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Just Caring: Parsimonious Care in Certain Uncertain Circumstances

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JUST CARING: PARSIMONIOUS CARE IN CERTAIN UNCERTAIN CIRCUMSTANCES

Uncertainty is a Hydra-headed phenomenon in health care. From a physician's perspective there often is uncertainty (many degrees) with respect to diagnosis (and the reliability of the technologies needed to establish a diagnosis), prognosis (and the infinite variety of genetic, physiological, pharmacological, behavioral, technological, economic, and cultural factors that affect the outcome of prognostic judgments),[1] the appropriateness of a therapeutic intervention (perhaps related to medical disagreement as documented in Wennberg research (1973) on small area variations in medical practice), the likely effectiveness of a therapeutic intervention, the risk/ benefit ratio of a therapeutic intervention (potentially complicated by co-morbid conditions), the likelihood of a patient complying with the behaviors needed to maximize the likelihood of a therapeutic outcome, the applicability of a clinical guideline to *this* patient in the clinic, the reliability of the evidence and research behind that guideline, the quality and reliability of other caregivers (formal and informal) whose effort is integral to the successful implementation of a therapeutic intervention, and, finally, the sheer randomness of natural events at various levels in the health care encounter. That is the background for this presentation.

Our question, however, is this: How should we address all this uncertainty in the economic/ political context of having to do health care rationing, and in the ethical context of having to do that rationing justly? Our working assumption, very widely endorsed, is that the need for health care rationing is inescapable because we have only limited resources available

[1] Smith et al. (2013) write: "The quest for prognostic certainty has been described by our colleague Dr. Faith Fitzgerald as the 'punctilious quantification of the amorphous.' In other words, no matter what we do, there will always be some uncertainty in prognosis." For an excellent overview of the sources and structure of uncertainty in medicine see Hatch (2016). For one model of how to address the problem of health care rationing in the context of medical uncertainty see Moreira (2011).

(money) to meet virtually unlimited health care needs (generated by expanding medical technology possibilities.)[2] Emerging medical technologies, more than anything else over the past fifty years, has contributed to the problem of escalating health care social costs. To provide some statistical background for appreciating the magnitude of this problem, total health care spending in the US in 1960 was $26 billion or 5.2% of GDP (or about $205 billion in 2015$). In 2015 total US health care spending was about $3.2 trillion, or 17.6% of GDP. Projections to 2024 estimate national health spending at about $5.4 trillion, or about 20% of projected GDP (Keehan et al., 2015).

To further complicate from an ethical perspective the problem of escalating health care costs, health care needs are not evenly distributed across the population. The 5% of the population with the greatest health needs consume about 50% of total health spending in any given year (Weismann, 2012). If we need to constrain health care spending, that group would be an obvious focal point. But they also have the greatest and most serious health care needs, which would suggest for many that they ought to have the strongest just claims to health care resources, as opposed to being the focus of efforts to save money by denying care. However, relative to the focus of this essay, physicians will attest that for very many of these patients they are *certain* that the costly interventions needed by these patients will be effective in restoring them to good health. Of course that means in other cases physicians are *uncertain* that many of these costly

[2] There are long-standing debates regarding a definition of rationing. Those debates cannot be rehearsed here. I am inclined to follow Ubel (2000) and endorse a broader rather than a narrower definition of rationing. Hence, rationing occurs whenever patients are denied access to beneficial health care (even if the benefits are only marginal), either explicitly or implicitly, in order to save money for an institution, an insurance company, an employer, or the government. The chapter in which Ubel discusses a reasonable definition of rationing is accurately titled "The Politics of Defining Health Care Rationing." No one wants to be associated with endorsing making rationing decisions (recall Sarah Palin's rhetoric of 'death panels'), which is why politicians and insurance executives and physician groups prefer very narrow definitions of rationing that exclude from that rubric their favored approaches to controlling health care costs.

interventions will achieve very much at all in the way of health benefit for these patients. The ethical question for us is whether that uncertainty is ethically relevant in determining whether these latter patients have just claims to costly resources when there is considerable uncertainty regarding both the likelihood of benefit and the magnitude of that benefit.

Another population group that makes disproportionate claims on health care resources is the elderly. In the US in 2015 those over age 65 represented about 13% of the population but they were responsible for 35% of health care expenditures that year, roughly $1.1 trillion. But we are faced with a growing population bulge from World War II that will result in the growth of that elderly population from about 43 million in 2015 to about 80 million in 2030, or about 20% of the projected population. The consequences of that are best reflected in actual and projected Medicare spending. Medicare spending in 2015 was about $650 billion. Projections for the ten-year period (2015-2024) put aggregated Medicare spending at about $8.3 trillion (Keehan et al., 2015). Not all Medicare patients are equally needy despite advanced age. On the contrary, the top 1% will actually be responsible for 20% of Medicare expenditures. As above, much of that spending will be very effective in yielding substantial health benefit for seriously ill patients in that age cohort while in many other cases there will be great costs and great uncertainty regarding proposed health care interventions for individuals in various health circumstances.

In my own work the health care cost containment problem is what I have referred to as the "Just Caring" problem (Fleck, 2009). That is, how can rationing be done justly *and* in a way that is congruent with our basic sense of compassion, especially if those patients are among the medically least well off? Further, we can imagine having to address the health care rationing problem at either the level of public policy or at the clinical level. At the policy level decision makers are distanced from the consequences of their decisions, such as statistical lives lost as a

result of policies designed to save money by, for example, denying $40,000 implantable cardiac defibrillators to patients in heart failure who were not likely to survive another two years. That is, the painful consequences of their choices are invisible to them as policymakers. That is what is not true at the clinical level wherein a clinician will have to face very directly the consequences of her decision, that is, an identified patient whose life will be shortened because that clinician will be expected to provide care parsimoniously, i.e., in some cases deny patients with metastatic cancer $100,000 drugs that might yield only a few extra months of life.

For the past several years there has been increasing emphasis on the obligation of physicians to provide parsimonious care, i.e., the prudent and cost-effective use of health care resources in caring for individual patients. Needless to say, this has become the focus of considerable controversy. This controversy was precipitated by a statement in the Ethics Manual of the American College of Physicians that read: "Physicians have a responsibility to practice effective and efficient health care and to use health care resources responsibly. Parsimonious care that utilizes the most efficient means to effectively diagnose a condition and treat a patient respects the need to use resources wisely and to help insure that resources are equitably available" (American College of Physicians, 2012). The last part of the quotation calls attention to the key moral justification for this directive, i.e., the need to protect *equitable* access to needed and effective health care for all. But critics respond that this directive represents an unethical compromise of the obligation of physicians to be loyal and uncompromised advocates for the best interests of the patient before them now.[3]

[3] Tilburt and Cassel (2013) will try to bypass the "loyalty objection" by arguing that parsimonious care is all about delivering health care more efficiently without any loss of quality, hence, no threat to the best interests of patients. They deny that parsimonious care is a form of health care rationing. I have argued in another essay (Fleck, 2016 forthcoming) that they are mistaken in this claim. There are, I argue, some instances of parsimonious care that are not instances of rationing. But there is in practice a very large overlap between what advocates describe as

We will have to address the "loyalty objection" later in this essay, though my view is that the need for bedside rationing is inescapable, just as a practical fact of medical life (Fleck, 2015). I have also argued elsewhere, given the complexity and uncertainty that is an inherent feature of the practice of medicine, that the best physicians can hope to do, ethically speaking, is to achieve "rough justice" with respect to bedside rationing decisions. That still will leave us with the central question of this essay: How much uncertainty with respect to various more or less serious health care consequences is ethically acceptable, i.e., "just enough," when bedside rationing or parsimonious care decisions are made?

Finally, there is the question of whether such decisions should be either *implicit* or *explicit*. "Implicit" means, in practice, that such decisions are essentially hidden from patients at the time medical care is provided. "Explicit" means, in practice, that these decisions are made with patient awareness at the time medical care is provided. Thus, an insurance contract or managed care contract that stated that care would be provided in the most efficient way possible consistent with standards of high quality medical care in order to control the costs of insurance for their clients would not satisfy my understanding of explicitness in this context because its application in any particular clinical context is utterly vague, certainly from the patient's perspective.

To focus discussion and analysis, some scenarios:

SCENARIO 1

parsimonious care and what is in fact health care rationing, i.e., denying patients marginally beneficial non-costworthy care.

(1) DRGs [Diagnosis-Related Groupings] were put in place in the Medicare program to control hospital costs. This is a fixed prospective payment calculated to cover adequately the average cost of a patient cared for under that DRG. If hospitals can treat a patient for less than that amount, they get to keep the profit. If care of that patient costs more, the hospital must absorb that loss. First-time uncomplicated heart attack patients used to be kept in the hospital for ten days (prior to 1984); under the relevant DRG (post 1984) such a patient is expected to be released within four days. However, what is known statistically is that some (relatively small) number of those patients will have a second heart attack on days 5-10. If they live some distance from the hospital, they will likely die. If they had still been in the hospital, they are more likely to have survived.

Is there an injustice here if a physician discharges a patient on day 4 being reasonably confident that the patient is stable enough? Is it ethically relevant that no particular type of patient is any more at risk under the DRG system than any other type of patient? That is, there is risk and uncertainty associated with discharging a patient from the hospital who had been very seriously ill because the financial incentives built into DRGs motivate that discharge. For most such patients permitting additional hospital days might reduce the risk of a potentially fatal adverse event outside the hospital to near zero. So those additional days might represent a net benefit for such patients, though that benefit is likely to be very marginal and very uncertain. Still, it is a benefit denied patients under DRGs *for the sake of saving money for both the hospital and the government*, which is to say such discharges are

correctly described as instances of rationing. Hence, something needs to be said by way of justifying the denial of that benefit.

It needs to be noted that physicians are ethically obligated to resist administrative economic pressures to discharge patients on the expected DRG day if those physicians believe those patients need additional hospital care (and are at significant risk of serious avoidable harm if denied those days). But if physicians are reasonably confident that specific patients in specific medical circumstances are very unlikely to suffer harm by being discharged in accord with typical expectations under a specific DRG, then physicians have not treated those patients unjustly in cooperating with the rationing scheme that is the DRG system. Put another way, if there is reasonable uniformity in the treatment of patients under DRGs, then from a moral point of view all will be roughly equally at risk for some adverse health event if discharged in accord with DRG expectations. In that respect we have rough justice of an egalitarian variety. There will be a small number of adverse events for patients, but those will be correctly described as being unfortunate, not unjust.

The assumption here that is part of the justification is that the risk of an adverse event is somewhat remote, which is to say that it is in the statistical vicinity of a serious automobile accident. If individuals freely assume the risks of driving and see such risks as reasonable, and if hospital discharges under DRGs create no greater risk than that (or other such risks people routinely assume), then there is nothing intrinsically unjust about using DRGs to control hospital costs. Again, what would alter the ethical legitimacy of this conclusion, using our heart attack scenario above, is if medical research identified some biomarker that predicted with 80% confidence

that some small set of patients were likely to experience a second serious heart attack within, say, two weeks of that first. If physicians (perhaps under administrative pressure) avoided testing these patients in this DRG for that biomarker and continued to discharge patients on day four, then those patients at that very elevated risk would have been treated unjustly.

SCENARIO 2

(2) Implantable cardiac defibrillators [ICDs] are intended to prevent sudden death from an arrhythmic event. Total cost is about $40,000 per procedure. Roughly 200,000 ICDs per year are implanted in the US at a total cost of about $8 billion. Roughly 80% of these devices never fire over a five-year period, which means they yielded no health benefit at all (Pauker, 2005; Kadish and Goldberger, 2011; Al-Khatib et al., 2011). Another 10% will fire inappropriately (no life-threatening arrhythmia), thereby causing some degree of harm. After five years the battery in these devices needs to be replaced. This is another $20,000 surgical procedure. If we have unlimited health care needs in the US and only limited resources to meet those needs, then prioritization decisions need to be made regarding which needs will be met and which will go unmet. If 80% of these ICDs do no medical good, then those implantations (in theory) should have no priority at all. The problem, of course, is that before the fact we have no idea which patients are in that 80% category. Moreover, only 10% out of that entire cohort are actually saved from premature death by this device. But we are completely uncertain who those 10% are.

We could choose to implant none of these devices. We could save $8 billion that way but we would likely be sacrificing 10,000 lives per year to save that money. On

the face of it, that choice appears to be neither just nor caring. Alternatively, if we have a medical test that can identify with 98% accuracy who is unlikely to have an arrhythmic event over the next two years, and if that can reduce by 30% the number of ICDs implanted (thereby saving $2.4 billion per year), but if that includes 1200 arrhythmic deaths [2% of 60,000], is a physician or managed care plan or government that implemented such a test as part of a parsimonious care strategy behaving unjustly?[4]

One response to this situation might be to emphasize the need for shared decision making. Let patients and physicians decide what they judge to be in their best interest. If this decision were just about the risks and benefits associated with the procedure itself, that would be a perfectly reasonable choice. But social resources, and their just use, are at stake, not just private resources. Some sort of social warrant is necessary to justify the use of those resources as a just use of those resources.

Conservative writers might invoke a "magic of the market" strategy to avert any sort of institutional or governmental rationing decision. They might insist that individual patients who were candidates for an ICD as a preventive measure should be responsible for 30% of the cost of that ICD. The argument, in brief, is that if it is not "worth it to them," then it is not worth it for society either. In other words, individuals would make their own self-imposed autonomous rationing decisions. The appeal to autonomy suggests a very strong sort of ethical justification. However, two other sorts of considerations speak against this proposal.

[4] I will note that such a test has actually been described in the medical literature. It is referred to as a T-wave alternans test. But it has been the focus of medical controversy as to whether it is as accurate and reliable as its advocates claim. We will not try to assess the competing arguments. Instead, we will simply stick with our hypothetical example, though mindful it has relevance to the real world. It is not entirely a philosophic fantasy.

Unlike our DRG analysis above where everyone under any specific DRG equally shares the risk, this proposal imposes all the risk on those who are financially less well off. For at least 80% of those who are financially less well-off this proposal would have no health consequences; they would not die prematurely as a result of an arrhythmic event. But 10% would die prematurely while that same 10% in those financially better-off would have their lives saved. It can be argued, certainly from an egalitarian perspective, that that represents an injustice. But there is an additional problem. Those who are financially less well-off are still paying taxes or insurance premiums that effectively subsidize 70% of the costs of an ICD for those who are financially significantly better-off. That is a very clear injustice (at least outside the fantasy world of Donald Trump).

There is another alternative, which I have often appealed to as offering a fair and reasonable approach to addressing these sorts of rationing decisions (Fleck, 2009). That is a process of rational democratic deliberation. Space does not permit a very thick description and justification for this process, but a brief description might be adequate. We have to imagine a representative body of ordinary citizens in good health making cost containing/ rationing policy choices for their future possible less healthy selves in their Accountable Care Organization or as recipients of Medicare or Medicaid coverage. They want excellent, effective, costworthy health care but within budgetary constraints so that costs to them in the form of taxes or insurance premiums to pay for the system as a whole are constrained. Choices will have to be made; priorities will have to be set. Not everything medically possible can be paid for from the common fund with which they are entrusted. Their deliberations are informed by

all the necessary expertise and evidence they would need to make responsible and reasonable choices, though there will remain many kinds of uncertainty that they will need to take into account. They are in many respects excellent impartial Rawlsian deliberators because their own future health care needs are largely unknown to them. They understand that they are binding themselves and their loved ones to the policy choices that they make. So their rationing choices would be autonomously self-imposed as a product of a fair deliberative process.

These deliberators could choose to fund as many ICDs as we do today, but they would have to consider how high a priority that choice ought to have relative to all other costly life-prolonging medical interventions that might be available as well, and that might do much more medical good. They could also choose to save $2.4 billion annually by endorsing the use of the discriminating test mentioned above, understanding that 1200 statistical lives now (real lives at the end of the year) would be sacrificed to secure those savings. If this risk of death is randomly distributed across all those denied access to an ICD at social expense because of this rationing protocol, then such premature deaths are unfortunate but not unjust.[5] Wealthy individuals could still buy an ICD for themselves. Permitting such a choice would not be unjust because no one is made worse off as a result of allowing this choice. In addition, there could be no social subsidy for that choice, such as a tax deduction.

SCENARIO 3

[5] Societies make decisions like this all the time, though they are hardly widely publicized. About 2000 individuals die each year at grade-level railroad crossings in the US. Those lives could be saved if we were willing to spend $200 billion or more to separate such crossings with underpasses or overpasses. But we do not make that choice because we have other priorities.

(3) Imagine a 92-year old with three-vessel coronary blockages greater than 80%. Bypass surgery ($80,000+) would address that issue, though there is a very significant chance (let's say 30-40%) the patient would die in surgery or very shortly thereafter. As things are now, as long as the patient understands and accepts these risks, we respect patient autonomy. But from the perspective of a commitment to parsimonious care this looks like a poor use of social resources. Under what circumstances is denial of bypass surgery to this patient for reasons related to the fair allocation of resources judged correctly to be "not unjust"?

Though I have provided this scenario as a case example, it is intended to be indicative of a broader problem. Specifically, the recent medical literature, especially the surgical literature, is filled with research regarding complex life-prolonging surgeries being performed on the hyper-elderly, patients in their late eighties, nineties, and beyond (Speziale et al., 2010; Greason et al., 2015). As one might expect, the outcomes have been mixed. There are very elderly vigorous individuals who will tolerate such surgeries with predictably good results, such as several extra years of reasonable quality life. Then there are frail elderly who may survive the surgery, but have very long and very costly recovery periods with diminished quality in their relatively brief remaining life.[6]

[6] Though the term 'frail' is a common term in English it has been given a much more sharply defined medical meaning in the past ten years or so. There are several different indices used to characterize frailty, but the general idea is that the frail elderly are unable to recover (or recover in a reasonable timeframe) as a result of major insults to the body, such as more complicated forms of surgery (Walston, 2015; Collard et al., 2012). Complications from surgery are more common, more serious, and more difficult to manage (Suskind et al., 2016). In one study (Heyland et al., 2015a; Heyland et al., 2015b) it was found that only 25% of patients over age 80 admitted to the ICU survived and returned to baseline levels of physical function at one year. See also Crippen (2015) on this point who writes: "Lawyers say that 10 guilty persons should be let go to avoid convicting one innocent. Similarly, in medicine, physicians believe that 10 patients with poorly predicted outcomes should have everything done in order to avoid terminating the life of one who might unexpectedly survive." The view in the quoted passage is one that Crippen rejects.

A prominent example in this latter category would be Dr. Michael DeBakey, prominent cardiac surgeon. He was diagnosed with a dissecting aortic aneurysm at age 97. He was not keen on surgical repair but friends and family persuaded him to have the surgery. He spent eight months in the hospital recovering from the surgery at a cost of more than a million dollars in 2006. He died one year later. Did Dr. DeBakey have a just claim to that intervention? Would he have been treated unjustly if he had been denied the surgery? Again, social resources are at stake; this is not simply a matter of shared decision making where a patient assesses the risks and benefits from their personal value perspective.

My claim is that appropriate limits could be determined through a process of rational democratic deliberation as described above. Here is one possible proposal. Very elderly patients who are medically categorized as being frail would be denied access to a specific list of complicated life-prolonging surgeries at Medicare expense if the surgeons were 80% confident that that patient would likely not survive another year with at least the same quality of life as prior to the surgery. Some surgeons may argue that they have seen cases such as this where they would have bet $100,000 that this patient would not survive a year after the surgery, but they ended up surviving another five years in a somewhat fragile state of health that was acceptable to them.

But the appropriate response to that argument is to ask what the practical implication is supposed to be. It would seem to be that surgery would have to be offered to all these frail patients, regardless of cost or likelihood of significant benefit because a surgeon could never be *certain* that patient would not survive a year. This might appear to be an "ethically safer" course of action, but in fact it would not be.

This results in a very distorted allocation of life-prolonging resources toward the hyper-elderly because the structure of the Medicare program and the taxes that support it are at the expense of public willingness to support further expansions of health reform aimed at securing assured access to necessary and effective and costworthy medical care for the currently uninsured and underinsured in our population. This is clearly an unjust outcome. The frail hyper elderly may be among the medically least well off, but it is also the case that they are among those least likely to benefit from access to the expensive care they need.[7] By way of contrast, the uninsured or underinsured non-elderly may not be as medically less well off as the hyper elderly, but they are much more capable of benefiting *and they have much more to lose if denied the medical interventions they need.*

SCENARIO 4

(4) Imagine a 15-bed ICU filled with patients who very much need intensive care. But a 56-year old patient from a very serious automobile accident is being treated in the ER and will need to be admitted to the ICU. With excellent ICU care there would be a 90% chance of full recovery to his former state of health. If he were placed in a non-ICU bed his chance for full recovery might be diminished to 70%. There is a 73-year old patient who has been in the ICU for 12 days with an end-stage metastatic GI cancer following a third line of targeted cancer therapy. Ideally, he needs another four days in the ICU. He is likely to survive this ICU stay but would have less than a 5% chance of surviving another two months. Would it be unjust to remove him from

[7] I discuss the ethical complexities associated with identifying the just claims to needed health care of those who are described as being among the "medically least well off" in an earlier essay (Fleck, 2011).

the ICU in favor of our 56-year old patient, even though both our 73-year old patient and his family are refusing removal and placement in a hospice program?

The assumption behind this scenario is that the 73-year old might not even get those two months if he is removed from the ICU. Is that an injustice? Does the 73-year old have a just claim to get the maximal benefit that he is capable of before giving up that ICU bed? Or is the 56-year old a victim of a greater injustice because he has more to lose?

The American Thoracic Society (1997) issued some ethical guidelines regarding access to an ICU bed when the ICU was full and patients outside the ICU needed admission. They endorsed a "first come, first served" rule as yielding the fairest result. That rule makes some ethical sense if we imagine that those already inside the ICU and those needing admission to the ICU are roughly equally needy and roughly equally likely to benefit from ICU care. It also is ethically reasonable even if we imagine that the patient outside the ICU *might have a somewhat better prognosis*. There is uncertainty there but it may not be sufficient to justify removing one patient from the ICU in order to admit another who might have a somewhat better prognosis. But it seems less ethically reasonable to interpret that rule in a strict sense when an occupant of an ICU can get no more than very marginal benefit from continued use of that bed while a patient at the door of the ICU could suffer very substantial loss (premature death) if denied access to that ICU bed (though we have to add there might something less than absolute certainty regarding prognosis for this latter patient).

What I will argue is that a reasonable resolution of these sorts of conflicts could be achieved through rational democratic deliberation. What set of rules and policies would such a deliberative group endorse when they consider that their future possible self (or that of a loved one) might be either that 73-year old already in the bed or the 56-year old needing access to that bed? And what level of clinical prognostic certainty would they want attached to such judgments in either case? The outcome of such a deliberative process would likely satisfy both egalitarian and utilitarian conceptions of health care justice while a strict application of the "first come, first served" rule would more often than not satisfy neither.

SCENARIO 5

(5) PCSK9s are LDL cholesterol lowering drugs. They are dramatically effective in lowering LDL (bad cholesterol) but they cost $14,000 per year and would be taken for the rest of an individual's life. Roughly 73 million Americans have LDL readings above 100 mg Dl, the point at which LDL lowering drugs are usually prescribed to reduce risks of strokes and heart attacks. These drugs can drive LDL down to the 30-50 mg Dl range. Roughly 19 million Americans are thought of as being at significantly elevated risk because of very high LDL levels (greater than 130 mg Dl). But if 19 million people were placed on PCSK9s, that would add $280 billion per year to the cost of health care in the US. Some statins can reduce LDL by 17% at a cost of a few hundred dollars per year, compared to PCSK9 LDL reductions of 45%--73%. What is unclear and uncertain is the number of heart attacks and strokes prevented by that more dramatic lowering of LDL [See Gutierrez et al, 2015].

Imagine a 63-year old with an LDL of 90 who wants to be placed on a PCSK9 because some evidence suggests his 10-year risk of a heart attack or stroke would be reduced by 0.1%. Would it be unjust to deny him access to this drug at social expense because it would be far from certain that *he would benefit* from this drug? Statistically speaking, we would have to say that *someone like him in clinically relevant respects* would benefit out of a thousand patients like him, the rest of whom would almost certainly not benefit. If we were ethically obligated as a matter of justice to prevent that heart attack or stroke in one of those thousand individuals, all one thousand would have to receive that drug at an annual cost of $14 million, or $140 million for that ten-year period. Given limited resources (money), and virtually unlimited and unmet health care needs (uninsured), it would be neither wise nor just to use social resources to reduce the risks described above. If our concern is to reduce the risk of morbidity or mortality associated with stroke or heart attacks, there would be too many other ways those same dollars could be spent to achieve that same purpose with hugely greater positive results. This too is an outcome that would be endorsed from both egalitarian and utilitarian perspectives. Individuals would be free to purchase these PCSK9s with their own unsubsidized resources because no one is made worse off by permitting such private purchases. But they could not justifiably claim that they had suffered an injustice if denied access at social expense.

SCENARIO 6

(6) There are now about 70 precision cancer drugs that target various genetic features of various metastatic cancers with costs of $70,000 to $150,000 or more for a course of treatment. They typically yield median gains in life expectancy measurable in weeks

or months. They typically fail in most patients either because of the genetic heterogeneity of the cancer or because cancer drug resistance develops, causing the drugs to become ineffective. There are roughly 600,000 cancer deaths each year in the US. A small number of patients are "super-responders" to these drugs. They gain multiple years of additional life instead of just a few months. Research is beginning to identify various biomarkers that would mark out these super responders, who obviously represent a better investment of social resources. Similar research might identify those who would be very minimal responders (a few weeks gain in life expectancy). Everyone else might be regarded as moderate responders (gains in life expectancy of two to eleven months). Should all these individuals have an equal just claim to whichever of these drugs might prolong their life a bit? Or would it be "just enough" if the drugs were only made available at social expense to individuals for whom biomarkers analysis predicted with a reasonably high level of confidence (80%) that these individuals would gain at least an extra year of life?

Overall, median gains in life expectancy associated with these drugs are about three months. But obviously there is a range around that median. What I referred to above as "moderate responders" occupy the bulk of that range. So there is considerable uncertainty regarding where any individual will fall within that range. The ethically and psychologically challenging problem associated with that range is that it does represent *some degree of effectiveness*. It is easy enough to think that most patients might imagine something like this: "My physician told me this drug might only give me two extra months of life, but it might also yield 10 months. I

would like to believe I might be at that higher end; that much extra time is worth it to me."

As noted above, if this were merely a matter of shared decision making, this would be the end of the conversation. But social resources are at stake, so questions of justice are clearly relevant. One important thing to consider is that if anyone with metastatic cancer has a moral right or just claim to these drugs, then everyone in similar circumstances would have that same right, at least from an egalitarian perspective. If the average price of these drugs is $100,000 for a course of treatment and 600,000 patients die of cancer each year in the US, total annual expenditures for these targeted therapies would come to $60 billion. We could go back to a "market approach" and require a 30% co-pay for anyone who believed that this was "worth it to them" for whatever gain in life expectancy they might gain. But that just brings back our earlier problem, namely, that those who were financially less well off, at least the lower half of the income spectrum, would be subsidizing with their health care premiums or taxes the 70% costs for those who were financially much better off. This seems obviously unjust from the perspective of multiple considerations of health care justice.

There is a possible policy response to that problem. The rule could be that neither Medicare nor Medicaid nor private insurance plans would pay for any of these targeted therapies as part of a comprehensive basic insurance plan guaranteed to all in our society because the cost was so great and the likely benefits were so marginal and so uncertain. Individuals, however, would have the right to purchase special "add-on" insurance riders for maximal cancer care at whatever price insurers would charge,

if insurers were willing to create such riders. Individuals would have to purchase such insurance when they were cancer-free, meaning that they had never had cancer, nor was there genetic information suggestive of elevated risk for cancer. If there were such predisposing genetic information, insurers could adjust their rates to reflect increased economic risk to themselves. Under these circumstances those who were financially less well- off would not be subsidizing those who were financially much more well-off. On the other hand, those who might otherwise turn out to be super responders to these drugs would not know before the fact that they had much more to lose than most others. This is because the relevant genetic data is related to genetic features of their cancer and its vulnerability to one of these targeted therapies. Still, the financially well-off would have the insurance (presumably), and in that respect the super responders among them would have that advantage over the potential super responders among those less well off.

Perhaps we should accept this last outcome as a matter of "rough justice." A judgment such as this could be left to a rational democratic deliberative process as described above. This would also be true for the question of whether there ought to be public funding for research that was aimed at better identifying biomarkers that would permit better stratification of patients into various tiers of responsiveness to these drugs. Of course, what will remain is the ethical challenge of marking off boundaries for possible survival strata. It is unlikely there will be bright lines given by the genetic data; there will remain an undivided continuum of responsiveness.

With these various cases in mind we can return to our broad question: When, if ever, should considerations related to the certainty/ uncertainty of treatment efficacy and outcomes be

regarded as a justice-relevant consideration that would potentially justify denying individuals access to these interventions at social expense? In this essay we cannot hope to provide a complete answer to this question, but we should be able to articulate a framework for considering this issue more justly than is currently the case in medical practice and health policy.

There are several ethical arguments often made that effectively minimize the ethical relevance of uncertainty in making rationing/ allocation choices. Most often the context of these arguments involves what is regarded as the risk of a "premature" loss of life or other serious medical harm that might be averted. The gist of these arguments is that we (society, Medicare/ Medicaid, a managed care plan) are ethically obligated to spend whatever it might take to save/prolong a patient's life so long as that effort is not clearly futile or so long as that effort is not virtually certain to leave a patient much worse off than would otherwise be the case. The most obvious situation where these arguments might be invoked would be with the targeted cancer therapies mentioned above in connection with metastatic disease.

Very briefly, appeal might be made to the Rule of Rescue argument, i.e., we cannot just let someone die if we have the ability to rescue them (though no guarantee the rescue will be successful), no matter what the cost. The Rule of Rescue is feasible so long as it is only rarely invoked, which is typically the case outside medicine. But within medicine the need for "rescue" is ubiquitous. The vast majority of people who die each year in the US would be candidates for costly rescue, and the vast majority of them would likely have already been rescued several times before dying (think cancer, heart disease, COPD, kidney failure, diabetes etc.) at great cost. This is simply the clear consequence of the successful development of all manner of life-prolonging technologies over the past fifty years. If the Rule of Rescue were rigorously used, there would be a huge misallocation of health care resources that would hardly be just or justified. That is,

we would be purchasing very marginal gains in life expectancy (and very diminished quality of life), denying effective resources to those who were "merely suffering" from disorders such as rheumatoid arthritis. An outcome such as that would be neither just nor caring.

Essentially the same considerations undercut the moral legitimacy of appeals to the "pricelessness of human life" or to the special moral status of "last chance therapies." The implication of the appeal to "last chance therapies" is that an individual is faced with imminent death and no alternative other than some last chance therapy. The practical problem (and the ethical problem) is that it is extremely rare that a last chance therapy restores someone to full health and extra years of life. The more common scenario is the story of Mr. Krieger, 88 years old, advanced dementia, late-stage heart disease, brought to the ER septic; the cost of his care was $323,000 for the last ten days of his life. Politically and rhetorically, it might be desirable to use a case such as that to call attention to how compassionate we are as a society for each and every life, but ethically and economically it would be disastrous (unjust, untrue, and unaffordable). Was there a chance (maybe 1%) that Mr. Krieger could be restored to his former demented self? Yes! From the perspective of health care justice should the effort to save Mr. Krieger have the same moral weight as saving a 46-year old (80% chance) from a genetically determined heart disease with a $300,000 artificial heart? No! Both are last chance therapy situations or situations where the rule of rescue could be invoked, but reasonable considerations of health care justice would require one and speak strongly against the other.

An appeal might be made to the distinction between identifiable lives and statistical lives, as if there were morally relevant certainty with regard to the first and considerable moral uncertainty with regard to the latter. That, however, is for the most part a moral illusion, especially if we believe that there are intrinsic ethical considerations such that it is always

ethically worse to sacrifice an identifiable life for the sake of a statistical life. There are circumstances in which there is such an ethically significant difference, but this is because the distinction is linked in a specific context to other ethically relevant factors that are the source of that difference (Brock, 2015).[8]

David Mechanic (1992) is a strong advocate for the ethical (and political) virtue of implicit rationing as opposed to explicit rationing. He accepts the premise of this essay that the need for health care rationing is inescapable. He is also very sensitive to the multiple kinds of uncertainty that characterize the practice of medicine. He writes, "Implicit rationing, despite some obvious limitations, offers the best opportunity to allocate care effectively in the context of uncertainty, a changing knowledge base, and heterogeneity in the American population and in patterns of illness (at 1722)." He acknowledges that this could erode trust between physicians and patients (assuming patients were aware that this was how things would work). But then he adds, "While troublesome, this disadvantage is more palatable than the lack of understanding and insensitivity likely to result from explicit rationing decisions in a micro-management mode by persons removed from the complicated situations and emotions associated with illness and the help-seeking process (at 1722)." One obvious critical question to ask would be: "more palatable to whom?" Implicit rationing would surely be more psychologically palatable to physicians and politically palatable to politicians or health care administrators who would not want to be thought of as members of any sort of "death panel." This response, however, entirely ignores the

[8] Paul Menzel (2015) is also a critic of the claim that there is an intrinsic moral distinction between saving identified versus statistical lives. See also the essay by Norman Daniels (2015) as well as other relevant essays in the volume edited by Cohen, Daniels, Eyal (2015).

question of whether such an arrangement would be ethically flawed from the perspective of health care justice.

As Rawls (1971; 1993) has argued (and as I have argued as well (Fleck, 2009)) publicity (visibility, transparency) is essential to just policies and practices, and to strengthening the bond of trust between physicians and patients when the need to make resource allocation decisions is inescapable. Some have argued (Sulmasy, 1992) that rationing decisions need to be made at some higher social or political level, not by physicians at the bedside. But Mechanic recognizes (as do I) that all such decisions must ultimately be made in practice at the bedside by physicians caring for individual patients (because no policy can be articulated that can be reasonably and justly sensitive to all the possible clinical details and uncertainties associated with caring for an individual patient). Further, what this implies is that while all of us as future possible patients want our physicians to be loyal to our best medical interests, we actually have a moral right only to their loyalty to our *just* best interests.

What should be regarded as the "just" best interests of patients in relation to all of our scenarios above, given all the uncertainties associated with the practice of medicine, and given the need to make various sorts of rationing/ parsimonious decisions regarding the care of individual patients. I have argued elsewhere (Fleck, 2009) that there is no simple answer to this question, that there are multiple conceptions of health care justice that might be invoked reasonably to yield concrete answers to these challenges. Further, there is no obvious theoretical reason why only one conception of justice must be used consistently to address all the complex rationing options that might present themselves. That is, there are no compelling arguments why we must be consistent utilitarians or strict egalitarians or prioritarians in addressing the entire range of health care rationing issues. One major reason why this is the case is what Rawls

(1993) has referred to as the "burdens of judgment." Consequently, what we need to rely upon instead are fair processes of rational democratic deliberation constrained by what I refer to as "constitutional principles of health care justice (Fleck, 2009, chap.5)." The ethical virtue of such an approach is that it yields rationing policies and protocols, along with their rationales, that are explicit and self-imposed.

As David Eddy (1996, Chap. 14) has noted, all of us are of two minds (internally) when it comes to issues of health care rationing and cost control. As taxpayers and insurance premium payers we want health care costs controlled because we want to be able to use our own resources for goods other than health care. But as patients, especially patients faced with a likely terminal illness, we want to have spent on our behalf (by our insurer) any amount of money that can purchase any sort of health care that might offer a chance, however small, of life-prolongation of acceptable quality. The critical ethical insight that motivates the deliberative process is that if I believe it is waste of money to spend $323,000 for Mr. Krieger (a stranger to me) for just ten extra days of life in advanced dementia, then I must be willing to say, as a matter of fairness, that if I were in a comparable situation, perhaps wanting to have spent on my behalf $156,000 for a course of nivolumab [Opdivo] for my metastatic non-small cell lung cancer for a chance for a median gain of three extra months of life, then I would have to be willing to deny myself that drug as well since I would be a stranger to all the others who would be bearing those costs. This same sort of argument will apply to our PCSK9 example or our ICD example or risky, complex, marginally beneficial surgery at a very advanced age.

The deliberative process will often be able to generate several options with respect to a particular rationing problem that all might be regarded as being "just enough," or what can be termed "rough justice." There is nothing intrinsically unjust about choosing, for example, to

fund nivolumab for a three-month gain in life expectancy. But we would need to realize that the economic implication of such a choice is that we are valuing that additional life expectancy, from the perspective of a Quality Adjusted Life Year [QALY] at about $600,000. The ethical implication of that (ethical consistency) is that every other anti-cancer drug that had a QALY value of less than $600,000 would have to be funded as well (since there is nothing ethically relevant that would distinguish nivolumab from seventy other targeted cancer therapies that currently have FDA approval). More than that, there is nothing ethically special about cancer, as opposed to any other life-threatening medical disorder. This implies that we (collective payers of health care tax or insurance dollars) would also have to be willing to pay for any other life-prolonging medical intervention for heart disease or COPD or ALS or MS or Type 2 Diabetes, etc. that had a cost per QALY of less than $600,000. This would effectively mean that we had given up trying to control health care costs. Since that outcome is neither politically nor economically nor ethically acceptable from either a personal or social perspective, we would have strong reason to take seriously the need for the deliberative process. Finally, it is noteworthy that the vast majority of participants in the deliberative process would be behind a real world Rawlsian "veil of ignorance" since they would have no idea what health crises might befall their future possible selves nor the future possible selves of others to whom they were emotionally attached. This fact negates the risk of special pleading by representatives of various disease groups that would otherwise threaten to undercut the moral legitimacy of the deliberative process.

In conclusion, uncertainty in medicine is ubiquitous and complex. As seen in our discussion, it generates numerous challenging ethical issues. Those issues, in their concrete clinical manifestations generally cannot be effectively addressed by appeal to somewhat abstract

philosophic theories of justice alone. In the final analysis we can hope for no more than "rough justice" in addressing the justice-relevant ethics issues generated by medical uncertainty. Using a fair process of rational democratic deliberation, suitably constructed and mutually respectful, may be the best approach we can take to achieving "just enough" results.

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