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The Grand Inquisitor's Choice: Comment on the CEJA Report on Withholding Information from Patients

Darlyn Pirakitikulr and Harold J. Bursztajn

Darlyn Pirakitikulr is a First-Year Student at Boston University School of Law.
Harold J. Bursztajn, MD, is an Associate Clinical Professor of Psychiatry, and is Co-Founder of the Program in Psychiatry and the Law at the Beth Israel Deaconess Medical Center Department of Psychiatry at Harvard Medical School, *hbursztajn@hms.harvard.edu.*

Historically, paternalism had been the accepted norm in doctor-patient relationships. By virtue of their knowledge and experience, doctors decided what treatment was in the best interests of patients. However, in recent years, medicine has changed from a predominantly paternalistic profession to one that is more patient-centered. The physician informs and advises the patient, but it is the patient who makes the decision. Given this evolution, the physician's dual duties of promoting the patient's health while supporting the patient's autonomy, by providing pertinent medical information, can at times become a balancing act. The physician must weigh, on the one hand, the value of the patient's liberty to make personal medical choices based on full disclosure of relevant information, and, on the other, the patient's health, which in rare instances might be compromised by full disclosure.

While instances of a patient's autonomy and health interests coming into conflict are often more apparent than actual, such instances have on occasion been dramatic. Moreover, due to the synergy of cognitive heuristics, emotional dynamics, and the socioeconomic forces that form the subtext of today's medical practices, such conflicts can be easily overestimated, so as to rationalize the expediency of silence — which can be conducive to seeing more patients in less time (in keeping with reimbursement patterns), as well as to avoid the moments of awkward angst, the emotional turmoil, which enters doctor-patient encounters when there is awareness of the transience of human existence. Thus the enduring temptation of withholding information and avoiding choices, as in the offer made by The Grand Inquisitor in Dostoevsky's *The Brothers Karamazov.* The Grand Inquisitor promises man everything in exchange for the one thing that makes him human: free will to choose or reject at any time what his conscience tells him is a moral good.[1] While the patient's well-being is certainly a priority, if the physician denies the patient liberty, the physician is in effect denying the patient free will, which is essential to being human.

While classically there has been a position of clinical silence on upsetting patient news,[2] in the "Report of the American Medical Association Council on Ethical and Judicial Affairs: Withholding Information from Patients: Rethinking the Propriety of 'Therapeutic Privilege'," the AMA concludes that fundamentally withholding information from patients without their knowledge or consent is unacceptable, yet leaves a loophole

for the persistent temptation to rationalize nonetheless doing so. The loophole rests on the reasonable-appearing proposal that physicians ascertain patients' preferences regarding the communication of their medical information, preferably before that information becomes available. It allows clinicians to delay the release of information in cases when they infer that would be the patient's preference or when a patient's preference for delay in being informed of upsetting information had been previously elicited.

The AMA proposal is well intended. However, its practical applicability must be taken into account. In what follows, we explore three areas of concern. The first deals with patients in pain and their need to have more time and support for any informed-consent process to be meaningful. The second is the fact that a managed-care-dominated climate has left physicians under enormous time pressures. The amount of face-to-face time physicians spend with patients has markedly decreased, with physicians instead spending more time on administrative burdens. Introducing the new AMA guidelines in such an environment lends itself to *pro forma* informed consent (going through the motions) rather than meaningful informed consent. Finally, the third issue we have identified is the extent to which information needs to be provided to physicians by drug and device manufacturers in a forthright manner, since initial misrepresentations or unsupported claims of efficacy and safety are difficult to correct in clinical practice and foster the clinical temptation to invoke therapeutic privilege as a rationalization.

The AMA guidelines call for physicians to ascertain patients' preferences for receiving medical information before such situations arise. Without knowledge about the future, physicians are asked to elicit preferences for information regarding scenarios that are difficult to imagine. This is all the more difficult because people are generally not good at anticipating their future preferences, even when facing mundane experiences.[3] The end result is likely not to meet the expectations of a reasonable patient to be informed in a reasonable and supportive manner.[4] Furthermore, the cognitive heuristics that people use to process large amounts of information efficiently, such as conservatism in updating their initial impressions and probabilities, have their pitfalls, such as premature cognitive commitment — that is, the tendency to come to conclusions based on insufficient data. To recognize these human factors in information processing is to conclude that full and meaningful disclosure is needed from the outset. Thus the AMA loophole for sequential disclosure under the rationalization of a plan for future disclosure needs to be closed. Not to close this loophole is to risk that the new guidelines will all-too-often become in practice, old wine in a new bottle.

It also needs to be explicitly recognized that patients who suffer — as those in pain, anxiety, depression, or in the shadow of the awareness of the transience of our existence do — require more time and support for the informed-consent process to be meaningful. Obtaining meaningful informed consent requires care and time because of variations in patients' capacity for understanding and the complexities of health conditions. At one extreme, some claim,

> When a person is in extreme pain, truly informed consent may not be possible. Caregivers have an ethical obligation to inform the capacitated patient about the salient effects and side-effects, benefits and risks of pain management options, especially those related to use of narcotics, to help the patient to reach an informed decision about treatment. But, despite the best efforts to provide relevant information and elicit the patient's values and wishes, severe pain may erode an individual's cognition and autonomy. A patient suffering such pain often can think of nothing except relief and will agree to anything that will provide it. For such patients, truly free and informed consent may be an illusion.[5]

However, it is a mistake to thereby throw out the baby with the bath water and, under the cloak of therapeutic privilege, to avoid informed-consent processes altogether or go through the motions of only a *pro forma* informed-consent process.[6] The capacity of people in pain to make decisions — when given support, time, multiple visits, and meaningful information regarding risks, benefits, and alternatives — can be enhanced. A meaningful discourse can lead to a therapeutic alliance. A therapeutic alliance is a vital social matrix for meaningfully and helpfully sharing uncertainty and helping a patient bear pain without the compounding bitterness, helplessness, and hopelessness that accompany aloneness. Thus, more often then not,

the conflict between autonomy and health is more an artifact of our rush in the clinic and our own incorrigibility than a fact of nature or the patient's incorrigibility.

Another issue to address is whether introducing the new AMA guidelines in the age of managed care will lead to *pro forma* consent rather than meaningful informed consent. Managed care has greatly changed the practice of medicine. Physicians are now under enormous financial and time constraints, and personal one-on-one doctor-patient relationships have been replaced by brief doctors' visits. As a result, instead of real relationships, doctors are finding themselves in mere contractual arrangements with other physicians, health-maintenance organizations, and the public.

In this time-strapped environment, the AMA proposal to obtain information about a patient's preferences for receiving medical information before that information is available would most likely be implemented in the form of a survey or form that the patient would have to fill out and sign upon visiting a physician. Because the *pro forma* signing of a consent form does not constitute informed consent,[7] it is necessary that such a form be fully explained to the patient, that the patient have an opportunity to ask questions, and that there be some sort of acknowledgment that the patient appreciates the implications of what he or she has just signed. In short, a substantial amount of time needs to be devoted to obtain true informed consent regarding information preferences, especially for frightened patients who face pain and uncertainty — an amount of time that is unlikely to be available in the age of managed care.[8]

From a risk-management perspective, we are learning that patients and juries value informed consent far more than managed-care companies do.[9] If adequate time and care are not given to this process, and if the patient signs the form without fully knowing its implications, the AMA regulations could, in effect, be used by physicians as a Trojan horse to excuse failure to obtain informed consent for certain treatments and procedures. Such rationalizations do not ensure either quality clinical care or adequate risk management. In many institutions, a liaison of sorts is appointed, whose sole purpose is to explain the informed-consent form to patients. Yet even in such a setup, the pervasive issues of time and cost remain. Moreover, the designated informed-consent liaison often lacks the meaningful authority and relationship with the patient to make informed consent a meaningful process.

Occasions when drug and device manufacturers withhold information from physicians are as troubling as the rationalization that information should be withheld or delayed in the name of therapeutic privilege. This is typically done out of the fear that negative studies could lead doctors to prematurely reject a treatment, and for competitive reasons — drug companies argue that such studies are trade secrets and therefore should not be available to the public. This creates a distorted scientific record that physicians must use to make clinical judgments. Keeping data secret has led to conflicting information, contradictory advice, and heightened fears, and the end result is that physicians are deprived of information they need to evaluate the risks and benefits of prescribing a course of treatment.

When drug and medical device manufacturers do not disclose full information about their products, physicians may be privy to only limited information, and they may not even be aware that they are operating with limited information. Delayed disclosure does not undo damage caused by an initial misrepresentation, as the first clinical impressions are often the last impressions.[10] While conservatism can be a useful heuristic to frugally manage a flood of incoming data so that it does not sweep away prior information, it has its pitfalls. These become readily apparent when, given people's inherent conservatism and disinclination to change their minds, an initial misrepresentation of efficacy or risk by a manufacturer leads to a persistent lack of truly informed consent by patients. While physicians do have an obligation to be truthful to their patients, it can be difficult for a physician to acknowledge to a patient that the physician has been fooled by a pharmaceutical manufacturer's marketing that misrepresented efficacy or discounted risk. Under such conditions, it may become too tempting to rationalize and opt to not upset a patient and delay informing a patient under the guise of therapeutic privilege, and to accede to a preference previously elicited from the patient to avoid upsetting information.

While we have primarily focused on three issues in our discussion of the proposed AMA guidelines, there are a number of other potentially significant issues. One such issue is the disclosure of information

concerning medical errors, which is explicitly excluded from these proposal guidelines. A survey of more than 2,600 surgeons and medical specialists recently published in the *Archives of Internal Medicine* revealed that there are wide variations in doctors' willingness to disclose errors and in the ways they would present the details to patients.[11] These errors ranged from the obvious to non-obvious, and the study noted that when error was not obvious, doctors were sometimes unwilling to disclose it, as patients might not have enough knowledge to fully understand the nature of the error that took place and as a result might be frightened unnecessarily. Physicians also expressed concern that patients often assume any adverse event is an error, when in reality the majority of adverse events are not errors and are unpreventable.

Such a climate of distrust of patients by physicians as the survey reveals is a sad commentary on what is endangered when medical care becomes less caring and more focused on time and the management of appearances. To foster an environment of trust and openness with patients, it is important for physicians to disclose potentially upsetting information such as their own potential financial conflicts, including indirect but subtle conflicts of interest such as industry support of advisory panels and departments of academic medicine. Yet such disclosure is all-too-often resisted, even in contexts outside patient care. A recent study reports that, of 170 members of a DSM [Diagnostic and Statistical Manual of Mental Disorders] panel who were investigated for possible conflicts of interest, 56 percent were found to have strong financial ties with the pharmaceutical industry. Moreover, the study found strong ties between the pharmaceutical industry and those who were responsible for developing and modifying diagnostic criteria for mental illness, and these connections were especially strong in diagnostic areas in which medications are the first line of treatment for mental disorders.[12] While such relationships may be entirely legitimate, and may not imply any wrongdoing on the part of physicians, an impression of wrongdoing may arise if the relationships are left undisclosed. The participation of academic researchers in clinical trials and their consultation with the pharmaceutical industry can be beneficial to the care of patients, but it is critically important to define and enforce the boundaries between promotional activities and the unbiased presentation of clinical and scientific information.[13]

Ultimately, therapeutic privilege is all-too-often a misnomer. Withholding information is not a privilege, as it burdens the doctor-patient alliance. If the term "therapeutic privilege" has any meaning, it is only because it is exercised after carefully listening to the patient. The doctor-poet William Carlos Williams spoke of "the poem which their [patients'] lives are being lived to realize." Mechanical adherence to prosaic guidelines is no substitute for caring and for listening to the poem of our patients' lives.[14]

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DISCLAIMER

Harold Bursztajn has served as both a plaintiff and defense-retained consulting and testifying expert, as well as an advisor to the judiciary in informed consent and pharmaceutical and medical product liability class action cases.

NOTES

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