

**Towards an Empirical Test for the Reasonable Person Standard in Bioethics**

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University of Pittsburgh, 2012

As Robert Veatch observes, bioethics as a field is fundamentally oriented towards being “applied to real problems of the real world.” That is, although theories of ethics do play a role in the field, these theories must be “integrate[d]...with detailed knowledge of the relevant facts and customs of a particular sphere of life.” One way of making this progression is to follow the two-tiered system of standard and operational test such as that used by Allen Buchanan and Dan Brock in their discussion of their balancing model of competence. In this paper I will argue in favor of a representative (although not naïve) empirical operational test for the reasonable person standard. In each of the three sections that comprise the first chapter, I will identify the normative goals of a bioethical context and compare the reasonable person standard to its main competitors in light of those goals. Then, in the second half of the paper, I will defend both the reasonable person standard itself and the use of empirical data as an operational test for it. This defense will only be a partial one, however, as there are certain limits to the empirical approach. The goal of this paper is to show how empirical data can be used, albeit with some limitations, to help bring some clarity and precision to a standard that is often criticized for lacking precisely those qualities.

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## **1.0 INTRODUCTION: NORMATIVE CONTEXTS AND THE REASONABLE PERSON STANDARD**

The reasonable person standard was originally articulated in tort law to elaborate the standard of care, breach of which was a requisite element of a successful negligence action. A defendant is determined to have fulfilled the standard of care if he or she acted as a reasonable person would have acted in the same or similar circumstances. More recently, the reasonable person standard has also become a decision-making tool in the context of medical research and clinical practice. Bioethicists have proposed the use of the reasonable person standard in three specific medical contexts: clinical informed consent, surrogate decision-making, and human subjects research. Despite this, the reasonable person standard is not uncontroversial. Some bioethicists claim that other standards are superior, while others claim that the reasonable person standard is too vague or too inflexible to serve as a means of ethical decision-making. Whether or not the reasonable person standard is an appropriate one to use in bioethics, it must be admitted at the very least that the bioethical reasonable person standard must be understood differently than the legal reasonable person standard.<sup>1</sup> The process of evaluating the bioethical

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<sup>1</sup> One reason for this is that the legal system and the medical system have very different normative goals. A second reason is that, in the context of law, juries are often asked to determine whether a defendant has satisfied the reasonable person standard. Because there is rarely anything like a jury in the medical context, the reasonable person standard cannot be understood exactly the same way in both contexts.

reasonable person standard begins by attempting to understand the context of medicine and how the reasonable person standard could be used to make ethical decisions therein.

As Robert Veatch observes, bioethics as a field is fundamentally oriented towards being “applied to real problems of the real world.” That is, although theories of ethics do play a role in the field, these theories must be “integrate[d]...with detailed knowledge of the relevant facts and customs of a particular sphere of life.”<sup>2</sup> As such, any bioethical thought will depend at least somewhat on the context of *medicine*. Medicine is the primary normative context in which bioethical reasoning and discussion occur. Tom Beauchamp and James Childress, however, note that, in order to speak to practical contexts at all, theories in bioethics must take into account not just the broad context of medicine but “a particular context or range of cases” within medicine.<sup>3</sup> Given this requirement, bioethicists must find some way to progress from relatively abstract guideposts (e.g. principles, paradigm cases, or goals) to relatively specific recommendations or evaluations. One way of making this progression is to follow the two-tiered system of standard and operational test such as that used by Allen Buchanan and Dan Brock in their discussion of their balancing model of competence.

There are at least three noteworthy aspects of standards as a means of applying theory to practical context. First, as Buchanan and Brock suggest, standards are answerable to a context-specific ethical goal. In the case of surrogate decision-making, the goal is to find an appropriate balance between respecting an individual’s autonomy and safeguarding his or her well-being with regards to honoring that individual’s decision. To be justified, a standard of competence must serve this normative goal of balancing well-being and autonomy. Standards alone,

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<sup>2</sup> Robert Veatch, “Medical Ethics: An Introduction.” *Medical Ethics*. Ed. Robert Veatch (Sudbury: Jones and Barlett Publishers, 1997), 5.

<sup>3</sup> Tom Beauchamp and James Childress, *Principles of Biomedical Ethics* (Oxford: Oxford University Press, 2001), 15.

however, are not sufficient to determine whether any given situation meets the standard in question. Rather, a standard must have an *operational test* that is used “for ascertaining whether a given standard...is met.”<sup>4</sup> The need for and possibility of identifying an operational test is the second noteworthy aspect of a standard.

The key attribute of an operational test is that it clarifies and concretizes whatever elements of a standard are vague. Operational tests will be more defensible the more that they do this validly (i.e., insofar as the concretization isn't arbitrary but actually measures the relevant elements) and reliably (i.e., insofar as they produce consistent results). The ease of finding an appropriate operational test will vary depending on the standard one seeks to apply and, of course, the degree of complexity – conceptual and material – of the normative context in which it is to be applied. The third noteworthy aspect of a standard, however, is that standards are not always needed. There are many cases in bioethics and elsewhere in which the proper ethical course is clear enough to make the use of a standard superfluous. In these cases, the ethical features of a situation can be clearly identified, and there is broad and well-founded consensus as to the proper course of action given those features. Using a more indirect evaluative approach, like a standard, in such cases would be superfluous, and so it would be an error to apply the reasonable person standard or indeed any standard to every case.

In order to understand the reasonable person standard as it has been applied in bioethics, then, it will be necessary to know the ethical goals of the various contexts in which it has been invoked and the operational test used to apply the standard to real cases, as well as to distinguish between those cases for which a standard is needed and those for which none is. The contexts and their normative goals may vary, but the definition of the standard itself should remain

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<sup>4</sup> Allen Buchanan and Dan Brock, *Deciding for Others: The Ethics of Surrogate Decision Making* (Cambridge: Cambridge University Press, 1990), 18.

consistent and stable, at least if there is to be one and the same standard across contexts. For the purposes of this paper, only three such contexts will be examined: disclosure in clinical informed consent, surrogate decision-making, and human subjects research. Although these are almost certainly not the only contexts in which the reasonable person standard has been used, they all have relatively well-defined ethical goals and are sufficiently diverse at least to begin the search for a generalized statement of the reasonable person standard and an appropriate operational test of that standard.

Initial examination of these contexts indicates three shared elements of the reasonable person standard: it asks what a (1) hypothetical (2) reasonable person would do, need, or want (3) in the same or similar circumstances as are present in the specific case under investigation. Thus when the actions, beliefs, or requirements of this hypothetical reasonable person are determined by an appropriate operational test to align with the ethically relevant facts of a given situation, the user of the standard will conclude that the situation is ethically acceptable.<sup>5</sup> Alternatively, should the two not align, the reasonable person standard will indicate which steps must be taken to bring them into alignment. All of this, however, can only happen after context-specific goals have been identified and the reasonable person standard is interpreted in light of those goals.

In what follows I will argue in favor of a representative (although not naïve) empirical operational test for the reasonable person standard. In each of the next three sections, I will identify the normative goals of a bioethical context and compare the reasonable person standard to its main competitors in light of those goals. Then, in the second half of the paper, I will defend both the reasonable person standard itself and the use of empirical data as an operational

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<sup>5</sup> Or, at least, that it is ethically acceptable insofar as the standard can determine.

test for it. This defense will only be a partial one, however, as there are certain limits to the empirical approach. The goal of this paper is to show how empirical data can be used, albeit with some limitations, to help bring some clarity and precision to a standard that is often criticized for lacking precisely those qualities.

## **1.1 THE REASONABLE PERSON, CLINICAL INFORMED CONSENT, AND CORE DISCLOSURE**

According to Beauchamp and Childress, over the past forty years “the primary justification advanced for requirements of informed consent has been to protect [the] autonomous choice[s]” of patients, and a secondary justification has been “to minimize the potential for harm” to those same individuals.<sup>6</sup> Informed consent for Beauchamp and Childress has seven elements, of which disclosure is a “pivotal” component.<sup>7</sup> Accordingly, they take the success or failure of the ethical goal of obtaining informed consent to depend in large part on the subsidiary goal of performing sufficiently robust disclosures to patients. It is for this reason that, within the relatively broad context of informed consent, the reasonable person standard has been often applied specifically to the matter of a core disclosure and is used to ask *which information would be needed* in order for any hypothetical reasonable person in a similar situation to make a materially informed choice. However, the reasonable person standard is not the only standard that has been invoked in this area. In order for its use to be justified, then, it must be not only

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<sup>6</sup> Beauchamp and Childress, *Principles*, 77.

<sup>7</sup> *Ibid* 80.

sufficient to achieve the ethical goal in question, i.e., to properly balance patients' autonomy and welfare interests, but also superior to all of its known competitors in doing so.

Before attempting such a justification, though, it is important to explore an ambiguity in the ethical goal of disclosure as phrased above. When one asks which information would be needed for any hypothetical reasonable person in a similar situation to make a materially informed choice, there are two ways of understanding the question. On the one hand, one might want to generate a single, fixed collection of information that can be provided to all patients in a given situation. Such a disclosure would contain the information that is necessary for materially informed decision-making in that situation, and so would serve as a baseline or beginning disclosure. This is the aim of a core disclosure and is the goal that the reasonable person standard has been said to achieve. On the other hand, one might want to know how to expand on the core disclosure so as to provide the patient with information that is not just necessary but is also sufficient to make a materially informed decision. This interpretation seeks not a minimal core disclosure, but one that satisfies the particular patient's informational needs more fully. While the reasonable person standard has not been proposed as a means of satisfying a robust set of informational needs, it will be instructive to keep this second interpretation in mind as well.

Traditionally, the standard that was invoked to evaluate disclosure approved those interactions in which physicians "conform with the customary disclosure that competent physicians would make under similar circumstances."<sup>8</sup> Considered in light of the primary goal of protecting autonomy, it is difficult to justify the use of this professional practice standard.<sup>9</sup> In

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<sup>8</sup> Jeffrey Botkin, "Prenatal Screening: Professional Standards and the Limits of Parental Choice," in *Obstetrics & Gynecology* (May 1990), 875.

<sup>9</sup> Of course, protecting autonomy was not considered the primary goal at the time this standard was widely used. Rather, consent was focused on bodily welfare and convincing patients to accept the treatments that served that interest.

order for this standard to protect autonomy, physicians would have to know which information is needed to protect the autonomy of patients in general. Yet in actuality the professional practice standard “reduces individual patients to generalized clinical scenarios,”<sup>10</sup> thus replacing the diverse interests of actual patients with the presumption of a one-dimensional desire to attain some idealized state of health.

Although this reduction of diverse interests to a smaller set of medical interests does not fit well with the primary goal of the informed consent context, either for a minimal core disclosure or a more robust disclosure, it can still serve the secondary goal of “[r]educing risk and avoiding unfairness and exploitation”<sup>11</sup> and it can still serve as a starting point for upholding patient autonomy. Presumably patients do (at least typically) want to achieve the medical outcomes that play out in these idealized clinical scenarios, and presumably they do therefore need the information required by the professional practice standard. Without this information, it would be difficult for patients to come to a sufficiently thorough understanding of the situations in which they find themselves to be protected from harm or to make informed choices in accordance with their own interests. Because patients’ interests are typically also more diverse than the narrow medical welfare interests that are served by the professional practice standard, however, it is implausible to suggest that their autonomy can be reliably protected using that standard.

The reasonable person standard improves on the professional practice standard by “tak[ing] the limits of disclosure out of the hands of physicians and plac[ing] them in the hands

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<sup>10</sup> Ryan Childers, Pamela Lipsett and Timothy Pawlik, “Informed Consent and the Surgeon,” *Journal of the American College of Surgeons* (April 2009), 629.

<sup>11</sup> Beauchamp and Childress, *Principles*, 77.

of a hypothetical individual who has reasonable requirements for information.”<sup>12</sup> This shift eliminates the problem of treating real patients like abstractions in medical textbooks, but that does not automatically mean that the reasonable person standard is the proper standard to use. Indeed, several authors have objected to the reasonable person standard on the grounds that, much like the professional practice standard, it holds a diverse population to a monolithic benchmark that has been established by a mere abstraction.<sup>13</sup> On this thinking, “the reasonable person standard...does not go far enough in tailoring the process [of disclosure] to patient individuality.”<sup>14</sup> A still-more responsive standard, the subjective standard, is said to resolve this problem by requiring physicians to disclose whatever information the current patient requires. On this standard, every patient’s autonomy would be protected, at least in theory. This theoretical protection, however, would not come for free. Indeed, its cost may even be prohibitive – at least, with respect to developing a core disclosure.

As Beauchamp and Childress observe, “patients often do not know what information would be relevant for their deliberations, and a doctor cannot reasonably be expected to do an exhaustive background and character analysis of each patient to determine what information would be relevant.”<sup>15</sup> In other words, if one defers entirely to the informational desires of individual patients without providing any kind of oversight at all, one does indeed jeopardize the autonomy of those patients who wrongly believe that they can identify the information that they themselves need in a core disclosure. This would not be a problem if patients always desired the

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<sup>12</sup> Botkin “Prenatal Screening,” 876.

<sup>13</sup> See e.g. Childers, Lipsett, and Pawlik, “Surgeon”; Robert Redmon, “How children can be respected as 'ends' yet still be used as subjects in non-therapeutic research,” *Journal of Medical Ethics*, 12 (1986); Elizabeth Boetzkes, “Genetic Knowledge and Third-Party Interests,” *Cambridge Quarterly of Healthcare Ethics* 8, (1999); and Evelyn Chan and Daniel Sulmasy, “What Should Men Know about Prostate-specific Antigen Screening before Giving Informed Consent?” *The American Journal of Medicine* (October 1998).

<sup>14</sup> Childers, Lipsett, and Pawlik, “Surgeon,” 630.

<sup>15</sup> Beauchamp and Childress, *Principles*, 83.

information that they in fact need, but of course this is not the case. Regrettable though this may be, some patients feel entirely comfortable consenting to undergo a procedure only to find out afterwards that they had been ignorant of material information. Accordingly, there is a philosophical reason to look outside of patients' actual desires. An additional problem for the subjective standard is that physicians have neither the time nor the information-gathering resources to determine the unique disclosure needs of any one patient, let alone each and every patient they see. It is important to note that this problem represents not a competing ethical goal but rather a practical side constraint in the context of informed consent. That is, the burdens that the subjective standard would place on physicians are not burdens to be compared to and weighed against the obligation that those same physicians have to protect their patients' autonomy. Instead, Beauchamp and Childress appear to reject the subjective standard because the conditions that would enable it to achieve the ethical goal of formulating a core disclosure are simply not feasible in the real world.<sup>16</sup>

The subjective standard is still the superior standard in other circumstances – say, in the latter phases of the disclosure process, in which it would be inappropriate to excuse physicians from disclosing information that an individual patient does need to know but that a hypothetical reasonable person would not need.<sup>17</sup> Because core disclosures are not meant to meet the individual informational needs of every patient, however, it would be a mistake to conclude either the subjective standard or the reasonable person standard must be used for minimal disclosures and more robust disclosures alike. The same point can be made on the grounds that the subjective standard can only be a standard in a procedural sense whereas the reasonable

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<sup>16</sup> On this point see also Childers, Lipsett, and Pawlik “Surgeon” and Robert Wheeler, “Consent in surgery,” *Annals of the Royal College of Surgeons of England* 88 (2006).

<sup>17</sup> Here, as earlier, a patient is only said to “need” that information without which his or her decision would not be sufficiently autonomous. These informational needs will, therefore, vary from individual to individual.

person standard can be used to standardize the content of a disclosure. The two standards can be used cooperatively in the informed consent process, but only if it is first understood which standard is best matched with which context-specific goal within that process.

Howard Brody, however, appears to argue in a 1989 article that the reasonable person standard is not appropriate to use at all. The reasonable person standard, Brody says, places too heavy a burden on physicians because, even though it does not commit them to learning every relevant detail of patients' lives, it seemingly requires them "to rattle off at a moment's notice a detailed list of significant risks attached to any of the many drugs and therapeutic modalities they recommend." Just as Beauchamp and Childress suggest that the subjective standard could not realistically be used to generate core disclosures, Brody presents a practical side constraint to the use of the reasonable person standard in the same context. Though the subjective standard may ask too much of physicians, it would also be implausible to expect physicians to rapidly reproduce "detailed lists[s] of significant risks" from memory. Worse still, he says that the reasonable person standard's focus on disclosure leads to autonomy-jeopardizing behaviors on the part of physicians, such as their paying attention only to "what they said to the patient [rather than] how the patient used or thought about that information subsequently."<sup>18</sup> In fact, however, the first of these is neither a problem for the reasonable person standard nor a side-constraint to it. Because the reasonable person standard does not *actually* require physicians to have perfect and instantaneous recall,<sup>19</sup> it would be incorrect to say that it truly does commit physicians to an obligation that they cannot meet.

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<sup>18</sup> Howard Brody, "Transparency: Informed Consent in Primary Care," *The Hastings Center Report* 19.5 (1989), 6.

<sup>19</sup> One possible way to avoid this would be for physicians to use materials that provide information in such a way as to be essentially equivalent to instantaneous and perfect recall, such as brochures or videos. See e.g. Chan and Sulmasy, "What Should Men Know," 272; Grant Gillett, "At Last – Some Reasonable Comments On Informed Consent," *The New Zealand Medical Journal* (October 2003).

As for Brody's increased focus on understanding, this is better understood not as an attack on the reasonable person standard but rather as an attempt to shift the informed consent process from focusing almost single-mindedly on the element of disclosure of information to a more balanced focus on disclosure as well as understanding, that is, to a focus on transparency. Because the main thrust of Brody's argument is to ensure that patients "see the basic reasoning [that a physician] use[s] to arrive at the recommended treatment" – in essence, to propose an alternative subsidiary goal for the primary ethical goal of protecting autonomy – it should be no surprise that the reasonable person standard can accommodate his argument. After all, standards inherit details from the ethical goals of the contexts in which they are placed, so there will not be any justified standard that is absolutely incompatible with such a goal, even when that goal is transparency. And indeed, Brody's own suggested replacement for the current model of informed consent is compatible with the reasonable person standard. One can simply adapt the reasonable person standard to the goal of transparency by saying that a physician has done an ethically acceptable job of disclosure when a hypothetical reasonable person would have understood the physician's basic thinking.<sup>20</sup>

Merely being compatible with the goal of transparency does not mean, however, that the reasonable person standard would do enough to ensure that physicians' thought processes are transparent to their patients.<sup>21</sup> Brody defines a transparency standard so that "disclosure is adequate when the physician's basic thinking has been rendered transparent to the patient," as measured by the "physician's own thinking" about what is relevant.<sup>22</sup> In a sense, this is an

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<sup>20</sup> Another possible way to seek to enforce the value of transparency would be to say that physicians must explain their reasoning until they are sure that each individual patient has understood their essential reasoning; this would be the subjective standard for transparency.

<sup>21</sup> Nor, of course, is the goal of transparency (as defined by Brody) necessarily an appropriate one for the context.

<sup>22</sup> Brody, "Transparency," 7.

extreme version of the professional practice standard as interpreted through the goal of transparency: rather than asking a group of physicians to determine which information is material, it asks individual physicians to determine when information has been understood and is material. The question that the transparency standard faces, then, is whether individual physicians can be trusted to know when their patients have comprehended their basic thinking or whether that understanding would be better measured by reference to a hypothetical reasonable person.

Here, as with the question of materiality, the issue will usually come down to a matter of values and interests. It is one thing to ask that a patient be able to memorize and recite his or her physician's basic reasoning, but Brody requires much more than that. In order for physicians to render their reasoning transparent to their patients, they must find a way to communicate that reasoning so that patients can parse it and fit it into a recognizable set of values and interests. Merely understanding, for example, that one's oncologist prefers one treatment over all the others because it lowers the risk of metastases is not enough unless one also understands what metastases are, why they might be considered to be bad enough to outweigh any additional burdens of the proposed treatment, and so on. One needn't agree with the oncologist's analysis – one individual can find another's thinking to be transparent and still disagree with it – but one would have to acquire a relatively deep level of understanding in order to satisfy Brody's goal of transparency. It is difficult to imagine, however, that individual physicians will reliably be able to help their patients reach such an understanding given that physicians as a professional group tend to operate with a very different set of interests and values than patients do. Just as in the case of determining materiality for a core disclosure, it seems necessary to take the matter of transparency out of the hands of physicians and place it, at least, in the hands of a hypothetical

individual with reasonable requirements for understanding – that is, it seems necessary to replace the professionally-driven standard with the reasonable person standard. Thus the reasonable person standard appears to be superior to Brody’s transparency standard even if he is right in arguing for transparency as being of primary importance.<sup>23</sup> There is, however, one apparent flaw in the reasonable person standard that cannot be explained away so easily: that it cannot (at least practically) be tested in an operational way and so cannot be used to inform action.

One objection leveled by several authors against the reasonable person standard is that “the determination of how much information a ‘reasonable person’ in the patient’s situation would want is extremely difficult.”<sup>24</sup> In essence, this claim states that the reasonable person standard is prohibitively difficult to operationalize and so cannot be relied upon in real-world settings. Like Beauchamp and Childress’s argument against the subjective standard, this objection attempts to identify a reason to reject the reasonable person standard that does not center on an ethical flaw. And indeed, if this complaint is accurate it is difficult to see how the reasonable person standard could succeed. After all, standards are meant to be used as a way of applying high-level ethical concepts to ground-level actions or requirements, so any standard that only has upward connections cannot succeed regardless of how enticing it might otherwise be. Whether the reasonable person standard can connect downwards as well as upwards will be investigated in detail at the end of this chapter, but assuming for the moment that the reasonable person standard does not face any unresolvable practical issues it seems fair to say that it is the best of the known standards for evaluating instances of informed consent, as it balances

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<sup>23</sup> If Brody errs in seeking to redefine the values at play in this context, the reasonable person standard is clearly superior: as an extreme version of the professional practice standard that would allow individual physicians to set their own limits, his transparency standard would fail for the same reasons that the professional practice standard fails.

<sup>24</sup> Dewey Zeigler, et al., “How Much Information About Adverse Effects of Medication Do Patients Want From Physicians?,” *Archives of Internal Medicine* 161 (2001), 707; see also Childers, Lipsett, and Pawlik, “Surgeon,” 629; and Botkin, “Prenatal Screening,” 876.

autonomy and welfare better than the professional standard while avoiding the side constraints that affect the subjective standard.

## 1.2 THE REASONABLE PERSON AND SURROGATE DECISION-MAKING

For Buchanan and Brock, finding a suitable standard to use in surrogate decision-making is a matter of ensuring that the standard properly reflects “the values of self-determination [i.e., autonomy] and the individual’s well-being.”<sup>25</sup> To this end, authors have proposed several standards, among them the substituted judgment standard, the pure autonomy standard, the best interests standard, the current interests standard, and, of course, the reasonable person standard. Unlike in the case of informed consent, however, the appropriate standard to apply in a given case of surrogate decision-making depends on the details of that case because of the wide variability in the ethically relevant factors a case may possess. In other words, identifying the proper standard for a given case will be in part a matter of identifying the relevant sub-context of surrogate decision-making to which that case belongs.

One of the most significant variables in surrogate decision-making is the extent to which the patient’s desires or preferences are epistemically available to the surrogate. When they are known (either through direct contact with the patient, the testimony of a trustworthy surrogate or proxy, or an advance directive), they must be taken into account even if they will ultimately be overridden.<sup>26</sup> Accounting for patients’ autonomy interests requires no less. Because the reasonable person standard does not even consider the desires or wishes of the actual patient in

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<sup>25</sup> Buchanan and Brock, *Deciding for Others*, 90.

<sup>26</sup> Say, because the desired procedure or treatment would be medically futile.

question, instead focusing entirely on those that a hypothetical patient would have, it would be inappropriate to use in this subcontext and is inferior to the pure autonomy and substituted judgment standards. By the same token, though, those standards are problematic when the patient's desires are *not* known. In such a case, a pure autonomy standard will have no instance of autonomous expression of preferences or values with which to proceed, and a surrogate decision-maker will not have the information he or she needs to substitute his or her own judgment grounded in that information for the patient's decision-making. For this reason the focus shifts entirely to well-being when an incompetent patient's previously expressed autonomous desires cannot be ascertained. This is the subcontext in which numerous sources agree that the proper course of action is to use the patient's best interests as a guide.<sup>27</sup> The proper way to establish what is in the best interests of such a patient, however, is somewhat more controversial.

The reasonable person standard, for example, would not face the same difficulties as the pure autonomy and substituted judgment standards when "a patient is unknown to the clinician [and] no readily interpretable advance directive is available"<sup>28</sup> because it does not rely on facts about the values and preferences of the individual patient. But it is not as clear that a hypothetical reasonable person would be able to reliably identify the best interests of an incompetent patient. Robert Redmon, for example, claims that treatment of a comatose patient can be justified by the reasonable person standard "on the grounds that if he were awake, and rational, it is reasonable to assume that he would agree to the treatment" and that treatment of a

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<sup>27</sup> See e.g. Ghan-Shyam Lohiya, Lilia Tan-Figueroa and Francis Crinella, "End-of-Life Care for a Man with Developmental Disabilities," *Journal of the American Board of Family Practice* (January-February 2003); Annas, George. "'Culture of Life' Politics at the Bedside - The Case of Terri Schiavo." *The New England Journal of Medicine* 352, no. 16 (April 2005): 1710-1715.

<sup>28</sup> Robert Palmer and Kenneth Iserson, "The Critical Patient Who Refuses Treatment: An Ethical Dilemma," *The Journal of Emergency Medicine* 15.5 (1997), 729.

child is justified when one can “expect [that] child to be pleased, to ‘agree retroactively,’ when she is an adult.”<sup>29</sup> Even assuming that Redmon does not mean to attempt to reconstruct the values of individual patients and so fall back into something like the substituted judgment standard, this approach is vulnerable to an objection made by Rebecca Dresser and John Robertson.

As they say, “a person’s interests may change drastically once incompetency develops” such that it is no longer appropriate to judge that person’s interests by the interests of someone who is awake and rational.<sup>30</sup> In order to avoid this mistake, Dresser and Robertson propose a current interests standard according to which the relevant question is “whether treatment actually serves the incompetent patient’s existing interests.”<sup>31</sup> Like the reasonable person standard, their current interests standard is also clearly capable of operating “[i]n cases in which there is no valid advance directive and in which substituted judgment is inapplicable,”<sup>32</sup> that is, in cases in which there is minimal or no information about the patient’s desires. At least on first glance, then, Dresser and Robertson appear to have found a competitor for the reasonable person standard in this subcontext, and a strong one at that. If they are correct in asserting that patients with unknowable values should not be treated in a way that disregards their current interests, it would be difficult to justify the use of a standard that asks “what a reasonable person would do under the circumstances”<sup>33</sup> or “what a reasonable person would want done under the same circumstances”<sup>34</sup> or any of the similar formulations that typically are used by proponents of the reasonable person standard. After all, presumably one must have at least some minimal level of

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<sup>29</sup> Robert Redmon, “Non-therapeutic Research,” 80.

<sup>30</sup> Rebecca Dresser and John Robertson, “Quality of Life and Non-Treatment Decisions for Incompetent Patients: A Critique of the Orthodox Approach,” *Law, Medicine, and Health Care* 17.3 (1989), 236-7.

<sup>31</sup> *Ibid* 240.

<sup>32</sup> Buchanan and Brock, *Deciding for Others*, 122.

<sup>33</sup> Lohiya, Tan-Figueroa and Crinella, “End-of-Life Care,” 59.

<sup>34</sup> Palmer and Iserson, “Critical Patient,” 729.

consciousness, rationality, and self-knowledge in order to be a reasonable person, yet it is precisely the lack of these qualities that makes a person incapable of expressing his or her own preferences. Since their standard is designed specifically so as to avoid this problem, Dresser and Robertson would seem to have proposed a superior standard.

On a closer look, however, matters are not so clean-cut. The reasonable person standard need not proceed by asking how the currently not-reasonable patient would decide if reasonable, thereby misattributing the interests that typically come along with being reasonable to someone who currently lacks that attribute. It could instead ask how a reasonable person would judge the best current interests of the patient in question. For example, Dresser and Robertson claim that “[t]he ‘pleasantly senile’ and other debilitated individuals who appear to receive benefits from their restricted lives...appear to retain sufficient mental capacity for continued life to hold material value for them.”<sup>35</sup> Rather than leaving it up to academicians or clinicians to weigh these matters according to their own judgment and so decide which “experiences provide ‘a life worth living’ to the patient...despite the burdens” of that individual’s condition,<sup>36</sup> this could be decided by reference to a hypothetical reasonable person – that is, it could be decided by the reasonable person standard. Thus the reasonable person standard can at least survive the initial challenge that Dresser and Robertson’s position poses.

Unfortunately, if neither standard can be eliminated due to a major flaw it will be somewhat difficult to compare them until an operational test has been specified for each. Insofar as a particular treatment is obviously in a patient’s best current interests, a hypothetical

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<sup>35</sup> Dresser and Robertson, “Quality of Life” 242.

<sup>36</sup> *Ibid* 241.

reasonable person would come to that conclusion (and vice versa).<sup>37</sup> When a plausible case can be made that each of a range of multiple treatment options (potentially including non-treatment) might be in an individual's best interests, however, one encounters the inconvenient fact that the hard cases are precisely those in which a person can wrongly identify an individual's best interests and still be counted as a reasonable person (as the phrase goes, those cases "about which reasonable people can disagree") – which is, of course, what makes them hard cases to begin with. This is not to say that a reasonable person could not be convinced of the right decision by, say, living out the consequences of making the wrong one. If 20/20 hindsight is the best that the reasonable person standard can guarantee, however, it does not seem to be very well suited for use in the original decision-making process or as a way of evaluating decisions that have already been made but that must be lived out by individuals who "can furnish us with little or no verbal data on how they experience their lives."<sup>38</sup> Of course, this is precisely the sort of ambiguity that an operational test is supposed to resolve. In the absence of such a test for the reasonable person standard, however, it is not clear that that standard will be superior to the one proposed by Dresser and Robertson. Further evaluation of the reasonable person standard within the context of surrogate decision-making, then, will have to be put off until a test for it can be specified.

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<sup>37</sup> On the other hand, if the patient's current best interests are easily identifiable and would be best served by only one treatment option, it would probably be unnecessary to use a standard. Again, the use of a standard is only called for when other, more straightforward decision-making methods are ambiguous, inconclusive, or uncertain.

<sup>38</sup> *Ibid* 241.

### 1.3 THE REASONABLE PERSON AND MEDICAL HUMAN SUBJECTS RESEARCH

Human subjects research in medicine, a third area in which the reasonable person standard has been invoked, is somewhat more complicated than the contexts of either clinical informed consent or surrogate decision-making. In particular, it appears to have multiple ethical goals – seven, according to Ezekiel Emanuel, David Wendler, and Christine Grady<sup>39</sup> – and so will have to be broken up into sub-contexts. Of the seven, only two are commonly associated with the reasonable person standard: obtaining informed consent from subjects and ensuring that the risk/benefit ratio of the proposed research is appropriate (i.e., human subjects protection).

In the former of these sub-contexts, the justification for using the reasonable person standard runs along the same lines as the justification of its use in the context of clinical informed consent. Because the operating values of the professionals (physicians, investigators) are liable to differ from the values of the vulnerable populations (patients, subjects) in both contexts, the professional practice standard will not suffice for research subjects any more than it will for patients. Likewise, researchers have no way of meeting the requirements of the subjective standard because they simply cannot devote their time to developing a deep personal understanding of each and every potential subject. As in the clinic, then, in human subjects protection the reasonable person standard offers an improvement on the professional practice standard without asking for the impossible (at least on its face).

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<sup>39</sup> See Ezekiel Emanuel, David Wendler, and Christine Grady, “What Makes Clinical Research Ethical?,” *Journal of the American Medical Association* 283 (2000), 2703. The authors characterize them as requirements instead of goals but this is a matter of phrasing only.

As for the second sub-context of evaluating the risk/benefit ratio, the main competitor for the reasonable person standard appears to be something akin to the professional practice standard. As Robert Veatch describes, rather than relying simply on physicians this standard also includes those with professional-level “knowledge of the law, social science, psychology, and religious traditions.” Nonetheless, one would expect that this alternative also has the same flaw as the traditional professional practice standard, i.e., that it runs the risk of wrongly substituting the values of professionals for those of laypeople (in this case, lay research subjects). This would not directly undermine the ethical goal in the same way that it would in the case of informed consent, as the fundamental value of ensuring a suitable risk/benefit ratio is not autonomy but “the need to avoid the exploitation of subjects.”<sup>40</sup> Nonetheless, the risk/benefit ratio must be calculated so as to take into account the risks and potential benefits that the proposed subject population would actually experience, an experience that would in turn be shaped by the actual values and interests of that population. And indeed, although this instantiation of the professional practice standard earns Veatch’s title of the *interdisciplinary* professional standard by virtue of its increased diversity, this change still does not go far enough. After all, just as whether “the reasonable person would want to know something is logically still an open question even if there is a consensus among the professional group” even if that group is composed of a wide variety of professionals instead of only medical ones, the consensus of an interdisciplinary professional group regarding the appropriateness of a risk/benefit ratio is not a substitute for the representative judgment of a subject population. It is for this reason that Veatch identifies the need for “the ability to judge community attitudes”:<sup>41</sup> without a profession

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<sup>40</sup> Emanuel, Wendler, and Grady, “Clinical Research,” 2706.

<sup>41</sup> Robert Veatch, “Human Experimentation Committees: Professional or Representative?,” *The Hastings Center Report* (October 1975), 36.

that centers on relating to diverse lay communities, a key piece of information will be missing and so the probability of exploiting subjects will be unnecessarily high.<sup>42</sup>

For these reasons Veatch suggests using “a group more skilled in representing...the views of the reasonable person” to weigh risks and benefits – in essence, a reasonable person standard.<sup>43</sup> Nor is Veatch the only author to employ the standard in this context. Robert Amdur and C.J. Biddle, following Baruch Brody, use it to evaluate the use of placebo controls in human subjects trials, saying that a study presents an acceptable level of risk only when “a reasonable person of an average degree of altruism and risk-aversiveness might consent” to participating.<sup>44</sup> Assuming that some group can successfully represent the views of the reasonable person (i.e., that a test can be found for the reasonable person standard), the judgment of that group will be superior to the judgment even of an interdisciplinary professional group – at least, when it comes to using the relevant set of values.

There is, however, a complication. The medical risks and benefits of a proposed study need to be thoroughly understood before they can be compared, yet the reasonable person standard only specifies the reasonableness of the hypothetical person and does not grant that person any particular knowledge or expertise (beyond, perhaps, that which a person could not lack and still be counted as reasonable). In the same way that clinicians may unintentionally disregard (or simply be ignorant of) their patients’ diverse interests, it may be the case that a hypothetical reasonable person just does not have the professional background necessary to compare the risks and benefits of an experiment.

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<sup>42</sup> Whether or not there is any such profession will be a question in the second part of this paper.

<sup>43</sup> Veatch, “Committees,” 39.

<sup>44</sup> Robert Amdur and CJ Biddle, “An algorithm for evaluating the ethics of a placebo-controlled trial,” *International Journal of Cancer* (October 2001), 266. See also Beauchamp and Childress, *Principles*, 323, in which the authors dispute the ethical appropriateness of any study in which a “reasonable person could have objective grounds before the trial for preferring” the treatment group to the control group or vice versa.

Rather than trusting an untutored hypothetical reasonable person, then, one may instead want the opinion of a hypothetical reasonable person who has received some degree of education about the proposed research. This notion, however, only emphasizes the importance of finding a sensible operational test for the reasonable person standard. As difficult as it may be to determine the beliefs, desires, or needs of an abstract person who is described only as “reasonable,” it is more puzzling still to know how such a person might react after taking into account technical information from experts. On top of this, it is unclear how much background knowledge a reasonable person would have to possess in order to understand the scientific details of a proposed trial in a relatively value-free way. This is problematic because, as Veatch rightly observes, the point of applying the reasonable person standard is to operate based on the norms specified by that standard. Should it be the case that a hypothetical reasonable person requires information that has a normative component and the values reflected in that component are in conflict with the values that the reasonable person standard would provide, the standard will be less reliable. So, for example, if a research protocol is intended to evaluate the efficacy of a new migraine drug and the medical experts can only make themselves understood by saying that at best the experimental treatment could offer “very good” pain relief, they will already have interfered with the way the process is supposed to work. The more that the hypothetical reasonable person requires such simplifications, the more the standard will be compromised relative to its promise to evaluate scenarios based on the needs of a hypothetical reasonable person; at the extreme, it will be capable only of reiterating the results of the professional standard. With all of this in mind, I now turn to the task of investigating potential operational tests for the reasonable person standard.

## 2.0 SECOND CHAPTER

Even if some standard or other is needed to make reliably ethical decisions in the three contexts listed in chapter 1, and even if the reasonable person standard is the one whose conceptual design is best suited to that task, it could still fail to be an appropriate standard to use. Much depends on finding a suitable operational test, and so most of this chapter will be devoted to defending what might be called a representative test. The particular representative test defended herein will be one in which the relevant values and interests are identified through the use of an empirical process in which populations are asked to identify their own values and interests in a way that is as direct as possible. In other words, this test constructs a hypothetical member of a population whose precise values and interests may not be held by any actual member of that population but which nonetheless represent the values and interests of the population as a group. Because values and interests are only honored when they are reasonable in some sense, it is fair to say that this representative test relies on a hypothetical reasonable person and so is a way of putting the reasonable person standard into practice. This test is limited in certain ways and must be designed carefully, and those nuances will be explored in this chapter. Before any of that, however, it will be helpful to see why the appropriate standard will have to be able to account for relevant differences in populations, and to show that the reasonable person has this capability.

## 2.1 *THE REASONABLE PERSON?*

### 2.1.1 Reasonable Person vs. Reasonable Population

One of the most striking criticisms of the reasonable person standard is found in the writing of Elisabeth Boetzkes. For Boetzkes, the reasonable person standard is meant to provide clear and unwavering answers to questions such as whether or not it is acceptable for health care professionals who discover a genetic disorder in a parent not to disclose that information to that parent's children. Before considering the possibility of using a representative test as a way of operationalizing the reasonable person standard, she lists and rejects two other tests.

The first of these tests "is basically a Rawlsian model in which the reasonable person, with defensible social values," analyzes the situation and presents a conclusion. This test, she says, is problematic in that it assumes "cultural homogeneity and gender neutrality" in order to guarantee that it will actually reach an answer. Without these assumptions, a Rawlsian test can only fall back on ethical theory, which Boetzkes claims cannot do the job by itself. Pure ethics, she says, "are underdetermined, inconclusive, or insufficiently contextual" and so cannot actually operationalize the reasonable person standard. Taking the perspective of one sort of reasonable person (e.g. a white male) would help to avoid these insufficiencies, but only at the cost of making the reasonable person standard into a means of arbitrarily imposing one group's values on other groups.<sup>45</sup> On the second rejected test, "case law [would] be the measure of reasonableness." Although Boetzkes credits this approach with rightly acknowledging the importance of contextual details in a way that the Rawlsian test does not, she is right to say that it would be too limited in scope. Because such a case-law test would be limited by "the exigencies

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<sup>45</sup> Boetzkes, "Third-Party Interests," 389-391

of cases finding their way to the courts,” it would be unable to address any scenarios that have not already been considered by the relevant legal bodies. Such a test would also be inherently conservative in virtue of being precedent-based – a conservatism that, as in the Rawlsian test, would wrongly privilege one perspective.<sup>46</sup>

In order to avoid this, one might attempt to pass over these monolithic tests in lieu of one that is more flexible – say, a test that seeks to identify the values and interests that most accurately represent a relevant population. For Boetzkes, however, the problem with replacing either the Rawlsian or case-law test with a representative test is that “within [any] one community, a number of subcommunities and relevantly different groups exist. Thus there are...a number of sets of defensible values (and which one should the reasonable person adopt?).” Although not all relevantly different groups will follow a different set of *defensible* values, Boetzkes is certainly correct to say that there are enough acceptable value sets that this test “will not yield a single answer to the clinician’s dilemma”<sup>47</sup> and so, assuming that a single answer is needed, will either fail to operationalize the standard or will operationalize it in a way that privileges one such value set over all others.

One potential response, she notes, is to attempt to boil down the competing communal value sets to the point where all that remains is “some small set of mutually agreed upon political values, such as tolerance.” Although this would have the effect of excluding many apparently valid considerations by removing those political values with significant but not sufficient support, it would at least go some ways towards finding a way to produce unambiguous and definitive answers to bioethical quandaries. The trouble, however, is that it is basically a Rawlsian response, and so has basically the same problems as what Boetzkes called the Rawlsian

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<sup>46</sup> *Ibid* 389

<sup>47</sup> *Ibid* 391-392.

test. Even if diverse communities are able to agree on a set of mutually acceptable political values, the content of those values will not be sufficient to guide action – as Boetzkes says, they would be too thin. Of course, this should not come as a surprise: if the diverse subcommunities were able to reach substantive agreements on a wide variety of ethical issues, they would hardly be diverse and they would almost certainly not need to look towards the reasonable person standard as a way of guiding action in the face of multiple possible preferences and values.

Though these are all good reasons for doubting that the reasonable person standard can provide the sorts of answers that Boetzkes requires of it, her requirements themselves seem to be misguided. In order for the reasonable person standard to produce only one analysis of a given medical scenario regardless of the actual individuals involved in that scenario, it would have to be the case that any reasonable person would want, need, or do the same thing in that scenario. This follows from the definition of the reasonable person standard, which states that the standard identifies that which some hypothetical reasonable person would want, need, or do in a given scenario. Very few authors seem to believe that all reasonable people would want, need, or do the same thing in the same situation, however. Instead, it is far more common to read, as Robert Redmon states, that “it is difficult to predict how altruistic the ‘reasonable person’ would be in a moral situation. It does make sense, however, to ask how a person with a particular moral outlook, particular values, virtues and vices, would act.”<sup>48</sup> While Redmon does not make it clear whether or not the person with a particular outlook counts (or could count) as a reasonable person for the sake of this discussion, Childers, Lipsett, and Pawlik do, saying that “what a

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<sup>48</sup> Redmon, “Non-therapeutic Research,” 81. Although altruism is typically defined so as to be supererogatory, Redmon appears to use the term to indicate any motivation other than sheer self-interest. Here he means to indicate the not-self-interested desire to contribute to medical progress by participating in research, which he believes is relevant to the calculation of a child’s best interests and so should be considered when determining whether it is permissible to enroll that child in a research protocol. Whether or not this is actually the case, the broader point remains: pinning down one and only one response on the part of a hypothetical reasonable person is not usually feasible.

‘reasonable’ person may want to know about a given medical intervention can vary depending on the unique characteristics of his or her disease, values, and life goals.”<sup>49</sup> At first glance, then, it seems possible to respond to Boetzkes by saying that the reasonable person standard need not attempt to construct *the* reasonable person, as though such a being existed. Rather, it only needs to make sure that its recommendations are consistent with what *some* reasonable person would want, need, or do. While this of course cannot be determined without a sufficiently detailed description of the scenario in which the decision is being made, even that description alone will not be enough.

Anyone attempting to look towards specific “values, virtues and vices,” however, must walk a fine line. On the one side is the threat of falling back into the subjective standard in the way that Redmon appears to when he says that, in the case of surrogate decision-making for a comatose patient, the proper test of the reasonable person standard is what that patient would agree to “if he were awake, and rational.”<sup>50</sup> If this is to be the test of the reasonable person standard, it will function the same way that the subjective standard does and will be open to the same criticisms. In particular, it would be very difficult for a physician to determine any particular patient’s moral outlook, values, life goals, and so on, let alone to do this for every patient. This objection is especially relevant for cases like Redmon’s, in which patients cannot communicate this information themselves. Indeed, one of the supposed advantages of the reasonable person standard is that it can operate in an environment in which *nothing* substantive is known about the patient as an individual. In a case described by Ghan-Shyam Lohiya, Lilia Tan-Figueroa, and Francis Crinella, for example, “[t]he patient was mentally incapable of preparing an advance health care directive, and he had never expressed a preference about end-

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<sup>49</sup> Childers, Lipsett, and Pawlik, “Surgeon,” 629.

<sup>50</sup> Redmon, “Non-therapeutic research,” 80.

of-life care or religion,” nor was such information supplied by his relatives or close acquaintances.<sup>51</sup> Should the reasonable person standard require physicians to acquire information about the specific values and goals of each and every patient they treat, it will be an infeasible if not an impossible standard to apply in many cases.

On the other hand, the reasonable person standard could aim to shortcut this process by understanding patients not as individuals but as part of a group that has a defensible set of values. In this case one would conduct some manner of research within each group in order to determine that group’s values or, more directly, in order to determine what a representative member of that group would want, need, or do in a given medical scenario. The responses of the group would then be taken as authoritative for each individual case that conforms to the clinical description of the scenario and in which the primary subject of discussion (usually the patient or prospective research subject) is a member of the group. This would eliminate the need to investigate each and every patient’s value set, but there are at least three problematic assumptions that must first be addressed. For one, this sort of representative test cannot function unless people can (at least generally) be sorted into discrete groups based on their values and interests. There is, after all, more than one way to separate a population by demographics,<sup>52</sup> and each member of that population will belong to multiple demographic categories even in the most homogeneous of societies; in the language of sociology, identities are intersectional.<sup>53</sup> So if it is discovered that Asian-Americans, Latin Americans, men, and women all have different defensible value sets

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<sup>51</sup> Lohiya, Tan-Figueroa, and Crinella “End-of-Life Care,” 59.

<sup>52</sup> By “demographics” I do not mean to denote only those categories that are the most immediately apparent, like sex or race. Rather, I use the word in its broader sense to mean “a particular sector of a population.” Although some of the contexts and scenarios in this paper presumably would require one to rely on those demographic qualities that are evident just on first glance, not all such contexts and scenarios would.

<sup>53</sup> Johan Galtung, “Cultural Violence,” *Violence and its Alternatives*, Ed. Manfred Steger and Nancy Lind (New York: St. Martin's Press, 1999), 39-56.

relative to a clinical scenario, for example, a person employing the reasonable person standard will have to be able to choose which value set to apply to Asian-American women.

Assuming that it is possible to make these decisions in a way that reliably tracks the values and goals of the individuals who belong to demographic categories with conflicting value sets, there is still another challenge for the shortcut method of referring to a group's values in lieu of an individual's values. Namely, that shortcut may, in fact, not be a shortcut at all. While determining the values and goals of an individual person is certainly a time-consuming task, it may be similarly difficult to determine the right group to which to assign any individual patient. This is again especially true in the cases in which the patient cannot communicate at all or in which treatment must be provided on an emergency basis. While there will always be some identity markers that are immediately apparent (race, sex, approximate age) there will also be others that are less obvious (religion, political affiliation, professional status).

Third, it may be argued that the entire point of using a reasonable person standard is lost if a population is partitioned into statistically relevant demographic categories. Historically, the reasonable person standard was used as a buffer against professional values being substituted for a broader set of interests, but it seems odd to expand that buffer. For example, it seems strange to think that people under the age of 30 would need to be defended from the values and interests of people over the age of 30 in the same way that people in general need to be defended from the relatively narrow interests of some medical professionals. Moreover, allowing the reasonable person standard to adapt to multiple groups' values may make it unsuited to the contexts in which it has been used. When it comes to establishing the content of a core disclosure, for example, generating multiple answers may seem to defeat the purpose. A core disclosure or a

policy for surrogate decision-makers, one might think, is not truly a core disclosure or a decision-making policy unless it applies to everyone.

Boetzkes challenges the first assumption in the context of managing the core disclosure given to women who might have genetically anomalous children, saying that “women’s decisionmaking processes are dynamic and individual. [They] will result in different choices, depending on the circumstances of individual women’s lives and their respective moral identities.” If the individual is the highest level of abstraction at which values and goals can be reliably correlated, as she suggests, there will be no groups to which to refer and so no group values or preferences for the standard to use. On the other hand, though, Evelyn Chan and Daniel Sulmasy claim to have found empirical evidence as to the desired “content of informed consent [disclosures] for PSA [prostate-specific antigen] screening,”<sup>54</sup> and Zeigler et al claim to have demonstrated a strong cross-demographic desire for “information from physicians concerning risk for adverse effects of medication, ‘no matter how rare’.”<sup>55</sup> If these studies are statistically reliable, they provide two points in favor of using an empirical process for the reasonable person standard’s operational test.

First, they show that it is at least sometimes possible to find medical scenarios about which groups of people agree. Thus even if Boetzkes is right to say that no group opinions can now be found among women with regard to the question of bearing a genetically anomalous child, it is not necessary to abandon an empirical approach altogether. Rather, one would only need to restrict its application to those cases where agreement exists. As for identifying the informational needs or desires of a woman whose child has a genetic disorder, such a case would simply have to be decided some other way. The second positive piece of evidence in the studies

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<sup>54</sup> Chan and Sulmasy, “What Should Men Know,” 272.

<sup>55</sup> Zeigler et al, “How Much Information,” 710.

of Ziegler et al. and Chan and Sulmasy is that they both find widespread agreement across demographic groups. This goes some way towards eliminating the need to draw dividing lines between demographic categories as well as the need to identify individual patients as belonging primarily to only one of potentially multiple demographic groups, and so it helps to address the potential flaws in the assumptions that underlie an empirical approach.<sup>56</sup>

Even if one accepts that there will be wide consensus in some cases, though, one might still question the applicability of the reasonable person standard when opinions are varied or empirical findings are inconclusive. For example, if Boetzkes is right about women and reproductive decisions, is the reasonable person standard inapplicable to that case? Here the intersectional nature of social identities can actually be a benefit to the reasonable person standard. Rather than simply accepting the initial finding that there is no single attitude that women take towards reproduction, it is possible to seek a more detailed view and so perhaps find agreements at the subcommunity level (for example, African-American women or women between the ages of 25 and 30). If this, too, fails to provide any convincing consensus, then the reasonable person standard may indeed not be applicable to that case at that moment in time. Because values and attitudes change over time, however, neither the presence nor absence of a consensus should be taken as the last word on the matter. Rather, groups should be re-surveyed as time passes in order to ensure that the reasonable person standard is not incorrectly operating on the basis of values held only or primarily by the dead.

The third assumption, that the reasonable person standard can be responsive to groups' values without losing either its essence or its usefulness, requires justification of an altogether

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<sup>56</sup> Note, however, that this should not be taken as an endorsement of the specific conclusions of those studies. Not every empirical study is a reliable one, and some do not even attempt to elicit the proper responses from their subjects. This matter is discussed further in section 2.2.1.

different sort. Although it is true that the reasonable person standard was historically intended to shield laypeople against the narrow interests that can come to dominate a professional's mindset, this is not a unique case but rather one instance of a more general scenario. Evaluating a situation using only a narrow set of professional values and interests is not problematic because the values and interests in question are professional but because they are narrow – that is, because they represent, at best, a small subset of the full set of values and interests at play. Accordingly, insofar as the reasonable person standard is concerned only with making sure that narrow professional values do not dominate bioethical decision-making, it will be unable to speak to the cases in which decision-makers wrongly rely on narrow value sets from non-professional sources. Worse yet, it will be unable to speak to those cases in which decision-makers wrongly rely on a robust collection of values and interests other than the collection that actually applies to the case at hand. This is the de facto presumption of “cultural homogeneity and gender neutrality” that Boetzkes is right to wish to avoid, for even if medical culture is not the culture in question there are still relevant differences that would necessarily go unconsidered by a monolithic reasonable person standard.

As for the matter of whether the concept of having, for example, multiple core disclosures is incoherent or self-defeating, one must start by remembering what the core disclosure is meant to accomplish. Core disclosures are part of the informed consent process, which exists to serve the autonomy and welfare of patients and potential research subjects. More specifically, they are intended to provide patients and potential research subjects with information about the medical decisions they face that is basic but that will support their ability to make those decisions in an informed way. Although much of this information will be the same for most if not all individuals, it is not difficult to imagine that there will be some variation

in the information that individuals need. Beauchamp and Childress, for example, begin their list of core information with “those facts or descriptions that patients or subjects usually consider material in deciding whether to refuse or consent to the proposed intervention or research,”<sup>57</sup> and it would hardly be surprising to find that such facts and descriptions vary across sub-populations. In the case that different groups want or need different information in this way, it would not advance, but would rather hinder the purpose of a core disclosure to insist on having only one core disclosure that contains only that information which is wanted or needed by a simple majority of the whole population. The idea of a core disclosure is to ensure that all patients or prospective research subjects receive equal protection and support, not to ensure that they all receive identical information, and so a reasonable person standard that points to the need for multiple core disclosures would not defeat the purpose of a core disclosure.

### **2.1.2 Two Difficult Cases**

It may seem, then, that the reasonable person standard can be applied with relative ease whenever a consensus exists among a group with defensible values, even if there may be some cases in which there simply is no such consensus. Unfortunately, however, things are not so clean-cut. There are at least two scenarios in which one must be able to distinguish between competing consensuses.

The first of these is when an individual belongs to two or more demographic groups which have conflicting consensuses (i.e., whose views on the matter in question point to mutually exclusive actions). For example, consider a patient who requires a routine blood transfusion at the risk of death is (for whatever reason) incapable of making that decision at the

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<sup>57</sup> Beauchamp and Childress, *Principles*, 81.

time but is known to be both a male and a Jehovah's Witness. In such a case, the reasonable person standard for surrogate decision-making will, at least initially, likely point in two incompatible directions. Assuming that men in general would want the transfusion and Jehovah's Witnesses in general would refuse it (and on the further assumption that both groups are using an acceptable set of values to make their decisions), anyone attempting to apply the reasonable person standard in the way described heretofore would have to choose to privilege the individual's sexual identity over his religious one or vice versa; it is, of course, impossible both to accept and refuse a transfusion. One potential way of avoiding this choice would be to simply abandon the standard altogether and thereby consign this sort of case to the same category as the cases in which there is no known consensus or agreement among any of the relevant social groups. There is, however, another option.

Because the empirical operational test for the reasonable person standard creates not just an abstracted set of values and interests but an approximated set thereof, it seems appropriate to seek the best such approximation that is available. To continue the example above, assume that only 70% of men would want the transfusion but that 90% of Jehovah's Witnesses would refuse it, with comparable statistical accuracy. In such a case one would not be given a choice between two pieces of conflicting evidence with equal weight. Rather, one piece of evidence can be taken to outweigh the other on the basis of its statistically significantly greater accuracy: given the information above, it would simply be a better guess to conclude that the reasonable person standard would support withholding the transfusion from a male Jehovah's Witness who cannot express himself and for whom no reliable surrogate can be found.

There are some complications and limitations to this approach, of course. For one, there may be times when one of the two demographic groups is a strict subset of the other. If women

typically want a procedure but women who are 65 years of age or older typically do not want that same procedure, it would be a mistake to compare the correlations of those two findings. The latter would always be a better guess when the patient falls into that age group because it would be free of irrelevant information. Another kind of difficulty would occur when there is no statistical significance between the conflicting findings. In that case, the empirical process could not produce any helpful results and would have to be set aside.

In addition to surveying more precisely defined populations, another way of sharpening the empirical component of the representative test would be to privilege the responses of those individuals who can speak directly to the experience of having made a given decision. Because the strength of the reasonable person standard is its adherence to the actual interests of the group in question, it would be appropriate to seek out only those members of the group who have the best understanding of their own interests. While this is normally a contentious subject – imagine trying to argue that men generally knew better than women (or vice versa) – there should be nothing controversial in acknowledging that people who have had direct, firsthand experience with a scenario are better equipped to evaluate that scenario than people who are attempting to do the same thing at a distance. Given the existence of “‘happiness gaps’...observed between the self-rated quality of life of people with health conditions and healthy people’s estimates of what their quality of life would be if they had those conditions,”<sup>58</sup> it would not be unfair or inappropriate for the reasonable person standard to privilege the input of individuals who are less strongly affected by the psychological biases that form those gaps.

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<sup>58</sup> Peter Ubel, George Loewenstein, and Christopher Jepson, “Disability and Sunshine: Can Hedonic Predictions Be Improved by Drawing Attention to Focusing Illusions or Emotional Adaptation?,” *Journal of Experimental Psychology: Applied* 11 (2005). See also Paul Menzel et al., “The role of adaptation to disability and disease in health state valuation: a preliminary normative analysis,” *Social Science & Medicine* 55 (2002).

Ideally, this would mean acquiring input from people who actually have lived with or lived through all of the potential kinds of health outcomes facing an individual patient. If an individual faces the choice between having a hand amputated and having that same hand transplanted, for example, it would be best to know how both amputees and transplant patients have responded to their respective treatments. Of course, this is not always possible, because sometimes the potential health outcomes include scenarios like death, in which case one cannot ask an individual to report on what it is like to live with or live through that health state. To the extent that an empirical comparison cannot be made between the competing options, the empirical process will be less (although not necessarily un-) reliable.<sup>59</sup>

Nonetheless, in the cases where such a comparison is possible it may well be unfair not to make use of it. If the reasonable person standard aims to uphold the values and interests of individuals in populations with defensible values and there is good evidence that the majority of those people would inadvertently choose to undermine their own values and interests due to something like a psychological bias, there is no reason why the reasonable person standard should not overrule the majority in favor of a better-informed or less biased minority. This is one way that the reasonable person standard can adapt to meet the objection that “patients often do not know what information would be relevant for their deliberations” and likewise often do not know which treatment option is in their best interests: insofar as reasonable individuals can be found who do know these things, they can serve as community representatives without

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<sup>59</sup> This is particularly relevant for the context of surrogate decision-making because there are many cases in which patients lack the ability to report on their condition for the same reason that they lack decision-making capacity. Because this makes an empirical comparison between competing options effectively impossible, the reasonable person standard may well be ill-equipped to deal with these cases.

compromising the standard's integrity.<sup>60</sup> There will still be hard cases for the reasonable person standard no matter how well an empirical process is designed or implemented, but it is far from impossible to perform such a test in a way that provides the needed results and that does so in a way that is broadly consistent with the purpose of the standard.

## 2.2 DELIMITING THE REASONABLE OPTIONS

Assuming that an empirical process that uses statistical data to inform the reasonable person standard can provide the needed specificity without thereby violating the spirit of the standard, there is still at least one more question to be asked. To wit, are there any limits to what the reasonable person standard can require?

As part of an argument against the standard, T.M. Wilkinson produces a dilemma about this very question. "If the test of what subjects should be told is what reasonable people would want to know, and if 'reasonableness' covers the *content* of views and not simply statistical unlikelihood," he says, "then information need not be provided which would only affect the decisions to participate of those with unreasonable beliefs."<sup>61</sup> This is an important point because a strictly representative test would only be able to consider the prevalence of a view within a given population (i.e., the percentage of people within that population who hold that view). A reasonable belief, on such a test, would simply be one that is held by a majority (or significant minority) of the population, regardless of what the belief actually is. This runs counter to the

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<sup>60</sup> However, demographic considerations would still have to apply. For instance, if the unbiased or less biased segment of a given population was composed (almost) entirely by males, applying the views of that segment to women would not necessarily be appropriate.

<sup>61</sup> T.M. Wilkinson, "Research, Informed Consent, and the Limits of Disclosure," *Bioethics* 15 (2001), 352.

intuition that some ideas cannot be reasonable no matter who believes in them because their content is unreasonable in and of itself. Wilkinson lists three examples of such beliefs: a fear of “genetically-engineered ingredients (which...have been proven safe)”; “an irrational fear of needles”; and anti-Semitism. Because all three are unreasonable beliefs, a reasonable person standard that governs content as well as statistical prevalence would judge all three beliefs to be unworthy of consideration and so would excuse researchers from disclosing information to satisfy information interests based on any of the three beliefs. He concludes that, while this is the correct judgment in the case of anti-Semitic beliefs, “[i]t seems clear that, in virtually all cases like [the first two], subjects should be told and that, at least, not telling them is at some cost to their autonomy.” On the other hand, if the reasonable person standard refrains from examining the content of views then it “provides no reason not to require disclosure of [a] researcher’s Jewishness,” and this, too, is unacceptable.<sup>62</sup>

Although Wilkinson’s dilemma was crafted in the context of disclosure for human-subjects research, it applies to the other contexts as well. Should the reasonable person standard restrict the range of permissible views based on their content, that restriction would have to be based in a set of values and preferences other than the set of values and preferences that is being judged unreasonable. This increases the risk of judging what an individual would need, want, or do based on interests that the individual does not in fact have.<sup>63</sup> Similarly, to overrule the representative judgment of a potential subject population is to accept a greater risk of misidentifying that population’s interests, at least *prima facie*. But if the reasonable person

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<sup>62</sup> *Ibid* 352.

<sup>63</sup> Note that this is a different risk than the risk of judging what an individual would need, want, or do based on interests that *one does not know that* the individual has. The reasonable person standard is typically used when an individual’s specific values and interests are not known, but this does not mean that there is no way to reduce the risk of attributing the wrong values and interests to that individual.

standard has no content-based restrictions, then patients could in theory identify any treatment whatsoever as being in their best interests, and prospective subject populations could demand any information at all from researchers. Nor would these options be limited to medical ones: as Wilkinson says, a total lack of content-based restrictions means that the reasonable person standard could not even exclude views like “It is in my best interests not to be resuscitated by a woman” or “This study poses too great a risk because it is run by Jews.” If the reasonable person standard is to be acceptable, it must find a way to resolve this dilemma.

One place to start is to examine Wilkinson’s concept of reasonableness. Although he never explicitly defines the term, he associates it with concepts such as “unjustified” and “irrational.” This is quite different from Boetzkes’s usage of the concept, according to which a reasonable person is one who believes and behaves according to an ethically “defensible set of values.” On this definition, neither an irrational fear of needles nor an unjustified fear of genetically modified food would count as unreasonable, for although both fears are ungrounded neither is ethically indefensible. Anti-Semitic beliefs, however, would still be excluded from reasonableness. It may therefore seem as though using Boetzkes’s definition of “reasonable” is sufficient to defeat Wilkinson’s dilemma. Unfortunately, this is not the case. Although Boetzkes’s definition of “reasonable” goes some way towards resolving the difficulties involved with adding a content-based constraint to an otherwise empirically-based reasonable person standard, there is at least one scenario that it cannot fully address, namely, when an action or belief is ethically defensible in a broad sense but does not seem to be compatible with the specific goals of the contexts in which the standard is applied. For instance, the “deeply rooted cultural...wish not to convey or receive negative information” present among some Navajo

certainly does not seem to be ethically indefensible but, if honored, would “essentially [remove] the ‘informed’ aspect” from informed consent.<sup>64</sup>

There are also examples of broadly ethical actions that run up against the goals of a specific context outside of the context of informed consent. Researchers may want to sweeten the risk/benefit ratio in their protocols by adding financial incentives for participation, and some patients who enter a doctor’s care in an incapacitated state may face a non-medical fate worse than death<sup>65</sup> if their capacity is restored so that it is in their best interests not to receive medically indicated treatment. Nonetheless, any attempt to tip the risk/benefit scales with money would run afoul of Emanuel, Wendler, and Gray’s rule that “extraneous benefits...cannot be considered in delineating the benefits compared with the risks,”<sup>66</sup> and it seems unequivocally wrong for a doctor to let a patient die or remain unconscious in order to keep that patient from returning to a terrible home life.

In all of these examples, the belief or action in question cannot be dismissed because it is ethically indefensible. But even though none of the beliefs or actions in these cases is ethically indefensible in the same way that, say, anti-Semitism is, they all seem to be the wrong beliefs to honor or actions to perform in their respective contexts. A further difficulty is that many of these cases cannot be resolved by homing in on the ethical goal(s) of the context in question. Even though it would advance an individual’s autonomy at no cost to that individual’s welfare if that individual were informed of his or her doctor’s political leanings – that is, even though such a disclosure appears to be fully in line with the ethical goals of informed consent – this information does not seem to fit in a standard disclosure, and no popular consensus would change this. More

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<sup>64</sup> Ruth Macklin, “Ethical Relativism in a Multicultural Society,” *Kennedy Institute of Ethics Journal* 8 (March 1998).

<sup>65</sup> An example might be of a patient who is enduring extreme abuse by caretakers.

<sup>66</sup> Emanuel, Wendler, and Gray, “Clinical Research,” 2705.

problematically yet, there are some cases in which the reasonable person standard cannot even be saved by limiting its range of responses to those that are broadly ethically defensible.<sup>67</sup> But that is not to say that the reasonable person standard cannot be saved at all.

To conceive of the reasonable person standard in the context of, say, human subjects protection in medical research as attempting to balance the risks and benefits per se is to forget that medical human subjects protection is itself a subcontext of medicine. Accordingly, the risks and benefits that must be balanced when one seeks to protect potential human subjects of biomedical research are only those risks and benefits that are pertinent when viewed through “the institutions, practices, and traditions of medicine.”<sup>68</sup> One way of accounting for pertinence is to use something like Wilkinson’s own Relevance Rule, which he develops in the context of disclosure but which can easily be made to apply to other contexts. According to this rule, researchers are obligated “to divulge [their views] (i) when they are relevant, where relevance is determined by some conceptual connection with the nature of the research and (ii) when there is some reasonably high chance that some potential subjects would consider those views significant in deciding on participation.”<sup>69</sup> If the second criterion is taken to be satisfied by empirical data, Wilkinson’s Relevance Rule begins to look a great deal like the empirical process for the reasonable person standard, on which information should be disclosed when a population desires it and it is medically relevant. It is important that the relevance be of a medical sort, however, and not just relevance broadly speaking. Again, to apply this same thinking to human subjects protection, it would certainly benefit a research subject to hand that person a seven-figure check,

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<sup>67</sup> Note that Emanuel, Wendler, and Gray forbid the use of “extraneous benefits” to balance out a research study’s risk/benefit ratio even in the case that those benefits far outweigh the risks, i.e., when it would plausibly be broadly ethically defensible to offer them.

<sup>68</sup> Beauchamp and Childress, *Principles*, 5.

<sup>69</sup> Wilkinson, “Limits,” 357.

but this kind of benefit is not one that is properly captured or addressed by medical institutions or practices and so is not one that should be permitted or factored in as a benefit when making bioethical calculations regarding the risk/benefit ratio of a proposed medical research project.

Because the reasonable person standard needs to have its considerations limited by what is relevant to the institutions and practices of medicine, some group will have to decide the boundaries of that relevance. While this task could again be handed off to the reasonable populations whose input would be delimited, it is not clear that the reasonable person standard ought to go that far. A belief about medical relevance is not, after all, a value or an interest itself even if it bears on values and interests. Using an empirical process to determine medical relevance, then, would not necessarily help the reasonable person standard to protect or promote the values and interests of reasonable people. Arguably, an independent constraint would be necessary even if an empirical process for determining medical relevance did protect or promote those values, because it is implausible to think that a medical system can function without some level of consistency.

If the population responsible for oversight of the empirical process should not be the reasonable populations whose input needs that oversight, perhaps this is the point at which the reasonable person standard should seek the input of a professional group. Physicians, however, probably are probably still not fit for this function, as their specialized training deals with practicing medicine but not understanding or analyzing the way in which ethical values are protected or promoted by its traditions, institutions, or practices. However much of the latter is required by the former, physicians simply do not have the in-depth understanding of the connection between ethics and medicine that one would expect of, say, bioethicists, whose training consists precisely in connecting the values of ethics to the practices and traditions of

medicine. Other specialties may be needed from time to time depending on the nature of the specific question being asked,<sup>70</sup> but it seems probable that bioethicists will be able to act as the central group that provides the required constraints on any empirical research that is done as part of an operational test for the reasonable person standard. And, since bioethicists already perform much of the research of this sort, they are well-positioned to do so.

### **2.2.1 Bioethicists Alone?**

Given the need to subject the preferences of populations to independent oversight, it may seem as though there is no need to obtain those preferences in the first place. Rather, one would simply rely on the independent oversight to identify what an individual should need, want, or do. In this case, the reasonable person standard would be used to identify the course of action that is appropriate in a given situation without privileging one set of preferences over another.

Although this approach has the advantage of being universally applicable should it succeed, its chances of success are rather slim because, as Boetzkes suggests, ethical thinking that proceeds without using a particular set of preferences is often incapable of reaching one and only one conclusion firmly. As such, in many cases it would be mistaken to think that the broad limits placed on the reasonable person standard<sup>71</sup> could be tightened enough to generate sufficiently specific recommendations for action in most cases. In the context of disclosure, for example, it may be the case that such specificity is not needed because one can always just add more to the

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<sup>70</sup> Physicians, for example, will probably need to be consulted to provide details of at least some cutting-edge research.

<sup>71</sup> Such broad limits might be, for example, ethical constraints regarding that which should not be done under any circumstances, as well as bioethical constraints regarding that which should not be done within the medical context.

content of a core disclosure during the process of informed consent.<sup>72</sup> When making decisions for those who lack the capacity to do so, however, there is no reliable way to accommodate such differences; one can disclose a range of information because disclosing one thing is not mutually exclusive with disclosing something else, but one cannot make a range of decisions. Similarly, it may be the case that there are some instances in which there really is clearly only one acceptable course of action. A patient who is admitted to the hospital with severe hyperkalemia, for example, will almost certainly lack decision-making capacity but can be cured so easily and at so little cost that, in the absence of access to specific knowledge of the patient's own values, a best interests standard would be very unlikely to permit non-treatment. In these cases, however, there is no need for a standard at all, properly speaking. Standards, after all, are designed to be employed when the dictates of ethics are unclear or imprecise, but this is not the case when there is strong ethical consensus that only one course of action is appropriate.<sup>73</sup> In order for the reasonable person standard to succeed as a standard across a broad range of contexts and cases, then, preferences seemingly must be involved at some stage or other.

One author who attempts to incorporate preferences into bioethical considerations without reducing those considerations to questions about preferences is Daniel Hausman. In his writings on health, Hausman argues that, "No matter how carefully considered, a population's consensus that  $x$  is a better health state than  $y$  does not make it so. To know that most people think that health state  $x$  is worse than health state  $y$  may be of interest, especially if one also finds out people's reasons. But...it no more settles the evaluation, than the opinion of the population

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<sup>72</sup> On the other hand, it is not the case that one can always just disclose more without jeopardizing the autonomy of some patients – that is, without some ethical cost.

<sup>73</sup> Although surrogate decision-making cases that feature a strong ethical consensus might seem to be operating under the best interests standard just in virtue of acting on the patients' best interests, it would be imprecise to say that any standard is being used, at least in the sense of "standard" employed herein. Such cases do not typically feature the use of an operational test, and they may even lack a well-defined ethical goal, so they cannot rightly be said to rely on any standard at all.

concerning policy alternatives determines which is best.”<sup>74</sup> While this is certainly true when it comes to determining relatively objective facts, this sort of reasoning is not immediately applicable to the reasonable person standard for the simple reason that the reasonable person standard is not used to determine facts that are as relatively objective as the ones that Hausman considers. Rather, the reasonable person standard, howsoever articulated, is used in contexts where individuals’ preferences and values bear heavily on the matter at hand. When attempting to identify the best interests of an incapacitated patient, for example, it is not enough to know which treatment option would result in greater health for that individual. It is never healthier to die than to live, yet there are cases in which there is a real question as to whether or not it would be in a patient’s best interests to be kept alive. Similarly, one frequently cannot deduce the materiality of a potential side-effect of a medication just from a detailed description of the side-effect itself, because information is material to any given individual only insofar as that particular individual would use the information in a decision-making process.

Hausman, however, provides several arguments to the effect that health evaluations depend on relatively objective facts even when those facts are not easily accessible. For one, he says, people often presume that “it is better to rely on evaluations made by those who are more knowledgeable,” which is a sign that “there are more or less accurate comparisons of health states [and so] the evaluation of health states involves the judgment of something ‘external.’” Indeed, one reason to choose a representative rather than an ideal understanding of the reasonable person standard is that it will be more accurate in virtue of attending to the actual values and preferences of populations instead of the values and preferences that those populations would have if they were idealized in some sense. Yet, as Hausman says, “if one

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<sup>74</sup> Daniel Hausman, “Why Not Just Ask? Preferences, ‘Empirical Ethics’ and the Role of Ethical Reflection,” unpublished manuscript, 27.

wants to measure preferences, one should seek a representative sample, while if one seeks to elicit *reliable* opinions, then one would look for respondents whose opinions are more likely to be correct.” If one really must make a choice between representativeness and reliability, the representative understanding of the reasonable person standard would seem to be a clearly inferior one.

His second argument is that most groups are rightly “committed to *overruling* some preferences,” such as ones that “value men’s health more highly than women’s health”<sup>75</sup> or that “cherish impairments such as epilepsy as signs of divine favor.”<sup>76</sup> Even if these preferences are informed and are stable under rational investigation (i.e., are not merely knee-jerk reactions instead of mature preferences), Hausman is right to suggest that they should be disregarded by decision-makers. If this is the case, however, it is difficult to see why decisions or evaluations should be based on preferences instead of the objective facts of the case. Then again, Hausman says, the very need to ensure that the preferences expressed by a population are stable under rational investigation is an indication that those preferences are actually “judgment[s] and dependent on reasons” rather than preferences as such.<sup>77</sup> Because these reasons pertain to “the character and consequences of health states,”<sup>78</sup> it seems as though it would be both more direct and generate more accurate results to consider the relevant health states themselves instead of attempting to generate a population-typical appraisal of those health states.

And, of course, there is no guarantee that a given population ever will be able to reach a set of preferences or judgments that are informed and stable under rational investigation. Too little information and investigation will obviously result in unreliability, which is why groups

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<sup>75</sup> Hausman, “Why Not,” 28-29.

<sup>76</sup> Daniel Hausman, “Valuing Health,” *Philosophy & Public Affairs*, 34 (2006).

<sup>77</sup> Hausman, “Why Not,” 32.

<sup>78</sup> Hausman, “Valuing Health,” 272.

such as the World Health Organization employ a battery of corrective methods when surveying populations about health-related matters.<sup>79</sup> Unfortunately, the same problem also arises with too much information and investigation.<sup>80</sup> In the best case, it appears, members of the surveyed population would be on par with experts, in which case there would seem to be no reason not to ask the experts directly,<sup>81</sup> in the worst case, members of the surveyed population would not be able to provide reliable enough responses at all. If this is all correct, any empirical component of the reasonable person standard would effectively be useless – or, worse still, would produce harmful results. However, there are good reasons to think that Hausman’s conclusions are overstated.

One such reason is that Hausman himself holds that “measuring preferences plays an important role” in evaluating health states because “[o]ne of the things that makes one health state better than another is that people prefer it.”<sup>82</sup> It is at least conceivable, therefore, that there could be some cases in which preferences act as the deciding factor when evaluating health states: if states X and Y are (nearly) equivalent on their objective merits but one group prefers X and a second group prefers Y, even Hausman would have to say that X is healthier for the first group but not for the second. Moreover, it is exceedingly unlikely that any expert would know about these preferences without having conducted at least some empirical research.

As Hausman suggests, this research should not ignore the differences between reliable and unreliable representatives of a given population. Reliability, however, does not necessarily presuppose objectivity or the existence of “something ‘external.’” While people can obviously have unreliable ideas about objective features of reality, individuals can also be mistaken about

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<sup>79</sup> For a partial list of these methods, see Hausman, “Why Not,” 34-35.

<sup>80</sup> Hausman, “Valuing Health,” 263.

<sup>81</sup> *Ibid*, 267.

<sup>82</sup> Hausman, “Why Not,” 35.

their own preferences, values, and interests. Removing biases and misconceptions from an individual's thinking is not the same as forcing that individual to focus on external factors, such as the character and consequences of a health state or the technical details of a medical procedure. That there are better (less biased, better informed) and worse reasoners is therefore not an indication of the need to choose between reliability and representativeness; that the truth of a belief depends on something external to the belief itself does not mean that it depends on something external to the believer. To the contrary, the two are actually mutually supportive in many cases: the more reliably a group can think about medical scenarios (e.g. living in various health states), the more its conclusions about those issues will represent the actual experiences of people in those scenarios.

Nor is the representative view of the reasonable person standard threatened by the fact that some people prefer morally or medically unacceptable things. Again, neither the reasonable person standard nor any other standard is needed to reject the view that a man's health counts more than a woman's, so to apply the reasonable person standard to that case would be an error to start with. In such instances, the matter should indeed be resolved on the merits of the objective components of the case – but since the reasonable person was never meant to apply to such cases in the first place, that is hardly a strike against it. As for Hausman's argument that people base their assessments of health states on reason-driven judgments rather than preferences, he is at best partly correct. Although judgments are based on reasons, those reasons are not all likely to be relatively objective. Just knowing the medical details of a medical condition is not necessarily sufficient to predict its effect on the health of any given individual, let alone its effect on far less objective factors such as materiality. To complete the picture, subjective considerations such as preferences and values must be included.

Hausman, however, could accept the importance of accounting for the values that people actually have while still arguing that populations should not be surveyed about specific medical scenarios. The way in which he could do this is by suggesting the use of a predictive test for the reasonable person standard. If experts can broadly identify a given population's values and interests, perhaps through the use of an empirical process like the one outlined above, they might be able to use those values and interests to deduce or predict that population's preference in any particular case. Knowing that members of a given population typically attribute great importance to their appearance, for example, might lead one to conclude that cosmetic side-effects of proposed treatments should be part of the core disclosure to members of that population even if those same side-effects would not appear in a core disclosure for a different group. Although this is certainly a more representative approach than one based solely on "external" factors in that it adheres to the actual preferences of the population in question more closely than would an approach that is focused on "external" factors, it will only work insofar as people reason about medical issues in straightforward, logical ways.<sup>83</sup> To the extent that populations have not just idiosyncratic values but also idiosyncratic ways of applying those values to medical scenarios, simply identifying their values will not be enough to correctly predict their interests in particular cases. Without taking into account the ways in which populations reason about medical issues, experts who try to translate general values into scenario-specific preferences risk idealizing those preferences. Alternatively, as Hausman suggests, they may not even be able to do that, because just having some general values may not even be enough to generate one specific evaluation of a medical scenario. "Health states can be

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<sup>83</sup> Or, perhaps more accurately: it will only work insofar as people reason about medical issues in the same straightforward, logical ways as the experts in question.

evaluated or judged in several different ways,”<sup>84</sup> so the expert-prediction test for the reasonable person standard may turn out to be inconclusive in the same way that pure ethical considerations are inconclusive.

A more fundamental problem with any attempt to idealize the reasonable person standard is that it is meant to serve individuals’ actual autonomy, best interests, or well-being, not the autonomy, best interests, or well-being that could be ascribed to them if they were idealized in some sense (in other words, the autonomy, best interests, or well-being that they should, in some sense, have). To return to an earlier example, it should not be the case that one could upset the balance between a patient’s autonomy and welfare just by telling that individual about the possibility of a negative health outcome following a medical procedure. In an ideal world, that is to say, there would be no reason not to include the possibility of negative outcomes in the core disclosure for a given procedure. But in the real world there are individuals for whom learning about the possibility of a negative outcome will generate a conflict between their welfare and their autonomy – namely, some members of the Navajo tribe. It may well be the case that people should, in some sense, not hold to the traditional Navajo beliefs that are responsible for this – those beliefs may, for instance, not be rational – but it would do no good to act on the idealization and not the reality.

This is not to say that the reasonable person standard will fail automatically in virtue of referring to an abstraction. Because it is used in cases where generalized policies are needed because case-by-case evaluations are not possible,<sup>85</sup> the reasonable person standard will always operate abstractly to some degree. But this does not mean that any degree or kind of abstraction

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<sup>84</sup> Hausman, “Why Not,” 35.

<sup>85</sup> One cannot, for instance, have a core disclosure unless that core disclosure is the same across at least some groups of people.

is acceptable. If some specific fact is known to be material for most people in a group but would not be considered material by an ideal member of that group, it would at least partially defeat the purpose of using a reasonable person standard to privilege the ideal interpretation over the representative one.<sup>86</sup> Regardless of whether or not an individual's autonomy (e.g.) should be protected by the disclosure of (or failure to disclose) a certain fact, the reasonable person standard should counsel the course of action that is most likely to actually protect that individual's autonomy (or best interests, or well-being, as the case may be).

Be this as it may, there is still the possibility that it is just not feasible to devise and operate a representative test for the reasonable person standard. As Hausman suggests, there may simply be too many cognitive obstacles to overcome: between “framing, instability, and inconsistency,”<sup>87</sup> there seem to be ample indicators that populations in general will not be able to provide reliable preferences. If not, perhaps these preferences will be too mercurial, so that any instance of a representative test will have a prohibitively short shelf life. And even if the test itself is not the problem, there is the question of whether or not its results can be used by physicians and other health care workers. After all, if it is overly taxing to expect physicians to recall one long list of potential side effects from memory, surely it would only make things worse to require them to recall multiple such lists and to pair each list with a group or population.

Before these objections are investigated individually, it must be noted that they apply to the predictive test as well as the representative one. Whatever cognitive obstacles are present for people in general are probably present for experts as well, so if biases are enough to make a

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<sup>86</sup> Again, this does not mean that the representative desire must be honored in every case. When that desire does not comport with ethics or medicine, it cannot legitimately be honored by bioethics.

<sup>87</sup> Hausman, “Why Not,” 23.

representative test unreliable then they would probably do the same to a predictive test. Likewise, if a population's relevant preferences change too quickly for a representative test to be useful, they would probably change too quickly for a predictive test as well. And, of course, a predictive test that separates the general population into many sub-groups will put just as much of a burden on health care professionals as a representative test that does the same thing. Moreover, even if all of the difficulties with the predictive reasonable person standard are overcome, it will be impossible to know that experts are making the right predictions without checking them against at least some examples of representative empirical findings, so in any case there will still be at least some reason to conduct representative research.

In all likelihood, though, neither a representative nor a predictive test will be significantly impeded by the pragmatic considerations listed above. By seeking those individuals who have lived with or lived through medical scenarios, researchers can eliminate many of the biases that might otherwise make their judgments unreliable. Other biases can be corrected by using proper experimental methods, some examples of which are listed in Hausman's articles.<sup>88</sup> As for the shelf life of a given preference, there may well be some medical issues that are so controversial or about which information changes so rapidly that any empirical research on the subject will be outdated by the time it could be put to use. In such cases, it is hard to imagine any test succeeding, and it may even be necessary to use another standard altogether. But most medical issues do not fall into this category, and most people have values and preferences that are stable enough to be relied upon. Last, it seems implausible to suggest that health care professionals cannot keep track of and use detailed and changing information about group preferences in the same ways that they keep track of and use detailed and changing information about human

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<sup>88</sup> See e.g. Hausman, "Valuing Health," 262-263.

biology. Again, there is nothing in the representative (or any other) test for the reasonable person standard that would require doctors or nurses to memorize any such information. Technology is more than capable of providing easy ways to find and retrieve information, so the most significant burden that would be placed on health care workers would be the relatively minimal one of learning how to use a new piece of software.

Of course, it would be impossible to implement any test without exerting at least some effort. But it does not seem that the effort required by the representative test is so great as to make the test impracticable. If this is the case, there appears to be little reason not to use the reasonable person standard as a way of ensuring that the relevant preferences of real people are honored as often as possible in the three contexts already identified.

### **2.3 CONCLUSION**

Ethical decision-making in medicine is often extraordinarily complicated. In order to make good decisions in the face of that complexity, one can use various standards as bridges between abstract ethical values and the concrete facts of the matter. There is no one standard to use in every case, however. Rather, the proper standard depends in large part on the context in which it is to be applied. Because there are some contexts in which individuals' diverse values and interests are central to ethical decision-making, any standard used in those contexts will have to be able to account for and adjust to those diverse values. The reasonable person standard can do this, and so is a strong candidate for use in those contexts. However, the reasonable person standard can be misused. It can be used monolithically, under the assumption that there is some such thing as the reasonable person rather than a collection of reasonable worldviews. It can also

be used naively, ignoring the real presence of biases and other cognitive deficiencies that make it difficult to assess things like health states. But these are obstacles that the reasonable person standard can overcome.

This does not mean, however, that it will always be obvious when and how to apply the reasonable person standard. Although the reasonable person standard is commonly applied in the three contexts in this paper, it may well be the case that one or more of them typically does not call for any standard at all. And even if decision-making is difficult enough in all three contexts to justify the use of something like the reasonable person standard, that does not mean that the standard can or should be applied to every case within those contexts. Because the reasonable person standard as outlined herein is designed to be responsive to peoples' values and interests, it should not be used when those values and interests are mostly or entirely irrelevant to the issue at hand. Moreover, as investigators have discovered, one must be exceedingly cautious when eliciting predictions about how an individual would react to a given medical scenario – even when one elicits those predictions from the individual him- or herself. Still, it is neither impossible nor prohibitively difficult to acquire reliable empirical data from representative members of society. In the absence of compelling ethical or bioethical consensus about a given question that pertains to the content of a core disclosure, to the best interests of a patient who lacks decision-making capacity, or to the risk/benefit ratio of a study that would use human subjects, the reasonable person standard can be relied upon to generate an answer.

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