CHAPTER 5

Autonomy

5.1 Introduction

The concept of autonomy has played a pivotal role in modern bioethics, as it has in the liberalism that has dominated political discourse over the last half-century. The focus on the importance of patient autonomy – with its emphasis on informed consent, patient rights, and the value of people making their own decisions about medical care – has transformed medical practice and clinical research. In this chapter, we analyze autonomy and relate it to the other components of our ethical theory.

We begin by describing what we take autonomy to consist in and distinguish two ways in which autonomy is morally important for bioethical questions. We then discuss respect for autonomy and its relationship to rights before delineating a taxonomy of ways in which someone's autonomy can be interfered with. We briefly evaluate two justifications for interfering with someone's actions: paternalistic justifications and the prevention of harm to others. One key normative role that respect for autonomy plays is in grounding the requirement to obtain consent from competent patients and research participants. We provide a detailed analysis of the conditions for valid consent. When someone is not competent to make their own decisions, someone else must decide on their behalf. The last part of our ethical analysis discusses this surrogate decision-making. Finally, we turn to two more specific applications of the theory that we have developed: the right to refuse treatment and the ethics of direct-to-consumer advertising of pharmaceuticals.

A preliminary point about terminology. Sometimes a distinction is drawn between the terms *capacity* and *competence* in the context of talking about someone's ability to make their own decisions autonomously. According to this way of distinguishing them, *capacity* describes someone's ability, whereas *competence* describes a legal power – someone is competent to make their own decisions if they have the legal right to do so. We do not

distinguish the terms in this way; when speaking in the legal sense we explicitly qualify the terms we use. Second, the term "autonomy" is used in multiple overlapping ways in everyday discussion, as well as in discussions of medical ethics. We attempt neither to provide an account of all these uses nor to capture everyday use of the term. Instead, we identify specific normative functions that autonomy talk serves and restrict our use of it to those functions. Similar points apply to the use of terms such as *coercion*, *manipulation*, and *persuasion*.

5.2 The Nature and Value of Autonomy

Autonomy means self-rule. In the words of the Belmont Report, "An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation."[1] In a moment, we will go into more detail concerning the criteria for determining whether someone is autonomous. Before that it will be helpful to distinguish two roles that autonomy plays in our ethical thinking: as a component of a flourishing life and as a ground for rights claims.[2] First, it is widely thought that having the capacity for autonomous action and the opportunity to exercise that capacity is good for human beings. Good parents bring up their children to be autonomous because they judge that it is good for a child to become someone who can think and act for herself. Autonomy might be intrinsically valuable for human beings, in the sense of being a component of well-being. In any case, autonomy is certainly instrumentally valuable: valuable because autonomous people tend to be good at identifying and pursuing what is in their own interests, and because the exercise of autonomy is (often) itself enjoyable or satisfying.[3] However, autonomy is only one component of – or contributor to – well-being. Someone might be more autonomous than their friend but also more depressive: ceteris paribus, they are then better off on one dimension of well-being and worse off on another. Indeed, it is possible that someone's autonomy could actively interfere with other valuable aspects of their life. For example, someone who is excessively focused on remaining independent from the influence of others might be inhibited from enjoying personal relationships that require some reliance on other people.

[1] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report* (Washington, DC: US Government Printing Office, 1978).

[2] See Stephen Darwall, "The Value of Autonomy and Autonomy of the Will," *Ethics* 116 (2006): 263–284.

[3] See the discussion of subjective and objective theories of well-being in Chapter 8.

In addition to being a component of a flourishing human life, autonomy plays a distinct normative role insofar as autonomous individuals have certain *rights* that are grounded in their autonomy. Crucially for bioethics, an autonomous person has the right to decide whether other people may do things to his body. He can exercise this right by refusing a medical treatment that his doctor thinks would benefit him. On the other hand, he can also exercise it by giving consent to a research procedure that will do him no good at all, but will provide data that may help other people in the future. Respecting this *autonomy as personal sovereignty* is therefore quite different from promoting someone's well-being. Although it may be good for someone to be autonomous, she may exercise her autonomy in ways that are actually detrimental to her well-being, and her autonomy grounds her right to do so. As Joel Feinberg puts it: "There must be a right to err, to be mistaken, to decide foolishly, to take big risks, if there is to be any meaningful self-rule; without it, the whole idea of *de jure* autonomy begins to unravel."[4]

Autonomy thus matters morally in two quite different ways. Both arise frequently in discussions of bioethical questions. For example, the benefit of being autonomous arises in discussions of patient empowerment and helping patients to make better, more informed decisions. The rights that are grounded in autonomy arise in discussions of informed consent. Thus, the contexts in which we care about these two types of autonomy overlap considerably. Nonetheless, for the purposes of making progress with problems in bioethics it is important to keep them conceptually distinct.[5]

Turn now from the normative role that autonomy judgments play to the nature of autonomy. We have already roughly indicated what it means to be autonomous: to be able to deliberate about one's actions in the light of one's values, make a decision on the basis of that deliberation, and act accordingly. It is also helpful to distinguish autonomous *agents* from autonomous *actions*. Most adults are autonomous agents in the sense that they have the capacity for autonomous action and the decision-making rights grounded in that capacity. It does not follow that every one of their actions is autonomous. We might doubt, for example, that an adult acts autonomously when they are heavily drugged or furiously angry. Roughly speaking, *an agent A performs action X autonomously if and only if (1)*

[4] Joel Feinberg, "Autonomy, Sovereignty, and Privacy: Moral Ideals in the Constitution," *Notre Dame Law Review* 58 (1982): 445–492, at 461.

[5] These two normative roles are frequently mixed together in bioethical discussion under the umbrella of "respect for autonomy." See, e.g., Tom Beauchamp and James Childress, *Principles of Biomedical Ethics*, 7th ed. (New York: Oxford University Press, 2013), 106–107.

A performs X (i) intentionally, (ii) with sufficient understanding, (iii) sufficiently free of controlling influences; and (2) A decided, or could have decided, whether to X in light of A's values.[6]

The conditions presented in this analysis merit some explication. First, to perform an action intentionally involves doing what one *has in mind* in acting. Suppose the action under consideration is lending someone money. To lend someone money intentionally involves acting with the idea of *lending* the money, rather than, say, handing it over as a gift. To lend it with sufficient understanding involves not only knowing what one is doing, but also grasping its major implications (e.g., that the other party is now indebted to you). To perform this action sufficiently free of controlling influences is to perform it more or less voluntarily, as would not be the case if one were coerced by another into advancing a loan or driven to do so by an irresistible compulsion to lend money. As a final condition of our analysis, one performs an action autonomously only if one is able to make the decision to act in light of one's own values (whether or not those values are actually considered during decision-making). In the case of the loan, for example, this means that if the individual had concluded that she *should not* make the loan, all things considered, then she could have refrained from doing so. This condition implies that only individuals who have values can act autonomously.

For bioethicists, one critical question concerning what it means to be autonomous centers on how to ascertain the threshold at which someone is competent, such that he has autonomy rights. In the remainder of the section, we address this question.

At the critical threshold of competence, someone is sufficiently autonomous to govern her own life. Among other things, this means that it can be appropriate to hold her responsible for her voluntary actions and that she is capable of being swayed by reasons. These implications correspond to aspects of the conditions for autonomous action. Only someone who is capable of acting intentionally and understanding what she is doing can be held responsible for her actions. Only someone who can be swayed by reasons is able to decide on the basis of her values. Being sufficiently autonomous does not mean that all of an agent's actions are rational or that they are based on full understanding of the possible consequences – no

[6] This analysis is nearly identical to that presented in Jennifer Desante, David DeGrazia, and Marion Danis, "Parents of Adults with Diminished Self-Governance," *Cambridge Quarterly of Healthcare Ethics* 25 (2016): 93–107, at 95. It is also similar to the one presented in Beauchamp and Childress, *Principles of Biomedical Ethics* (104–105) except that the latter analysis has nothing approximating our second condition.

human being is completely autonomous. Nevertheless, all who meet a critical threshold are equally in possession of autonomy rights.

The capacity for autonomous action is frequently regarded as a global capacity: someone is either competent or not. A typical middle-aged adult has autonomy rights; a typical young child does not. This global view has come under sustained criticism from bioethicists who regard the capacity for autonomous action as task- or domain-specific.[7] On the domain-specific view someone can be autonomous with respect to some decisions but nonautonomous with respect to others, such that she has the moral right to make decisions with regard to some aspects of her life but not all.

This domain-specific view is suggested by laws that assign different legal powers at different ages. For example, the age at which someone can give consent to sexual intercourse in the United Kingdom is sixteen, but the age at which someone has the right to vote is eighteen.[8] It is also not uncommon to take a domain-specific attitude to the assessment of someone's capacity in certain medical contexts. For example, assessments of a prospective participant's ability to consent to research in the Clinical Center of the US National Institutes of Health are tailored to the specific research protocol in which he would be enrolled. These assessments evaluate, for example, the prospective participant's understanding of the risks, benefits, and purpose of that protocol, and his reasoning regarding the participation decision.[9]

The domain-specific view can be justified in the following way. There is a threshold level of ability to make decisions for oneself that grounds one's right to do so. If someone does not meet this threshold, then she lacks the right to make her own decisions. But different decisions can be easier or more difficult for an individual to make. For example, decisions about

[7] For discussions of decision-making competence that defend the domain-specific view, see Allen Buchanan and Dan Brock, *Deciding for Others* (New York: Cambridge University Press, 1989), 17–86; Bernard Gert, Charles Culver, and K. Danner Clouser, *Bioethics* (New York: Oxford University Press, 1997), 131–148; and Beauchamp and Childress, *Principles of Biomedical Ethics*, 115–120.

[8] Of course, nothing magical happens during development such that at age sixteen or eighteen someone transitions from being unable to make their own decisions to being able to do so. The process of normal development is gradual and, in any case, varies among individuals. However, for purposes of public policy it is helpful to have clear lines to determine when people acquire the relevant legal powers for the majority of the population. Since age is correlated with cognitive development, it is sensible to use it for a first approximation to competence.

[9] Some of the commonly used instruments for assessing capacity to consent to clinical care and research assume a global view. Others are designed to be adapted to the specific decisions that patients and prospective participants are asked to make. See L. B. Dunn, M. A. Nowrangi, B. W. Palmer, D. V. Jeste, and E. R. Saks, "Assessing Decisional Capacity for Clinical Research or Treatment: A Review of Instruments," *American Journal of Psychiatry* 163 (2006): 1323–1334.

participation in clinical research may be more cognitively demanding than decisions about clinical care; decisions about what to wear today may not require the ability to plan that is necessary to make decisions about college or retirement, whose effects will not be felt for many years. A person may therefore be capable of making some decisions sufficiently well that she has a right to do so, but not others.

5.3 Respect (and Disrespect) for Autonomy

Respect for Autonomy and Rights

To respect someone's autonomy, as we understand it, requires respecting her autonomy rights. Common to these rights is the right to make certain decisions for oneself. For example, a competent individual's right to control her own body gives her a claim against other people that they not touch her without permission. Interference with someone's exercise of autonomy involves a prima facie (that is, apparent) rights violation. It will not be a rights violation, however, if it uses a permissible method of interfering (e.g., persuading someone of a course of action by providing compelling reasons) or if the person interfering has the right to do so (e.g., despite having a right to freedom of movement you have walked onto my property, so your right does not extend this far).[10] Moreover, as argued in Chapter 2, we consider rights to be morally very important, but not absolute. A rights violation is therefore pro tanto wrongful: the wrongfulness of violating someone's rights can sometimes be outweighed, on balance, by other morally important considerations. What is needed to outweigh a rights claim will depend on the nature of that claim, including the importance of the interest the right protects. For example, one's interest in controlling personal information is very substantial but not as great as one's interest in avoiding torture. Consistent with this judgment, we think there are multiple situations in which it is justifiable to require people to disclose personal information, overriding their right to privacy, but no actual cases in which it is permissible to override someone's right not to be tortured (Chapter 4).

In bioethics, cases involving disrespect for autonomy commonly arise as a result of attempts to control someone's decision. For example, if a

[10] We use the term "interference" in a deliberately broad manner here, so as to include those ways of intervening in someone's decision-making that prove to be morally innocuous, even though they might vex the actor in question.

hospital's staff insist on providing treatment to a competent patient who has refused it, they attempt (illegitimately) to control her decision about what care she will receive. It will therefore prove helpful to lay out a taxonomy of ways in which one party may control or attempt to control another's decision.[11]

Coercion, Offers, Undue Inducements, and Exploitation

Coercion is the bluntest method of control. *Occurrent coercion* involves the direct use of physical force: a patient who is being held down on a bed or locked into a room is coerced in this way. *Dispositional coercion*, by contrast, occurs when one party issues a credible threat to another in order to secure compliance with her demands.[12] For example, a public-sector pharmacist who refused to dispense needed medicines without a kickback would be engaged in dispositional coercion.

Someone who engages in coercion attempts to control another individual by altering the options that are open to him (or, at least, purporting to do so). For example, the robber who says "Your money or your life!" purports to alter her victim's options by removing from him the option of keeping both his money and his life. This is not the only way in which it is possible to influence someone's behavior by altering his options. Offers can also have this effect. In contrast to a threat, an *offer* is a proposal to make someone better off if he complies with the request of the person making the offer. For example, someone who enrolls in a research study because she will be paid $100 has been motivated by an offer.[13]

Before proceeding to the ethical analysis of these methods of control, it is worth noting the relationship, or the lack of it, between the method used

[11] This taxonomy draws on the taxonomy in Amulya Mandava and Joseph Millum, "Manipulation in the Enrollment of Research Participants," *Hastings Center Report* 43 (2013): 38–47.

[12] The distinction is from Thomas Mappes, "Sexual Morality and the Concept of Using Another Person," in Thomas Mappes and Jane Zembaty (eds.), *Social Ethics*, 3rd ed. (New York: McGraw-Hill, 1987): 248–262. The account of dispositional coercion according to which coercion essentially involves a threat to violate another's rights unless they comply with the coercer's demands can be found in Alan Wertheimer, *Coercion* (Hoboken, NJ: John Wiley & Sons, 1987).

[13] Note that someone might not be better off *overall* if they accept an offer. For example, if you offer me $5 to wash your truck, I might be worse off overall if I accept since my time would be better spent doing something else. Nonetheless, you make me an offer, since you attempt to motivate me by making me better off relative to my current financial situation if I do as you request. Likewise, complying with a threat could make someone better off overall, even though the threat is a proposal to make the person worse off if they do not comply. For example, if Fabian threatens to punch the drunk Arturo unless he hands over his car keys, it may make Arturo better off by preventing him from getting into an accident.

and its effectiveness. One might find it natural to assume that coercion is more forceful and effective than making an offer. Yet physical force may be weak – a slight shove may not move me anywhere, for example. A threat may be easy to resist – your saying that you'll spill water on my shoes is a threat, but likely one I'll laugh off. On the other hand, an offer may be impossible for a reasonable person to resist – if you promise to pay for my child's otherwise unaffordable chemotherapy, then I will likely agree to whatever you propose. All these methods, then, vary in their ability to control someone's actions, and none is intrinsically more controlling than the others. Instead, one person's ability to control the actions of another will depend on that person's psychology and the context in which the interaction takes place.

Turn now to the ethical analysis. Threats and offers are generally distinguished on the basis of whether they involve a proposal to make someone worse off or better off. This naturally prompts the question: Worse off or better off than what? One possibility is to use a *descriptive baseline*. For example, by threatening to kill her victim, the robber proposes to make her victim worse off than she would otherwise have been. But descriptive baselines struggle with cases of omission. For example, the pharmacist who refuses to provide medicine to a patient without a bribe seems to coerce him (we would not say that the pharmacist now had a legitimate claim to the bribe money). Yet the patient is not worse off than he otherwise would have been. We therefore favor using a *normative or moralized baseline*. Whether a proposal is a threat depends on whether carrying out the threat would make the person threatened worse off than she *should* be.[14]

On our view, coercion, whether occurrent or dispositional, typically involves the violation of the coercee's rights.[15] The robber's threat, for example, violates her victim's right to dispose of his property as he sees fit by presenting a risk of harm that the robber has no right to impose. There is therefore a high bar that must be passed in order to justify coercion. Offers, on the other hand, typically do not involve violating someone's rights.

[14] Note that an analysis of threats based on normative baselines has difficulty making sense of the idea of legitimate coercion. For example, legal sanctions – such as the threat to fine or imprison citizens who do not pay their taxes – are generally regarded as paradigmatic instances of coercion. Yet, if the government has the right to force its citizens to comply with the tax laws, then it does not propose to violate their rights by punishing those who do not comply. For discussion, see Scott Anderson, "Coercion," in Edward Zalta (ed.), *Stanford Encyclopedia of Philosophy* (Winter 2017 edition; available at https://plato.stanford.edu/archives/win2017/entries/coercion/).

[15] Here we follow Wertheimer, *Coercion*.

To see the contrast, consider a parallel case to the case of the robber. Suppose that a surgeon honestly advises her patient that he needs an operation if he is to survive. In effect, she says, "This operation or your life!" As with the robber's victim, the patient faces death if he does not comply. Yet we would not say that the surgeon acts wrongly here. This is because she is not responsible for the risk of death that her patient faces. Relative to the appropriate baseline – which is the patient facing death if he goes without surgery – she is proposing to make him better off.

Though offers do not typically violate anyone's rights, that does not mean that their effect on decision-making is wholly unproblematic. In the context of research, one common objection to paying substantial amounts of money to research participants is that such payments constitute "undue inducements" to enroll in the research study. For example, the Council for International Organizations of Medical Sciences (CIOMS) states in their guidelines: "Compensation must not be so large as to induce potential participants to consent to participate in the research against their better judgment ('undue inducement')."[16]

Clearly, inducing someone to act by offering them an incentive is not in itself ethically problematic. It is not wrong to pay someone to work when they would not work for free. The concern that animates CIOMS seems to be about how the incentive might affect the quality of someone's decision-making. If an offer led someone to make a poor decision, by their own lights, then one might be concerned that their autonomy had been compromised. For example, if the immediate prospect of payment made a prospective research participant irrationally downplay the risks of a research study, this might be problematic.[17] It is important to be precise about when this is a problem. We are not saying that an offer impedes someone's autonomous decision-making whenever it induces her to act in a way that she would not act in the absence of the offer. A rational decision about whether to take up an offer must be one that includes weighing the value of what is offered. Rather, an offer would be problematic if it induced her to act in a way that she would not act if she were thinking clearly.

It is common to raise concerns about "undue inducement." Whether offers of payment often present real risks to the autonomy of people's

[16] Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Health-Related Research Involving Humans*, 4th ed. (Geneva: CIOMS, 2016), Guideline 13.

[17] Ezekiel Emanuel, "Undue Inducement: Nonsense on Stilts?," *American Journal of Bioethics* 5 (2005): 9–13.

decision-making is an empirical matter. We do not know of data that support the claim that payment worsens decision-making. The limited data that exist on the relationship between perceptions of risks and payment for research enrollment suggest that payment does not impair decision-making.[18]

The issue of "undue inducement" is usually raised when an offer is thought to be too high. But offers are more often unethical because they are too low. Suppose that a clinical research group is conducting a study that involves infecting healthy volunteers with malaria parasites in order to test the effectiveness of a new antimalarial drug. The study involves a battery of invasive tests, a week-long inpatient stay, the risks of malaria infection, and treatment with an experimental drug. Studies like this usually pay participants several thousand pounds. In this case, the research is recruiting in an area with pervasive high unemployment. The research group's recruiter therefore thinks that they could get sufficient volunteers to enroll if they cut the remuneration to £500. If this would be wrongful, it is because it is exploitative.

Exploitation occurs when one party takes advantage of another's vulnerability in order to obtain an unfair distribution of benefits and burdens from their interaction.[19] In the malaria study, the research group would be able to offer an unfairly low payment because the people in the area are so desperate for paid employment. They take unfair advantage of the poverty of prospective research participants. Questions of exploitation frequently arise in bioethics – for example, one might perceive exploitation in charging patients high prices for drugs or in conducting research in a population that does not stand to benefit from the results of the research.

A final way in which offers can be ethically problematic may arise when a conditional offer is made to someone who lacks any reasonable alternative to accepting. Suppose someone is suffering from chronic kidney disease and can no longer afford the medical bills for dialysis. Faced with a choice between kidney failure and, at best, a transplant that he also would not be able to afford, they would do whatever it takes to get treatment, whether that be borrowing money at very high rates of interest

[18] See J. P. Bentley and P. G. Thacker, "The Influence of Risk and Monetary Payment on the Research Participation Decision Making Process," *Journal of Medical Ethics* 30 (2004): 293–298; Scott Halpern et al., "Empirical Assessment of Whether Moderate Payments Are Undue or Unjust Inducements for Participation in Clinical Trials," *Archives of Internal Medicine* 164 (2004): 801–803; and Leanne Stunkel et al., "Comprehension and Informed Consent: Assessing the Effect of a Short Consent Form," *IRB* 32 (2010): 1–9C.

[19] Alan Wertheimer, *Exploitation* (Princeton, NJ: Princeton University Press, 1999).

or enrolling in research studies where care is subsidized.[20] The alternative – not having life-preserving medical care – is so bad that almost any condition could be attached to an offer that would provide the care. Assuming that the party to whom he turns has no obligation to help, this is not a situation that involves coercion in the sense just discussed. However, if the lender can put whatever terms he likes on the loan or the researcher can dictate the terms on which people enroll in her study, then, in that regard, the patient is subject to someone else's will.[21] Since independence from the will of others is usually one contributor to well-being, subjection to another's will typically makes someone's life go worse. Many of the cases in which people are prone to describing offers as "coercive" are cases in which the alternative to accepting the offer is unbearable. We think that this analysis in terms of subjection to the will of another better captures the underlying ethical concern that motivates them.

Three points are worth making about this idea that a conditional offer can be bad for someone when the alternative to accepting the offer is unbearable. First, if the offer is effective, then it is likely to make the recipient of the offer better off overall. The person who chooses to enroll in a research study in order to get free care may be worse off in one respect because he is subject to the researcher's will, but much better off in another respect because he gets treatment for his disease. On balance, then, he is likely to be better off. It is therefore an open question whether such offers should be prohibited. It is also an open question whether the party making the offer ought to avoid making it (thereby keeping her hands clean, but not benefiting someone she could benefit) or should just sweeten it (further compensating for the setback to autonomy interests by promoting other interests). Second, many cases of so-called coercive offers will also be exploitative. Someone whose situation is so desperate that a conditional offer leaves him subject to the will of the person making the offer will also be someone who is likely to agree to an unfair distribution of benefits and burdens. Likewise, in both cases there is an identical solution: providing

[20] In the United States, nondirected kidneys for transplantation are considered a public resource. However, the costs of the medical procedures associated with transplantation, including pre- and postoperative care, fall upon the individual and their medical insurance. Assessment of transplant candidates therefore includes assessment of their ability to meet financial costs. See, e.g., UC Davis Transplant Center, "The Evaluation Process" (2016) (available at https://health.ucdavis.edu/transplant/heart/the-evaluation-process.html; accessed September 28, 2020).

[21] For a complete articulation and defense of this claim, see Joseph Millum and Michael Garnett, "How Payment for Research Participation Can Be Coercive," *American Journal of Bioethics* 19 (9) (2019): 21–31.

greater benefits both makes an offer less bad for the recipient overall and makes the transaction less exploitative. Finally, it is important to emphasize that these cases arise only when someone has no good alternative to complying with the wishes of the person making the offer. As noted above, the fact that someone is motivated by an offer is not sufficient to show that it is ethically problematic.

Deception, Manipulation, and Persuasion

Thus far, we have described forms of control that involve altering the options available to someone. An alternative way to affect someone's decision is instead to alter their perception – broadly speaking – of the choice situation. One way to do this is through deception. *Deception* involves one person deliberately inducing another to believe something that the first party believes to be untrue.[22] This might involve telling a lie – "This won't hurt a bit!" But deception might also be achieved through *conversational implicature*, as when a crucial fact is omitted from a description that the listener is expected to interpret as complete. Telling a patient that side effects of a surgery "include possible infection, bleeding, and postoperative pain" but not mentioning the risk of stroke or seizure would be deceptive, since he can reasonably expect, and the surgeon can anticipate that he reasonably expects, that she would mention those risks if they were known. Though it is common for people to try to avoid lying directly and instead to deceive in other ways, we do not regard the differences between these methods of deception as ethically important in themselves.[23]

Someone's perception of his choice can also be affected through *motivational manipulation* – which occurs when one party intentionally causes another to act on desires that, on reflection, he would not consider sufficient reason to engage in the action.[24] Consider, for example, a patient who wants to change his primary care doctor and so asks his current doctor

[22] See, e.g., Sissela Bok, *Lying* (New York: Vintage, 1978), 14; and James Edwin Mahon, "The Definition of Lying and Deception," in Edward Zalta (ed.), *Stanford Encyclopedia of Philosophy* (Winter 2016 edition; available at https://plato.stanford.edu/archives/win2016/entries/lying-definition/).

[23] For an attempt to argue that lying, as opposed to other forms of deception, is particularly bad, see Jennifer Jackson, "Telling the Truth," *Journal of Medical Ethics* 17 (1991): 5–9. For a response, see David Bakhurst, "On Lying and Deceiving," *Journal of Medical Ethics* 18 (1992): 63–66. For further analysis of the wrongfulness of deceit, see Colin O'Neil, "Lying, Trust, and Gratitude," *Philosophy & Public Affairs* 40 (2012): 301–333.

[24] Mandava and Millum, "Manipulation in the Enrollment of Research Participants," 40.

to transfer his medical records. She sighs, looks him in the eye, and tells him she feels really bad that he's severing their relationship. If he now feels guilty and backtracks, then she will have successfully manipulated him. Note that this need involve no threats and no deception: simply by stimulating a desire in him not to make her feel bad, the guilt-tripping physician gets her way.

Consider a different doctor–patient encounter. Suppose that a patient is contemplating surgery for his lower back pain. His doctor lays out the evidence regarding the effectiveness of surgery as opposed to continuing with physical therapy, as well as the possible side effects of the operation. She reminds him that his pain tends to wax and wane and that his current pain is likely to diminish of its own accord over the next couple of weeks. Suppose that over the course of their discussion, this information is sufficient to make him decide against surgery, just as the doctor thinks he should. Nevertheless, it would be a stretch to say that she has manipulated him, where that has a negative connotation. When someone attempts a balanced presentation of facts that she considers relevant to someone's decision, or when she shows him the logical links between his reasons and an action, she is engaged in *persuasion*, not manipulation.[25]

These three ways to alter someone's perception of his options warrant quite different ethical judgments on the basis of the different ways that they affect an individual's ability to act autonomously. Deception directly interferes with someone's ability to make decisions according to her own preferences and values. This makes deception pro tanto wrongful.[26] Deception may also have additional normative effects. For example, the fact that someone was deceived into performing some action might constitute an excuse for what they did. Likewise, consent from someone who is deceived about a fact that would be material to his decision will be invalid because it will violate the disclosure requirement (as discussed below).[27] On the other hand, we consider persuasion, defined as an attempt to affect someone's decision through the honest use of reasons, to be ethically unproblematic. Persuasion does not undermine someone's

[25] For a similar definition of persuasion, see Ruth Faden and Tom Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), 261.

[26] For further discussion on what exactly makes it wrongful, see O'Neil, "Lying, Trust, and Gratitude"; Alan Strudler, "The Distinctive Wrong in Lying," *Ethical Theory and Moral Practice* 13 (2010): 171–179; and Bernard Williams, *Truth and Truthfulness* (Princeton, NJ: Princeton University Press, 2002), chap. 5.

[27] This observation does not preclude the possibility of someone giving valid consent to being deceived (David Wendler and Franklin Miller, "Deception in the Pursuit of Science," *Archives of Internal Medicine* 164 [2004]: 597–600).

capacity to make her own decision in the light of her values and preferences; if anything, it augments it.

The ethical analysis of motivational manipulation is more complex. First, when one party successfully manipulates another, he causes her to act on the basis of her immediate desires, not the values and preferences that she would, on reflection, choose to involve in her decision-making (or, more subtly, not putting the same weight on those values and preferences that she would without his influence). She makes his decision-making process worse, relative to his values, without his agreement to do so. Thus, we think that motivational manipulation is pro tanto wrongful.[28] However, although motivational manipulation is morally problematic because of how it interferes with autonomous decision-making, it does not follow that it is on a par with coercion or deception. Someone subject to motivational manipulation can still have other good options available and can still have all the information that she needs to make her own decision. That is, she retains the ability and access to the information necessary to make a decision that reflects her own values and preferences. We do not, therefore, think that being manipulated is sufficient to excuse someone from wrongdoing or to invalidate his consent.

Consider the following example. A patient with a treatable form of cancer has nonetheless refused the recommended chemotherapy because hair loss and severe nausea are among the side effects. His oncology team, having provided all the information about the pros and cons of the treatment and recommended that he proceed, now consider alternative strategies. In discussion, his family reveals that he has a soft spot for one of the younger doctors, who reminds him of the daughter he never had. The team sends this doctor into the patient's room, where she listens to his stories, laughs at his jokes, mildly reprimands him, and asks why he's delaying getting treatment. Feeling buoyant and wanting to please, the patient agrees to start chemo.

If the patient agreed to the treatment because the doctor threatened him, or because the doctor lied about whether there were any side effects, then his consent to the procedure would clearly be invalid. Those would be cases of coercion or deception. In this case, however, the fact that he was manipulated into agreeing does not render his consent invalid. Moreover, the fact that receiving the treatment was very much in his interests makes it plausible that the manipulation was in fact morally justified. It would be justified, we think, if the expected net benefits of the treatment were large

[28] Mandava and Millum, "Manipulation in the Enrollment of Research Participants," 40.

enough to outweigh the pro tanto wrong of manipulation, and if there were no other ways to get his agreement that were less ethically problematic.

Recent discussions of "nudging" in the context of health care have also generated concerns about manipulation. According to Richard Thaler and Cass Sunstein's characterization: "A nudge . . . is any aspect of the choice architecture [i.e., the context in which individuals make decisions] that alters people's behavior in a predictable way without forbidding any options or significantly changing their economic incentives."[29] Examples include setting as a default that people are organ donors and requiring them to opt out if they do not want to donate; attaching photographs of patients to X-rays to encourage radiologists to read them more carefully; and describing cancer treatments in terms of probability of survival versus probability of mortality, thereby making it more likely that patients will opt for treatment.[30]

Thaler and Sunstein, and others since, have documented a wide variety of nudging techniques, and there is not space here to evaluate them all. As they understand the term, a "nudge" will not involve coercion or deception, since it is designed to leave people free to decide for themselves. Some nevertheless will involve manipulation. Take the framing effect of describing the probabilities of treatment outcomes in terms of survival or mortality. Multiple studies presenting participants with hypothetical choices have found that they are more likely to select surgery and more invasive or toxic medical treatments when they are presented with information framed in terms of survival than in terms of mortality.[31] For example, patients in the waiting room of a multispecialty outpatient clinic were asked to watch one of two videos and then presented with a hypothetical choice about whether to undergo angioplasty on the advice of their doctor.[32] Both videos described the potential risks of angioplasty, but one ended by saying, "ninety-nine percent of patients undergoing the procedure do not have any of these complications." The other ended saying, "These complications are seen in one out of a hundred people who undergo the

[29] Richard Thaler and Cass Sunstein, *Nudge* (New Haven, CT: Yale University Press, 2008), 6.

[30] These examples and others are listed in Jennifer Blumenthal-Barby and Hadley Burroughs, "Seeking Better Health Outcomes: The Ethics of Using the 'Nudge,'" *American Journal of Bioethics*, 12 (2012): 1–10.

[31] Annette Moxey et al., "Describing Treatment Effects to Patients," *Journal of General Internal Medicine* 18 (2003): 948–959.

[32] Hitinder Singh Gurm and David Litaker, "Framing Procedural Risks to Patients: Is 99% Safe the Same as a Risk of 1 in 100?," *Academic Medicine* 75 (2000): 840–842.

procedure." When the reason for angioplasty was simply to relieve chest pain, significantly more respondents who watched the former (positively framed) video said they would agree to the treatment than those who watched the latter (negatively framed) video. Since the information that is provided is the same, one interpretation of what is going on in cases like this is that describing it in terms of survival makes the positive outcome more salient and describing it in terms of mortality makes the negative outcome more salient.[33] Insofar as this leads the decision-maker to give too much or too little weight to the risks of the procedure, it is manipulative.[34]

We noted above that in some cases manipulation seems clearly permissible, given the benefits to the individual manipulated. Does this mean clinicians should regularly set up discussions to manipulate their patients into making the decision that the clinician thinks best? No. First, motivational manipulation is still pro tanto wrong because it is disrespectful of autonomy, even though the wrong can be outweighed. Second, competent adults are frequently better judges of what is in their own interests than are others. Third, clinicians may have their own biases to guard against; for example, they may tend to favor more aggressive interventions than someone's situation warrants. Fourth, clinicians and medical researchers have a duty of beneficence to help patients and prospective research participants make good decisions, where this means making good decisions *by their own lights*. Thus, they have a (limited) duty to enhance patient and participant autonomy. Fifth, it is plausible that warranted trust in medical professionals and medical institutions will be better for patients over the long run. Frequent manipulation for short-term benefit is likely to undermine that trust. Finally, even if manipulation were in a patient's interests, it could be justified only if the clinician lacked ways to benefit him that would be less morally problematic, such as taking the time for persuasion. Permissible manipulation, then, is the exception, not the rule. We discuss this issue again later in the chapter when we examine the ethics of direct-to-consumer pharmaceutical advertising.

5.4 Justifying Interference

The autonomy rights of competent persons restrict what others may do to them without permission. People typically also have interests in acting

[33] R. Noggle, "Manipulation, Salience, and Nudges," *Bioethics* 32 (2017): 164–170.

[34] Note that framing effects may be correctable with relatively simple debiasing interventions (Sammy Almashat et al., "Framing Effect Debiasing in Medical Decision Making," *Patient Education and Counseling* 71 [2008]: 102–107). It may therefore be possible to present data on survival and mortality rates without manipulating the decision-maker toward one outcome or another.

autonomously, and some justification must be given for interfering with those interests. In this section, we address two broad classes of interference with autonomy: interference for someone's own good and interference for the good of others.

Paternalism

When we interfere with someone's choices or decision-making for their sake but without their consent, we engage in *paternalism*. If I hide your cigarettes so that you won't smoke because I'm concerned that you will get cancer, I act paternalistically. If a physician deceives a patient so that they will consent to a procedure the physician thinks is in the patient's best interests, the deception is paternalistic. Likewise, according to common understandings of the term, when we stop a curious child from rifling through the knife drawer, we act paternalistically. Institutions, too, may be paternalistic. For example, the US Food and Drug Administration (FDA) regulates the sale of food, drugs, and medical devices. Without sufficient evidence of the safety and efficacy of a new drug, the FDA will not allow its sale.[35] Making these drugs available only with a prescription from a physician may also be regarded as paternalistic: the most plausible justification for not allowing individuals to decide for themselves which drugs to buy is that this prohibition protects them.

It is helpful to distinguish hard and soft paternalism.[36] *Hard paternalism* is typically understood to involve one party interfering with the voluntary, relevantly informed actions or decision-making of an autonomous agent for the sake of that agent. *Soft paternalism* involves one party interfering with the actions or decision-making of someone who is not competent for that individual's sake. Both types of paternalism involve one party's substitution of their own judgment for that of the individual who is treated paternalistically. Human beings typically have interests in governing their own lives, even when they lack the capacity for autonomous action and so lack autonomy rights. Thus, even soft paternalism bears some burden of justification, though the bar for justifying it is much lower. It must be justified by showing that it is in the interests of the person whose acts are interfered with, where we understand interests sufficiently broadly to encompass their interest in choosing for themselves.

[35] Similar functions are performed by the European Medicines Agency and Health Canada.
[36] Joel Feinberg, *Harm to Self* (New York: Oxford University Press, 1986), 12–16.

Though most cases of paternalism involve interfering with someone's actions for the sake of their well-being, Seana Shiffrin gives an amended analysis that both expands the scope of what counts as paternalistic and explains what is ethically problematic about hard paternalism. She notes that, first, paternalism does not always entail that the person acting paternalistically thinks that the agent's judgment *about* his interests is inferior to hers.[37] She may act paternalistically because she judges him unable to act in the way that would best *secure* his interests (according to his own judgment) – as when she interrupts a friend who is speaking to articulate one of his points better than she thinks he would. Second, paternalism does not have to relate to the well-being of the agent at all. If I hide a friend's cigarettes because I am concerned that his wife will be grief-stricken if he dies, then I act paternalistically toward him.[38] What unites these phenomena as hard paternalism is that the person acting paternalistically substitutes her own judgment or action for the other party's in a sphere over which the other party has legitimate control. Shiffrin writes: "The essential motive behind a paternalist act evinces a failure to respect either the capacity of the agent to judge, the capacity of the agent to act, or the propriety of the agent's exerting control over a sphere that is legitimately her domain."[39] Someone who acts paternalistically toward an autonomous agent therefore disrespects him by disregarding his authority to govern his own life and by implicitly asserting that her own judgment or action is superior or more effective.

Hard paternalism involves one party substituting her judgment or action for that of an autonomous person who is acting voluntarily and knows, basically, what she is doing. Since, by definition, this is an interference with someone's decision about a matter over which she has legitimate control, hard paternalism is pro tanto wrong. Like other rights violations, such interference faces a high bar for justification. By contrast, soft paternalism can generally be justified by showing that it is in the individual's interests. Challenges arise in cases of uncertainty and marginal autonomy.

Suppose a middle-aged patient is going to have his wisdom teeth removed and asks the dentist not to anesthetize him. The clinician may be uncertain whether the request is autonomous: Is the patient ignorant of

[37] Seana Shiffrin, "Paternalism, Unconscionability Doctrine, and Accommodation," *Philosophy & Public Affairs* 29 (2000): 205–250, at 215.

[38] Ibid., p. 217.

[39] Ibid., p. 220. Shiffrin does not distinguish hard and soft paternalism, but we consider her insights about what she calls "paternalism" helpful for understanding what we classify as hard paternalism.

some key fact, such as what it means to have a tooth extracted? Is there a problem with his capacity to understand what is going on and make decisions for himself? Or is he perfectly capable of making decisions and places a very strong value on having genuine experiences? Here, the dentist may need to assess her patient's understanding of the operation and his decisional capacity before she proceeds.

Note that delaying the operation in order to reeducate a patient or check that he is really capable of making a decision in the light of his own values need not be paternalistic in a problematic way, even if the clinician is doing it because she judges that the patient's original decision is probably a bad one.[40] According to Shiffrin's analysis, the wrong of hard paternalism involves a failure to respect someone's capacity to judge or act. We can only fail in this way once we have good reason to think that someone is acting autonomously. Thus, there is nothing problematic about delaying an operation until the dentist is confident that her patient's decision is autonomously made. Moreover, this suggests that in cases where someone might be choosing nonautonomously, and where acting on that nonautonomous choice might have serious consequences, there are good reasons to take the time and effort to ascertain the true status of the choice. If it seems as though someone would not make the choice they have selected were they acting autonomously, this is reason to check. Likewise, if the consequences of their choice would be a severe harm.

Some people's capacity for autonomous action is marginal. For example, someone with mild to moderate Alzheimer's disease may be able to reason well and have settled values and preferences, but be unable to retain in short-term memory enough information about her condition and the care options presented to her to make good decisions on her own. Similar considerations apply to marginal cases as to cases of uncertainty. Again, where there is doubt about someone's decision-making, it is not paternalistic to check it. And where the decision is particularly consequential, this gives stronger reasons to be sure that the person making it is capable of doing so autonomously. Finally, it is important to remember that making decisions for oneself is conducive to well-being, not just a matter of rights.

[40] Note that ignorance about some pertinent facts is not sufficient to justify interference by others. If you happen to have a much better understanding of stereo equipment than I do, that does not license you interfering with me buying a new set of speakers, even if you correctly judge that my preferences would be better satisfied by your selection. I still understand what I'm doing – exchanging money for speakers. On the other hand, if I were confused enough that you realized I was buying cupboards under the misapprehension that they were speakers, that would justify interference. I would no longer be autonomously *buying speakers*.

People with marginal autonomy who are judged to lack capacity with regard to a particular decision should still be involved in decision-making as far as that is possible because it is (typically) good for them. For example, it would generally be good for a ten-year-old to play as active a role as possible in deciding whether to enroll in a pediatric clinical trial.

Interference for the Sake of Others

It is one thing to interfere with someone's decisions for that person's own sake. It is quite another to do so for the sake of other people. Virtually everyone, including those who would object to hard paternalism, accept that there are substantial limits on what autonomous individuals are ethically permitted to do. Earlier in the chapter, we characterized the basis of autonomy rights in terms of a person's sovereignty over their own life. A key question for determining the limits of autonomy rights is therefore what the boundaries of someone's own life are. One commonly accepted boundary is at the point where one person's actions would pose excessive risk of harming another or would otherwise violate their rights. Consider a patient who is admitted to a hospital with active tuberculosis and a cough. Such a patient is highly contagious. The standard of care for infectious tuberculosis patients includes isolation from other patients. We would think it perfectly legitimate for the hospital to require this patient to accept isolation within the health care facility as a condition of admission, because otherwise they would impose a substantial risk of harm to others.[41]

The prevention of harm to others is one clear justification for restricting the liberty of autonomous individuals. Are there other justifications? According to John Stuart Mill's "harm principle," there are not. In *On Liberty* Mill writes:

> The object of this Essay is to assert one very simple principle . . . that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.[42]

[41] See World Health Organization, *Ethics Guidance for the Implementation of the End TB Strategy* (2017) (available at http://who.int/tb/publications/2017/ethics-guidance/en/).

[42] John Stuart Mill, *On Liberty*, in John Gray and Gordon Smith (eds.), *JS Mill's on Liberty in Focus* (London: Routledge, 2012), 30.

Mill here clearly rejects paternalism as a justification for interfering with autonomous action. The harm principle would also rule out interfering with someone's actions on the grounds that what they are doing offends others or is contrary to their moral beliefs (*legal moralism*). For example, the fact that many people are disgusted by the idea of human cloning, or gender reassignment, is not sufficient reason to prohibit either, if we adopt the harm principle. Likewise, that some people regard suicide as immoral does not provide grounds for preventing other people from taking their own lives. In these cases, some harm to other parties, or some violation of the rights of other parties, would have to be demonstrated in order to justify restricting someone from doing as they wish.

The harm principle has been extremely influential in liberal thinking and has served as a bulwark against both legal moralism and hard paternalism. However, we think that preventing harm to others is neither necessary nor sufficient to justify interfering with the liberty of autonomous individuals. It is unnecessary because there are other wrongs that justify intervention. For example, we think that the government may legitimately prohibit exploitative wage offers and impose a minimum wage, even if no one is harmed by the unfair level of compensation.[43] Likewise, harm to others is insufficient because rights have thresholds such that the obligation to respect someone's rights is only pro tanto. If the benefits to others of overriding someone's rights – including autonomy rights – are sufficiently great, then this can justify doing so.[44] In the context of liberty, we can see this principle at work in many areas of everyday life where a low risk of harm to innocent nonconsenting others is nevertheless thought to be justifiable. For example, it is commonly thought that parents are permitted to take their children on car trips, thereby putting them at a very small risk of serious harm, even when there is no benefit to the children themselves. Presumably, insofar as this practice is ethically

[43] In Chapter 4, we argued that depriving someone of something to which they have a legitimate claim constitutes a harm. One might think that individuals have claims to fair wages, in which case paying less than a fair wage would indeed be harmful. Whether this is correct depends on the appropriate counterfactual for assessing what would otherwise have happened to the worker. It would be ethically permissible for the employer to pay them a fair wage or not employ them at all. Thus the unfairly low wage is either a *harm* because less than they would have received if their claims were respected or a *benefit* because more than they would have received if their claims were respected. We are not certain which comparison is most apt. However, it seems to us that the wrong of exploitation does not depend on a judgment that it is harmful and neither does the justification for prohibiting exploitative transactions.

[44] At least in principle. See Chapter 4's discussion of torture for an example of a right that we think should never be overridden in practice.

acceptable, it is because the costs to the parents of restricting their liberty in order to avoid this risk of harm to their children would be too great.

5.5 Consent

One way in which autonomy rights are commonly exercised is through consent. By giving valid consent to an act, an individual can transform it from an act that would be morally forbidden into a permissible act. They do this by *waiving* their right with respect to the other party. For example, if a surgeon attempted to operate on a competent patient without his permission, she would be assaulting him. With his valid consent, the surgeon's acts of cutting her patient's body open are transformed from assault into appropriate surgery. He has waived his right against her cutting him in specific ways. Given how frequently decisions regarding health care and research involve someone giving consent, it is important that we analyze the conditions under which consent is valid. We do so here under the assumption that consent in the context of medicine is the same normative phenomenon as consent in other areas of life, such as sexual relations, even though the contexts may be very different. In each of these contexts, valid consent involves one person exercising an autonomy right to transform an act that would be a rights-violation into one that is permissible (provided no other ethical constraints apply). Differences in the information that is required for consent or the institutional safeguards needed to protect voluntariness, for example, should emerge from how the same conditions for valid consent can be met when the context is different. Further, we do not draw a distinction between "consent" and "informed consent." Whether someone has successfully exercised their rights depends on whether *valid* consent has been obtained and all forms of valid consent include informational components.

In analyzing consent it is vital to separate the question of whether someone's choice constitutes valid consent from whether it was a good choice. Here it is helpful to recall the two roles that autonomy plays in our ethical thinking (Section 5.2). One is that the capacity for autonomous action is a ground for autonomy rights. The other is that being and acting autonomously is a contributor to or component of one's well-being. As we saw in our earlier discussion of autonomy, someone may exercise her autonomy rights in foolish ways. In other words, she may make a poor choice but have the right to do so. Someone might, for example, give valid consent to having her lip pierced, but this might end up being a decision she regrets.

The process of obtaining consent in clinical care and research can and ideally should serve the goals of both helping someone make a good decision and obtaining his valid consent. However, these two goals can come apart. Someone might give valid consent but choose something that predictably does not best serve his values and preferences. Conversely, someone's consent to an act can be invalid – say, because he has been deceived about what is proposed – even if the act in question would be best for him. In this regard, it is important to note that the obligations to help people make good decisions are much weaker than the obligation to obtain valid consent. It is beneficial for someone to make a better decision, but the obligations of clinicians and researchers to benefit other people are limited (Chapter 6). On the other hand, not obtaining valid consent to an act that requires it would constitute a violation of the person's rights.

Consent can be analyzed in terms of five elements: (1) capacity, (2) disclosure, (3) understanding, (4) voluntariness, and (5) authorization.[45] The satisfaction of each of these elements is required in order for consent to be valid. In the paragraphs that follow, we explain what is required for each and note the ways in which consent can be invalidated, drawing on our analysis in Section 5.2. We then turn to the question of how decisions should be made for people who cannot decide for themselves.

Capacity

An individual has the capacity to give consent when she is autonomous in the sense described at the beginning of this chapter: she is capable of deliberating about her actions in the light of her values and making a decision on the basis of that deliberation. An individual has the capacity to make a specific consent decision when she is capable of deliberating and deciding about that specific choice in the light of her values. Centrally, this involves being able to understand the aspects of the decision that relate to the rights she is being asked to waive through consent and being able to reason about whether to waive those rights. Note that it does not require that she be able to understand *everything* that might be germane to her decision. Nor does it require that her ultimate choice is a rational one. As just discussed, respect for autonomy includes respect for decisions that are

[45] See, e.g., Ruth Faden and Tom Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), 274, although the authors use the term "consent" instead of "authorization."

poorly made, provided that it is the agent herself who is responsible for the quality of the decision-making.

We do not have more specific criteria for identifying the threshold of ability to reason, understand, and make decisions on the basis of one's values that underlies the capacity to consent for oneself.[46] For certain individuals – such as adolescents and addicts – this uncertainty is reflected in uncertainty about whether such individuals should be allowed to make important decisions. Suppose Alfred, an adult patient, leaves a psychiatric unit, knowing he needs the care offered there, only because he is addicted to alprazolam (a sedative) and believes he can find relief by getting some alprazolam outside the unit. Does Alfred have decision-making capacity? This is a difficult case and might remain difficult even with further details. Arguably, Alfred understands both his need for treatment and his addiction, but is incapable of deciding (rationally, in accordance with his own values) to remain in the psychiatric unit; his addiction undermines his capacity. On the other hand, perhaps he understands the advantages of remaining in the hospital but places a higher value on the immediate relief that alprazolam can deliver and on freedom from institutional rules; in this case, his choice to leave might reflect genuine capacity. A third possibility is that the only rational choice (given his own values and priorities) was to remain in the hospital, and he had the capacity to do so, but he simply did not because he did not try hard enough to resist the temptation to leave. This would be an instance of weak will rather than incapacity.

Disclosure

Ethically and legally, many acts of consent require the prior disclosure of certain information. For example, contracts are expected to include information about what is being agreed to by both parties, what process will be followed if one party does not act as agreed, and so forth. Likewise, clinicians and researchers are expected to disclose pertinent information about what they are proposing to do. One common view is that this disclosure requirement is derived from the understanding requirement: the information that must be disclosed for consent to be valid is the information that must be understood, and it must be disclosed because it must be understood.[47] In the words of Alexander Capron: "Plainly,

[46] For discussion see citations in notes 7 and 9.

[47] Consistent with such a view, it might be that more information should be disclosed than must be understood, but that the additional information is not information that is required for *valid consent*.

comprehension is essential for truly informed consent, for the act of disclosure would otherwise be pointless."[48] This view would make sense if the function of the disclosure requirement were to enable understanding. However, we believe that the function of the disclosure requirement *as it relates to the validity of consent* is not to enable understanding but to respect the right of autonomous individuals to make their own decisions. That means not illegitimately controlling someone's decision regarding consent by intentionally withholding relevant information or providing false information. It does not mean ensuring that the person giving consent understands all the information that would help them make a good decision.[49]

An example can show why we hold this view. Suppose Diego mentions to his friend that he has a really sore neck. The friend innocently suggests that he help Diego "crack" it. Diego agrees and his friend holds his head and twists vigorously in both directions, producing a satisfying pop. In fact, Diego's friend has yanked his neck beyond its safe range of motion and the next day it is so stiff he cannot turn his head. Here, we take it, though both people might be acting foolishly, there is nothing awry with Diego's consent. Contrast this case with one in which Diego mentions the same thing to an osteopathic doctor. Suppose that doctor tells Diego that she can help by twisting his neck in exactly the same way. However, she knows that this would be past the safe range of motion (perhaps she hopes to drum up more business for her practice by injuring him). In such a case, most people would judge that Diego's consent to the twisting would be invalid. But his understanding of what will happen is identical. The difference lies in what he has been told (or not told). In the latter case, but not the former, information is withheld that Diego would reasonably expect to be told. Withholding the information about the risks of twisting his neck allows the osteopath to control Diego's decision. His ignorant friend does not control his decision because his friend knows no more than Diego about the risks.[50]

For example, we would not be concerned if a research participant did not recall the name and number to call if they had questions about the research. However, it is plausible that this information should be included on the consent form.

[48] Alexander Capron, "Legal and Regulatory Standards of Informed Consent in Research," in Ezekiel Emanuel et al. (eds.), *Oxford Textbook of Clinical Research Ethics* (New York: Oxford University Press, 2008), 625. For statements of this view, see, e.g., Declaration of Helsinki, Paragraph 26; and Beauchamp and Childress, *Principles of Biomedical Ethics*, 124, 131–137.

[49] The discussion that follows is derived from Danielle Bromwich and Joseph Millum, "Disclosure and Consent to Medical Research Participation," *Journal of Moral Philosophy* 12 (2015): 195–219.

[50] Note that this sort of control can arise through negligence, as well as deliberate action. For example, if the osteopath did not care either way whether Diego agreed, but knew that she was omitting relevant information, this would also constitute illegitimate control.

Analyzing the disclosure requirement in terms of illegitimate control reveals the information that must be disclosed in order to fulfill the requirement. The person requesting consent must disclose all the information about the act she is proposing that she knows, has reason to think is relevant to the individual's consent decision, and that she thinks the person giving consent would reasonably expect to receive. She must disclose the information in a manner that gives him a fair opportunity to understand it. If she does all this, then she does not make use of her informational advantage in order to control what he does. To play this out with another simple example, consider what must be disclosed in order to give consent to participate in a clinical research study. The information that we might reasonably predict would be relevant to someone's decision includes what the study is about, what procedures will be conducted and what they involve, what the risks and potential benefits are, and how participation in the study augments or replaces alternative treatment options. Moreover, in the context of clinical research, it is plausible that potential participants would expect to receive this information, so that withholding it would be deceptive. In order that potential participants have a fair opportunity to understand this information, it should be disclosed in lay language, in simple writing or orally for people who are illiterate or do not read well, and so on. The clinician seeking consent should encourage follow-up questions and answer any questions patiently.

Understanding

We have established what information must be disclosed in order to obtain valid consent and how that information must be disclosed. We have argued that it is a separate question what must be understood.[51] Provided that the disclosure requirement has been met and the person giving consent is competent, the understanding requirement is minimal. Three conditions are necessary and sufficient to meet it.[52] The person giving consent must understand (1) that he is giving consent and not doing something else; (2) what signifies consent in this context, that is, how to

[51] Understanding has been studied most thoroughly in the context of consent to clinical research. Surveys of research participants around the world suggest that understanding of facts about risks, procedures, and study purpose is highly variable and often very poor. See Amulya Mandava et al., "The Quality of Informed Consent: Mapping the Landscape: A Review of Empirical Data from Developing and Developed Countries," *Journal of Medical Ethics* 38 (2012): 356–365.

[52] Joseph Millum and Danielle Bromwich, "Understanding, Communication, and Consent," *Ergo* 5 (2018): 45–68.

indicate consent; and (3) what he is agreeing to, that is, what the person obtaining consent will be permitted to do that she was not permitted to do before. The first two conditions are necessary for a token of consent to constitute the act of intentionally giving consent. The last condition derives from the point of consent, which is to redraw the normative boundaries in the way that the two parties agree upon.

An example may make these conditions clearer. Suppose that a nurse asks his patient for consent to draw her blood and she agrees. If she mishears and thinks that he asked whether she's feeling comfortable, her agreement will not constitute consent. Likewise, if he asks her to sign a consent form and she does not realize that her signature signifies consent – instead, she thinks she's signing a petition – then she will not have consented in any morally relevant sense at all.[53] These possible errors concern the first two conditions. Third, prior to consent, the nurse was not ethically permitted to penetrate his patient's arm with a needle nor to remove her blood. The third condition is met when she understands that the nurse will now be permitted to do those things – that is what redrawing the normative boundaries consists in.

The minimal nature of the understanding requirement is consistent with the underlying function of autonomy rights, which is to protect the sovereign authority of a competent individual to decide what happens in their own life. This includes the right to decide foolishly, for example, by declining information that is made available. The minimal understanding requirement also allows individuals to pursue their interests by agreeing to actions and transactions that they fail to fully grasp. For example, Franklin Miller and Steve Joffe describe the misunderstandings that are rife among participants in phase 1 oncology trials.[54] Such participants frequently conflate clinical care and research, underestimate the risks and overstate the benefits, and exaggerate their personal prospects of benefit. Nevertheless, Miller and Joffe contend, the decision to enroll in phase 1 trials is frequently consistent with participants' values and preferences. Provided that the participants are given a fair opportunity to understand the information relevant to their decision, we think that they are able to give valid consent despite these misunderstandings.

[53] It does not follow that the nurse would be at fault if he innocently believed her to have understood what signing the consent form signified. It is one thing to ask whether someone has given valid consent and another to ask whether someone proceeding on a token of consent has acted in a blameworthy manner.

[54] "Phase 1 Oncology Trials and Informed Consent," *Journal of Medical Ethics* 39 (2013): 761–764.

Here, it is worth noting again the dual functions that the consent process may play. Assuming the disclosure was adequate, *valid* consent is consistent with very minimal understanding. A *good* decision may require much more understanding. In circumstances in which the person proffering consent does not have a right to an intervention, it may therefore be legitimate to refuse to provide it until they demonstrate substantial understanding of what it entails. For example, consider a first-in-humans trial of a new drug in healthy volunteers, that is, in research participants who do not have a health condition that the drug is designed to treat. Plausibly, the volunteers do not have any right to be offered participation in the trial. In that case, it is no violation of their rights to exclude participants who fail a quiz that assesses their understanding of the procedures and associated risks that the trial involves. By contrast, patients in ordinary clinical settings often have a right to the intervention that is indicated for their condition. Requiring such patients to demonstrate a higher level of understanding than that required for valid consent would illegitimately deprive them of something to which they have a right.

Voluntariness

Saying that consent is voluntary means that the token of consent is proffered intentionally and free of the illegitimate control of another party. Failure to meet the disclosure requirement involves illegitimate control and so invalidates consent through rendering it involuntary. This applies to cases of outright deception, as well as cases where information is withheld or is disclosed in a way that the person can be expected to misunderstand. Voluntariness may also be undermined by coercion, which is another form of illegitimate control. For example, someone who consents to a medical procedure because her husband wants her to undergo it and she is afraid of what he will otherwise do has not given voluntary consent.

Consent is either valid or it is not. But, as noted earlier, control is a matter of degree. Thus, whether a form of illegitimate control renders consent invalid will depend on how controlling it is. A weak threat – say, a physician's threat to reveal some rather trivial piece of private medical information to her patient's child – may be noncontrolling, while deception about some fact that would make a difference between consenting and declining would be enough to render consent invalid. The exact threshold at which this occurs will be a matter of judgment.[55]

[55] See the taxonomy of control in Section 5.3.

Authorization

Depending on the context, various tokens can signify authorization or consent. In many situations, saying "Yes," to a request for consent is sufficient. In others, a simple gesture may be enough (such as in response to "May I sit here?"). It is even possible for consent to be tacit – implied without being explicitly expressed. When the chair of a meeting proposes a motion and asks, "Any objections?" then the silence of the other members of the committee may be sufficient to signify consent.[56]

Medical research typically involves written authorization. Medical care may involve written authorization for some procedures, such as those that are risky or involve the transfer of private information. In terms of the validity of consent, there is nothing special about having the token in writing. Provided that its significance is understood by all parties involved, a nod can confer valid consent just as well as a signature on a form. What matters is that all five conditions are met. Nonetheless, there can be reasons for preferring one token to another that are not related to the validity of consent. For example, *used correctly*, a written informed consent form can help to ensure that all the relevant information is conveyed to potential participants in a study, give them time to go over the information they have been provided, and provide a record of the consent token. In other situations a written consent form would be problematic. For example, when research is conducted with a stigmatized population a written consent form could put research participants at risk. For example, an HIV study enrolling gay men might not require participants to sign consent forms if study sponsors are concerned about a potential breach of privacy.[57]

Exceptions to the Consent Requirement

Consent to medical care or research is not always required. In some cases, this is because the acts performed by the relevant professionals are not acts against which people have rights. For example, consider a research study that involves recording how people behave in public places. Generally speaking, people have neither a right against being observed when they

[56] A. J. Simmons, "Tacit Consent and Political Obligation," *Philosophy and Public Affairs* 5 (1976): 274–291, at 278–281.

[57] See David Wendler and Jonathan Rackoff, "Informed Consent and Respecting Autonomy: What's a Signature Got to Do with It?," *IRB* 23 (3) (2001): 1–4, for some cases in which different social and cultural contexts affect the appropriate form that consent tokens should take.

are in public nor a right against someone making written notes of what is observed. Thus, research that involves these acts does not require consent from the subjects of research – there is no right for them to waive through consent.

In other cases, there is a right involved, but there are good reasons to override it. For example, suppose that a researcher obtained blood samples and medical histories from a large number of patients with type II diabetes. She got consent from these patients to carry out diabetes research. Ten years later, with many new tools for genetic analysis at their disposal, she and her colleagues want to use the samples to see if people who become obese are more likely to have genes that predispose them to heart disease and mood disorders. Is she permitted to do so?

The first question to answer is whether the scope of the original consent covered the new research studies. If the consent form, interpreted as we could reasonably expect the participants to interpret it, would include heart disease and mood disorder research, then they would likely already have given valid consent for this research. Assume that the consent form signed by the participants clearly restricts the scope of the research, so they did not give consent to these new research uses. The second question is then how difficult it would be to obtain consent for the new proposed research. If it would be straightforward – names and contact information are on file and the research will not be unduly affected by excluding participants who cannot be recontacted – then further consent (or "reconsent") should be obtained. If it would be very burdensome or impossible to obtain consent for the new research study, then we must assess, third, whether carrying out the research without consent can be justified. Since, we are assuming, consent would ordinarily be needed for what is proposed, it is pro tanto wrongful to proceed without consent. The value of the research must therefore be sufficiently great to outweigh this pro tanto wrong. How great that value must be will depend, in turn, on how serious the rights violation is.[58] Fourth, just as when conducting risk/benefit assessments we look to minimize the risks consistent with the scientific goals, when the consent of research participants is not going to

[58] More precisely, the calculation involves weighing the incremental net value of conducting the research without obtaining consent against the bad of overriding participant rights in the specific ways the research involves. The incremental net value is found by subtracting the predicted net value of the research that could be done consistent with obtaining consent from the predicted net value if consent is not obtained. The net value includes both the valuable outputs of the research and the costs of conducting it (with and without reconsent).

be obtained, the extent to which the researchers interfere with their rights should be minimized.[59]

Finally, there are cases in which consent does not need to be obtained from a patient or research participant because they lack the capacity to give their own consent – for example, because they are unconscious, are cognitively impaired, or have not yet developed sufficient capacity to reason about their actions. We now turn to such cases.

5.6 Decision-Making for Others

Consider a patient with moderate dementia as a result of Alzheimer's disease. Though she can still recognize family members and still expresses preferences, she is confused about her condition and cannot recall details of what her doctor tells her thirty seconds later. There is no doubt that she lacks the capacity to make her own decisions about health care. She has been diagnosed with breast cancer and there are multiple options regarding treatment. Someone must decide what to do. Who should make that decision and how should they make it?

Regarding who should decide, there are two possibilities: either the patient, while competent, appointed someone to make decisions on her behalf or she did not. If she did – for example, by completing a written advance directive – then that person should be her surrogate decision-maker, provided that he is himself capable, available, aims to make ethically appropriate choices, and so forth. If she did not herself assign a surrogate decision-maker, then someone must be appointed to take that role. This will be the case for many people who are incapable of making their own decisions. Only a minority of adults in Canada, the United Kingdom, and the United States have completed advance directives, and there are many people – including children and people who are congenitally severely cognitively disabled – who are never competent to decide for themselves.[60] Some incompetent individuals have court-appointed

[59] Related issues arise in the context of research that involves deceiving participants. This is common practice in a great deal of psychological research, for example, where participants are often not told the true purpose of the study in which they are enrolled until after their participation. For an overview, see David Wendler and Franklin Miller, "Deception in Clinical Research," in Emanuel et al., *The Oxford Textbook of Clinical Research Ethics*, 315–324.

[60] See D. Aw, B. Hayhoe, and L. K. Bowker, "Advance Care Planning and the Older Patient," *QJM: An International Journal of Medicine* 105 (2011): 225–230; Pew Research Center, *Views on End-of-Life Medical Treatments* (November 2013); available at: www.pewforum.org/2013/11/21/views-on-end-of-life-medical-treatments/; Jaya Rao et al., "Completion of Advance Directives among US Consumers," *American Journal of Preventive Medicine* 46 (2014): 65–70; and Ana Teixeira et al.,

guardians who are legally granted decision-making power for health care and research participation (among other things). Children also typically already have parents or guardians with the legal power to make decisions on their behalf. For other incompetent patients, the individual legally authorized to make decisions varies considerably by jurisdiction. In many US states and Canadian provinces, legislation provides a next-of-kin hierarchy for clinicians to identify an appropriate surrogate.[61] For example, in Maryland, they would select the highest person on the following list who is available: spouse, adult child, parent, sibling, other relative. Other jurisdictions have further detailed categories of relatives further down the hierarchy (e.g., grandparent, aunt or uncle, grandchild), explicitly allow for unmarried partners or close friends, and may specify how disagreements are to be resolved and what range of decisions can be made by the surrogate. By contrast, in the United Kingdom, unless a surrogate decision-maker has been designated by the patient or a court, health care professionals have the authority to make decisions about treatment.[62]

Whether appointed by the patient or not, a surrogate decision-maker does not have carte blanche to decide as they wish, ethically speaking. First, if the incompetent person has completed an advance directive that expresses specific preferences for care or research, then those preferences should usually be followed, subject to the same constraints on the use of resources that apply to everyone.[63] For example, someone might write in his advance directive that he does not want to be kept on life support if he is not expected to recover consciousness. That constitutes an exercise of his autonomy right to refuse treatment and so should be honored. However, second, in many cases there will not be specific instructions from the

"What Do Canadians Think of Advanced Care Planning? Findings from an Online Opinion Poll," *BMJ Supportive & Palliative Care* 5 (2015): 40–47.

[61] For the United States, see Erin DeMartino et al., "Who Decides When a Patient Can't? Statutes on Alternate Decision Makers," *NEJM* 376 (2017): 1478. For Canada, see statutes listed at Canadian Nurses Protective Society, "Consent for the Incapable Adult" (available at https://cnps.ca/consent-adult; accessed September 28, 2020).

[62] British Medical Association, "Advance Decisions and Proxy Decision-making in Medical Treatment and Research: Guidance from the BMA's Medical Ethics Department" (London: BMA, 2007).

[63] Where someone's stated preferences seem to deviate substantially from what would be in their interests, there is room for caution about following the advance directive to the letter. First, this may be an indication that the advance directive, as stated and interpreted, does not actually express what the individual meant to express. Second, the individual's present interests could yet be important enough to override their prior exercise of autonomy. For detailed discussion of these points in the context of advance directives and dementia patients, see Ronald Dworkin, *Life's Dominion* (New York: Vintage, 2011); and Rebecca Dresser, "Dworkin on Dementia: Elegant Theory, Questionable Policy," *Hastings Center Report* 25 (1995): 32–38.

incompetent person or the instructions that have been given require interpretation. In that case, some standard must be used to guide surrogate decision-making.

Two standards are widely cited: *substituted judgment* and *best interests*. According to the substituted judgment standard, the surrogate should decide as she judges the patient would decide, were he competent. According to the best-interests standard, the surrogate should choose the option that she judges to be in the best interests of the patient or would bring about the greatest net benefit to him. Sometimes these standards are ordered hierarchically: the surrogate should use the substituted judgment standard if the patient's preferences are known or can be reasonably inferred and otherwise should use the best-interests standard.[64] As will become clear, we partly dissent from this mainstream understanding of standards for surrogate decision-making.

In this context, it is crucial to distinguish between the speech act of making a decision about one's health care and simply expressing one's preferences about treatment. When someone completes an advance directive, they exercise an autonomy right. Likewise, when someone gives consent to a medical intervention they exercise an autonomy right. Simply saying what one thinks about treatment – "I would never want to be kept on a machine like that" – is expressing a preference but not exercising a right.[65] Likewise, a substituted judgment, even one that is highly accurate, does not constitute the exercise of a right.

What then is the moral relevance of a substituted judgment? We think that substituted judgments can sometimes play an important role as a result of the close relationship between a person's preferences and what is in her interests. As we discuss in Chapter 8, any plausible theory of well-being should show considerable deference to each individual's authority regarding what is good for her. To a large extent what someone would decide to do, on reflection and taking relevant facts into account, is likely to be a good guide to what would be good for her. Thus, substituted judgment is relevant *insofar* as it predicts what would be in an incompetent individual's interests. There will be important exceptions to the generalization that substituted judgment is a guide to someone's interests. For example, someone might have an exaggerated fear of radiation, such that he would have refused a clinically indicated X-ray if he were conscious. Absent explicit instructions to the contrary, if he is unconscious and a

[64] For a nuanced treatment, see Buchanan and Brock, *Deciding for Others*, 93–151.
[65] Cf. ibid., 115–117.

surrogate must decide on his behalf, she should probably disregard this fear and do what she judges to be in his interests. Here, a substituted judgment would give the wrong result.

We also think that it is a mistake to adopt a best-interests standard in those cases in which there is no advance directive. In fact, it is widely accepted that the best-interests standard, literally understood, cannot be the right standard for making decisions on another person's behalf.[66] This is because people's interests frequently conflict and so trade-offs must be made. Consider, for example, the triage decisions made at admissions for the emergency room of a hospital. Even though each individual would benefit from being seen sooner rather than later, not everyone can see a physician immediately. The triage nurse must therefore make decisions that weigh factors such as the urgency of someone's condition, how long she has been waiting, the capacity of the hospital, and so forth. He cannot – and therefore is not obliged to – act in each person's best interests. This is true whether the people in line for care are able to make their own decisions or not.

A more plausible conception of the best-interests standard would accept that there are limits to what can be done to promote someone's interests, but say that surrogate decision-makers should still choose on someone's behalf whatever would maximize her well-being within the constraints of distributive justice.[67] However, we think that even this is too weak. A competent individual should sometimes not put her interests above those of others, even if she has the right to do so. Likewise, if she is deciding on behalf of someone else, she should not always put his interests above those of others, even if justice does not forbid it.

In fact, we think very similar moral constraints apply to incompetent as to competent individuals. The standard we prefer for making decisions on someone else's behalf is a *reasonable subject* standard.[68] According to this standard, the surrogate should decide on the incompetent individual's behalf as he would decide if he were a rational agent acting prudently within the constraints of what morality requires. That is, the surrogate should do what is in the incompetent individual's interests when they are

[66] For discussion in the context of making decisions for children, see David Archard, "Children's Rights," in Edward Zalta (ed.), *Stanford Encyclopedia of Philosophy* (Winter 2014 edition; available at http://plato.stanford.edu/archives/win2014/entries/rights-children/). The points Archard makes generalize to other noncompetent patients.

[67] See Buchanan and Brock, *Deciding for Others*, 192.

[68] For a full elucidation and defense of this standard, see Joseph Millum, *The Moral Foundations of Parenthood* (New York: Oxford University Press, 2018), chap. 6.

the only interests that are relevant. But when other people's interests or claims are also implicated by a decision, then those interests and claims should be taken into account just as they should be by a competent individual. This standard will frequently coincide with choosing the option that best promotes the patient's well-being, but it allows us to justify certain exceptions. For example, it explains why it can be permissible to enroll an incompetent individual into research that poses net risks to him – for example, in some pediatric studies featuring no prospect of direct medical benefit to child participants (Chapter 4).

To summarize, if someone has completed an advance directive while competent, when he loses decision-making capacity his surrogate decision-maker should first endeavor to follow the guidance in the advance directive. Where this is indeterminate, she should follow the reasonable subject standard by making decisions on his behalf that promote his interests within the constraints of morality. Where someone has not completed an advance directive while competent, when he loses decision-making capacity his surrogate decision-maker should go straight to following the reasonable subject standard. For those individuals, such as young children, who have never had the capacity to make their own decisions, the reasonable subject standard likewise applies.

This chapter's first five sections have elaborated relatively theoretical aspects of autonomy. In the final two sections we illustrate with a pair of specific bioethical applications of our theoretical account: the right to refuse treatment and the ethics of direct-to-consumer marketing of pharmaceuticals.

5.7 The Right to Refuse Treatment

Respect for autonomy grounds stringent rights against interference with one's body. As a result, with very limited exceptions, other people may not do things to the body of a competent adult without their permission. In particular, as the discussion of paternalism showed, attempting to promote someone's interests is not a sufficient ground to justify bodily interference. This right has been widely – and we think correctly – interpreted as grounding a right to refuse treatment. For example, if my doctor recommends prescription painkillers for my lower back pain, it is up to me whether I take them or not. The right to refuse treatment is the mirror of the requirement that professionals obtain consent to treatment. Both are grounded in respect for autonomy rights.

The right to refuse treatment includes the right to refuse life-saving treatment. Someone with advanced cancer may still have treatment

options that offer a good prospect of extending her life for a few months. Nevertheless, she may decide that the life extension is not worth the horrible side effects of going through more chemotherapy. She would rather be made as comfortable as possible and allowed to die from her disease. If she is competent, well-informed about her treatment options, and decides voluntarily, then we see no reason not to respect her wishes.[69] (If she is not competent, then the considerations of the earlier discussion of decision-making for others apply.) The right to refuse life-saving treatment includes both forgoing and withdrawing life-sustaining treatment. For example, a competent individual might exercise this right to demand that mechanical ventilation or intravenous nutrition be stopped.

Matters become more controversial when the decisions being made seem less reasonable to other parties. Consider the case of Dax Cowart.[70] In 1973, a propane gas explosion left Cowart blind, unable to use his hands, and severely burned over two-thirds of his body. He repeatedly refused treatment and asked to be allowed to die. A psychiatrist who was brought in to evaluate Cowart judged him competent to make his own decisions. Nevertheless, his requests were overruled and he underwent a series of incredibly painful treatments. Many years later, Cowart no longer wanted to die, but maintained that he should have been allowed at the time to die rather than experience the pain.

Many people regarded Cowart's decision as unreasonable. But the fact that he made different decisions than they would make on his behalf does not entail that he was incapable of making his own decisions. Being autonomous means being able to make decisions in the light of one's values and preferences, not having some specific set of values and preferences. Nor should we assume that severe pain renders someone incapable of making decisions about treatment. Provided that he was capable of understanding information about his situation and reasoning about what to do, Cowart was competent to make his own decisions. As we discussed in Section 5.3, if a decision seems unreasonable and is likely to have serious consequences, this gives clinicians a reason to take the time to ensure that it is indeed the voluntary decision of an informed, competent adult. Once they are confident of this, overruling the person's refusal of care would constitute objectionable paternalism.

[69] See also the discussion of physician assistance-in-dying in Chapter 4.

[70] For discussion, see Dax Cowart and Robert Burt, "Confronting Death: Who Chooses, Who Controls?," *Hastings Center Report* 28 (1998): 14–24.

While we acknowledge that cases like Dax Cowart's are challenging for all involved, we think that the ultimate moral verdict is clear: the patient's autonomous decision should be respected. Other cases are harder to resolve. Jodi Halpern describes the case of Ms. G, a fifty-six-year-old woman with diabetes mellitus and kidney failure who had just had a second above-the-knee amputation.[71] Ms. G's husband had informed her that he no longer loved her and was leaving her for another woman. Believing that she would never be loved again, Ms. G refused life-saving dialysis. Here, there was reason to think that Ms. G was mistaken in her certainty about the hopelessness of her postamputation future: she had been equally depressed following her first surgery and yet had recovered to lead a fulfilling life. Should her doctors respect her repeated refusal of treatment?

The first question to ask in cases like these is whether the patient's beliefs are actually unreasonable, in the sense of clearly not being warranted by the evidence. If the patient and her clinicians disagree about her prognosis or overall life prospects, then this does not mean that she is being irrational. Suppose, though, that it is clear that what she is saying is not warranted. The second question to ask is whether she is really expressing beliefs about how the world is or is expressing something else. To say, "No one will ever love me again" might be an expression of one's belief that the future will be as lonely as the present; but it might instead be an expression of just how lonely one feels right now. Such feelings are not in themselves reason to doubt someone's capacity either. Suppose, though, that the patient's statements are unwarranted and are also really expressing beliefs. The third question to ask is whether those beliefs can be swayed by evidence or by having different people talk to her, or whether they will change with time. To attempt to persuade someone in this situation that she is mistaken, and to have multiple people attempt to do so, seems caring rather than objectionably paternalistic. It is as though a man about to cross a shaky bridge is refusing to believe that the bridge will collapse, despite strong evidence to the contrary, and passersby are doing everything they can to persuade him not to continue.

Finally, if a patient is refusing treatment on the basis of unwarranted beliefs that are resistant to change, we must decide whether her decisions should be respected or overridden. Is she competent to make this decision or does her recalcitrant belief render her incompetent and justify soft paternalistic intervention? Here, we think that a responsible clinician faces

[71] Jodi Halpern, *From Detached Concern to Empathy* (New York: Oxford University Press, 2001), 1–4.

a dilemma for which we do not have a ready resolution. On the one hand, it is hard to square acceding to such decisions with the underlying motivation for respecting autonomy – that it allows people to live their own lives in accordance with their own values and preferences. After all, someone cannot actually live her life in accordance with her values and preferences if she is fundamentally mistaken about the facts relevant to making decisions about her life. On the other hand, if someone is incompetent whenever they make decisions on the basis of mistaken beliefs, then this standard risks expanding the scope of incompetence too far. For example, given the complexity of the stock market, it is possible that everyone whose retirement fund includes investments in stocks is making some of their financial decisions on the basis of false beliefs. But surely we do not want to treat all adults of only moderate numeracy as unable to make their own financial decisions.

5.8 Direct-to-Consumer Marketing of Pharmaceuticals

In the majority of jurisdictions around the world, direct advertising of prescription pharmaceuticals to patients, or "direct-to-consumer advertising" (DTCA), is prohibited. The United States and New Zealand permit it, provided certain safeguards are in place. In the United States, in 2014, drug makers spent $4.5 billion on DTCA, including print media, television, and online advertising.[72] The majority of these advertisements are product-specific: they name a drug, state its therapeutic uses, and make claims about its effectiveness and safety. Following FDA requirements, they must also include information about the most significant risks.[73] Most, however, omit other information that might be pertinent to a patient's decision about treatment, such as success rates for the drug, risk factors for the condition, costs, and alternative treatments (including nonpharmaceutical lifestyle changes patients could make).[74] Moreover, like marketing for other products, pharmaceutical advertisements do not rely simply on propositional content but deliver that content in ways that

[72] Jason Millman, "It's True: Drug Companies Are Bombarding Your TV with More Ads than Ever," *Washington Post* (March 23, 2015) (www.washingtonpost.com/news/wonk/wp/2015/03/23/yes-drug-companies-are-bombarding-your-tv-with-more-ads-than-ever/).

[73] Food and Drug Administration, "Basics of Drug Ads" (www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm; accessed September 28, 2020).

[74] Michael Wilkes, Robert Bell, and Richard Kravitz, "Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications," *Health Affairs* 19 (2000): 110–128.

are intended to sway their audience, such as by associating their products with attractive people leading desirable lifestyles.

DTCA has been widely criticized on the grounds that it increases demand for more expensive medications, misleads patients about the risks and benefits of different therapies, leads to inappropriate prescriptions, distorts the doctor–patient relationship, and contributes significantly to the overmedicalization of the US population.[75] In 2015 the American Medical Association adopted a policy that supported a ban on DTCA.[76]

The effectiveness of pharmaceutical advertising in increasing prescriptions for brand-name drugs is not in doubt. Its overall effect on patient well-being is less clear, since that depends on whether a patient population is currently undertreated or overtreated with pharmaceutical products. DTCA seems both to encourage people with serious health conditions to seek treatment and to lead patients to request interventions that are not medically appropriate. For example, a randomized controlled trial sent standardized patients to their primary care physicians with requests for brand-name medications, general requests for medication, or no request at all.[77] The standardized patients reported either symptoms of major depression (for which medication would be indicated) or adjustment disorder (for which medication would not generally be recommended). Requests for medication of any type substantially increased the proportion who were offered "minimally acceptable initial care" for major depression, but also substantially increased the proportion of those presenting with adjustment disorder who were prescribed antidepressants.

In analyzing the ethics of DTCA it is important to separate the question of what individual pharmaceutical companies and advertising agencies should do from the question of how the behavior of these actors should be regulated. We start with the former. Consider a simple case first. In 2008, the FDA wrote a warning letter to Bayer Healthcare Pharmaceuticals regarding two of its television advertisements for Yaz, an oral contraceptive also approved for treatment of premenstrual dysphoric disorder (PMDD) and moderate acne in women choosing to use an oral

[75] For an overview of arguments on both sides, see C. Lee Ventola, "Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?," *Pharmacy and Therapeutics* 36 (2011): 669.

[76] American Medical Association, "AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices" (November 17, 2015 press release; www.ama-assn.org/press-center/press-releases/ama-calls-ban-dtc-ads-prescription-drugs-and-medical-devices).

[77] Richard Kravitz et al., "Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial," *JAMA* 293 (2005): 1995–2002. Note that "standardized patients" here is a euphemism, in that these individuals were pretending to have the symptoms in question.

contraceptive. The letter criticizes the advertisements for suggesting that Yaz would be appropriate for treating the more common and milder premenstrual syndrome (PMS), an indication for which it was not approved.[78] Advertisements that are misleading in this way are straightforward to evaluate. Deception disrespects the autonomy of the people viewing the advertisement, and false beliefs about the safety or efficacy of pharmaceutical products are likely to be detrimental to patient well-being.

Note that, as discussed earlier in this chapter, deception does not have to involve outright lying. If an advertisement does not make literally false statements but implies propositions that are untrue, it is deceptive. For example, if a medication were known to increase the risk of stroke and this information were not revealed in an advertisement, it would be deceptive. It would be deceptive because it is reasonable for a consumer to believe that the major risks of a medication will be stated in a pharmaceutical advertisement, and so the omission of stroke implies that stroke is not one of the risks.

But most of the advertising that is criticized is not outright deceptive in this way. For example, footage of handsome middle-aged people playing sports and picnicking together in the sunshine might engender positive feelings, but it is not (usually) conveying propositional content. Likewise for stirring music, calm colors, and reassuring voices. Following the taxonomy given in Section 5.2, if this advertising is ethically problematic, it is because it involves motivational manipulation.[79] It may dispose people to be positively inclined toward a drug even though they have been given no reason to be so inclined and even though – on reflection – they would likely reject the nonpropositional content of the advertisements as a reason to take the drug.

[78] Food and Drug Administration, Warning Letter (October 3, 2008; available at http://wayback.archive-it.org/7993/20170111082225/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm049750.htm).

[79] Paul Biegler and Patrick Vargas argue that these features of pharmaceutical advertisements are ethically problematic because this nonpropositional content involves evaluative conditioning, whereby a stimulus with positive valence (e.g., the attractive couple picnicking) is paired with something that has neutral valence (e.g., the drug being marketed), thereby transferring its positive valence. Consequently, the authors claim, this leads viewers to develop unjustified beliefs about the efficacy and safety of advertised pharmaceutical products ("Ban the Sunset? Nonpropositional Content and Regulation of Pharmaceutical Advertising," *American Journal of Bioethics* 13 [2013]: 3–13). This undermines the autonomy of the viewers' choices about treatments. We think that the ethical wrong that Biegler and Vargas identify is better captured by the sort of insult to autonomy that motivational manipulation involves – it is pro tanto wrongful because it involves illegitimately bypassing the viewer's rational belief-forming mechanism.

Motivational manipulation illegitimately interferes with autonomous decision-making and so is pro tanto wrongful. It is also liable to reduce the quality of someone's decisions and so reduce the autonomy of those decisions, which is detrimental to their well-being. These consequences are added to whatever the net effects of pharmaceutical advertising are on other aspects of patient well-being – an empirical question and one for which there is probably not a single answer for all products and indications. How are we to evaluate the ethics of this sort of advertising? Since the manipulation is pro tanto wrongful, if there is a way to obtain the beneficial effects without manipulative advertising, that alternative should be taken. The propositional content of the advertisements clearly could be conveyed without the rest – an advertisement could provide the information about the product in a way that is designed to be as neutral as possible. Thus, the burden of proof for an individual company defending its DTCA is to show that the net benefit to patients of the manipulative advertisements is so much larger than the net benefit to them of non-manipulative advertisements that it justifies the affront to autonomy. Though this is an empirical matter, we suspect that it is a high hurdle to surmount.

For individual companies, then, we think it likely that much of their advertising should be more neutral in tone.[80] This does not yet tell us what would be the optimal policy, that is, whether regulations and oversight should be highly restrictive or could be relatively lax (as they currently are in the United States). Set aside the substantial legal difficulties that would stand in the way of restricting nondeceptive advertisements in the United States, where commercial speech is protected by the Constitution. Still legislators would have to address additional empirical questions. To what extent would restrictions on DTCA affect the overall volume of pharmaceutical sales? What difference would this make to longer-term research and development priorities? Would lower levels of prescriptions be overall beneficial to society or detrimental? We do not have the data and economic models to provide an answer to these questions here.

[80] Note that this judgment applies well beyond pharmaceutical advertising. Any company whose marketing predictably makes consumers' decision-making worse will be acting in a way that requires ethical justification. Some people will find it implausible that so much marketing could be unethical. We challenge them to explain why it should be ethically permissible to undermine someone's decision-making without their permission and without counterbalancing benefits to them. As with pharmaceutical advertising, of course, how such marketing should be regulated is a distinct question.