patients ahead of other considerations, including personal financial interests. This obligation requires that before entering into contracts to deliver health care services, physicians consider carefully the proposed contract to assure themselves that its terms and conditions do not create untenable conflicts of interest or compromise their ability to fulfill their ethical and professional obligations to patients. Those physicians who enter into contracts with corporate entities, such as private equity firms, management service organizations, professional services corporations, insurance companies, or pharmaceutical benefit managers, who act within their capacity as a physician, even as administrators or intermediaries, also have a duty to uphold the ethical obligations of the medical profession.

Ongoing evolution in the health care system continues to bring changes to medicine, including changes in reimbursement mechanisms, models for health care delivery, restrictions on referral and use of services, clinical practice guidelines, and limitations on benefits packages. While these changes are intended to enhance quality, efficiency, and safety in health care, they can also put at risk physicians' ability to uphold professional ethical standards and can impede physicians' freedom to exercise independent professional judgment and tailor care to meet the needs of individual patients.

As physicians seek capital to support their practices or enter into various differently structured contracts to deliver health care services—with group practices, hospitals, health plans, investment firms, or other entities—they should be mindful that while some arrangements have the potential to promote desired improvements in care, other arrangements have the potential to put patients' interests at risk and to interfere with physician autonomy.

When contracting with entities, or having a representative do so on their behalf, to provide health care services, physicians should:

(a) Carefully review the terms of proposed contracts, preferably with the advice of legal and ethics counsel, to assure themselves that the arrangement:

(i) minimizes conflict of interest with respect to proposed reimbursement mechanisms, financial or performance incentives, restrictions on care, or other mechanisms intended to influence physicians' treatment recommendations or direct what care patients receive, in keeping with ethics guidance;

(ii) does not compromise the physician's own financial well-being or ability to provide high-quality care through unrealistic expectations regarding utilization of services or terms that expose the physician to excessive financial risk;

(iii) ensures the physician can appropriately exercise professional judgment;

(iv) includes a mechanism to address grievances and supports advocacy on behalf of individual patients;

(v) is transparent and permits disclosure to patients;

(vi) enables physicians to have significant influence on, or preferably outright control of, decisions that impact practice staffing;

(vii) prohibits the corporate practice of medicine.

(b) Negotiate modification or removal of any terms that unduly compromise physicians' ability to uphold ethical or professional standards.

When entering into contracts as employees, preferably with the advice of legal and ethics counsel, physicians should:

(c) Advocate for contract provisions to specifically address and uphold physician ethics and professionalism.

(d) Advocate that contract provisions affecting practice align with the professional and ethical obligations of physicians and negotiate to ensure that alignment.

(e) Advocate that contracts do not require the physician to practice beyond their professional capacity and provide contractual avenues for addressing concerns related to good practice, including burnout or related issues.

(f) Not enter into any contract that would require the physician to violate their professional ethical obligations. When contracted by a corporate entity involved in the delivery of health care services, physicians should:

(g) Terminate any contract that requires the physician to violate their professional ethical obligations and report any known or suspected ethical violations through the appropriate oversight mechanisms. (I, II, III, V, VI, VIII, IX)

2. ORGAN TRANSPLANTATION ALLOCATION DECISIONS

CEJA Opinion; No reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2025 Annual Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 08-A-25, "Laying the First Steps Towards a Transition to a Financial and Citizenship Need Blinded Model for Organ Procurement and Transplantation." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the online edition of the *Code of Medical Ethics*.

E-6.2.1.1 Organ Transplantation Allocation Decisions

When making organ transplantation allocation decisions, physicians have a responsibility to provide equitable and just access to health care, including only utilizing organ allocation protocols that are based on ethically sound and clinically relevant criteria.

When making allocation decisions for organ transplantation, physicians should not consider non-medical factors, such as socioeconomic and/or immigration status, except to the extent that they are clinically relevant.

Given the lifesaving potential of organ transplants, as a profession, physicians should:

(a) Make efforts to increase the supply of organs for transplantation.

(b) Strive to reduce and overcome non-clinical barriers to transplantation access.

(c) Advocate for health care entities to provide greater and more equitable access to organ transplants for all who could benefit. (I, III, V)

REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports were presented by Rebecca Brendel, MD, Chair:

1. AMENDMENT TO OPINION 1.1.1 "PATIENT-PHYSICIAN RELATIONSHIPS"

Reference committee hearing: see report of Reference Committee on Ethics and Bylaws.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED

The Council on Ethical and Judicial Affairs (CEJA) believes that the AMA *Code of Medical Ethics* and the profession would be well served by amending guidance to provide a more robust discussion of the nature of patient-physician relationships and physicians' associated ethical obligations. Indeed, the practice of medicine has changed in ways that demand a thorough review and potential reconceptualization of the obligations of both individual physicians and the profession as a whole.

At the 2025 Annual Meeting, testimony was heard that CEJA Report 06-A-25, "Amendment to Opinion 1.1.1 'Patient-Physician Relationships'," does not address "political and administrative influence" on the patient-physician relationship, and the report was referred back to CEJA.

In light of these considerations, CEJA has amended the body of the report and the recommendations to better reflect the reality of these external influences. As the first opinion of the *Code*, Opinion 1.1.1 is the foundation that supports all other *Code* opinions, many of which also address the important issues raised by the House. As the foundational opinion, Opinion 1.1.1 ought not be exhaustive and is not designed to address all of the important issues in the opinions that ultimately rely upon it.

BACKGROUND

Relevant House Policies

Several House policies reference the importance of the patient-physician relationship. Though not an exhaustive list, the following policies capture the spirit of the patient-physician relationship expressed within AMA House policy: H-165.837 "Protecting the Patient-Physician Relationship", H-225.950 "AMA Principles for Physician Employment", and H-275.937 "Patient/Physician Relationship and Medical Licensing Boards".[1–3] The patient-physician relationship as expressed by these policies is understood to be fundamental and paramount to the practice of medicine. This relationship is understood to carry certain obligations for physicians, including the duty to be patient advocates, to prioritize patient care, and be transparent regarding cost-sharing arrangements. Other considerations, including personal financial concerns, are to be secondary to the relationship. Furthermore, this relationship is not perceived as purely contractual, as termination of employment does not necessarily end the relationship between a physician and persons under their care (H-225.950).

Relevant Code Provisions

Within the AMA *Code of Medical Ethics*, the patient-physician relationship is understood as: "fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering[… that is] based on trust" (Opinion 1.1.1).[4] This relationship is primarily represented as emerging from a physician's fiduciary duty to patients, in which both parties enter into this fiduciary relationship via a consensual agreement. Though not an exhaustive list, the following opinions capture the spirit of the patient-physician relationship expressed within the *Code*: Opinion 1.1.1 "Patient-Physician Relationships", Opinion 1.1.3 "Patient Rights", Opinion 1.1.5 "Terminating a Patient-Physician Relationship", Opinion 1.1.6 "Quality", Opinion 1.1.7 "Physician Exercise of Conscience", Opinion 8.6 "Promoting Patient Safety".[4–9] These opinions demonstrate that the patient-physician relationship entails fiduciary responsibility, mutual respect, support for the continuity of care, open communication, quality care, and trust.

In addition, the *Code* offers several opinions that highlight the importance of minimizing outside influence on the patient-physician relationship, such as political or administrative pressures that might negatively impact the relationship. Opinion 3.1.1 "Privacy in Health Care"[10] and Opinion 3.2.1 "Confidentiality"[11] underscore the

importance of respecting patients' privacy and confidentiality in all clinical settings and the fundamental importance of doing so to maintain trust in the patient-physician relationship. Similarly, Opinion 11.1.1 "Defining Basic Health Care" states that physicians, both individually and collectively, share an obligation to "advocate for fair, informed decision making about basic health care that[…] [c]onsiders best available scientific data […] [and] seeks to improve health outcomes to the greatest extent possible"—focusing on the importance of science-based medicine and equity-focused policies regardless of political or administrative pressures to the contrary[12].

Opinion 11.2.1 "Professionalism in Health Care Systems" notes that models for financing and organizing the delivery of health care services can "pose ethical challenges for physicians that could undermine the trust essential to patient-physician relationships" and acknowledges, "[f]ormularies, clinical practice guidelines, decision support tools […], and other mechanisms intended to influence decision making, may impinge on physicians' exercise of professional judgment and ability to advocate effectively for their patients, depending on how they are designed and implemented."[13] To support physicians in upholding their ethical obligations, the Opinion states that all such tools should be designed in keeping with science-based medical practices and implemented fairly. This focus on equity is also supported by Opinion 11.2.7 "Responsibilities to Promote Equitable Care".[14] Lastly, Opinion 11.2.2 "Conflicts of Interest in Patient Care" states, "[t]he primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Under no circumstances may physicians place their own financial interests above the welfare of their patients."[15] The Opinion concludes, "[w]here the economic interests of the hospital, health care organization, or other entity are in conflict with patient welfare, patient welfare takes priority."[15] These opinions emphasize the importance that physicians be allowed to practice science-based medicine grounded in medical ethics without undue pressure from outside influences, including political or administrative pressures that might in any way prevent physicians from upholding their professional and ethical commitments. Regardless of external influences, and often in spite of them, physicians have an ethical duty to support the patient-physician relationship to the best of their ability.

ETHICAL ISSUE

Current guidance in Opinion 1.1.1 "Patient-Physician Relationships" focuses heavily on legal considerations about when a relationship is established and has little purchase on the ethical concerns raised by extensive changes to the practice of medicine that have recently occurred. Among these changes are the continuing development of technology (such as augmented intelligence), the use of team-based care, the rising number of employed physicians (as contrasted with those in private practice), interference in the patient-physician relationship by third parties (such as health care administrators, insurers or government), and the recognition that physicians have an obligation to advocate for changes to institutions, policies, and practices in order to improve patient care and promote health care justice.

A major change to the patient-physician relationship over the past few decades has been an increased recognition of the importance of patient autonomy. Ironically, however, this move away from paternalism towards patient autonomy in the setting of the patient-physician relationship has taken place while medicine has come to be dominated by large institutions, financial concerns such as cost-containment, changes in financing designed to influence patient and physician behavior, commercialization, an increasing reliance on markets, and other pressures that have had a de-professionalizing effect on physicians. These changes have led in turn to a loss of autonomy for both physicians and patients. Even as the discretionary space of physicians has shrunk, their responsibilities have expanded. Physicians are now called to engage in cultural competency and humility, trauma-informed approaches to care, and to recognize past harms and historical contexts of patient populations. They are called upon to be the mechanism by which medical inflation will be controlled. They are called upon to advocate not just only for their own individual patients within systems of care but to advocate for changes in the social systems that determine health care needs and distribute illness, injury, and disability unjustly.

Recognizing that each patient brings different experiences to the relationship is now seen as a crucial part of establishing trust within a patient-physician relationship. The question that arises, however, is how is that trust to be earned within systems that often appear untrustworthy and designed to frustrate the commitment of physicians to act for the good of their patients?

ETHICAL ANALYSIS

The patient-physician relationship is foundational for medical ethics. It is characterized by the nature of illness, the need for healing, and a commitment to help, culminating in a decision to take action directed toward healing and the

alleviation of suffering caused by disease, injury, or disability. This relationship is inherently unequal. The patient is unavoidably in a position of vulnerability and dependency, while the physician holds the knowledge and the resources that the patient needs.[16] The sick, injured, and disabled therefore have little choice but to trust that their physicians will use the power of medicine for their good as individual patients. That trust is established by the physician's act of profession—the commitment, generally undertaken through an oath, to be worthy of patients' trust—and the patent's agreement to cooperative collaboration.

The heart of professionalism is thus the public commitment of physicians to use their medical knowledge, skills, and judgment for the good of their patients. Moreover, since patients are first and foremost persons, true healing can only take place when the uniqueness and personhood of patients are taken into account, incorporating their biological particularities, beliefs, relationships, emotions, values, and goals into medical decisions. This requires a mutually respectful, trusting collaboration aimed at serving the patient's good. For patients, this entails an obligation to seek care and be as candid as possible with their physicians.

All medical actions are oriented towards the ethical centrality of the patient-physician relationship. While the paradigmatic instance of this dynamic is serious illness, or injury, the care of patients with chronic conditions also requires a sustained, trusting relationship. Palliation, too, aims at the relief of medical suffering and provides healing in a holistic sense even when cure is not possible. Prevention is also oriented towards the good of individual patients and requires trust that interventions are appropriate for that aim. Public health efforts provide the common resources necessary to promote healing and prevent illness, injury, and disability, and thus unite societal commitments to justice and prevention of harm with physicians' duties of beneficence, nonmaleficence, and respect for persons.

This understanding of the patient-physician relationship makes medicine an inherently moral enterprise, qualitatively different from the commercial transactions of providers and consumers. The patient-physician relationship itself is part of the healing process and not a commodity or product. Even economists recognize that the demand for health care is substantially inelastic and nonfungible, placing it outside the assumptions of normative market economics. Medical knowledge is not property that physicians own. It is a social good built up by the work of generations of physicians, scientists, and researchers and made possible by the generosity of generations of patients who have contributed to the advancement of medical progress (and who, it is acknowledged, have not always consented to such participation).

Medicine does not exist in a vacuum. Natural, historical, socioeconomic, and political circumstances always condition the patient-physician relationship. Physicians, for instance, do not always live up to the ideals of the profession. Structural social inequities result in unequal access to health care. While the patient-physician relationship itself is not a market commodity, markets provide many of the goods and services that physicians rely on to care for patients. Unfortunately, this also means that these goods and services are subject to the vicissitudes and inequities inherent to market systems, sexism, racism, and other unjust forms of discrimination.

Political decisions, for good or for ill, can also have a tremendous impact on care, affecting the distribution of physicians, the services they can provide for patients, the conditions under which physicians work, and the tenor of the patient-physician relationship. Therefore, if the good of the patient is the central moral focus of medicine, a commitment to justice will be required to ensure the integrity of the patient-physician relationship and to make the services of physicians available to all who stand in need of their care. In a pluralistic, liberal democracy, this requires, in turn, that professions be granted a relatively independent status outside other social institutions such as the market and the government. Too much encroachment by the market or the government into the legitimate authority of the medical profession ultimately undermines the central moral focus of medicine: the patient-physician relationship. Likewise, without the proper degree of self-regulation and respect for other social institutions, the medical profession itself can lose track of its own moral center. The good of the patient ought never to be made subservient to the political or financial ends of physicians, governments, or markets. Determining what the good of the patient is requires that physicians have the freedom and flexibility to adopt a patient-centered approach to care that allows for patients to feel heard and respected.

As the profession of medicine continues to change, there are concerns about how these changes impact patient-physician relationships and thus the relevance of the patient-physician relationship itself. However, despite the evolving landscape of the medical profession, the patient-physician relationship remains vital to the practice of medicine and to medical ethics. Regardless of changes to their roles that physicians face, clinical encounters will always be subject to the professional and ethical obligations that emerge from patient-physician relationships.

When we examine the patient-physician relationship, what we are really after is the source of the obligations that ground medical ethics. While medicine has always been practiced under non-ideal circumstances that can make it difficult to carry out these obligations to a maximal extent, we recognize that current circumstances are making it more difficult than ever. Moreover, we recognize that a patient-physician relationship may arise in a variety of contexts, and that these may not always be geared towards benefiting the patient, the physician, or both. The goal of this report, however, is to outline the core aspects of ethical and just patient-physician relationships and articulate gaps in the current *Code* Opinion 1.1.1. in order to better support patients and physicians as the medical profession and health care ecosystems continue to evolve.

Trust and the Patient-Physician Relationship

The pressures of increasing de-professionalization and de-personalization in the healthcare environment have sometimes obscured or even seemed to denigrate the value of the patient-physician relationship. New ethical questions have arisen as systems of care have changed in ways that have made it more difficult for physicians to fulfil their duties that arise from a recognition that this relationship is central to the meaning and value of the profession. While the patient-physician relationship has responded and evolved in light of these challenges and in the face of other technological, economic, and sociocultural changes, there can be no doubt that patients' trust in medicine has declined. Nonetheless, there is also a renewed interest in the relational aspect of the patient-physician relationship and new attempts to build the trust that sustains it.

Trust is in many ways the cornerstone of any interpersonal relationship. Social psychologists who study trust have noted that the development of dyadic trust is a process that involves commitment, cooperation, and the building of confidence in benevolent values, motives, goals, and intentions.[17] Trust—and distrust—may be enacted in the immediate but is also built over time. Interpersonal trust is also impacted by (and in turn impacts) social trust, as social trust influences the development of interpersonal trust which then also impacts trust in the institutions in which interpersonal interactions take place.[18]

To protect the patient-physician relationship, then, a central goal of the medical profession should be to foster trust in health care, which has been in sharp decline for the past half century.[19] One of the primary means to engender trust is through good communication. Research has shown that aspects of physician communication can impact patient outcomes (such as medication compliance) and patient satisfaction (which is associated with greater continuity of care), and that patient-centered approaches to care, which consider the patient's perspective on equal ground with the physician's clinical diagnosis, enhance communication and the patient-physician relationship.[20]

Fostering Trust to Support the Patient-Physician Relationship

Research on physician communication practices have found at least five broad communication categories including: information giving, information seeking (questioning), partnership building, rapport-building behaviors (both verbal and nonverbal behaviors that explicitly convey emotional content), and socioemotional behaviors.[21] How patients and physicians view these aspects of communication, and the patient-physician relationship in general, are not always the same, however. In one study comparing physician and patient evaluations of the relationship, researchers found that while physicians identified their technical expertise and knowledge as vital for establishing trust in the relationship, emphasizing the importance of competence, devotion, serviceability, and reliability, patients stressed the importance of interpersonal skills as more important, such as caring, appreciation, and empathy.[22] Recognizing this difference in perceptions is crucial for understanding how trust can be gained or lost, especially considering that researchers found trust to make the largest contribution to patient-physician perceived satisfaction.[22]

Patient satisfaction is strongly associated with positive physician communication behaviors. Because physicians' communication behaviors vary widely, however, there is significant room here for improving patient-physician relationships. One study found that only 33% of physicians were rated "excellent" on all four communication behaviors analyzed, while 12% were rated either "fair" or "poor" on all four behaviors.[23] Patient-physician communication is one of the strongest factors that impact patient satisfaction and is fundamental to facilitating shared responsibility and trust.[24]

Communication is not the only value that engenders and supports trust. Research has found that clinicians whose patients expressed trust in them worked in environments that placed an emphasis on quality, communication, clinical

cohesion, and alignment of values between clinicians and organizational leaders.[25] Like communication, physician empathy has also been regarded as central to patient-centered care, and research has found that empathy correlates with patient satisfaction, adherence, outcomes, and enablement.[26] Other models of trust establish foundational factors that include competency, motive, and transparency.[19]

The Future of Patient-Physician Relationships

When considering the source of the ideal patient-physician relationship, its emergence is simultaneously contractual, dependent on virtues, and relational. All three of these conceptual models rely on trust, and trust in turn is supported by additional values. Interpersonal trust is reliant upon collaboration, respect, empathy, and reciprocity. Contractual trust is reliant upon competency, transparency, aligned motives, and continuity. These values in many ways become ideal virtues within health care that help create trust in the institution of medicine over time, which is crucial for initial clinical encounters as well as for individuals who lack capacity. Regardless of external influences, such as political or administrative pressures, physicians have a responsibility first and foremost to their patients and to supporting the patient-physician relationship. When these influences create conflicting priorities, physicians should ensure that their actions align with their professional and ethical obligations.

Physicians have an ethical duty to support the patient-physician relationship by upholding the virtues of the profession. This ethical duty is grounded in medical professionalism and the commitment to serve as healers. The relationship that patients and physicians enter into is sustained by trust—in both the profession as whole, as well as in both the patient and the physician who agree to participate in a cooperative and collaborative partnership. This trust gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest. This partnership is unique in that it is inherently unequal in terms of vulnerability, yet equal in importance with respect to both individuals' contributions to the relationship; similarly, the relationship is not a commodity product, yet it involves interacting with market economics. The patient-physician relationship is contextual—biological, historical, socioeconomic, and political elements will always be relevant—but it is also fundamentally a moral activity.

Honavar writes, "[the p]atient–physician relationship is a complex psychosocial interplay of vulnerability, trust, and authority in a professional setting".[27] Currently, the *Code* primarily speaks to the importance of trust within the patient-physician relationship without acknowledging that the reason trust is crucial is because of the unequal vulnerabilities and authorities at play. The power dynamics of every patient-physician relationship will be different, of course, but it is crucial that the *Code* address such concepts as patient vulnerability, the importance of respect, communication, and competency in establishing trust. Ultimately, Opinion 1.1.1 must move beyond the current language that focuses on when a patient-physician relationship begins in order to more fully address how to ethically and justly sustain the relationship. Furthermore, knowing that the practice of medicine will continue to change and that as a result, so too will patient-physician relationships, the *Code* needs to clearly acknowledge that patient-physician relationships are inherently dynamic, contextual, and will continue to evolve.

RECOMMENDATION

Your Council on Ethical and Judicial Affairs recommends that Opinion 1.1.1, "Patient Physician Relationships" be amended by addition and deletion and the remainder of this report be filed.

> The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. ~~The relationship between a patient and a physician is based on trust, which gives rise to~~ The relationship that emerges between a patient and a physician must be based on trust. The physician's obligation to be trustworthy entails additional ethical duties such as a commitment to act for the good of patients; to uphold respect for patients as persons; to develop good communication skills; and to be professionally competent. This trust is fostered by physicians' ethical responsibility~~y~~ies to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare. When external influences negatively impact this trust, or the patient-physician relationship directly, physicians individually and collectively should advocate for changes to ameliorate the situation and promote a more hospitable environment in which patient-physician relationships may flourish.
>
> A patient-physician relationship ~~exists~~ commences when a physician begins to serve a patient's medical needs. ~~Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate).~~

~~However, in certain circumstances a limited patient-physician relationship may be created without the patient's (or surrogate's) explicit agreement. Such circumstances include:~~ The contexts that may lead to a patient-physician relationship vary: they generally occur as a response to a request by a patient or a patient's surrogate, but can also include certain contractual, legally mandated, or emergency settings without the explicit request or consent of the patient.

While the patient-physician relationship may involve one patient and one physician in today's complex health care system, such relationships often involve multiple members of a care team, patient family members and surrogates. The core values of the patient-physician relationship, however, remain unchanged. How these values are implemented will depend on many factors, including the setting, the needs of the patient, the duration of the relationship, and the training, expertise, and experience of the physician, and will necessarily reflect the myriad ways that patients and physicians interact. While every patient-physician relationship will be different and will change over time, the fundamental importance of establishing and sustaining trust through respect for persons, good communication, and professional competency will always be crucial at every layer, node, and time of the relationship. It is the duty of physicians, therefore, to uphold these values and support patients and the primacy of the patient-physician relationship to the best of their ability in all practice settings and at all times.

~~(a) When a physician provides emergency care or provides care at the request of the patient's treating physician. In these circumstances, the patient's (or surrogate's) agreement to the relationship is implicit.~~

~~(b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment.~~

(c) ~~When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient-physician relationship exists.~~

Fiscal Note: Minimal

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2. SUPPORTING EFFORTS TO STRENGTHEN MEDICAL STAFFS THROUGH COLLECTIVE ACTIONS AND/OR UNIONIZATION

Reference committee hearing: see report of Reference Committee on Ethics and Bylaws.

HOUSE ACTION: REFERRED

Council on Ethical and Judicial Affairs (CEJA) Report 8, "Supporting Efforts to Strengthen Medical Staffs Through Collective Actions and/or Unionization," was introduced by CEJA at the 2025 Annual Meeting and was referred. CEJA Report 08-A-25 responded to Policy H-405.946, "Supporting Efforts to Strengthen Medical Staffs Through Collective Actions and/or Unionization," which was adopted at the 2023 Annual Meeting and asks the following:

1. Our American Medical Association will reevaluate the various efforts to achieve collective actions and/or unionization for physicians nationally.

2. Our AMA will request CEJA to review the advisory restricting collective action in section 1.2.10 of its Code of Medical Ethics to allow for more flexibility on the part of physicians who have exhausted other non-disruptive methods for reform.

The House testified against the word "could" in recommendation (c) of CEJA Report 8-A-25, noting that its use is too broad, nonspecific, and might restrict physicians' ability to take collective action. CEJA appreciates that the use of "could" created an insurmountable bar, and so as a result, in recognition of physicians' fiduciary duties and the need for physician advocacy, CEJA has reached a balance by changing "could" to "would likely" in recommendation (c) for greater clarity.

BACKGROUND

The consolidation of hospitals and physician practices in recent years has led to a shift in the practice of medicine away from the independent practice model to one in which physicians increasingly find themselves working as employees. In 2012, only 5.6 percent of physicians were directly employed by hospitals, with 23.4 percent of physician-owned practices having some hospital ownership; however, by 2022, a total of 74 percent of practicing physicians were employed, including 52.1 percent of physicians employed by hospitals or health systems and 21.8 percent employed by other corporate entities.[1] Paralleling this increase in corporate intrusion into medicine has been the rise of unionization within the profession. While the number of physicians who are members of a union is relatively small, and mostly among house officers, their ranks saw an approximately 26 percent increase in just five years from 2014–2019.[2] As of 2021, an estimated 5.9 percent of practicing physicians were union members, with union contracts covering 8.1 percent of practicing physicians.[1] Currently, two of the main physician unions are the Federation of Physicians and Dentists and the Union of American Physicians and Dentists.

As the financing, organization, and leadership of the health care system change, the practice environment increasingly makes it challenging for physicians to provide the kind of care patients want and deserve. Physicians are now increasingly held to strict performance metrics that many feel are more about meeting corporate financial goals than they are about providing quality patient care. As a recent New York Times article puts it, "longer-term consolidation of health care companies has left workers feeling powerless in big bureaucracies. They say the trend has left them with little room to exercise their professional judgment."[3] There is a growing sense among physicians that current working conditions are increasingly compromising the patient–physician relationship, physicians' health, and medical professionalism, driving burnout, moral injury, and retirement from medicine.

Unions are seen by some as a mechanism for physicians to exert influence on corporate health systems where physicians have less autonomy than in private practices.[4] Unions' power for collective bargaining comes from their ability to organize members to take collective action. Unionization, however, is not the only means by which physicians can organize and take collective action. Hospitals' organized medical staff has been a means by which physicians have exercised authority over decision making and culture, but the authority and scope of responsibility of the organized medical staff has been limited.[5] While employed physicians in large systems have not typically explored re-invigorating the organized medial staff, this remains an alternative means by which physicians can reclaim lost authority and exercise collective action.[5]

Physicians may undertake many forms of collective action, both in the public arena and within health care institutions. Public actions include, but are not limited to, public advocacy, media campaigns, lobbying, negotiation, and litigation. Collective actions in the clinical setting increasingly are being considered as additional forms of collective action, particularly to effect change in specific clinical environments. Some of these are not disruptive, such as negotiation with administrators. Disruptive actions are also being considered, such as picketing, refusal to comply with corporate directives deemed unethical, withholding billing, work slowdowns, or striking. A primary concern surrounding the use of these disruptive collective actions by physicians in the clinical setting is that some of these actions may impact patient care and thus be in direct conflict with physicians' professional and ethical duties to not abandon patients and to prioritize patient care above self-interest.[6]

Relevant Laws

In 1935, Congress passed the National Labor Relations Act (NLRA), amended in 1947 through the Taft-Hartley Act, which guarantees private sector employees the right to unionize, engage in collective bargaining, and take collective actions such as strikes.[1] The NLRA covers most private sector employees but does not cover independent contractors, supervisors, or managers. Part-time physicians working as independent contractors, physicians in private practice, and physicians considered to serve a supervisory role, such as medical directors or tenured medical faculty, are currently excluded.[2]

When Congress passed the 1974 amendments to the NLRA, which extended coverage to nonprofit hospitals, it added Section 8(g), requiring health care employee unions to give at least a ten-day notice before engaging in any strike or picketing to ensure that hospitals have sufficient time to make appropriate arrangements for the continuity of patient care in the event of a work stoppage.[2]

Laws prohibiting the corporate practice of medicine are an under-appreciated mechanism for physicians to use in reclaiming clinical authority. Most states have had laws dating to the 1880s that prohibit the corporate practice of medicine, but little attention has been paid to the potential use of such laws to prevent health care institutions from infringing upon the clinical decision-making authority that properly belongs to physicians.[7]

Relevant AMA Policy Provisions

In 2019, the AMA modified two relevant policies: H-385.973 "Collective Negotiations" and H-385.976 "Physician Collective Bargaining."[8,9] Both support the right of physicians to engage in collective bargaining and express the AMA's commitment to work for the expansion of which physicians are eligible for that right under federal law. This includes supporting efforts to narrow the definition of supervisors such that more physicians are protected under the NLRA.

Though not policy, the AMA's Advocacy Resource Center has also issued a recent Issue Brief: "Collective bargaining for physicians and physicians in training" that outlines AMA policy on physician unions and collective bargaining, including the interpretation that the AMA's position is that "physicians should refrain from the use of the strike as a bargaining tactic, although in rare circumstances, individual or grassroots actions, such as brief limitations of personal availability, may be appropriate as a means of calling attention to needed changes in patient care."[2]

Relevant Code *Provisions*

The AMA *Code of Medical Ethics* Opinion 1.1.1, "Patient-Physician Relationships," states that the core tenets of the clinical encounter for the physician are "to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare." This foundational opinion emphasizes the primary ethical duties of physicians to prioritize patient care and regard their responsibility to the patient as paramount. The Principles enumerated in the Code also indicate that such duties extend beyond the bedside and that physicians have a responsibility to seek changes to laws that are contrary to the best interests of the patient.

Opinion 1.2.10, "Political Action by Physicians," currently states that not only *can* physicians seek to change policies or laws that they find contrary to the best interest of patients but they in fact *have* an ethical duty to do so, though they also "have a responsibility to do so in ways that are not disruptive to patient care."[10] While the opinion states that "[s]trikes and other collective actions […] should not be used as a bargaining tactic", it also adds that "[i]n rare circumstances, briefly limiting personal availability may be appropriate as a means of calling attention to the need for changes in patient care."[10] However, this permissibility must be balanced by the opinion's first directive that physicians participating in advocacy activities should "[e]nsure that the health of patients is not jeopardized and that patient care is not compromised."[10]

This is in line with Opinion 1.1.6, "Quality," which states that "[a]s professionals dedicated to promoting the well-being of patients, physicians individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable."[11] Taken together, by stating that "physicians have an ethical responsibility to seek change" at times (Opinion 1.2.10) and that they also have an "obligation to ensure" quality care (Opinion 1.1.6), these opinions highlight the fact that certain conditions may arise that actually demand action be taken by physicians to improve patient care.

Opinion 9.3.1, "Physician Health & Wellness," similarly outlines that physicians have a responsibility to take action when their own health or wellness is compromised.[12] The opinion stipulates that physicians have a responsibility both individually and collectively to ensure and promote health and wellness among physicians, and that when their health or wellness is compromised, individual physicians should fulfill this responsibility by "taking measures to mitigate the problem."[12] Physician health and wellness is necessary for effective healing and the provision of quality care, and collective action may be an appropriate means of securing institutional conditions that are conducive to patient health and well-being.

Additional Relevant Policy

The World Medical Association recommends that physicians adopt the following guidelines regarding collective action:

1. Physicians who take part in collective action are not exempt from their ethical or professional obligations to patients.
2. Even when the action taken is not organized by or associated with the Constituent Member, the Constituent Member should ensure that the individual physician is aware of and abides by their ethical obligations.
3. Whenever possible, physicians should press for reforms through non-violent public demonstrations, lobbying and publicity or informational campaigns, and/or through negotiation or mediation.
4. If involved in collective action, Constituent Members should act to minimize the harm to the public and ensure that essential and emergency health services, and the continuity of care, are provided throughout a strike. Further, Constituent Members should advocate for measures to review exceptional cases. If involved in collective action, Constituent Members should provide continuous and up-to-date information to their patients and the general public with regard to the demands of the conflict and the actions being undertaken. The general public must be kept informed in a timely manner about any strike actions and the restrictions they may have on health care.[13]

ETHICAL ISSUE

What are the ethical considerations regarding participation in collective labor action by physicians? Since certain collective actions can be disruptive, they present a potential risk to patient care and thus create a dilemma for physicians, particularly when collective actions may create immediate risks to patients, even if intended as a means to improve patient care in the long term. What collective actions by physicians are ethically permissible must be examined to ensure that the primacy and quality of patient care are protected. The core ethical issue is whether physicians who embrace tactics used by organized labor will also still be able to embrace their role as professionals.

REVIEW OF RELEVANT LITERATURE

While not all collective actions by physicians may impact clinical practice, disruptive actions such as strikes result in practical challenges to clinical care. This report defines a disruptive collective action by physicians as any collective action that disrupts the day-to-day workflow of physicians within the health care systems in which they practice. Some of these actions may have the potential to decrease quality of care and cause patient harm.

The normative ethics literature on the use of collective actions by physicians is generally cautious about collective actions that present a risk to patients, such as striking. A common stance is that, provided adequate precautions are taken to minimize the risk to patients, the primary goal of the collective action is to improve patient care, and the disruptive action is considered only as a last resort after all other means have been exhausted, physician strikes may be ethically justifiable.[6,13,18,19,20] However, strikes and other disruptive collective actions become ethically problematic when they are done for any reason other than for improving patient care, such as for increasing physicians' income.[6,18]

One line of argument in favor of permitting disruptive collective actions that might harm patients, such as strikes, is to suggest that physicians are, and have always been, workers like any other set of workers, and that claims of professionalism that would place physicians in a special position of privilege in recognition of a higher set of ethical standards have always been a mere pretense. On this view, there is nothing intrinsically "special" about medicine as opposed to any other form of work. There are some limits on what forms of collective action may be undertaken that are due to the critical nature of the service physicians provide, but there is no reason to maintain the fiction that they cannot engage in strikes or job actions because they are professionals called to put patient interest ahead of self-interest. The ethical question thus becomes how to draw limits on the scope of permissible collective action that recognizes physicians as laborers with all the rights of laborers, while drawing limits that protect the public from harm.

A second line of argument is a variation on this first line of argument—asserting that while medicine is ideally construed as a profession with intrinsically special rights and obligations, one must now, however reluctantly, accept

the de-professionalization of physicians as a socioeconomic and historical fact. On this view, physicians have been forced out of their professional status by changes in the financing and organization of health care and the only available means of asserting power now is through unionization and the means of negotiation that have been used for the last two centuries by other workers in resolving disputes with their employers. Again, the operative ethical question becomes one of setting limits on these actions in accord with the vital nature of the service physicians provide.

A third line of argument attempts to reconcile a conception of physicians as professionals, obligated to place patient interest above self-interest, with an understanding that, under certain circumstances (such as those experienced by house officers and, increasingly, physicians employed in large health care systems), there is a *de facto* imbalance in power between the administrators and the employed physicians. They argue on consequentialist grounds that if impediments to good patient care are sufficiently serious, and the goal of a disruptive collective action (such as a strike) is to improve patient care in the long run, then if potential harm to patients in the short-run is minimized, the action is undertaken only as a last resort, and the goal of improving patient care through the action is foreseeably achievable, such an action could be justified.[6,19] These commentators reject the idea that a disruptive collective action with the potential to harm patients could be ethically and justifiably undertaken solely to advance the welfare of physicians. However, they generally recognize that the motives for such actions will often be mixed, and admit that the argument that physician welfare could be sought as the primary (or even secondary) goal of a strike but justified as a necessary means for achieving patient welfare in the long run might either be self-deceived, or, at least, difficult for the public to believe.[6,19,21]

Others have held that strikes by physicians are almost never justifiable.[22-24] Strikes by physicians raise serious questions at the heart of what it means to be a physician. As Pellegrino has written:

> Whatever justification they may have, strikes or "slow downs" by segments of the profession have seriously damaged the image of medicine as a profession dedicated to service above its own interests. One of the distinguishing features of the medical profession has thus been compromised by physicians themselves. Those who choose to pursue self-interest, as union members may, cannot at the same time demand a superior moral position in society.[22]

Contrary to the arguments favoring physicians strikes, opponents have appealed to the principle that the duty to promote the good of the patient is always paramount, and that strikes will always harm patients, at least to a modest degree. In fact, they argue, this is the point of the strike—to disrupt care, inconvenience, or possibly harm patients, even if minimally, in order to pressure administrators into acceding to the demands of the striking physicians. Even granting that the ultimate aim of the strike is to improve patient care in the long run, patients will be harmed in the short run, and this conflicts with the profession's ancient duty to protect patients from harm.

Moreover, opponents take issue with the consequentialist argument that some patients could justifiably be exposed to potential harms now for the sure benefit of others in the future. They argue that a primary principle of ethics is that persons should always be treated as ends in themselves and never as means only. Physician strikes, by their nature, instrumentalize some patients, using their potential harm as means of achieving physicians' ends, even if those ends are justifiable and good.

Additionally, the effect of strikes on public trust in the profession must be considered. Trust is the glue that holds the patient-physician relationship together. The sense that one's own health as a patient could in any way be jeopardized or used as a bargaining tool might lead to public distrust in the profession.

While there is not a substantive body of empirical research on the effects of physician strikes on patient outcomes, there are some data. Although the majority of available empirical evidence shows that strikes have minimal impact on patient care,[25-28] much of the data are of relatively poor quality, are at risk of bias, and suffer from a lack of generalizability.[26,27] Furthermore, most studies examine patient mortality as the primary outcome of interest, which has limitations as an indicator of deleterious change in patient health outcomes.[25] Importantly, a 2019 study found a slight increase in 30-day readmission rates for Black patients on strike days in the UK, suggesting that the ways in which strikes impact staffing are unlikely to affect all patient groups equally, with minority groups more likely to experience worse care when hospital systems are under strain[28] This observation has critical importance in determining care for vulnerable populations when considering collective actions. Additionally, there is a lack of crucial research on how collective actions by physicians impact patient perceptions of and trust in both the medical profession and

health care institutions. Reports of strongly negative public perceptions during a recent physicians' strike in Korea, while not systematic, suggest a note of caution.[29]

ETHICAL ANALYSIS

In its review of Opinion 1.2.10, "Political Action by Physicians," CEJA has examined the ethics of collective actions by physicians. While the practical issue for consideration is whether disruptive collection actions by physicians, such as but not limited to strikes, may be permissible, the ethical dilemma is whether physicians can, in fact, fully understand themselves as professionals called to prioritize patient welfare over their own self-interest while engaging in tactics that have the potential to harm patients in the short term, even if the ultimate goal of the action is proposed to be long-term patient benefit.

Historically, physicians retained strong independence in clinical practice, and self-regulation permitted this professionalism to flourish. However, the growth of the health care sector has seen an increase in the complexity of health care systems, the transition to a majority physician employment structure, and as a result, a loss of physician independence and control in clinical practice. This bureaucratization has led physicians to seek other non-physicians to run the administrative aspects of their practices, and decreasing margins has led physicians to seek capital infusions and buyouts from private equity firms and venture capitalists, further driving the financialization of medicine and the employment of physicians.

The result is a general loss of control over practice conditions that have driven dissatisfaction, burnout, and early retirement from the profession. However, the issue is not necessarily employment itself, but the associated loss of independence of clinical practice and control over the clinical environment, which many today see as the de-professionalization of medicine.

For those seeking to maintain and restore physician authority and independence, the primary avenue has been to pursue legal and political actions, such as lobbying (either independently or through medical associations). However, with the change towards physician employment, physicians are now considering the use of tools that laborers have historically relied on for negotiating, such as legally permissible collective actions, in their attempts to improve patient care. This acceptance of the tools of organized labor, however, is in tension with medicine's self-understanding and public representation of itself as a profession with distinct privileges granted by society in recognition of its commitment to a distinctive set of ethical duties. Certainly, some forms of collective action are not likely to violate the norms of medical professionalism.[30]. Disruptive collective actions, however, which have the potential to disrupt the day-to-day workflow of physicians, decrease quality of care, and cause harm to patients, seem prima facie to violate the medical profession's fundamental duty to do no harm and care for patients. Any disruptive collective action that causes harm to patients is inherently inconsistent with the responsibilities and duties of physicians.

Disruptive collective actions that create the potential for harm to patients, even minimally, and even if undertaken for the purpose of improving the care of other patients in the future, are therefore to be avoided. This does not mean, however, that all forms of disruptive collective action must be avoided. Certain forms of disruptive action, such as collective refusal to comply with administrative directives that are understood as antithetical to good patient care or otherwise incompatible with the norms of professional ethics, may be ethically justified. Other forms of disruptive action that are aimed at disrupting administrative processes such as billing but do not disrupt service to patients, might also be justified. Disruptive actions should only be undertaken, however, as a last resort when good faith negotiations have broken down and the aim of the action is to improve patient care.

CONCLUSION

Physicians must uphold their central ethical and professional responsibilities to patients when considering collective actions. When considering disruptive collective actions, physicians should take into account that the care of current patients must be continued and not compromised; urgent, emergent and otherwise needed medical care must still be provided; and all other non-disruptive actions that do not negatively impact patients must first be exhausted. Additionally, the primary goal of the action must be to improve patient care and not solely physician self-interest. To protect the integrity of the profession, patients and the public should also be informed well in advance and be continuously updated with respect to the demands being made and the actions being undertaken, with the terms for resolving disruptive actions made public and open to scrutiny and discussion. Whether all these conditions can ever be met in a physician strike or work slowdown remains an open question.

Physicians thinking about participating in disruptive collective actions therefore must first consider their professional responsibilities and obligations.

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following recommendations be adopted and the remainder of the report be filed:

1. That Opinion 1.2.10 be amended by addition and deletion with a change in title as follows:

Advocacy and Collective Actions by Physicians ~~Political Action by Physicians~~

Like all Americans, physicians enjoy the right to advocate for change in law and policy, in the public arena, and within their institutions. Indeed, physicians have an ethical responsibility to seek change when they believe the requirements of law, ~~or~~ policy, or practice are contrary to the best interests of patients. However, advocacy actions should not put the wellbeing of patients in jeopardy.

Collective action is one means by which physicians can advocate for patients, the health of communities, the profession, and their own health. Physicians have a responsibility to avoid disruption to patient care when engaging in any collective action. When considering collective actions that have the potential to be disruptive, whether aimed at changing the policies of government, the private sector, or their own institutions, there are additional considerations that should be addressed. These include avoiding harm to patients, minimizing the impact of actions on patient access to care, maintaining trust in the patient-physician relationship, fulfilling the responsibility to improve patient care, avoiding mental and physical harms to physicians, promoting physician wellbeing, upholding the values and integrity of the profession, and considering alternative measures that could reasonably be expected to achieve similar results with less potential effect on patient and physician wellbeing.

When considering participation ~~Physicians who participate~~ in advocacy activities, including collective actions:

(a) ~~Ensure that the health of patients is not jeopardized, and that patient care is not compromised.~~ Physicians should recognize that, in pursuing their primary commitment to patients, physicians can, and at times may have an obligation to, engage in collective political action to advocate for changes in law and institutional policy aimed at promoting patient care and wellbeing.

(b) ~~Avoid using disruptive means to press for reform. Strikes and other collective actions may reduce access to care, eliminate or delay needed care, and interfere with continuity of care and should not be used as a bargaining tactic. In rare circumstances, briefly limiting personal availability may be appropriate as a means of calling attention to the need for changes in patient care. Physicians should be aware that some actions may put them or their organizations at risk of violating antitrust laws or laws pertaining to medical licensure or malpractice.~~ Physicians may also engage in collective action to advocate for changes within their institutions, including changes in patient care practices, physician work conditions, health and wellbeing, and/or institutional culture that negatively affect patient care.

(c) Physicians should refrain from collective action that would likely jeopardize the health of patients or compromise patient care.

(d) Physicians may consider engaging in disruptive forms of collective action that do not compromise patient care only as a last resort, with the primary objective to improve patient care and outcomes by calling attention to and/or making needed changes in practices, protocols, incentives, expectations, structures, and/or institutional culture.

(e) Disruptive actions, including strikes, that could directly compromise patient care should be avoided and should not be used solely for physician self-interest.

(f) Physicians should avoid forming workplace or other alliances, such as unions, with ~~workers~~ colleagues and others who do not share physicians' primary and overriding commitment to patients.

(g) Physicians should refrain from using ~~undue influence or pressure colleagues~~ punitive or coercive means to force others to participate in advocacy activities or collective actions, or to penalize others ~~and should not punish colleagues, overtly or covertly,~~ for deciding not to participate in such activities.

2. That Policy H-405.946(2) be rescinded as having been accomplished by this report.

Fiscal Note: Minimal

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3. ETHICAL IMPETUS FOR RESEARCH IN PREGNANT AND LACTATING INDIVIDUALS

Reference committee hearing: see report of Reference Committee on Ethics and Bylaws.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED

Policy D-140.949, "Ethical Impetus for Research in Pregnant and Lactating Individuals," was adopted at the 2024 Annual Meeting and asks "that our Council on Ethical and Judicial Affairs (CEJA) consider updating its ethical guidance on research in pregnant and lactating individuals."

BACKGROUND

More than four million individuals give birth in the United States every year[1] and 70 percent of these individuals will require at least one prescription medication while pregnant.[2] Despite the widespread use of medications during pregnancy, most information about the efficacy and safety of medication used during pregnancy comes from the post-marketing setting and is not derived from clinical research trials.[3]

Only a dozen medications have been approved by the United States Food and Drug Administration (FDA) for use during pregnancy, and those medications are for gestation- or birth-related medical issues.[4] Therefore, any medications utilized to treat chronic health conditions in pregnancy are used without FDA approval ("off label"). Only 2.4 percent of those commonly used medications for chronic health conditions have included pregnant individuals in controlled human clinical trials. The lack of clinical trial data is a result of the historical exclusion of pregnant and lactating individuals from clinical trials. Exclusion of pregnant and lactating individuals from clinical trials has often occurred

due to the fear of harming the fetus or newborn, as well as concern that physiologic changes in pregnancy or during lactation will impact the results of pharmacologic trials.[3,5] The effect of this exclusion is that physicians and patients are forced to make decisions about whether to utilize medications during pregnancy without adequate fetal and maternal safety data.[6]

ETHICAL ISSUE

Pregnant and lactating individuals have been systematically excluded from clinical trials for decades out of concern for negative effects on fetuses and nursing infants. This exclusion has resulted in a paucity of evidence regarding safe and effective medication use in these groups of individuals. Due to the existing knowledge gaps surrounding the use of medications during pregnancy and breastfeeding, physicians and patients are faced with making treatment decisions without appropriately understanding the potential benefits and risks to both the pregnant individual and their fetuses or nursing infant. Additionally, these knowledge gaps prevent physicians from being able to appropriately counsel pregnant patients regarding the risks, benefits, and alternatives of treatments. At issue is how to balance respect for pregnant and lactating individuals with the potential benefits and harms of research.

REVIEW OF RELEVANT LITERATURE

Pregnant and lactating individuals have historically been considered "vulnerable" and subjected to additional research protections and exclusion from research.[7] This problem is known as the "protection-inclusion dilemma", whereby groups deemed "vulnerable" are "over-protected" and excluded from research, leading to justice issues including a "lack of relevant health data for under-represented populations."[8] The consequence of the protection-inclusion dilemma is that most of the medications pregnant individuals are prescribed are not FDA approved for pregnancy. This is problematic because while "there are significant physiologic changes in pregnancy, including near doubling of maternal blood volume and alterations in binding proteins, the pharmacokinetics [PK] and efficacy of drugs in pregnancy are, by and large, unknown."[7] This uncertainty for prescribers results in dosages labelled for use in nonpregnant individuals being used for pregnant individuals, "with little consideration for the PK changes that occur during pregnancy."[9]

Although the negative effects of excluding pregnant and lactating individuals in clinical trials have been noted for years, little has been done in that time to address the significant knowledge gaps in research that remain. For example, many Institutional Review Boards (IRB) "continue to regard pregnancy as a near-automatic cause for exclusion, regardless of the costs of exclusion or the magnitude or likelihood of the risks of participation," and the lack of research data leads to persistent disparities for chronic disease management among pregnant individuals.[5]

Relevant Laws

The FDA has several relevant regulations. 45 CFR 46, Subpart B "Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research", provides regulations regarding research involving pregnant individuals. 45 CFR §46.204 – "Research involving pregnant women or fetuses" states that:

> Pregnant women or fetuses may be involved in research if all of the following conditions are met:
>
> (b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.[10]

Additionally, as of January 21, 2019, the Common Rule no longer labels pregnant individuals as "vulnerable" with regards to IRBs. This is because while pregnant individuals have historically been deemed vulnerable, it has since been recognized that while some individuals who are pregnant may be vulnerable, being pregnant in and of itself does not automatically denote vulnerability. [11,12] The 2024 updated version of the World Medical Association's Declaration of Helsinki reinforces this point, stating that "[w]hen such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion."[11]

Relevant Code Provision(s)

The *Code of Medical Ethics* encourages the inclusion of pregnant individuals in clinical trials, when appropriate, so long as the research "balance[s] the health and safety of the woman who participates and the well-being of the fetus with the desire to develop new and innovative therapies" (Opinion 7.3.4). However, the *Code* also places constraints on physicians involved in maternal-fetal research, advising that they should "[e]nroll a pregnant woman in maternal-fetal research only when there is no simpler, safer intervention available to promote the well-being of the woman or fetus" (Opinion 7.3.4).

ETHICAL ANALYSIS

A multitude of historical, legal, scientific, and societal factors have resulted in the exclusion of pregnant and lactating individuals from clinical trials for decades. However, the ethical principle of justice necessitates that the benefits and burdens of research participation be fairly distributed across all groups, including pregnant and lactating individuals, because failure to do so produces disparities that impact both safety and quality of care for pregnant and lactating individuals, fetuses, and nursing infants.

Concerns for fetal safety have served as the primary justification for the exclusion of pregnant individuals from clinical trials for decades, but this exclusion has paradoxically resulted in substantial maternal and fetal harm. Because information about toxicity and dosing for pregnant and lactating individuals has not been determined through smaller scale and well-controlled clinical trials for most medications, far more pregnant and lactating individuals who require medications for chronic medical conditions are being exposed to potentially harmful medications via "off label" uses.

Examples of this harm can be seen in the historical use of thalidomide and diethylstilbestrol in pregnant individuals. While the tragic consequences of their use have been cited as reasons to exclude pregnant individuals from clinical trials, it was actually the lack of controlled data from clinical trials that caused such widespread detrimental effects due to the teratogenic effects of these drugs not being examined until post-marketing surveillance data was available. Had smaller scale and better controlled clinical trials been conducted, mass marketing and exposure to these medications for pregnant individuals may have been avoided because the teratogenic effects would have been discovered during trials.[13]. Another example is that of ACE inhibitors, which were used in pregnant individuals for three decades prior to the 1996 discovery that its use in the first trimester can cause congenital anomalies.[5]. Had it been studied more rigorously through smaller scale clinical trials with individuals consenting to the risks of participating in research, this discovery may have been made much sooner and far fewer individuals would have been exposed to this drug in the first trimester without knowing the risks of doing so.

Historically, concern for pregnant individuals and fetuses has centered on defining this population as "vulnerable", thus needing broad shielding from risks, such as medical research. Such an approach to research practices has been deemed "overly paternalistic, disempowering, or coercive."[14] Pregnant and lactating individuals are not automatically vulnerable, and this approach does not respect their autonomy to assess the benefits and risks of participation for themselves and their fetuses or newborns.[15] Pregnant and lactating individuals should always be provided the opportunity to decide whether research participation is in their best interest through informed consent. If pregnant or lactating individuals are unable to be included in research, alternative ways to rectify any gap in knowledge should be developed. For example, pregnant and lactating individuals should be instructed on how to participate in research registries and adverse event reporting programs.

CONCLUSION

The historical exclusion of pregnant and lactating individuals from clinical trials has resulted in a lack of data about the appropriate safety, dosage, and efficacy of most medications in this group. This knowledge gap has created an ethical imperative to include more pregnant and lactating individuals in clinical trials. While consideration of maternal, fetal, and nursing infant well-being should be important criteria included in guidelines for research, wholesale exclusion of pregnant and lactating individuals from clinical trials comes with its own risk to fetal and maternal safety. Theoretical risks for fetal harm should not automatically be assumed to outweigh potential risks of ongoing nonparticipation. Currently, the *Code* does not reference this disparity. Nor does it refer to lactating individuals. It also does not contain gender neutral language, i.e., it references women and not individuals.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that following being adopted and the remainder of the report be filed:

1. Research involving pregnant and lactating individuals, including but not limited to, research regarding interventions intended to benefit pregnant or lactating individuals and/or their fetuses or nursing infants, must balance the health and safety of individuals who participate and the well-being of their fetuses or nursing infant against the desire to develop new and innovative therapies. Although it is important to carefully consider potential fetal risks involved when pregnant and lactating individuals participate in research, it is critical to realize that large scale exclusion from participation by these individuals has also precluded potential benefits and in some cases resulted in harm for this group. The paucity of data on safe and effective medical treatment during pregnancy and breastfeeding has resulted in physicians and patients choosing between pursuing medical interventions with uncertain risks to themselves and their fetuses or nursing infants, or foregoing the interventions altogether, which might itself cause harm due to undertreatment of medical conditions.

   Understanding both the potential risks of participation and of non-participation, physicians conducting research must obtain the informed, voluntary consent of pregnant or lactating individuals, and adhere to general principles for ethical conduct of research as in all human participant's research. In addition, physicians conducting research should:

   (a) Include pregnant and lactating individuals in research for which they would otherwise be eligible in order to establish a greater knowledge base, produce relevant data, and promote respect for individuals.

   (b) Consider excluding pregnant and lactating individuals only when a study poses a substantial risk of significant harm to them or their fetuses or nursing infants, and:

      i. specify why the research excludes pregnant and lactating individuals;

      ii. seek alternative research methodologies to rectify gaps in knowledge.

   (c) Where scientifically appropriate and available, base studies that include pregnant and lactating individuals on well-designed, ethically sound, existing research with nonhuman animals or nongravid human participants to better assess potential risks.

   (d) Minimize risks to the fetus or nursing infant to the greatest extent possible, especially when the research is not conducted primarily to investigate potential benefit for fetuses or nursing infants, but rather for the development of important biomedical knowledge that cannot be obtained by any other means.

2. AMA Policy D-140.949 be rescinded as having been accomplished by this report.

Fiscal Note: Minimal

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