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DEALING WITH DYING:
HOW INSURERS CAN HELP PATIENTS SEEKING LAST-CHANCE THERAPIES (EVEN WHEN THE ANSWER IS "NO")

Kathy L. Cerminara†

"Making decisions and policies about payment for promising but unproven last-chance therapies presents the most difficult moral and clinical policy challenge a health care system can face."1

Insurers denying coverage for last-chance therapies encounter patients in dire circumstances who fuel political rhetoric and present vibrant media images. Typically, a television newscast or a fiery speech portrays a terminally ill patient (most touchingly a child) who requires an extremely expensive treatment to live. Opposing that patient, his or her family, and a community of supporters, is a heartless insurer, refusing to pay for the treatment. In reality, however, the question of whether to cover a last-chance therapy would never arise on facts this clear-cut. The media stories and political rhetoric run counter to reality. Questions of whether to cover last-chance therapies arise only in cases in which treatments are of unknown efficacy, at best, and when health care professionals lack definitive lifesaving options. Denials of coverage for last-chance therapies because those therapies are experimental or investigational can never reliably be said to deny patients treatments that would have saved their lives.

Nevertheless, despite this reality, when insurers deny coverage for last-chance therapies, patients and their families increase panicky efforts to obtain coverage. Their panic magnifies as they proceed through external review of coverage decisions. Such review, consisting essentially of opportunities to appeal coverage denials to entities

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1 NORMAN DANIELS & JAMES E. SABIN, SETTING LIMITS FAIRLY 81 (2002) [hereinafter SETTING LIMITS].
unrelated to the insurance company denying coverage, was designed to assure patients that the decision-making process is not self-serving, tainted by conflict of interest, or lacking scientific foundation. It seldom succeeds in achieving this goal, however, when patients are seeking coverage of last-chance therapies. In those cases, even after an independent, external review organization examines and affirms an insurer’s determination that a treatment is experimental or investigational, patients denied coverage continue to feel ill-served by the health care system. On one hand, this may seem to be inevitable because patients diagnosed with life-threatening illnesses, grasping at straws, may never be satisfied unless their insurers pay for every treatment they seek, no matter how outlandish. On the other hand, tragic choice theory and recognition of the role that the therapeutic misconception plays in such settings would indicate that such patients react as viscerally as they do because, despite the extra layers of procedure provided by external review, they are left at the end of the day refusing to accept the reasons for coverage denials and feeling abandoned because of the ways in which their insurers have treated them.

This Article will propose a more therapeutic approach toward making decisions and communicating with patients about coverage (or lack thereof) for last-chance therapies. First, it will explain why those involved in the dramas that unfold whenever last-chance therapies are sought seize upon last-chance therapy suggestions as unflinchingly as they do. Second, it will examine the current system of external review of coverage denials. Although intended to assure patients of the validity of denials of coverage in cases in which denials are indeed appropriate, as currently configured, external review has not fulfilled its potential for assisting patients in accepting the decisions of their insurers regarding last-chance therapies. Instead, because the procedures in place ignore the special characteristics of last-chance therapy coverage requests, they fall far short of assuring procedural justice to patients seeking coverage. Finally, to remedy such shortcomings, this Article will propose that insurers incorporate interdisciplinary coun-

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2 In this sense, because this Article, in part, examines “how law shapes behavior and affects outcomes” with regard to coverage decision-making, it is one of a recent series of pieces taking a therapeutic jurisprudential approach toward health care law. See Mark A. Hall, Law, Medicine, and Trust, 55 Stan. L. Rev. 463, 466-68 (2002) (describing the development and application of therapeutic jurisprudence). See also William M. Sage, Managed Care’s Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance, 53 Duke L.J. 597 (2003) (discussing the dilemma and conflicting relationship between medical necessity, health insurance, and therapeutic benefit). About therapeutic jurisprudence generally, see Bruce Winick & David B. Wexler, Law in a Therapeutic Key (1996).
Dealing with dying and mediation techniques into the procedures they follow when determining whether to cover last-chance therapies. Using a well-rounded, multi-disciplinary, interactive process for coverage decision-making would better assist patients seeking last-chance therapies. Indeed, such procedures would help those patients deal with dying in a more therapeutic way, even when the answer to their pleas for coverage of particular treatments must be "no."

I. PARTICIPANTS IN LAST-CHANCE THERAPY DRAMAS HAVE UNIQUE SETS OF GOALS AND NEEDS

Patients and their families, the health care providers serving them, and society in general have unique sets of goals and needs that must be addressed in last-chance therapy coverage decision-making. Understanding those goals and needs is crucial to understanding why external review processes, as currently configured, will not help patients believe the system is legitimate. Such an understanding will also pave the way to reforming the process that insurers should follow when facing these types of decisions.

A. Patients Seeking Coverage of Last-Chance Therapies and Their Families Are in Vulnerable Positions

"Last-chance therapies" are "unproven treatments [that patients with life-threatening illnesses] believe may make the difference between life and death."3 In such a case, "a person [is] faced with death in the near future unless she or he has access to a very expensive medical intervention that offers only a relatively small chance of a relatively small gain in life expectancy."4 Many times, although not always, the medical intervention under consideration is the subject of ongoing research, so medical researchers, who may or may not also be treating physicians, see patients who are "desperately ill, [for whom] conventional treatment has failed, [and] no alternative therapies exist. . . . [T]he reason the patient is at the research institution, or wishes to come to it, is to receive the only therapy left that anyone thinks might

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3 Setting Limits, supra note 1, at 67. Use of the term "unproven" is not limited to describing last-chance therapies. Complementary and alternative medicines also are sometimes called "unproven," a phenomenon which can seem unnecessarily prejudicial since much everyday clinical medicine is also "unproven" in the sense of being unsupported by controlled, double-blind clinical research. See E. Haavi Morreim, A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science, 31 J.L. MED. & ETHICS 222, 223-26 (2003).

be of benefit.\textsuperscript{5} Thus, last-chance therapies are those that are unproven in the sense of being backed by definitive medical, scientific evidence showing efficacy, when recommended or considered for administration to a patient who has a short time to live absent treatment.

1. These Patients and Their Families Are Emotionally Distraught

Some patients seeking coverage of last-chance therapies will be in the final stages of what has been a long struggle with an illness or a condition. Some others will only recently have learned of their diagnoses and will be grappling with the news even as they struggle to obtain coverage. Regardless of the amount of time they have had to deal with the news that they need to seek last-chance therapies, these patients and their families are in vulnerable states.

Upon first glance, it may seem as if the two groups of patients are radically different from each other. Patients who have been recently diagnosed with end-stage illnesses for whom conventional therapies are ineffective seem to differ greatly from patients who have lived with the diagnosis and progression of illness for some time but who are finally nearing the stage at which only last-chance therapies offer any hope. For example, those in the first group arguably may be more fragile because late-stage diagnosis has deprived them of time to reach a level of acceptance of their situations. If these groups of patients are indeed radically different from each other, perhaps they require separate consideration.

Insurers should not, however, assume that patients who have lived a while with a diagnosis requiring resort to last-chance therapies are greatly different from those who have been recently diagnosed. To some extent, these two groups of patients are merely at different points along a continuum, rather than in entirely separate categories.\textsuperscript{6} And, at least to that extent, although individual cases will of course involve individual deviations, these patients may be considered as sharing some major characteristics—characteristics which have been overlooked in the current decision-making process.

Elisabeth Kübler-Ross’s classic work describing the dying process notes that all news of impending death will be translated in the unconscious mind into news that one will be killed—a far more violent proposition than simply dying.\textsuperscript{7} Recently diagnosed patients seeking

\textsuperscript{5} Angela R. Holder, \textit{Funding Innovative Medical Treatment}, 57 ALB. L. REV. 795, 795 (1994).
\textsuperscript{6} See infra text accompanying notes 8, 9.
\textsuperscript{7} ELISABETH KÜBLER-ROSS, \textit{ON DEATH AND DYING} 2 (1969) ("In simple
coverage of last-chance therapies are in the beginning stages of either dying or becoming "survivors." For patients diagnosed with such diseases, the choice is not truly between being cured or dying. There are those who will "survive," living with the experience and the disease from then on as "survivors" (emotionally, at least), and then there are those who will die. Both they and persons who are finally facing imminent death after a long illness, however, are feeling assaulted.

Family members, too, are disinclined to listen calmly to the news that a patient is dying. They are in the position of watching someone they love go through the traumatic experience of learning that he or she is likely to face mortality earlier than anticipated. They also may feel some guilt at an unconscious level. Like a child, wishing a parent dead because he or she is angry and then feeling guilty if the parent actually dies (even though from totally unconnected causes), any feelings of anger family members experienced previously may unconsciously transform into guilt at death or a diagnosis of impending death. Thus, patients feeling attacked are also surrounded by shell-shocked family members who have their own reasons for attempting to deny impending death.

derms, in our unconscious mind we can only be killed; it is inconceivable to die of a natural cause or of old age.

8 See Gina Kolata, New Approach About Cancer and Survival, N.Y. TIMES, June 1, 2004, at A1 [hereinafter Kolata, New Approach] (discussing how the experience of being a survivor of a disease such as cancer is a unique state in itself). Kübler-Ross similarly considered as "dying" all the patients she interviewed as part of her work in the late 1960s; she and her colleagues interviewed those patients at various points "at any time between the making of a diagnosis until just before death." Kübler-Ross, supra note 7, at 23. In some cases the patients even had remissions without relapses. Id.

9 Kolata, New Approach, supra note 8, at A1 (drawing from statements made by cancer survivors to portray a common mentality toward the disease). The term cancer survivor "entered the lexicon" about twenty years ago, "in a wrenching essay in the New England Journal of Medicine." Gina Kolata, In One Word, an Entire Debate on Cancer, N.Y. TIMES, June 1, 2004, at A14 [hereinafter Kolata, In One Word]. See also Fitzhugh Mullan, Seasons of Survival: Reflections of a Physician With Cancer, 313 NEW ENG. J. MED. 270, 271 (1985) ("Survival, in fact, begins at the point of diagnosis, because that is the time when patients are forced to confront their own mortality.").

Cancer researchers believe that the term "survivor" is useful for describing this phenomenon, although Kolata cautions that the term can be "a totally incendiary word within the community." Kolata, In One Word, supra, at A14 (quoting Ellen Stovall, president and chief executive of National Coalition for Cancer Survivorship). "Some who object to being called survivor want to say they are cured; others that they are living with cancer. Some want to put cancer behind them, and feel that being called a survivor is like getting an invisible brand." Id.

10 "[I]n our unconscious mind we cannot distinguish between a wish and a deed." Kübler-Ross, supra note 7, at 2-3.
The first stage of dying in the Kübler-Ross chronicle is characterized by denial and isolation. A diagnosis of terminal illness, or impending death from any cause, is devastating and traumatic to hear. Even physicians, with scientific training and an ability to clinically detach, experience panic upon learning of life-threatening diagnoses relating to themselves. During this initial, panicky stage of denial, when it is natural to feel and to become isolated, Kübler-Ross says:

[w]hat all of our patients stressed was the sense of empathy which counted more than the immediate tragedy of the news. It was the reassurance that everything possible will be done, that they will not be “dropped,” that there were treatments available, that there was a glimpse of hope – even in the most advanced cases. If the news can be conveyed in such a manner, the patient will continue to have confidence in the doctor, and he will have time to work through the different reactions which will enable him to cope with this new and stressful life situation.

And therein lies the rub: a physician might fall into the trap of offering even less-than-hopeful treatment options because he or she is seeking to respond to this patient need in order to reassure the patient facing a terminal diagnosis. Perhaps even believing him or herself that a current research project offers the best “treatment” for this pa-

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11 See, e.g., Kolata, New Approach, supra note 8, at A14 (describing one physician’s experience of fear once he learned he had B-cell lymphoma); Mullan, supra note 9, at 271 (explaining that because of the severity and acknowledgment that an individual has cancer, fear and anxiety are commonly the initial emotions after diagnosis).

12 Kübler-Ross, supra note 7, at 33.

13 Kübler-Ross advises:

[i]f a doctor can speak freely with his patients about the diagnosis of malignancy without equating it necessarily with impending death, he will do the patient a great service. He should at the same time leave the door open for hope, namely, new drugs, treatments, chances of new techniques and new research. The main thing is that he communicates to the patient that all is not lost; that he is not giving him up because of a certain diagnosis; that it is a battle they are going to fight together – patient, family, and doctor – no matter the end result. Such a patient will not fear isolation, deceit, rejection, but will continue to have confidence in the honesty of his physician and know that if there is anything that can be done, they will do it together. Such an approach is equally reassuring to the family who often feel terribly impotent in such moments. They greatly depend on verbal or nonverbal reassurance from the doctor. They are encouraged to know that everything possible will be done, if not to prolong life at least to diminish suffering.

Kübler-Ross, supra note 7, at 26.
that physician might mention a research protocol or other experimental "treatment" as a possibility in order to offer hope and a source of support. Though patients generally like and value choice, as recognized throughout bioethics, experiencing panic and isolation in this situation, they may not want choice or may not know what to do with it because of emotion and lack of expertise. Fixating upon the doctor's "recommendation," which the doctor may only have offered in an effort to ensure that the patient did not feel abandoned or hopeless, means that the patient will see an insurer's denial of coverage, if coverage is indeed denied, as unfair and will be bitter.

For a patient with a terminal diagnosis, after denial and isolation comes anger, although anger is not neatly trammeled into one portion of the dying process. In times of denial and anger, it is natural to find a source of blame (besides oneself) for the illness. It would be natural to find someone to blame for the inability to cure the illness. One natural target for blame in cases of incurable illness is an insurer refusing to pay for a treatment, even if that treatment is, at best, an extremely long shot. If the doctor is "recommending" the "treatment," then the natural source of blame for not receiving the treatment is the insurer. If the insurance company denies coverage, it becomes the bad-guy corporate entity trying to second-guess an expert.

Once through denial and isolation, and then anger, in Kübler-Ross's taxonomy, a patient will proceed through bargaining, depression, and finally acceptance. Patients in these phases may still be less knowledgeable about science and medicine than they ideally would like, but they pass out of the initial, panicky phase. Bargaining, depression and acceptance will follow, assuming that the patient works through the complete cycle. Yet, throughout, Kübler-Ross

14 See infra text accompanying note 30.
15 SHERWIN B. NULAND, HOW WE DIE: REFLECTIONS ON LIFE'S FINAL CHAPTER 229 (1994).
16 See KÜBLER-ROSS, supra note 7, at 4 ("The process of grief always includes some qualities of anger.").
17 "If we have been unable to face the sad facts in the first period and have been angry at people and God in the second phase, maybe we can succeed in entering into some sort of an agreement which postpones the inevitable happening. . . ." Id. at 72.
18 There may be two types of depression: "reactive depression," or a despair that comes about because of current circumstances, and "preparatory depression," which "does not occur as a result of a past loss but is taking into account impending losses." Id. at 75-76.
19 Id. at 78 (describing a state reached only when the patient is able to work through his anguish and anxieties).
20 According to Sherwin B. Nuland, "every experienced clinician knows that some patients never, at least overtly, progress beyond denial; many others retain large
noted: "[i]n listening to our terminally ill patients we were always impressed that even the most accepting, the most realistic patients left the possibility open for some cure, for the discovery of a new drug or the 'last-minute success in a research project.'" Patients are likely to fixate on any mention of such options, even if they have passed through the initial, panicky stage of first hearing a terminal diagnosis.

Thus, even well after initial diagnosis, even if a patient has proceeded beyond denial and anger about that diagnosis, it would be easy for a patient to feel anger when an insurer denies coverage of a last-chance therapy. The patient will be unhappy with the terms of the bargain pursuant to which he or she obtained the insurance in the first place. Indeed, considering the agency problems inherent in the acquisition of health insurance in an employer-based system, and the imbalance of knowledge and the uncertainty of need in the health care market, the patient can hardly be said to knowingly have entered into that bargain in the first place.

2. Patients and Their Families Do Not Realize That What They Seek Often Are Not "Therapies"

Moreover, one basic truth emerges when dissecting the view that still-experimental procedures, practices, and drugs constitute "treat-
ment” or “therapy” at all. Some may be effective. But some, perhaps most, last-chance therapies may not constitute therapies at all, and may even be detrimental to the health of the person undergoing the “treatment.” This Article uses the terms “therapies” and “treatments” when describing experiments and medical research that may or may not provide any benefit. But it does so only because of the widespread usage of these terms in this setting and because of the near-impossibility of eliminating the terms “therapies” and “treatments” from this discussion. It would be preferable to eliminate the terms altogether, to reduce the “therapeutic misconception” that arises from their use. 25

A “therapeutic misconception” exists when a person participating in a clinical trial, serving as a research subject, believes that he or she is receiving treatment through the trial. 26 In a placebo study, this misconception may even lead a research subject to disregard warnings that he or she may be randomized into a placebo arm of the study and thus may not receive treatment at all. Clinical trials websites often reinforce and even encourage the misconception. 27 A person grasping at straws when faced with the news that conventional treatment will not provide a cure often mistakenly perceives a last-chance therapy as therapeutic or potentially therapeutic. 28 According to at least one study, researchers believe that participants in Phase I clinical trials enroll in those studies “mostly for the possible medical benefit” 29

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25 Writing about the challenges inherent in achieving informed consent in this context, Nancy M. P. King has noted the same reality, stating that “[t]he attempt to distinguish ‘experiment’ from ‘treatment’ and ‘researcher’ from ‘physician’ seems especially doomed precisely when these terms appear most troublesome and in need of sorting out . . . when patients are desperately ill and standard therapies are risky and of low efficacy; [and] when treating physicians are also engaged in or associated with clinical research on their patient’s conditions.” Nancy M. P. King, Experimental Treatment: Oxymoron or Aspiration?, HASTINGS CENTER REP., July-Aug. 1995, at 6, 12.


29 Oberman & Frader, supra note 28, at 309 (quoting Eric Kodich et al., Ethical Issues in Phase I Oncology Research: A Comparison of Investigators and Institutional Review Board Chairpersons, 10 J. CLINICAL ONCOLOGY 1810, 1812 (1992)). The AMA Council of Ethical and Judicial Affairs recognizes the potential for the therapeutic misconception by delineating specifically guidelines intended to
problem with that belief is that Phase I clinical trials are intended to study toxicity and the workings of the treatment being studied; they are decidedly non-therapeutic. The misconception, however, is so strong and so common that physicians even share in it.\textsuperscript{30}

Indeed, the very structure of insurance contracts lends credibility to the misconception. Generally, one must call a last-chance therapy a "treatment" to even argue for coverage.\textsuperscript{31} "Treatment" is covered if "medically necessary" but not if "experimental" or "investigational." It is hard to say that research is "medically necessary," and it is inaccurate to say that true treatment is being received in the course of an experiment.\textsuperscript{32} It is more accurate, when a patient has no chance with conventional treatment but might have a chance of benefit if enrolled in a research study, to say that some treatment is medically necessary, but the only treatments available of known efficacy are palliative, and the patient's only chance for a benefit in the form of cure or remission may lie in research.

Language compounds the confusion. The misnomers "experimental treatment" and "investigational treatment," used commonly in insurance contracts, help perpetuate the therapeutic misconception by using the word "treatment." The term "last-chance therapy," although commonly used in everyday parlance, goes a step further. It conveys not only the therapeutic misconception, but also a real sense of urgency, much like the urgency felt when, running late to the airport, one realizes that one is booked on, and may be about to miss, the "last flight out." The difference, of course, is that while it is clear that "the

\textsuperscript{30} Oberman & Frader, \textit{supra} note 28, at 309-10.  

\textsuperscript{31} An exception would be in those states mandating coverage of certain clinical trials. \textit{E.g.,} N.C. GEN. STAT. § 58-3-255 (2003). Further, some plans provide for such coverage absent a mandate. \textit{See} Norman Daniels & James E. Sabin, \textit{Last Chance Therapies and Managed Care: Pluralism, Fair Procedures, and Legitimacy,} HASTINGS CENTER REP., Mar.-Apr. 1998, at 27, 40 [hereinafter \textit{Last Chance Therapies}].

\textsuperscript{32} This is especially true when a research study is in Phase III of clinical trials, because then the subject (who thinks of him or herself as a patient) is randomized into a group that may not even receive the controversial "treatment." In Phase I and Phase II, at least, we can be sure that the subject/patient is receiving the alleged "treatment," but the researchers at these stages are shooting in the dark on toxicity and efficacy of the substance or procedure being studied. \textit{E.g.,} Sharona Hoffman, \textit{Regulating Clinical Research: Informed Consent, Privacy, and IRBs}, 31 CAP. U. L. REV. 71, 81-83 (2003); Sharona Hoffman, \textit{The Use of Placebos in Clinical Trials: Responsible Research or Unethical Practice?}, 33 CONN. L. REV. 449, 466-69 (2001).
last flight out” will transport a passenger to his or her destination, it is by no means clear that a “last-chance therapy” will help a patient. Such a therapy, in fact, may even increase the patient’s discomfort to no good end. The therapeutic misconception, assisted by such labels, nevertheless increases the urgency felt by the patient faced with a coverage denial, for it results in a likely unfounded belief that an insurer denying coverage is standing in the way of the patient’s obtaining a beneficial drug or procedure.

B. Health Care Providers Feel a Need to Offer Something

Faced with such patients, physicians offer last-chance therapies for a number of reasons. Naturally, and as a matter of training, physicians want to give their patients hope. They, or at least some members of the treating team, likely also feel the pressure of the technological imperative, pushing them to attempt all possible avenues of potential cure. They may even believe that the law compels them to mention all possible treatments, even those with infinitesimal chances of success. Thus, physicians with patients for whom last-chance therapies may offer the last possibility of cure are likely to believe they must discuss those therapies with their patients. The result leaves insurers trying to explain to those patients why the therapies proposed actually do not offer hope in a realistic sense.

Traditional medical training often advises physicians to always provide some ray of hope for patients.\(^3\) The most obvious way to do that is to offer hope for a cure, because even a small chance of cure provides some hope. Kübler-Ross’s studies of the terminally ill, for example, indicated that they “showed the greatest confidence in the doctors who allowed for such hope – realistic or not – and appreciated it when hope was offered in spite of bad news.”\(^34\) Sensing this (and perhaps as a matter of training), physicians are inclined to offer “treatments” even if the chance offered by the treatments is slim at best. Unfortunately, physicians try so hard to provide hope in this sense that they sometimes grasp at straws to do so.\(^35\) Physicians feel

\(^{33}\) \textit{Nuland, supra} note 15, at 222 (“A young doctor learns no more important lesson than the admonition that he must never allow his patients to lose hope, even when they are obviously dying.”). \textit{See also Köbler-Ross, supra} note 7, at 123 (discussing the importance of always giving the patient hope).

\(^{34}\) \textit{Köbler-Ross, supra} note 7, at 123. Kübler-Ross continues: “This does not mean that doctors have to tell them a lie; it merely means that we share with them the hope that something unforeseen may happen, that they may have a remission, that they will live longer than is expected.” \textit{Id.} Yet many doctors may take that too far. \textit{See infra} Part III.A.2.

\(^{35}\) Some physicians see the need to offer hope as requiring hope of a cure or a treatment. It would be far better if, rather than feeling a need to offer hope in the
the need to give hope, to assure their patients that they will not be abandoned, and they may not realize that they are being too hopeful if they also begin to believe the therapeutic misconception themselves, as part of the hope-giving process. Their very adoption of a hopeful tone, ironically, may even encourage the patient to read more hope into their words than they intend to convey.

There exists in American medicine a technological imperative counseling that all potential treatments must be attempted. It is all too common – indeed perhaps all too human – to believe, with respect to medical procedures, that "if we can, we should." Indeed, it is this very technological imperative that has fueled scientific progress in the form of medical research, arguably at the expense of assuring access to basic health services in this country. The technological imperative would counsel that a patient should undergo an as-yet-unproven therapy because it might work (and if does, we can, so we should). The imperative is also apparent in the tendency some physicians have to refuse to give up in situations in which a patient is nearing the end of life but can only be kept alive through artificial means such as respirators and feeding tubes. In that setting, patients have fought for, and won, the right to refuse the administration of the life-prolonging treatment that some physicians desire to provide. In the last-chance therapy setting, in contrast, physicians are offering technological advances to patients who are more than willing to undergo them.

Even if some physicians understand the need to resist the technological imperative in some cases, a patient may be able to find others who do not, sometimes without even switching doctors. A patient facing the need for last-chance therapies is usually in a state so advanced that a team of physicians, rather than a single physician, will monitor and administer care. Some physicians on the team may believe in always offering hope of a cure, in honoring the technological imperative, in fighting until the last breath. Thus, physicians (not to mention other members of the care-giving team, such as nurses) may

form of cure or treatment, those physicians worked also on offering hope of a good death. See NULAND, supra note 15, at 223-24; see also discussion infra Part III.A.2. (encouraging insurers also to do just that).


37 See generally DAVID J. ROTHMAN, BEGINNINGS COUNT: THE TECHNOLOGICAL IMPERATIVE IN AMERICAN HEALTH CARE (1997) (proposing that American’s borderline obsession with medical technology creates both beneficial and detrimental effects on American health care culture).

find among themselves differences of opinion leading to mixed messages, the most positive of which is likely to resonate most deeply with the patient.

Finally, physicians may feel that they must offer access to last-chance therapies because of informed consent law. Informed consent law requires disclosure of reasonable alternative therapies, and at some point, once they are proven enough to offer some real hope, some experimental or investigational treatments may fall into this category. There is obscurity in the term "reasonable," however, and alternative therapies that are "reasonable" are the only ones that doctors must offer. Physicians need not offer all therapies, and indeed they could not do so, for it is nearly impossible to be aware of, let alone knowledgeable about, the thousands of research protocols under way at any given time.

C. The Health Care System Cannot Pay for Everything

Although its interests are not foremost in patients' minds, the health care system as a whole cannot be forgotten in examining the forces at work in decision-making about last-chance therapy coverage. Patients, their families, and their physicians are not the only ones with special stakes in a last-chance therapy coverage decision. Unless and until coverage of the costs associated with undergoing experimental or investigational procedures or drugs is provided through a system of social welfare, or mandated by statute, insurers' determinations of whether to cover such procedures and drugs constitute the method by which society allocates resources among these and various other

39 See Holder, supra note 5, at 806.
40 See NULAND, supra note 15, at 247 (explaining how a term like "reasonable" is ambiguous and exposes differences between the expectations of doctors and patients). Compare Martin v. Richards, 531 N.W.2d 70, 78 (Wis. 1995) (requiring disclosure of alternatives generally accepted in the medical community), with Morris v. Ferriss, 669 So. 2d 1316, 1327 (La. Ct. App. 1996) (stating if alternative is not a reasonable option, an "accepted medical treatment for the condition," it need not be disclosed). Compare Opinion 10.01: Fundamental Elements of the Patient-Physician Relationship, in CODE OF MEDICAL ETHICS, supra note 29, at 281 ("The patient has the right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives."), with Opinion 8.20: Invalid Medical Treatment, in CODE OF MEDICAL ETHICS, supra note 29, at 238 (stating that physicians and patients should decide "[a]mong the various treatments that are scientifically valid, medically indicated, legal, and offer a reasonable chance of benefit for patients").

health care options. Whether last-chance therapies are "therapies" or not, they present difficult resource-allocation issues. Especially when one considers that it is not only private insurers but also governmental payers that are making these determinations, societal considerations must rank high on the list of concerns of participants in these dramas.

On one hand, society would like to encourage scientific progress, so there is some argument in favor of covering last-chance therapies because of the potential for advancing the state of medicine. It is important that clinical trials enroll sufficient participants to result in scientifically valid findings so that medical progress will continue. Scientific progress is valuable, and it is no doubt true that progress cannot occur without experimentation. The question is who should pay for that progress. There is, after all, not enough money to pay for all ongoing research, all available proven treatments, and all basic and preventative health care.

Denial of coverage for last-chance therapies because they are experimental or investigational thus is perhaps the most striking example of decision makers attempting to camouflage "tragic choices" in medical care.42 "Tragic choices," as described in the classic work of Guido Calabresi and Philip Bobbitt, exist when "[a]ction in the context of necessary scarcity brings ultimate values, the values by which a society defines itself, into conflict."43 Orentlicher describes the "tragic choices" model of Calabresi and Bobbitt as one "in which society chooses to disguise its justifications for making difficult life-and-death decisions, in order to avoid a paralyzing social conflict over disparate values."44 Organ allocation is a classic example. With emphasis on "tissue matching between donors and recipients," the organ allocation system that has been put into practice in this country can encourage the public to think incorrectly that a scientific, value-neutral method of selection is being used, when in reality a choice has been made to favor patients who will gain the most years of benefit from a transplant over patients who have been waiting longest for a transplant or patients who do not tolerate kidney dialysis very well.45

Economic resources are no different. Clark Havighurst discusses "[t]he public’s occasional psychological need to suppress its aware-

42 GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 17 (1978).
43 Id. at 18.
45 Id. (citations omitted).
ness of the scarcity of resources” in health care as being “illustrated most poignantly by its ability to tolerate tragedies that are revealed only through statistics while at the same time mobilizing virtually unlimited resources to save a single human life.”

The lack of empirical evidence supporting the expenditure of funds on last-chance therapies is a major motivating factor in most insurers’ decisions to deny coverage. There is nothing wrong with that; it is morally defensible to attempt to balance both concerns about the care of an individual patient and concerns about how to conserve resources so as to best provide for a population of patients. Recent history proves that major expenditures of money on experimental or investigational treatments have indeed caused great wastes of resources that could have been used to help many people. The famous, or infamous, example of high-dose chemotherapy with autologous bone marrow transplant (HDC-ABMT, sometimes called simply ABMT) still rankles both insurers and patient advocates, serving as a reminder of how easily scarce health care resources can be wasted if used on unproven therapies.

46 Clark C. Havighurst, American Health Care and the Law, in The Privatization of Health Care Reform: Legal and Regulatory Perspectives 1, 10 (M. Gregg Bloche ed., 2003). Calabresi and Bobbitt themselves illustrate “the differences in the value we place on life in different situations” by noting that “the United States will spend a million dollars to rescue a single, downed balloonist but will not appropriate a similar sum to provide shore patrols.” Calabresi & Bobbitt, supra note 42, at 21.

In the insurance coverage context, the appropriate analogy might be to compare how individual decision makers feel about coverage with respect to a single, identified person with how an insurance company feels about coverage with respect to a number of covered lives. When individual lives rather than covered lives are at stake, the choices become far more tragic and difficult — thus likely contributing to the courts’ tendency to provide coverage in tragic cases. See Gerard F. Anderson & Mark A. Hall, The Management of Conflict Over Health Insurance Coverage, in The Privatization of Health Care Reform: Legal and Regulatory Perspectives, supra note 46, at 82, 86 (citing an example where the court ordered insurance coverage for an unproven treatment for AIDS). See also William M. Sage, Unfinished Business: How Litigation Relates to Health Care Regulation, 28 J. Health Pol’y, Pol’y & L. 387, 401 (2003) (explaining the prevalence of “doctor-centered” views in litigation, as opposed to regulation, by noting that “[t]he courtroom is the last bastion of the ‘identified life’”).

49 See Norman Daniels & James Sabin, Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers, 26 Phil. & Pub. Aff. 303, 317-18 (1997) [hereinafter Limits to Health Care]. Such concerns thus stand in contrast to concerns about conserving expenditures related to desires to keep shareholders happy or to maintain high CEO salaries. Id. at 305. The latter concerns are not morally defensible, for they are not “accepted as relevant by people who are disposed to finding mutually justifiable terms of cooperation.” Id. at 329.

50 For examples of usage of the abbreviation “ABMT” alone, see Sage, supra note 2; Anderson & Hall, supra note 46.
1. The Case Study of HDC-ABMT

In the late 1990s, women with breast cancer for whom conventional treatment offered no hope became aware of HDC-ABMT as a treatment option when oncologists began recommending its use on the basis of the results of some Phase I and Phase II clinical trials. Those trials indicated that the treatment might improve survival rates and shrink tumors, but they were not large-scale, randomized, Phase III clinical trials, which result in the most scientifically valid information. Once oncologists began recommending HDC-ABMT, however, the treatment became “relatively common,” with its use “diffusing rapidly,” even though clinical research had not yet established that it was superior to conventional treatment.

Despite its lack of proven effect, those who heard about HDC-ABMT desperately wanted to try it when they heard that some physicians believed it was effective. Patients seeking coverage of HDC-ABMT began using both litigation and the legislative process to pressure their insurers to cover the treatments. Once some insurers were hit with substantial verdicts for refusals to cover HDC-ABMT (even though the really large verdicts were awarded in cases involving evidence of hypocrisy and especially blameworthy decisionmaking), and once state legislatures began mandating coverage of the treatment, insurers simply began paying for the treatments, despite their beliefs that coverage was unwarranted because HDC-ABMT was still experimental.

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51 Michelle M. Mello & Troyen A. Brennan, The Controversy Over High-Dose Chemotherapy With Autologous Bone Marrow Transplant for Breast Cancer: A Cautionary Tale About Allowing Politics and Legal Pressures to Overwhelm Science in Evaluating New Therapies, HEALTH AFF., Sept.-Oct. 2001, at 101, 103-05. See also Francis, supra note 41, at 227 (asserting that randomized trials are the most indicative of actual efficacy).


53 For a general discussion of these verdicts, see Francis, supra note 41, at 243-50.


55 See U.S. GEN. ACCOUNTING OFFICE, supra note 52, at 11. Francis, supra note 41, at 233-42 (discussing state statutes mandating insurance coverage of medical treatments).

56 U.S. GEN. ACCOUNTING OFFICE, supra note 52, at 2; William P. Peters &
Increased access to HDC-ABMT did not, however, mean that the United States became a healthier place for women with breast cancer in the 1990s. In all, more than 41,000 patients, at a cost of about $80,000 each, underwent HDC-ABMT for breast cancer in the 1990s. By the year 2000, it became clear from randomized Phase III clinical trials that patients treated with HDC-ABMT actually survived no longer than did patients treated with conventional treatment. Even worse, the highly toxic treatment not only made patients desperately ill but also killed patients itself, whereas standard-dose treatment did not.

HDC-ABMT is far from a unique example. More recent technological advances that could constitute last-chance therapies include Herceptin therapy for certain breast cancer patients, and the totally implantable artificial heart for persons with end-stage congestive heart failure. HDC-ABMT is notable, however, because it was highly publicized; solid evidence of costs exists; and many studies of it have been conducted. It serves as an example of the dangers of assuming scientific efficacy before all experimental phases have been concluded, and it illustrates why insurers are reluctant to fund therapies early in the experimental process.

Despite the cautionary tale of HDC-ABMT, it undoubtedly remains true that many patients faced with the diagnosis of late-stage breast cancer hearing of another promising treatment (such as Herceptin therapy) will want to try that treatment even before clinical research definitively proves its worth. Even in the face of the experimental nature of the treatment and warnings about its possible ghastly effects, some patients operating under a therapeutic misconception

Mark C. Rogers, Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer, 330 NEW ENG. J. MED. 473 (1994).

57 Mello & Brennan, supra note 51, at 110. The stated cost is an average figure, but other estimates of the cost of a course of ABMT treatment have ranged as high as $200,000. See e.g., Sharona Hoffman, A Proposal for Federal Legislation to Address Health Insurance Coverage for Experimental and Investigational Treatments, 78 OR. L. REV. 201, 212 (1999).

58 Edward A. Stadtmauer et al., Conventional-Dose Chemotherapy Compared with High-Dose Chemotherapy Plus Autologous Hematopoietic Stem-Cell Transplantation for Metastatic Breast Cancer, 342 NEW ENG. J. MED. 1069, 1069 (2000). For a discussion of the results of other studies, see Mello & Brennan, supra note 51, at 105.

59 Mello & Brennan, supra note 51, at 111 ("The recent randomized clinical trials reported treatment-related mortality rates ranging from zero to 7 percent among HDC-ABMT recipients, while the standard-dose control arms of the studies had no such deaths.").

60 Fleck, supra note 4, at 257.
will still request it. Moreover, not only will they desire the treatment, but they will want their insurers to fund the cost of it regardless of the language in their coverage documents.\textsuperscript{61} Indeed, if the research on HDC-ABMT had later revealed that the treatment was indeed effective, the families of those who had died after being denied coverage because it was experimental would have been furious with their insurers, because the insurers' refusal to cover the treatments had deprived lost family members of a chance to live.

2. Similarities to Futility Determinations

To bioethicists, "last-chance therapy" situations and notions of futility might even seem to overlap or be the same. In some senses last-chance therapy coverage denials resemble situations in which physicians refuse to provide treatment they deem futile.\textsuperscript{62} In instances of futility, physicians use their technical expertise to say a treatment no longer provides medical benefit to the patient. Daniels and Sabin say that the difference between "last-chance therapy" situations and futility situations is that last-chance therapies "are marked by uncertainty" -- they are promising but unproven.\textsuperscript{63} In contrast to the uncertainty existing regarding the value of last-chance therapies, they say that futile treatments are proven; physicians know what benefit they could provide, but they provide no medical benefit in the case at hand.

\textsuperscript{61} Anderson & Hall, supra note 46, at 86 (noting that in Bradley v. Empire Blue Cross & Blue Shield, 562 N.Y.S.2d 908 (Sup. Ct. 1990), "the court ordered an insurer to cover ABMT treatment for an AIDS patient despite evidence that his physician was the only one in the country who had ever used the treatment in this fashion and despite the patient's having signed an informed consent form that emphasized the experimental nature of the treatment."). See also Francis, supra note 41, at 215 (discussing patients' efforts to obtain coverage for expensive therapies despite their insurers' denials of coverage).

\textsuperscript{62} See Orentlicher, supra note 44, at 158. See also id. at 127-28 (noting that "[c]ases of medical futility involve a reversal of the traditional life-sustaining treatment disagreement between patient and physician . . . situations in which patients have not expressed a readiness to die, but physicians wish to withhold ventilators, dialysis, feeding tubes, or other life-sustaining treatment anyway"). Orentlicher notes that futility cases are ostensibly independent of cost considerations. The explicit claim is not that the treatment provides some potentially meaningful benefit but the costs are too high to justify the small benefit produced. Rather the claim is that the treatment will not provide any meaningful medical benefit. Even if the treatment were inexpensive, it still would not be appropriate to offer the treatment to the patient.

\textsuperscript{63} SETTING LIMITS, supra note 1, at 83 n.1.
Such an easy distinction between futility and last-chance therapies, however, may not be appropriate. Arguably it is, if we are discussing only situations of scientific, or quantitative, futility.\textsuperscript{64} If, however, we focus on physician assertion of qualitative\textsuperscript{65} futility, then the distinction between futile treatments and last-chance therapies becomes less clear. Sometimes physicians or health care institutions assert futility as a reason to refrain from treating, not when treatment is of \textit{no} benefit, but when treatment would consume so many resources that it would unfairly impact on others’ ability to receive health care.\textsuperscript{66}

In the latter situation, like denials of coverage because of the investigational or experimental status of the proposed treatment, some people argue that physicians’ assertions that treatment will be futile often constitute rationalizations for rationing medical care.\textsuperscript{67} Orentlicher agrees “with the critics of futility that few treatments truly are futile in the sense that futility doctrine suggests. In general, there is \textit{some} benefit that could be gained from treatment, even if the benefit may be of marginal value, and the costs of treatment may be very high.”\textsuperscript{68} He argues that “it seemingly is wrong in terms of moral the-

\textsuperscript{64} See Lawrence J. Schneiderman et al., \textit{Medical Futility: Its Meaning and Ethical Implications}, 112 \textit{ANNALS INTERNAL MED.} 949, 949 (1990) (defining quantitative futility as existing when treatments do not have a realistic chance of working).

\textsuperscript{65} Qualitative futility exists when the medical benefit that would result from treatment is so small or lacking in meaning that it should not be considered a benefit. \textit{Id.}

\textsuperscript{66} See Steven H. Miles, \textit{Informed Demand for “Non-beneficial” Medical Treatment}, 325 \textit{NEW ENG. J. MED.} 512, 514 (1991) (commenting on the Helga Wangelie case). But see Marcia Angell, \textit{The Case of Helga Wangelie – A New Kind of “Right to Die” Case}, 325 \textit{NEW ENG. J. MED.} 511, 512 (1991) (arguing that this view of futility is not appropriate if it were to result in forcing refusal of treatment a family or patient otherwise would have wanted). \textit{See also MEISEL & CERMUNARA, supra note 38, §§ 13.03[B] & [C] (differentiating between a broad view and a narrow, physiological view of futility); Lois Shepherd, Sophie’s Choices: Medical and Legal Responses to Suffering, 72 \textit{NOTRE DAME L. REV.} 103, 130-31 (1996) (“Futility, as applied, means that the doctors do not think the treatment will enable you to have a good enough life. If the medical profession cannot give you a better life, then perhaps you should have no life at all.”).}

\textsuperscript{67} \textit{ORENTLICHER, supra note 44, at 129 (describing some commentators’ arguments).}

\textsuperscript{68} \textit{Id.} at 130 (emphasis in original). He goes on to suggest that determining whether a treatment is futile is not merely a matter of science:

By calling a treatment medically futile, a physician is suggesting that we have a situation in which treatment provides no medical benefit. [But]. . . [t]he concept of futility conveys not only the idea of no benefit; it also indicates that lack of benefit has been ascertained by applying well-defined medical criteria.

\textit{Id.} at 132-33.
ory to withhold life-sustaining treatments by invoking the concept of futurity. Rather, physicians should justify their decision to deny desired care by citing cost considerations.\textsuperscript{69} But:

we can understand the desire for a concept of futility in terms of the need to avoid explicit rationing. . . . If physicians claim that a treatment offers no real benefit, then it seems that no one is wronged by withholding the treatment. If, on the other hand, physicians were to acknowledge that the treatment offers some benefit, but still denied the treatment so resources could be preserved for other patients, then the patients denied treatment would feel that their needs were being unfairly ignored.\textsuperscript{70}

Physicians in this situation are experiencing the same sort of decision-making in which insurers engage regarding last-chance therapies.\textsuperscript{71} Just as physicians arguing that a treatment is qualitatively futile are not saying the treatment is totally without any scientific benefit, so too are insurers not exactly denying that requested last-chance therapies might offer some benefit. They are saying instead that the scientific evidence does not yet indicate that the benefit is certain enough to pay for the treatment. Yet patients still feel that the sought-after treatments offer (or could offer) some benefit, just as families or patients fighting physician futility determinations do. In both situations, the patients (or families or surrogates in the cases of patients without decision-making capacity) feel that their needs are being unfairly ignored.

In that sense, debates over coverage of last-chance therapies and those over physician assertions of futility of certain treatments may have more in common than they initially appear to. The commonalities may appear instructive when considering why external review as currently configured, although a step toward legitimacy in decision-making, does not go far enough in facilitating deliberative dialogue with patients and easing the way toward acceptance of decisions (or at least of the legitimacy of the process by which they are reached).

\textsuperscript{69} \textit{Id.} at 130.
\textsuperscript{70} \textit{Id.} at 130-31.
\textsuperscript{71} See also King, \textit{supra} note 25, at 12 (describing questions of what constitutes experimental treatment, "surprisingly," as "turn[ing] out to be almost indistinguishable from those being raised by the futility debate"). Cf. Robert M. Veatch, \textit{Doctor Does Not Know Best: Why in the New Century Physicians Must Stop Trying to Benefit Patients}, 25 J. MED. \& PHIL. 701, 717 (2000) (suggesting that the principle of justice may be used to determine if patients are eligible for scarce medical resources).
DEALING WITH DYING

II. EXTERNAL REVIEW HAS NOT RESPONDED TO THESE PARTICIPANTS’ (PARTICULARLY PATIENTS’) GOALS AND NEEDS

As insurers began extensively to manage care in the 1980s and 1990s, and even as managed care began disintegrating into “consumer-driven health care” in the early 21st century, many patients—not only those facing questions about access to last-chance therapies—struggled to understand why insurers were second-guessing the decisions of their physicians. As important, patients struggled to understand the rules governing such second guesses, and to navigate dispute resolution systems to complain about the results. For a while, policy analysts and legislators believed that patients would find a solution in external review of plan decisions on issues such as whether a proposed treatment was medically necessary (so as to permit coverage) or whether it was experimental or investigational (so as to deny coverage).

External review adds an extra layer of procedure to the typical process of a pre-service coverage denial. Typically, an insurer will communicate its decision on a claim for coverage by sending a letter—usually a form letter—and including in that letter any information that may be required by law. The patient then has a certain amount of time (usually set forth in the notice of denial) to appeal to a person or group authorized to handle appeals within the same insuring entity. Timing may be accelerated in urgent cases, but, regardless of timing, these appeals are almost exclusively paper processes, meaning that the review is conducted of medical records and other treatment information presented on paper. Once a first-level internal appeal has been decided, the person or group deciding that appeal generally will send another letter—again, usually a form—to communicate the decision made. This notice likely will contain information about avenues either for further (second-level) appeal within the insuring entity, or for external reviews. If a state mandates or an insurer voluntarily offers external review, the patient gets a chance to argue, again usually

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72 E.g., 29 C.F.R. § 2650.503-1(g) (2004) (stating requirements for determinations by ERISA-governed employee health care coverage plans).
73 E.g., 29 C.F.R. § 2560.503-1(h) (stating that a claimant can appeal “to an appropriate named fiduciary of the plan, . . . who shall consult with a health care professional who has appropriate training and expertise in the field of medicine involved in the medical judgment”).
74 E.g., 29 C.F.R. § 2560.503-1(h)(3)(vi) (providing for expedited procedures in urgent cases).
75 E.g., 29 C.F.R. §§ 2560.503-1(i), (j).
on paper,\textsuperscript{76} to an outside entity (but not yet a court) that the coverage denial was incorrect.

It is likely fair to say that people thought external review would cure many of the ills plaguing the health care dispute resolution system. Although the first state-mandated external review system appeared well before managed care became commonplace in American medicine, most were required by law only in the late 1990s.\textsuperscript{77} By this time, patients in America seeking coverage for treatments from insurance companies had built up a head of frustration with insurers, who appeared to them to be second-guessing their physicians in denying coverage for treatments physicians recommended. Lack of transparency and inequities characterized the procedures that those patients had to follow in seeking reversal or revision of their insurers’ decisions. Many hoped that permitting patients to ask independent experts to review some of their insurers’ denials of coverage would help patients accept those decisions to deny coverage.

Unfortunately, while achieving some of its goals, external review has not proven to be an unqualified success. In some senses, it has helped ease patients’ suspicions about insurers’ motives in making coverage decisions. In the last-chance therapy setting, however, external review has proven to be of no benefit in terms of helping patients denied coverage to believe in the legitimacy of the system.

A. The Current State of External Review

External review is a formal process to resolve disputes between health plans and patients by submitting those disputes to expert decision makers independent from either the health plan or the patient.\textsuperscript{78} It came about as an attempt to assure patients facing denials of coverage that their insurers truly had stewardship obligations and scientific efficacy, rather than profit-motivated economy and self-interest, in mind when denying payment for certain treatments.\textsuperscript{79}

\textsuperscript{76} See infra Part II.A.


\textsuperscript{78} Id. at v. See also id. at 1.

\textsuperscript{79} See, e.g., TRUDY LIEBERMAN ET AL., KAISER FAMILY FOUNDATION & CONSUMERS UNION, A CONSUMER GUIDE TO HANDLING DISPUTES WITH YOUR EMPLOYER OR PRIVATE HEALTH PLAN, 2003 UPDATE 1 (2003), available at http://www.kff.org/consumerguide (asserting that external reviews “provide an unbiased way to resolve disputes between patients and their health plans”). Of course,
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For example, in Illinois, in a system of external review made famous in a recent Supreme Court case,80 a state statute requires that a health maintenance organization (HMO) refusing to cover a recommended treatment as not medically necessary submit the dispute to a reviewing physician "holding the same class of license as the primary care physician [who recommended the treatment], who is unaffiliated with the [HMO], jointly selected by the patient . . . , primary care physicians and the [HMO]."81 If the independent reviewing physician considers the treatment to be medically necessary, then the HMO must cover that treatment. There is nothing in the statute requiring that the reviewing physician refer to the definition of "medically necessary" appearing in the coverage contract, although reviewing physicians apparently do in fact refer to such contractual definitions in making their decisions.82

Other external review statutes apply to disputes between health plans and patients over treatment that the health plans refuse to cover as experimental or investigational. In California, for example, the Friedman-Knowles Experimental Treatment Act of 1996 built on a system of voluntary external review used initially by Aetna and then by Northern California Kaiser Permanente in the early to mid-1990s.83 Pursuant to that Act, which has since been amended to expand external review programs to include medical necessity decisions as well,84 the legislature mandated that "every health care service plan" provide "an external, independent review process" to examine all decisions regarding experimental or investigational therapies if the patients seeking coverage met certain criteria. Pursuant to this process, a patient dissatisfied with a denial of coverage because a proposed treatment is deemed experimental or investigational, or his or her physician, now may, with required certification of certain facts, ask an independent review organization contracted with the state to review the medical records and other evidence of the patient's illness and the

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81 215 ILL. COMP. STAT. ANN. 125/4-10 (West 1993).
82 See Moran, 536 U.S. at 382 n.12. For in-depth analysis of the problems that would arise if reviewers did not refer to contractual definitions of "medical necessity," see E. Haavi Morreim, ERISA Takes a Drubbing: Rush Prudential and Its Implications for Health Care, 38 TORT TRIAL & INS. PRAC. L.J. 933 (2003).
83 See SETTING LIMITS, supra note 1, at 73-76.
treatment's efficacy. An independent review organization's decision that coverage is appropriate is binding on the insuring entity, and, accompanied by reasoning, will (with identifying information deleted) be available to the public upon request.

Daniels and Sabin have described California's procedure as one in which both "[t]he fact and appearance of conflict of interest was removed." That was in fact the purpose. If patients seeking coverage proceeded through independent review by experts, the thought was, those patients would feel more confident about the decision-making process and be assured that appropriate and equitable decisions were made. If outside experts confirmed a health plan's decision that a treatment was experimental or investigational, after all, then the decision could not have stemmed from inappropriate concern about the health plan's pocketbook. Such procedures provided an extra layer of procedural justice as patients attempted to achieve coverage.

1. Goals of External Review

Patients generally needed such assurance because of the nature of the American health care system. The private nature of the system invites concerns (on both the provision of care end and the coverage end) about money-making motives. The diffuse, complex, and confusing nature of dispute resolution with regard to coverage issues, moreover, confounds most patients, leaving them unable to truly understand what is happening throughout the coverage determination procedure. The procedures by which patients can complain about insurer decisions are notoriously varied and confusing. Additionally, the challenges insurers face in managing care decisions for popu-

86 CAL. HEALTH & SAFETY CODE § 1374.34 (made applicable to cases of investigational or experimental treatment through § 1370.4).
87 CAL. HEALTH & SAFETY CODE § 1374.33 (made applicable to cases of investigational or experimental treatment through § 1370.4).
88 SETTING LIMITS, supra note 1, at 74.
lations using limited resources when physicians are making decisions for individual patients lead to inevitable tensions between desires for treatment and inability or reluctance to pay for the administration of that treatment. Finally, those tensions arise against a backdrop of perceived unfairness because some people have adequate remedies when a denial of coverage results in medical injury, and some do not.\footnote{92}

External review was supposed to change at least some of that. Although concerns about binding-arbitration-like external review solutions manifested themselves in a number of ways,\footnote{93} some legislatures adopted external review particularly as a method of dealing with denials of coverage for treatment deemed experimental or investigational.\footnote{94} External review has been held to be a permissible way for the states to try to ensure that insurers act appropriately when denying coverage, in that the Employee Retirement Income Security Act of 1974 (ERISA) does not prevent states from legislating in this area, as it does with respect to certain other insurer decisions made in the name of managing care.\footnote{95} Intended to achieve noble procedural jus-

\footnote{92} For a recent example, see Aetna Health Inc. v. Davila, 124 S.Ct. 2488 (2004) (holding that a state statute providing for recovery for personal injury when health plan decision was negligent was preempted by the Employee Retirement Security Act of 1974 (ERISA)). Insured persons whose cases are governed by ERISA cannot gain "make-whole relief." \textit{See id.} at 2503 (Ginsburg, J., concurring). \textit{See also} Cicio v. Does, 385 F.3d 156 (2d Cir. 2004), \textit{vacating} 321 F.3d 83 (2d Cir. 2003) (concerning ERISA preemption of claim based on plan medical director's alleged negligent denial of coverage for experimental procedure).

\footnote{93} Cerminara, \textit{Contextualizing, supra} note 23, at 552-53 (providing examples of the flaws in differing methods of health care arbitration). In addition to procedural justice concerns, if arbitration-like external review results in an alternative remedy for an ERISA § 502 claim, then the statute mandating that review would be preempted. \textit{See} Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 378 (2002). In Moran, the Supreme Court ruled, somewhat illogically, that the external review system in Illinois, although binding, constituted a medical second opinion rather than being the equivalent of arbitration. \textit{Id.} at 383-84. \textit{Cf} Sage, \textit{supra} note 2, at 627 (pointing out that the Illinois law refers in its title to dispute resolution).

\footnote{94} As noted, California's Knowles-Friedman Act initially was aimed solely at review of treatments deemed investigational or experimental.

\footnote{95} \textit{Compare} Moran, 536 U.S. at 355 (holding that ERISA did not preempt Illinois external review law pursuant to which a reviewer had required an HMO to cover an unconventional type of surgery), \textit{with} Davila, 124 S.Ct at 2502 (holding that ERISA did preempt Texas statute under which patients who had suffered injury as a result of their health plans' decisions not to cover recommended treatments could demand compensation for that personal injury). Even within the external review context, ERISA preemption continues to result in inequity because state laws regarding external review can apply only to decisions made by insured, and not to self-insured, ERISA plans, by virtue of ERISA's deemer clause. \textit{See} 29 U.S.C. § 1144(b)(2)(B) (2000); Moran, 536 U.S. at 371 n.6.
tice goals, external review thus has been given a boost through state legislatures and the United States Supreme Court.

2. Realities of External Review

In reality, however, external review programs have been only somewhat successful in achieving their procedural justice goals. While external review of medical necessity decisions seems partially to have assured patients of the integrity of the decision-making process, leading those patients to somewhat enhanced acceptance of coverage denials, patients seeking coverage of experimental or investigational treatments continue to express dissatisfaction with, and distrust of, plan decision-making procedures when coverage is denied. Procedural justice principles, indicating that patients might more easily accept even negative decisions as long as they believe they were treated fairly during the decision-making process, do not seem to apply to coverage denials when proposed treatments are deemed experimental or investigational.

Moreover, few patients use the procedures. This might tend to indicate that many people still do not know about or understand that review procedures are available to them in cases of coverage denials. Alternatively, it might tend to indicate that people do not understand how to access such procedures. The fact that some states do not mandate that patients be told anything about external review until internal appeals processes are completed might contribute to patients' lack of awareness of, or understanding of, such procedures. Thinking positively, the relatively low rate of usage might mean that providing the option of external review itself actually has led to increased perceptions of legitimacy of the decision-making process – enough so that patients are not tempted to seek the external review, but instead are reassured by its very availability.

96 See INST. FOR MED. QUALITY, CAL. HEALTHCARE FOUND., INDEPENDENT MEDICAL REVIEW EXPERIENCES IN CALIFORNIA, PHASE II: CASES INCLUDING MEDICAL NECESSITY 32 (2003), available at http://www.imq.org/imqdoc.cfm/1 [hereinafter PHASE II REVIEW].
97 PHASE I REVIEW, supra note 89, at 10-15.
98 POLLITZ ET AL., supra note 77, at v-vii.
99 See id. at 10.
100 Last Chance Therapies, supra note 31, at 33-34 (describing Kaiser experience and using low usage of procedure there as evidence that when the patients' concerns about insurer trustworthiness and potential conflict of interest were addressed in advance by the option of going outside of Kaiser for independent consultation, patients and families were much readier to enter into a reflective dialogue with their Kaiser physicians about what treatment approach really made sense for them.)
Of note is the fact that external review apparently has not uncovered widespread pockets of insurers denying coverage inappropriately. Reviews overturn coverage denials only about half the time. Arguably, on one hand, this should act as a confidence-builder in coverage decision-making processes; even though people are dismayed with coverage denials, independent experts say that the insurers are actually doing the right thing about half the time. On the other hand, the insurers are only doing the right thing about half the time. Being wrong half the time is not exactly a stellar record. And if one is predisposed to believe that improper motives underlie insurers’ decision-making, then one also might tend to view a system in which external reviews overturn denials only about half the time as casting doubt on the independence of those external reviews. Such suspicion surely is speculative; the requirements of independence are explicit and clear, and there is no evidence that any of the external review organizations are in fact self-interested.

B. External Review, as Typically Configured, Ignores Inevitable Emotions

Clearly then, external review alone is not enough to fulfill the high hopes policymakers had about enhancing confidence in the health care decision-making system, at least in the context of decision-making about last-chance therapies. As indicated by studies done in California, external review as configured in most statutory schemes at this time does not help people accept the decisions of their insurers to deny coverage because a treatment is experimental or investigational. It is easy to make patients happy when deciding to approve coverage, but that is not always the right thing to do. Decisions denying coverage for some treatments are inevitable; no plan can cover all treatments, and indeed none contract to do that. The challenge is to make and convey denials in ways that help patients

101 Pollitz et al., supra note 77, at v-vi; Phase I Review, supra note 89, at 9; Phase II Review, supra note 96, at 16.


103 There may be some argument that external review organizations might wish to rule for certain insurers because they would like to do more business with those insurers in the future. That also is speculation, however, and in some states the system by which the independent review organization is chosen is set up to preclude that possibility. See, e.g., Mo. Ann. Stat. § 376.1387(1) (West 2002).

104 Phase I Review, supra note 89, at 2; Phase II Review, supra note 96, at 32.
accept them. As Bill Sage has noted with regard to medical necessity
decision-making, external review systems are better than a simple
denial accompanied by an offer to review the decision within the same
internal corporate structure, but they do not go far enough to assure all
patients that they are being heard and that they are not being aban-
donened at the time that they are being denied coverage.\textsuperscript{105} Instead, for
a number of reasons, a patient's quest for coverage of last-chance
therapies can practically be guaranteed to result in conflict, thus justi-
fying a conflict management,\textsuperscript{106} rather than a dispute resolution, ap-
proach on the part of insurer decision makers. This is especially true
when one considers the vulnerable state of patients and families en-
gaged in the struggle to obtain coverage for last-chance therapies.

1. As a Tragic Choice, Decision-Making Regarding Last-Chance
Therapies Will Cause Conflict

As noted, last-chance therapies present stark examples of the
tragic-choice phenomenon. As Daniels and Sabin state:

Important values, all of which command respect and attention,
inevitably come into conflict in these difficult situations, es-
pecially giving some . . . priority to meeting the urgent claims
of patients in last-chance situations, providing stewardship of
collective resources, producing the public good of scientific
knowledge about the effectiveness of unproven therapies, and
respecting patient autonomy through collaborative decision-
making about risks and benefits.\textsuperscript{107}

Societies often cannot resolve difficult life-and-death decisions ex-
PLICITLY because doing so would cause too much social discord.\textsuperscript{108} The
disappointment and anger patients express upon coverage denials rep-
resent that discord on an individual level.

As previously noted, when an insurer has stewardship of a fund of
money to be used to pay for the treatments of all persons within a
covered population, that insurer cannot approve coverage of all treat-
ments. Contract exclusions of coverage for experimental and investi-

\textsuperscript{105} Sage, supra note 2, at 623.

\textsuperscript{106} See Cerminara, Contextualizing, supra note 23, at 583-84 (proposing an
alternative "conflict management" approach to resolving health care disputes).

\textsuperscript{107} SETTING LIMITS, supra note 1, at 81-82.

\textsuperscript{108} ORENTLICHER, supra note 44, at 123 (describing the writings of Calabresi
& Bobbitt). Orentlicher notes that subterfuges disguising tragic choices often are
successful for a time, but that eventually the public recognizes that they represent
illusions that conflict has been avoided. Id. at 127. That recognition may mean that
the public will demand a change in the method of resource allocation. Id.
gational treatments are predicated on a cost-benefit analysis,\textsuperscript{109} based upon a determination that it is better to allocate scarce resources to pay for proven treatments, which are far more likely to benefit their recipients, than for treatments that may or may not be of any value and often are expensive. Enforcing those exclusions, even in the face of a sympathetic case, is necessary to ensure equitable, predictable,\textsuperscript{110} and adequate distribution of resources.

In discussing futility, Orentlicher describes the argument advanced by some that instead of invoking ethical principles to refuse to provide ethically futile care, physicians should explicitly admit that they are rationing care.\textsuperscript{111} Orentlicher rebuts that argument and states as follows:

The problem with [the argument that physicians should just explicitly ration care] is that it overlooks the tragic choices problem. The likelihood of unresolvable social conflict means that it is often not possible to engage in rationing explicitly when life-and-death decisions are being made. Accordingly, societies commonly look for implicit ways to ration. The use of futility can be seen as an implicit rationing strategy that makes it possible for doctors to deny life-sustaining care in appropriate cases.\textsuperscript{112}

Similarly, as discussed earlier, when an insurer decides to deny coverage for a last-chance therapy based upon the "experimental" or "investigational" treatment exclusions in contract language, it is making an inexplicit resource-allocation decision. The problem arises when people realize that the insurers are in fact engaging in rationing. Although disguised, the rationing should be of no surprise since everyone knows that insurers are business people. People may be more ready to believe that insurers are rationing than they are ready to believe physicians are, because insurers are supposed to be in business for the money, whereas tradition has accorded to physicians a warm, professional, and caring image. Matters are convoluted, however, by the merging issues of coverage and care in the managed care system,

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\textsuperscript{109} ROBERT P. JERRY, II, UNDERSTANDING INSURANCE LAW § 64[c][3] (2d ed. 1996).
\textsuperscript{110} Predictability matters for purposes of determining risk. This is essential to an insurer, whose role is to assume risk in exchange for a price calculated to make the assumption of risk a winning proposition. See HEALTH INS. ASS'N OF AM., THE BUSINESS OF INSURANCE: A COMPREHENSIVE INTRODUCTION TO INSURANCE 9-12 (1998).
\textsuperscript{111} ORENTLICHER, supra note 44, at 6.
\textsuperscript{112} Id.
\end{flushright}
and by insurers’ assurances on websites and in plan documents that their health care professionals will work with patients’ health care professionals to see that patients receive good care. Moreover, even with the most business-like of insurers, it is jarring to come up against reality in a setting in which one’s life is at stake. Revealed tragic choices always cause discord, and recognition of the not-exactly-hidden resource allocations involved in insurers’ denials of coverage for last-chance therapies will cause people to rebel. This is especially so because even physicians can disagree regarding “the definition of experimental treatment and when a new treatment is no longer experimental.”

2. Last-Chance Therapy Decision-Making Brings Patients Face to Face with the “Misconception” Part of the Therapeutic Misconception

Patients being denied coverage of last-chance therapies, then, are coming face to face with the fact that rationing is part of the market forces underlying insurance contracts. At the same time, they are being robbed of hope. Recall that the therapeutic misconception exists when a patient does not fully appreciate – or subconsciously refuses to acknowledge – the experimental part of the description of a last-chance therapy. This may be even more likely to occur when the patient is a child and the person desiring, consenting to, and seeking coverage of the last-chance therapy is a parent, desperate because his or her child faces death. In that setting, Oberman and Frader have labeled participation in clinical trials in the hope of attaining life-saving treatment as “a societal death ritual... the way in which our society presently permits parents to grieve the horror of grave illness and premature death in children.”

When physicians offer last-chance therapies, patients are being told that there exists a treatment that is being tested that might do them some good. That gives the patients hope, however ill-founded. Insurers then bring those patients back to reality with the news that the


114 Orentlicher, supra note 44, at 147.

115 Oberman & Frader, supra note 28, at 315.

116 Id. at 317.
costs will not be covered because the "treatment" is experimental or investigational. Perhaps part of the issue is whether an appropriate amount of information is being provided, in the appropriate way, during the discussions between patients and doctors about last-chance therapies. When doctors fall into the trap of the therapeutic misconception along with their patients, attempting too hard to give hope of cure to those patients, they leave insurers to burst the patients' bubbles of hope with the reality that the value of a last-chance therapy is unknown and often speculative at best.

Moreover, the explosion of information about ongoing research that is available on the Internet means that many patients' hopes in last-chance therapies are not even traceable to their physicians. Many patients obtain a great deal of information themselves from the Internet. Internet sites about clinical trials are often worded in ways that promote the therapeutic misconception.\textsuperscript{117} Alternatively, or perhaps additionally, patients participate in support groups that are heavily involved in clinical trials.\textsuperscript{118} In support groups, patients hear clinical trials being described as treatment, similar to the message that was spread when AIDS activists began demanding access to clinical trials by carrying signs stating, "A Drug Trial is Health Care Too."\textsuperscript{119} Thus, there are other sources, besides doctors, that lead to and encourage the therapeutic misconception. Insurers need to be aware of, and take account of, the misconception when dealing with patients seeking coverage for last-chance therapies.

**III. A MORE THERAPEUTIC APPROACH WILL BETTER ASSIST IN HANDLING THESE CONFLICTS**

It may seem as if last-chance therapy coverage decision-making presents a no-win situation for insurers. Coverage approvals leave patients satisfied, but then are not always appropriate. Coverage denials will always be issued into an atmosphere of uncertainty and odds-playing, and they will always leave someone disappointed. Patients are likely almost always to be dissatisfied with the \textit{ex post} coverage effects of their insurance contracts that they did not foresee \textit{ex ante}.

\textsuperscript{117} See Goodman, supra note 27, at 71.

\textsuperscript{118} See, e.g., Clinical Trials Help, at http://www.clinicaltrialshelp.org (last visited Apr. 8, 2005). See also Coalition of Nat’l Cancer Coop. Groups Inc., Knowledge is Power: Educate Yourself Now on Cancer Clinical Trials, Newsweek: Special Advertising Sec., 2004, at 1, 2 (The advertising supplement says, "When you participate in a trial, in addition to receiving quality treatment, you are playing an important role in the acquisition of medical knowledge.") (on file with author).

If insurers were, however, to take better account of the situations in which patients and their families find themselves when seeking coverage of last-chance therapies, then the process can be less antagonistic. Rather than taking place in a combative setting, it can take place in an atmosphere inviting deliberation and reason-giving, and can permit patients and their families to feel some of the positive effects of procedural justice that external review procedures were supposed to produce.

This Article is not about how to define "experimental" or "investigational" in insurance contracts or statutes so that patients seeking coverage of last-chance therapies will be satisfied. Many definitions have been proposed and discussed in the literature. Rather, this Article focuses on the procedures to follow in communicating with patients about the decision-making process and about decisions, so as to properly apply whatever contract definitions are in effect and concurrently to help patients respect the process and the eventual decision, even if the decision is to deny coverage. Going a step or two beyond external review, it expands upon ideas found in sources as diverse as political philosophy and alternative dispute resolution literature. Expressly multidisciplinary in approach, the procedures recommended will help insurers build confidence in the legitimacy of their decision-making in even this trickiest of areas. Reaching, in some places, to bioethics for inspiration, this Article recognizes the value of making the last-chance therapy coverage decision-making process more "therapeutic," as recommended by Bill Sage with regard to medical necessity decision-making.

In an article focusing primarily on medical necessity determinations, Sage proposes an alternative approach to decision-making in managed care, arguing that "health plans should make a serious attempt to identify traditional ethical values associated with healing and build them into coverage determinations." Sage recommends that, in denying coverage, health plans should emulate doctors conveying a


professional opinion that a specific therapy is not advisable. Doctors, in doing so, "also maintain hope, offer explanations and alternatives, and assure patients that they will not abandon them." Insurers should act similarly.

When insurers make decisions regarding last-chance therapies, they should be cognizant of the special situations in which the patients and families seeking coverage find themselves. In addition to being in the traditionally vulnerable, relatively uninformed state in which all patients find themselves, they have been told that death will result unless they undergo a last-chance therapy. They likely are operating under a therapeutic misconception that has led them to fixate on that therapy as a cure, rather than as the experiment it almost certainly is. They may be about to be brought face to face with the fact that insurance cannot pay for everything, and that it, in fact, will not pay for something so experimental as the procedure they wish to undergo or the course of drugs they wish to take. Anything short of full support with an open pocketbook is likely to upset them, so insurers should treat these patients with kid gloves from the very beginning.

Doing so, as Sage notes, almost certainly will require voluntary efforts on the part of insurers, for even if policy mandates are warranted, they may not be effective. Some have suggested that "policy-makers need to develop more aggressive and comprehensive approaches for facilitating voice" among patients regarding all sorts of concerns about health care, and the approach outlined hereafter is designed to help patients achieve a voice through a dialogue with their insurers. In the wake of the Moran decision, however, ERISA preemption concerns may have limited the form of procedural mandates states will feel free to implement in the near term. One non-legislative way to ensure that insurers revise their procedures may be to work toward amendment of the National Committee for Quality Assurance (NCQA) requirements for health plan grievance procedures. Insurers wishing NCQA accreditation (as most do) would then feel pressure to institute improved procedures. Another way to

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122 Sage, supra note 2, at 631.
123 Mark Schlesinger et al., Voices Unheard: Barriers to Expressing Dissatisfaction to Health Plans, 80 MILBANK Q. 709, 747 (2002) (mistakenly characterizing external review procedures as "mediation").
124 C.f. Leatrice Berman-Sandler, Independent Medical Review: Expanding Legal Remedies to Achieve Managed-Care Accountability, 13 ANNALS HEALTH L. 233, 285 (2004) ("While the Court may be narrowing the scope of ERISA preemption, in so doing, it has created a box for state-based IMR [Internal Medical Review], which while protecting IMR from preemption, also constrains it.").
125 Limits to Health Care, supra note 49, at 348 (proposing a regulative strategy to address fears of accountability).
convince insurers to "reprofessionalize" voluntarily is to demonstrate to them why it will benefit them to do it, for it will indeed benefit them.

A. Last-Chance Therapy Coverage Decision-Making Should Be a Multidisciplinary, Textured Dialogue

Daniels and Sabin have identified four conditions that are necessary to enhance the legitimacy of a health care coverage decision-making process: (1) limit-setting decisions, and the grounds for making them, must be public; (2) the grounds for decisions must be ones that fair-minded people can agree are relevant to meeting health care needs fairly under reasonable resource constraints; (3) limit-setting decisions must be subject to revisions and appeal, and the process for doing so must itself meet the first two conditions; and (4) there must be some form of regulation to ensure that the other conditions are met. In the course of discussing such considerations, they suggested that an external review procedure might be of use in last-chance therapy coverage decision-making. Nevertheless, even as they did so, they recognized that a single type of process was not likely to work for every limit-setting situation. Rather than a single approach, they noted that health care coverage decision-making may be a matter of choosing from among "best practices." They identified at least three different practices they believed were valuable. While only external review has caught on, at least in a widespread fashion, with policymakers and insurers thus far, the other two incorporated more thoroughly concepts of shared decisionmaking of the type explored below.

Specifically, insurers should establish a more personal, multidisciplinary process, incorporating dialogue with all affected parties in last-chance therapy dramas. Concurrently with implementing these procedures, empirical studies should track their effect on patient satisfaction (or lack thereof) with decisions, much as the California and Kaiser studies have done regarding current external review procedures. The results of such research would assist in further developing legitimate, shared decision-making procedures in this most critical area.

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126 Sage, supra note 2, at 651.
127 SETTING LIMITS, supra note 1, at 11-12; Limits to Health Care, supra note 49, at 323.
128 Last Chance Therapies, supra note 31, at 38.
129 See id. at 35-36.
1. Begin at the Beginning

Rather than treating requests for coverage of last-chance therapies like any other requests for coverage, insurers should flag them as they come into the office and begin treating them specially at that moment.

One key is to provide full information, from the very beginning, about what the insurer will be doing with the claim, what substantive contract provisions apply, and what procedures are available for internal levels of appeal and for external review. Research from California reveals that sometimes patients do not know of the availability of external review, and thus are unclear about what rights they may have. As a Kaiser study points out, in states in which claimants are not advised of a right to external review until internal appeals are completed, people who chose not to go through internal appeals did not know there was an option to ask an independent expert about what the insurer did. Had they known that that option existed down the line, they might have gone through the internal process. One way to keep people from feeling disappointed later is to assure up front that they know of procedural options.

Another key is to provide, even at that early stage, some extra hand-holding, perhaps in the nature of personal contact with an identified person whose job is to ask the person seeking coverage if all information was understood and to assure that person that the insurer is standing by him or her. After Hurricane Andrew in South Florida, amid the sad and discouraging negative events such as looting and dishonest contracting, there were bright spots such as the insurers who sent agents to the scene with checkbooks to help immediately. Those agents, appearing on the scene of the 1992 hurricane that caused nearly $25 billion in damages, devastated mile after mile of South Florida and directly caused 26 deaths, brought a level of personal contact and caring to the scene. Clearly, a health insurer will not send a person with a checkbook to visit every patient with a last-chance therapy coverage request. The difference, of course, is that after a hurricane there is no doubt the insurer must pay (although the amount to be paid may be a subject of dispute), whereas there is substantial doubt whether an insurer must pay for a last-chance therapy. But a personal touch helps assure the insured that he or she is not alone. People going through trauma, like hurricane survivors and patients

130 PHASE I REVIEW, supra note 89, at 10.
131 See generally POLLITZ ET AL., supra note 77, at 10.
seeking coverage of last-chance therapies, feel isolated already; they
do not need impersonal bureaucracy compounding those feelings.
Hearing a personal voice, even just to offer to help decipher the pa-
perwork, can help avoid that.

2. Use a Multidisciplinary Team

Perhaps related to the latter point, there is almost undoubtedly
some value in bringing a multidisciplinary team in on every case of
requested coverage of last-chance therapies. Hall, speaking of physi-
cians dealing with patients, describes the ill as being in a state of
“‘wounded humanity.’”\(^\text{133}\) Just as physicians exert a great deal of
power when dealing with their vulnerable patients in the context of
medical care decisions, so do insurers exert a great deal of power
when dealing with vulnerable patients in the context of coverage deci-
sions, especially when a decision will determine whether a patient will
receive a course of care she perceives as being the only one that can
save her life. The task of properly dealing with those patients can
involve many disciplines, and there is no reason why insurers should
refrain from including those many disciplines in the process of dealing
with the patient.

For example, if coverage is likely to be denied professionals from
a range of disciplines can help convey the reasoning behind the likely
impending denial of coverage. An insurer may wish to involve a
medical expert to discuss the proposed treatment with the patient. The
patient’s own doctor, in fact, can and likely should be involved. So-
cial workers, nurses, mental health professionals, or grief counselors
all may be appropriate persons to involve in the process, depending on
the state of the patients and their families. Accountants or claims ad-
justers should not be involved, because their presence can highlight
the tragic choices tradeoff that is part of what is shocking the patient.

The goal of such a multidisciplinary team would be to encourage
patients to recognize (and to assist them in recognizing) the tradeoffs
inherent in the proposed last-chance therapy, to discuss the therapeutic
misconception, and to assure the patient that he or she will not be
abandoned even if coverage is denied. It may be helpful, for instance,
if an appropriately trained person were to discuss with a patient the
concept of “number needed to treat” (NNT). The NNT is the number
of patients that must be treated with the procedure or drug in question
to prevent one additional bad outcome. If a treatment that the patient
believes is a possible cure has an NNT of twenty, then that would

\(^{133}\) Hall, supra note 2, at 478 (quoting S.K. Toombs, The Meaning of
Illness 45 (1992)).
mean that twenty patients would have to receive the treatment before one is cured by it. Another point to be explained might be toxicity of the treatment. Many experimental treatments are highly toxic, causing as much, if not more, agony as the patient's original malady, perhaps to no good effect at all. Team members such as chaplains, social workers and mental health professionals might encourage patients to think about the quality of life that they would have during the treatment, especially in light of the odds of the treatment helping them (or not). Hospice care and appropriate palliative measures leading toward a good death may in fact lead to a much more pleasant remaining life, of equal length. Talking in such terms can help the patient recognize the "misconception" part of the therapeutic misconception without presenting the news in cold, hard type in a form denial letter.

The point is that insurers must recognize that physicians, out of belief in the therapeutic misconception themselves or in a zealous attempt to offer hope to their patients, very well might be painting some patients a rosier picture about potential last-chance therapies than reality. An insurer certainly should not suggest that the physician refrain from offering a therapy he or she thinks is a reasonable alternative, although it may be appropriate for some physicians to re-think their practices in this area just a bit. Rather than gagging physicians, insurers should join them in the effort to assure that patients do not feel abandoned by the health care system. Both the physician in the provision of care and the insurer in the coverage of care can offer hope, even if a particular last-chance therapy will not be covered.

As noted throughout the earlier discussions about dying patients, hope is important. Insurers denying coverage should not slap patients in the face with the news that there is no hope. Instead, they should work with patients and their families to realize where the real hope lies. Maybe it is in the suggested last-chance therapy, if the evidence shows enough of a chance that the insurer wishes to cover it, and if the patient still wishes to undertake it after hearing more about its

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134 GOODMAN, supra note 27, at 61 & n.18.
135 See supra text accompanying note 59.
137 See generally NAT'L TASK FORCE ON END-OF-LIFE CARE IN MANAGED CARE, MEETING THE CHALLENGE: TWELVE RECOMMENDATIONS FOR IMPROVING END-OF-LIFE CARE IN MANAGED CARE 12, 44 (1999), available at http://caepp.edc.org (recommending, among other steps, use of a "mixed management" approach to care of the terminally ill and assignment of "a skilled, trained community volunteer or professional advocate to each patient and family confronting advanced incurable illness").
risks and benefits. But maybe hope lies in other avenues. Sherwin Nuland writes that physicians too often believe, mistakenly, that offering hope consists only of offering cure or remission.\footnote{Nuland, supra note 15, at 223.} If a physician has done this, and offered too much hope (or, perhaps more accurately, hope of the wrong kind), the insurer should not compound the problem by acting in impersonal, rote fashion as coverage is refused. Instead, a multidisciplinary team can offer what would be paid for, in a therapeutic manner. Assurances of payment for non-experimental treatments, adequate pain management, or hospice may help to offer hope of a different kind: a redefined hope.\footnote{See id. at 233 (suggesting patients and their families need to find hope not in elusive therapies but in realistic ways, thus redefining hope). See also id. at 246 (expressing the belief that commonly effective therapies are the most reasonable care in which people can place hope).} Perhaps as important as anything else is assurance that the patient will not die alone.\footnote{Think of the slogan “Like a good neighbor, State Farm is there.” State Farm will be there, even though it may not always pay. Health insurers should offer as much (to be there, even if not with freely opened checkbooks).}

3. Engage in a Dialogue

In sum, the goal for insurers should be to engage in a deliberative dialogue regarding the proposed last-chance therapy. Just as an Oregon Blue Cross/Blue Shield transplant coordinator, described by Daniels and Sabin as “one-third nurse clinician, one-third nurse manager, and one-third ethics professor,” engaged in discussions with patients while explaining why coverage might or would be denied,\footnote{Last Chance Therapies, supra note 31, at 35; Limits to Health Care, supra note 49, at 345; Setting Limits, supra note 1, at 76-77. See also Last Chance Therapies, supra note 31, at 35-36 (discussing special process adopted by a Minnesota health maintenance organization to establish a special category of “promising treatments” to be covered even though investigational).} so too could a multidisciplinary team discuss matters with a patient seeking a last-chance therapy. If coverage will be denied, the denial should be conveyed through more than a flat-out “no,” with no reasoning beyond a clinical explanation of why the treatment was considered investigational or experimental. Reason-giving is crucial for legitimacy purposes, and it should involve more than the issuance of a form letter with some documentation attached. Moreover, the California studies have noted that it sometimes is not clear in the external review process whether information always reaches its destination, and they stress the importance of patients being assured that the information they have provided relevant to their conditions has reached
appropriate decisionmakers.\textsuperscript{142} Engaging in a dialogue rather than a bureaucratic series of notices, missed calls, and frustration, is the most straightforward way to do this.

The suggestion is that insurers deal with patients as individuals, not as covered lives or enrollees. Insurers certainly do not have physician-patient relationships with their insureds, but to the extent they are administrators of health plans they are indeed fiduciaries under the law with respect to those insureds.\textsuperscript{143} Just as a physician facing a futility situation confronts a conflict between her duties of fidelity and stewardship of resources, insurers making decisions about last-chance therapies face like conflicts. Even if their fiduciary status does not carry with it a duty to give precedence to individual patients over populations of covered lives, viewing those patients as individuals will better address the patients' anxiety, panic, and fear of abandonment. In many clinical settings, when physicians face issues of allocation, "patients understand the need for priority setting if the case is made simply and honestly,"\textsuperscript{144} perhaps in part because the clinicians and patients have individualized relationships. There may be more of a chance that patients will understand insurers if they are approached as individuals and invited into a dialogue during the process.

This can, for example, be a good way to diffuse the anger a patient might direct toward the insurer. When patients are dying, anger is often "displaced in all directions and projected onto the environment at times almost at random."\textsuperscript{145} The projection would hardly be random in the case of an insurer denying payment; one can certainly understand why a patient would direct anger toward that insurer. But even when entirely random,

[a] patient who is respected and understood, who is given attention and a little time, will soon lower his voice and reduce his angry demands. He will know that he is a valuable human being, cared for, allowed to function at the highest possible level as long as he can.\textsuperscript{146}

\textsuperscript{142} PHASE I REVIEW, supra note 89, at 22. Such factors are important whether relating to the internal review or the external review process. See Nguyen v. Healthguard of Lancaster, Inc., 282 F. Supp. 2d 296, 300-01 (E.D. Pa. 2003) (involving denial of coverage based on medical necessity where crucial patient information repeatedly was not forwarded in both internal and external review context).
\textsuperscript{143} Pegram v. Herdrich, 530 U.S. 211, 222-23 (2000).
\textsuperscript{145} KUBLER-ROSS, supra note 7, at 44.
\textsuperscript{146} Id. at 46.
Bioethics offers an example of a field in which disagreements such as this often arise because patients, or more commonly patients' families or surrogate decision makers, are angry and intensely emotional about proposed medical courses of action. Medical institutions have developed a method of encouraging dialogue among all the interested parties in cases of bioethical conflict. Within medical institutions, ethics committees bring together all the parties with stakes in an ongoing conflict to try to encourage a sharing of views, information, and opinions. A physician approaching a case in which it appears as if further treatment is futile, for example, may know that certain angry family members wish that treatment be continued indefinitely. It may even be that other members of the care team disagree with the futility assessment. One of the physician's options at that point would be to call for an ethics consult, so that the members of the standing ethics committee, along with the members of the care team, can discuss the matter and then can engage in a dialogue with the family members (and the patient if the patient has decision-making capacity) regarding the physician's decision that a treatment is futile.

The process can resemble mediation, and in fact, trained mediation specialists have begun working explicitly on the use of mediation techniques when working through bioethical conflicts. Mediation fosters dialogue, and mediation techniques have proven to be valuable with regard to many bioethical disputes.\(^{147}\) Like last-chance therapy coverage disputes, many bioethical conflicts involve life-or-death matters, an imbalance of power and knowledge among those involved, a high level of uncertainty about the most appropriate care, and urgency.\(^{148}\) Mediators can frame the discussion, allow patients and family members to have their say, permit members of the care team to completely air their points of agreement and disagreement, and direct the conversation toward possible appropriate outcomes. In one case, for example, mediation assisted a family, some of whom were very angry, in understanding that their terminally ill brother would not receive scarce platelets and in fact should have a Do Not Resuscitate (DNR) order put on his chart.\(^{149}\) The resource allocations inherent in that case closely resemble the types of tragic choices presented by futility cases and last-chance therapy cases. The use of mediation


\(^{148}\) Cf. Nancy Neveloff Dubler, *Mediating Disputes in Managed Care: Resolving Conflicts Over Covered Services*, 5 J. Health Care L. & Pol'y 479, 480 (2002) (listing a similar set of characteristics shared by bioethics disputes and more general managed care coverage conflicts).

\(^{149}\) Dubler & Liebman, *supra* note 147, at 15-19.
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techniques in such settings is intended to ensure that the “concerns and needs of family members [and the patient are] identified, acknowledged, respected, and [to the extent possible] accommodated.” Conversation permits those concerned to begin to come to terms with their impending loss by expressing some of their frustrations and anger and by having someone listen and respond.

The idea is to foster conversation and reason-giving so that patients do not feel abandoned. Although Daniels and Sabin spoke of the need to have some level of publicity associated with reason-giving, there is no reason to assume that the publicity condition requires hearings resulting in written opinions or case law. Indeed, external review does not involve such proceedings as most external reviews are conducted on paper only, with no hearings or in-person contact. Rather than engaging in paper reviews, with decisions communicated via letter, decisions could be reached and communicated through a dialogue, encouraging give-and-take in a personal setting, with some later commemoration of the salient facts of the patient and the proposed treatment, stripped of identifying characteristics, sent to the insurer’s central headquarters to provide a database of guidelines to consult in future cases.

B. How This More Therapeutic Process Will Help

Insurers may hesitate to engage in this rather complex, unwieldy process for what could be hundreds or even thousands of patients at any one time, especially when they are not likely to be required to do so by law. They should not hesitate, however, because this is a golden opportunity to buttress their legitimacy, to build continuing relationships with insureds, and to create a record of fair process.

Legitimacy of process matters. Procedural justice research shows that. So too does consideration of how external review in California has helped some patients denied coverage on medical necessity grounds accept those denials. The “special nature of health care” imposes upon all its organizational participants “justifiable social expectations of moral behavior beyond those attributed to organizations that make widgets or purvey potables.” In the last-chance therapy context especially, insurers should worry about legitimacy. There, of

150 Id. at 19.
151 Limits to Health Care, supra note 49, at 325.
152 LIEBERMAN ET AL., supra note 79, at 19.
154 If for no other reason, insurers should be worried because of the “halo
all places, limit-setting is necessary, so insurers should begin giving reasons for denials in a more understandable and accessible way. As Daniels and Sabin have stated, "because health care limit setting inevitably raises moral controversies, for a decision-making process to be and be seen as fair, it must foster thorough deliberation about the facts, reasons, and principles that are relevant to the dispute."  

Even if last-chance therapy coverage is approved, the special attention paid to the patient seeking it will have been valuable. Increased personal attention and dialogue can help ensure that all information reaches its intended destinations in a timely manner, which itself can help cut down on the time and aggravation costs of decision-making. To the extent that such assurances help avoid unnecessary grievances and appeals, they are valuable. In addition, incorporation of mediation techniques can take less time and money, and promote more positive continuing relationships than other methods of coverage decisionmaking.  

Such a process will also encourage, over time, the development of a set of guidelines to be used in addressing similar cases, perhaps with an eye toward contractual revisions as technology progresses or as clarification is required. Regardless of whether coverage is approved or denied, the positive effects on the patient/insurer relationship (which, after all, is a continuing one) could help patients through a difficult time.  

In cases of denial, there will always arise situations in which patients will continue to be dissatisfied. For example, when similarly situated patients are treated differently by different insurers, as they inevitably will be, someone will always cry foul.  

Even with alternative dispute resolution, conflict still arises, "and the life and death stakes for some patients will ensure that they will use every avenue to effects" that could emanate toward the physicians associated with them, affecting relationships between patients and physicians. If patients distrust insurers, there may be derivative lack of trust that spreads to the physicians who associate with the distrusted insurers. Allen Buchanan, *Trust in Managed Care Organizations*, 10 KENNEDY INST. ETHICS J. 189, 191 (2000). Should that occur, the physician-patient relationship could be damaged. Hall, *supra* note 2, at 475 (discussing the "halo effect" of patients' trust in an institution being influenced by their trust in individual physicians at that institution). See also David Mechanic & Sharon Meyer, *Concepts of Trust Among Patients With Serious Illness*, 51 SOC. SCI. & MED. 657, 658 (2000).  

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155 *SETTING LIMITS*, *supra* note 1, at 4.  
156 *Dubler*, *supra* note 148, at 500.  
157 *Id.* at 498. See also *MEISEL & CERMINARA*, *supra* note 38, at § 3.25[A][d] (making the same point about ethics committee consultations).  
158 *Last Chance Therapies*, *supra* note 31, at 29 (describing the media's focus on some coverage denials for "investigational" treatments); *Holder*, *supra* note 5, at 797 (noting that the same policy coverage terms can be interpreted differently by different judges).
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obtain coverage, including the courts." In some instances, even patients who have been treated in the most direct way possible, by physicians and insurers who believe further treatment would be more detrimental than helpful, will refuse to accept anything less than all-out war on their disease, and likely will fight to get coverage of even the most experimental of last-chance therapies.

If and when that happens, having engaged in a good process beforehand will assist an insurer. Based on their empirical studies, Anderson and Hall have noted that insurers’ procedures can affect the way that health insurance coverage disputes are decided in court. In bioethics disputes as well, the involvement of ethics committees in processes leading up to the courtroom dispute has resulted in courts looking more favorably upon the actions of health care institutions and providers. The lesson seems to be that, while good process before a dispute reaches a court will not insulate a decision maker from being overturned in court, it certainly cannot hurt, and it may even help the court look favorably upon that decision maker.

Finally, insurers certainly cannot avoid the big-picture public relations and business implications of last-chance therapy decision-making. This is a hot political potato, as demonstrated by all the state statutes requiring clinical trials coverage and external review procedures. Negative media attention of the sort accompanying the Nelene Fox case can do severe harm to a company’s public image. This is an era of consumer-driven health care, when consumer satisfaction measures are publicized on the Internet and when employers consider satisfaction as an indication of quality when deciding what health plans and what health plan administrators to offer their employees.

159 Anderson & Hall, supra note 46, at 94.
160 E.g., TIMOTHY E. QUILL, A MIDWIFE THROUGH THE DYING PROCESS: STORIES OF HEALING AND HARD CHOICES AT THE END OF LIFE 10-13 (1996) (recounting the story of Cynthia, who, even with the advice of a physician who was unafraid to confront the possibility of death with his patients, had to try a course of experimental treatment before deciding to forego treatment and accept palliative care and hospice).
161 Anderson & Hall, supra note 46, at 91.
162 Limits to Health Care, supra note 49, at 347 (asserting that courtrooms are disadvantageous places to introduce technical assessments of evidence); MEISEL & CERMINARA, supra note 38, at § 3.25[A][d].
163 See infra note 54; see also Stone, supra note 113, at 30-31 (describing process triggered by such publicity).
164 Cf. SETTING LIMITS, supra note 1, at 49 ("Fear of litigation and exposure in the media are the most commonly expressed objections to [the] proposal that organizations be more explicit and accountable about the reasons underlying their limit-setting decisions regarding new technologies.").
Serving patients well, even if saying “no” to requested last-chance therapies, cannot but help.

IV. CONCLUSION

In summary, it is clear that external review has not cured the health care dispute resolution system with regard to patients’ requests for coverage of last-chance therapies, even if it has done some good in the area of medical necessity determinations. Insurers making decisions regarding coverage of proposed last-chance therapies must take into consideration the mental states in which patients seeking last-chance therapies are operating. They must recognize that denials of coverage in this setting force patients to face a classic example of a tragic choice in health care. Such denials also require patients to acknowledge the fact that no treatment is available to definitively help them live.

Against this backdrop, a bureaucratic, paper-based decision-making process will do little or nothing to help patients accept the sometimes-inevitable coverage denials, and in fact may increase the chances that patients will react negatively to coverage denials. Instead, as in certain bioethical settings, it will prove more useful in this coverage setting to incorporate multidisciplinary teams to work through a dialogue about the myriad social, emotional, and medical issues raised by requests for coverage of last-chance therapies. In this sense, communication about the decision-making process and about the decision itself will be handled in a conflict-management, rather than a dispute-resolution, style, and patients will be treated as individuals rather than as covered lives.