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Repository Citation

Idziak, Janine Marie (2011) "Forgoing Drugs on Grounds of Cost: A Perspective from Catholic Health Care Ethics and Social Teaching," *Marquette Elder's Advisor*: Vol. 13: Iss. 1, Article 3.

Available at: <http://scholarship.law.marquette.edu/elders/vol13/iss1/3>

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FORGOING DRUGS ON GROUNDS OF COST: A PERSPECTIVE FROM CATHOLIC HEALTH CARE ETHICS AND SOCIAL TEACHING

Janine Marie Idziak*

This paper will explore the *ethical dimensions* of decisions to forgo (or even deny) drugs on grounds of cost in the case of elderly long-term care residents. The specific ethical framework employed will be that of Catholic health care ethics and social teaching. We will begin by describing the various accounts of the role of cost in making decisions about forgoing medical treatments found in Catholic health care ethics, historical and contemporary. A hypothetical case study will be introduced to aid in critically assessing these accounts. Finally, we will propose four principles to govern decisions about providing or denying drugs on grounds of cost. These governing principles will attempt to balance respect for the sanctity and inherent value of each human life with the common good of the community.

COST AND THE ORDINARY/EXTRAORDINARY TREATMENT DISTINCTION

Familiar to many is the distinction between *ordinary* and *extraordinary* medical treatments and the accompanying principle that ordinary treatments must always be undertaken but that it is morally permissible to forgo treatments which are extraordinary in character.¹ Less well known is the fact that,

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historically, the cost of a treatment factored into the determination that a particular treatment qualified as "extraordinary" in character.

In his doctoral dissertation *Conserving Human Life*, originally published in 1958, Bishop Daniel Cronin notes that "moral theologians have always taken into account the element of expense when discussing the ordinary and extraordinary means of conserving life."² Specifically, "[t]hey have constantly taught that any means of conserving life which imposes an excessive hardship on an individual because of cost is an extraordinary means."³ Historically, such terms as *sumptus extraordinarius* (extraordinary expenditure), *media pretiosa* (high priced means), and *media exquisita* (very best means) were used for this concept, which goes back to such Catholic moralists as the sixteenth century Spanish Dominicans Francisco de Vitoria and Domingo Banez and the sixteenth century English Benedictine Gregory Sayrus.⁴

In his book, *Catholicism and Health-Care Justice*, Philip Keane notes that "the traditional Catholic moral manuals of the pre-Vatican II era regularly mentioned high cost as a factor that could render a medical treatment extraordinary and non-obligatory."⁵ Indeed, the manual of the Jesuit Edwin F. Healy, revised in 1956 shortly before the beginning of Vatican II, went so far as to stipulate \$2,000 as the line of demarcation "between low-cost (and therefore ordinary) treatments and higher-cost

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1. *General Policy on the Use of Life-Sustaining Treatments*, LORAS COLLEGE, <http://www2.loras.edu/~CatholicHE/Arch/Death/policies.html> (last visited Dec. 14, 2011).

2. DANIEL A. CRONIN, ORVILLE N. GRIESE & ALBERT S. MORACZEWSKI, *CONSERVING HUMAN LIFE* 107 (Russell E. Smith ed., 1989).

3. *Id.*

4. *Id.* at 86–87, 107.

5. PHILIP S. KEANE, *CATHOLICISM AND HEALTH-CARE JUSTICE* 42 (2002).

(and therefore extraordinary) treatments.”⁶ In the 1997 fourth edition of their classic textbook *Health Care Ethics: A Theological Analysis*, the Dominican health care ethicists Benedict Ashley and Kevin O’Rourke likewise give an example of forgoing life-sustaining treatments on grounds of cost: “A father who contracts cancer may determine that, rather than spend his life savings on surgery and hospitalization, he will devote his savings to the education of his children, allowing the cancer to take its natural course.”⁷ In a 2005 journal article, O’Rourke likewise gives the example that “drug therapy for patients with AIDS may offer hope of benefit” but that “some patients might deem it an excessive burden because of the expense involved.”⁸

The cost factor is found not only in the writings of theologians but also in magisterial documents. The 1980 Vatican *Declaration on Euthanasia* attempted to clarify the ordinary/extraordinary treatment distinction in terms of the concepts of “proportionate” and “disproportionate” means.⁹ In discussing decisions to forgo medical treatments, the document states that “it will be possible to make a correct judgment as to the means by studying the type of treatment to be used, its degree of complexity or risk, *its cost* and the possibilities of using it, and comparing these elements with the result that can be expected.”¹⁰

6. *Id.* (citing EDWIN F. HEALY, *MEDICAL ETHICS* 68 (Loyola Univ. Press 1956)).

7. BENEDICT M. ASHLEY & KEVIN D. O’ROURKE, *HEALTH CARE ETHICS: A THEOLOGICAL ANALYSIS* 424 (4th ed. 1997).

8. Kevin D. O’Rourke, *The Catholic Tradition on Forgoing Life Support*, 5 NAT’L CATHOLIC BIOETHICS Q. 537, 547 (2005). Recent discussions of using/forgoing medical treatments take it for granted that the cost factor is to be considered. See Daniel J. Daly, *Prudence and the Debate on Death and Dying*, HEALTH PROGRESS, Sept.–Oct. 2007, at 49, 52 (“In the case of a physician trying to discern the proper treatment of a patient in natural decline, he or she must know, among other things, the patient’s physical, spiritual, and psychological condition; *the patient’s (and/or the patient’s family’s) economic situation*; the patient’s relationships; the effects of the patient’s treatment on the society at large; and the prognoses for various treatments.” (emphasis added)).

9. Congregation for the Doctrine of the Faith, *Declaration on Euthanasia*, VATICAN (May 5, 1980), http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_faith_doc_19800505_euthanasia_en.html.

10. *Id.* (emphasis added).

The document continues:

Therefore one cannot impose on anyone the obligation to have recourse to a technique which is already in use but which carries a risk or is burdensome. Such a refusal is not the equivalent of suicide; on the contrary, it should be considered as an acceptance of the human condition, or a wish to avoid the application of a medical procedure disproportionate to the results that can be expected, or a desire *not to impose excessive expense on the family or the community*.¹¹

Noteworthy is the explicit expansion of the cost consideration from the impact on the patient and his or her family to the impact on *the community*.

The position of the *Declaration on Euthanasia* is reiterated in the current edition of the *Ethical and Religious Directives for Catholic Health Care Services* (ERD) from the United States Conference of Catholic Bishops:

A person has a moral obligation to use ordinary or proportionate means of preserving his or her life. Proportionate means are those that in the judgment of the patient offer a reasonable hope of benefit and do not entail an excessive burden or impose excessive expense on the family or the community.

[] A person may forgo extraordinary or disproportionate means of preserving life. Disproportionate means are those that in the patient's judgment do not offer a reasonable hope of benefit or entail an excessive burden, or impose excessive expense on the family or the community.¹²

In fact, the cost factor enters into the ERD's explanation of informed consent to medical treatments: "Free and informed consent requires that the person or the person's surrogate receive all reasonable information about the essential nature of the proposed treatment and its benefits; its risks, side-effects,

11. *Id.* (emphasis added).

12. UNITED STATES CONFERENCE OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES 26-27 (5th ed. 2009) (Directives Nos. 56 and 57).

consequences, *and cost.*"¹³

What we have described thus far can be considered "the tradition" within Catholic health care ethics.

In March of 2004, Pope John Paul II delivered an allocution at the end of a conference on the vegetative state.¹⁴ This allocution is significant for charting current Church teaching on the provision of medically assisted nutrition and hydration.¹⁵ However, a careful reading of the allocution also reveals a radical departure from the tradition regarding the relevance of cost to undertaking or forgoing a medical treatment:

Considerations about the "quality of life," often actually dictated by psychological, social and economic pressures, cannot take precedence over general principles. First of all, *no evaluation of costs can outweigh the value of the fundamental good which we are trying to protect, that of human life.*¹⁶

More simply stated, it is affirmed that the value of a human life (and its preservation) is worth more than seemingly any amount of money.

Indeed, the allocution goes on to affirm *a societal responsibility to provide financial assistance* to families caring for patients in a vegetative state. It comments that "[the families] cannot be left alone with their heavy human, psychological and financial burden," so "society must allot sufficient resources for the care of this sort of frailty, by way of bringing about appropriate, concrete initiatives such as . . . financial support and home assistance for families when patients are moved back home. . . ." ¹⁷

13. *Id.* at 17 (Directive No. 27) (emphasis added).

14. John Paul II, Life-Sustaining Treatments and Vegetative State: Scientific Advances and Ethical Dilemmas, Address Before the International Congress (March 20, 2004), available at http://www.vatican.va/holy_father/john_paul_ii/speeches/2004/march/documents/hf_jp-ii_spe_20040320_congress-fiamc_en.html.

15. Congregation for the Doctrine of the Faith, *Responses to Certain Questions of the United States Conference of Catholic Bishops Concerning Artificial Nutrition and Hydration*, VATICAN (August 1, 2007), http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20070801_risposte-usa_en.html.

16. John Paul II, *supra* note 14 (emphasis added).

17. *Id.*

Thus we have discovered two strains of thought within Catholic health care ethics on the relevance of cost to decisions about medical treatments. "The tradition" allows forgoing medical treatments on grounds of excessive expense for the patient, his or her family, or even the community. A more recent strain of thought virtually rejects the cost factor as justifying forgoing a medical treatment, radically breaking with the tradition. We will propose and analyze a case study as the springboard for critical analysis of these various positions.

CASE STUDY

Joe, 85, is a resident of the St. Francis Care Center. He was admitted eight months ago after his second heart attack. His wife, Janet, is also 85, and being a full-time caregiver for Joe was a strain on her.

Dr. Mangrum, Joe's cardiologist, has been honest with him that his heart is "just giving out." However, Dr. Mangrum has told Joe that a new medication is available that would likely give him "another six months."

Joe is still mentally alert. Although Joe is restricted in his physical activity and is easily fatigued, he is able to enjoy playing cards, watching television, and visiting with members of his church who come to see him.

Janet has expressed that she would like to have her husband with her as long as possible, especially since they will celebrate their sixtieth wedding anniversary in five months. They are also awaiting the birth of another great-grandchild.

The cost of the new medication for Joe for six months would be \$60,000.¹⁸

A number of questions can be posed about this case scenario. From an ethical point of view, would it be permissible for Joe to decide to forgo using this new medication on grounds

18. See Peter Singer, *Why We Must Ration Health Care*, N. Y. TIMES MAG. July 19, 2009, at 38, available at <http://www.nytimes.com/2009/07/19/magazine/19healthcare-t.html> (case study modeled after Peter Singer's discussion of the drug Sutent).

of cost? Ought Joe forgo this medication on grounds of cost? On the other hand, should Joe even be placed in a position of having to make a decision about using or forgoing beneficial medication on grounds of cost? Or, from another point of view, can we (and should we) as a society restrict health insurance payments for expensive medications that are limited in their life-prolonging effects?

CASE STUDY ANALYSIS: FOCUSING ON THE PATIENT

Let us add some details to the aforementioned case. Let us further suppose that Joe is a private pay resident and that Medicare would require a 25% co-pay for this new cardiac medication.¹⁹ In six months this would be \$15,000, over and above regular nursing home costs. Let us further suppose that the Joe's and Janet's savings have been dwindling because of nursing home costs and that Joe is concerned about his wife's financial welfare after his virtually inevitable death within the next year. He does not want his wife to end up on Medicaid since this might mean lower quality of care for her should she ever need long-term care.

"The tradition" of Catholic health care ethics would judge it morally permissible, in these circumstances, for Joe to make a decision to forgo the new cardiac medication for himself on grounds of excessive expense for his wife (that is, his family). Does this seem right? We find ourselves morally outraged when, for example, we hear accounts of people who are forced to decide not to use needed medications on a regular basis, or not at all, because they cannot afford it.²⁰ Our moral gut reaction is that this kind of situation should not exist. People should not

19. *Id.* at 41.

20. *Id.* Consider, for example, a case reported by Peter Singer: "Dr. Art Kellermann, Associate Dean for Public Policy at Emory School of Medicine in Atlanta, recently wrote of a woman who came into his emergency room in critical condition because a blood vessel had burst in her brain. She was uninsured and had chosen to buy food for her children instead of spending money on her blood-pressure medicine. In the emergency room, she received excellent high-tech medical care, but by the time she got there, it was too late to save her." *Id.*

be deprived of medically needed and beneficial medications just because of their financial situation. In the case of some long-term care residents, a person suffering from a severe heart condition (like Joe) might also be suffering from other medical conditions (co-morbidities) such as Parkinson's disease and/or dementia. These conditions might well enter into our calculus about the value of using a very expensive drug to achieve a limited prolongation of life. But Joe represents our proverbial "hard case."

In the case of Joe, the expensive medication would clearly be beneficial for him in ways beyond a brute prolongation of biological life for six months. Prolonging Joe's life through the use of the new medication would be beneficial to him on a *personal level*: it would likely give him and his wife the joy of celebrating their sixtieth wedding anniversary as well as seeing the birth of another great-grandchild. Those extra six months might also give Joe the opportunity for increased spiritual preparation for death, perhaps including the reconciliation of strained relationships. In the spirit of John Paul II's allocution we might ask, Isn't Joe's life worth more than the cost of the medication?

This intuition is reinforced by the strong emphasis placed by Catholic social teaching on the sanctity of human life and the dignity of the human person:

Human personhood must be respected with a reverence that is religious. When we deal with each other, we should do so with the sense of awe that arises in the presence of something holy and sacred. For that is what human beings are: we are created in the image of God.²¹

Persons in long term care—like Joe in our hypothetical case study—share no less in the inherent dignity and sacredness of human life. The fact that his death is foreseeable from his cardiac medical problems does not make his life any less

21. Statement by U.S. Catholic Bishops, *Economic Justice for All: Pastoral Letter on Catholic Social Teaching and the U.S. Economy* (1986), available at <http://www.osjspm.org/admin/document.doc?id=93> (citing *Genesis* 1:27).

valuable.

At this point, someone might assert that Joe, just like every other person, has a right to health care. Indeed, in their 1993 document *A Framework for Comprehensive Health Care Reform*, the Catholic Bishops of the United States present “the sanctity of human life and the dignity that belongs to all human persons” as grounding for the claim that “all people have a right to health care.”²² This document goes on to “insist that every human being has the right to quality health services, regardless of age, income, illness, or condition of life.”²³ Since responsibilities correlate with rights,²⁴ it would seem that John Paul II’s allocution is correct in affirming a societal obligation to assist patients and families financially with health care costs.

CASE STUDY ANALYSIS: FOCUSING ON THE COMMUNITY

In our hypothetical case study, we have thus far focused on the impact of the cost of the medication for the patient and his immediate family. However, there is a communal dimension of the case to consider, namely, the impact on the health insurance program of which the patient is a part, *ex hypothesi*, some of the cost of Joe’s medication will be covered by health insurance. Will paying for very expensive medications for patients like Joe mean that premiums will increase for other people?²⁵ Will it mean that health care services for other categories of patients may be cut from coverage?²⁶

22. CATHOLIC BISHOPS OF THE U.S., *A FRAMEWORK FOR COMPREHENSIVE HEALTH CARE REFORM: PROTECTING HUMAN LIFE, PROMOTING HUMAN DIGNITY, PURSUING THE COMMON GOOD* 1 (June 18, 1993).

23. *Id.* at 3.

24. *An Introduction to the Principles of Catholic Social Thought*, UNIVERSITY OF NOTRE DAME, <http://social.concerns.nd.edu/mission/cst/cst3.shtml> (last visited Dec. 13, 2011).

25. Singer, *supra* note 18, at 39.

26. O’Rourke, *supra* note 8, at 553 (internal citations omitted):

Community Interest

The community is also mentioned as a stakeholder when decisions about life support are necessary. People belong to small and large communities. In a small community, the expense and care that a

While the Catholic tradition places value on the life of the individual, this tradition also sees humans as essentially social beings who achieve fulfillment *in relationship with others*. Catholic social teaching rejects the pure individualism that has characterized American society and affirms the value of the community. Concomitantly, the Catholic tradition holds a concept of the *common good*.²⁷ Recognition of the social dimension of human life and of a common good provides grounding for the traditional view of Catholic health care ethics that imposing excessive expense on the community justifies forgoing a medical treatment.²⁸

Strictly speaking, the language of the *Ethical and Religious Directives for Catholic Health Care Services* gives an individual *permission* to make a decision to forgo a medical treatment on grounds of imposing excessive expense on the community.²⁹

particular therapy might impose could be a factor when decisions about life support are made, because if funds are not expended for one person, they may benefit another person. In religious communities, for example, there is usually a fund to finance health care. But this fund is not an insurance fund in the strict sense; the members of the community contribute to it. Thus, if a community member requires extensive therapy, others in the community may not have access to adequate therapy, or the contributions of individual members may have to be increased.

Recently, a friend of mine who is prominent in the field of bioethics was afflicted with a serious stroke, and refused extensive therapy, stating that he did not want to expend the funds of his community upon therapy that would have doubtful success. In other words, he determined that in his condition, and given the finances of the community, such care would not offer hope of benefit and was therefore extraordinary, even though it would have prolonged his life.

At present, given the method of paying for health care in the United States, the larger community, the state, or the insurance company do not often become a significant factor in making decisions about forgoing life support. While the funding methods of state-sponsored health care and insurance companies are too complicated to discuss in this article, if care is withheld or removed from one person, there does not seem to be a direct benefit for another person, and the uninsured do not benefit from cost reduction for the insured. This situation could change if universal health care ever becomes a reality within the social policy in the United States.

27. PONTIFICAL COUNCIL FOR JUSTICE AND PEACE, COMPENDIUM OF THE SOCIAL DOCTRINE OF THE CHURCH 71–75 (2005).

28. ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES, *supra* note 12, at 26–27.

29. *Id.*

Should we go a step further and say that an individual has or ought to have a *moral obligation* to forgo a medical treatment which is of this character *out of regard for the common good*? Concomitantly, on grounds of “excessive expense for the community,” could *societal decisions* be justified that would limit access to health care services on grounds of cost? In other words, do we find in traditional Catholic health care ethics a strain of thought which could support societal decisions to *ration* health care services on grounds of cost?

Our hypothetical case of long-term care resident Joe is related to an actual case discussed by ethicist Peter Singer in a New York Times editorial entitled “Why We Must Ration Health Care.”³⁰ Singer relates that in 2008 Britain’s National Institute for Health and Clinical Excellence (NICE) initially recommended that the National Health Service should not offer the drug Sutent for advanced kidney cancer.³¹ Specifically, “NICE had set a general limit of £30,000, or about \$49,000, on the cost of extending life for a year. Sutent, when used for advanced kidney cancer, cost more than that, [while offering] only about six months extra life.”³² According to this criterion, long-term care resident Joe would not be entitled to receive the new cardiac medication because it cost \$60,000 for a predicted life extension of only six months.

John Paul II’s allocation asserted that “no evaluation of costs can outweigh the value of the fundamental good which we are trying to protect, that of human life.”³³ Upon reflection it does not seem that we can implement such an unqualified claim in a health care context. As ethicist Philip Keane points out, “health care is only one of a number of basic human goods[, and w]e also have to think about the responsibility of society to provide for other goods, such as education, housing, transportation, communication, and aesthetic human

30. See Singer, *supra* note 18, at 39–40.

31. *Id.* at 40.

32. *Id.*

33. John Paul II, *supra* note 14.

experience."³⁴ In other words, the financial resources that can be devoted to health care will always be finite and limited in scope. As Keane speculates, "[i]t is not possible for even a truly just society to provide for every conceivable health-care good."³⁵

GUIDING PRINCIPLES

Thus far, our reflections have pulled us in two different directions. Traditional Catholic health care ethics tells us that a patient may choose to forego medical treatment on the grounds of imposing excessive expense on himself/herself or his/her family. This standard strikes us as unacceptable as it stands. Someone having to forgo medically indicated and clearly beneficial treatment simply on grounds of cost does not seem to respect the sacredness and inherent value of each and every human life. Indeed, "[w]hat may be an ordinary expenditure for a very rich man would not be an ordinary expenditure for most of us."³⁶ Further, we now recognize a *right to health care*, a concept which was not part of the framework of discussion when this principle of Catholic health care ethics was formulated. On one hand, society has a responsibility to ensure access to health care for individuals. On the other hand, the Catholic tradition is not purely individualistic but recognizes a social dimension to human life, the value of community, and the common good. These support the principle of Catholic health care ethics governing forgoing treatment on the basis of excessive expense for the community.³⁷ This is a factor which could limit an individual's access to health care services. Thus, we are in a position of having to balance what is owed to an individual with the needs of the larger community. We propose four guiding principles for working through this dilemma.

34. KEANE, *supra* note 5, at 8.

35. *Id.*

36. Scott M. Sullivan, *The Development and Nature of the Ordinary/Extraordinary Means Distinction in the Roman Catholic Tradition*, 21 *BIOETHICS* 386, 390 (2007).

37. ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES, *supra* note 12, at 27.

1. *Every person has a right to a basic and reasonable level of health care services which should be guaranteed by the structures of his or her society, e.g., through health insurance programs.*

In examining more carefully the concept of a right to health care, we find that the claim of a right to health care is often interpreted in such terms as a right of access to a “decent minimum” of health care³⁸ or to a “reasonable standard” of health care.³⁹ Even the aforementioned document from the U.S. Catholic Bishops speaks in terms of a right to “adequate” health care and a “decent level” of health care.⁴⁰ As Catholic health care ethicist Philip Keane reiterates, “[w]hat a just society ought to do in behalf of distributive justice is to pick out a basic and solidly reasonable floor of health-care services and make sure that all citizens have access to at least these services.”⁴¹ This principle entails that society has an obligation to commit sufficient financial resources to ensuring that everyone enjoys a basic and reasonable level of health care services.

2. *As much as possible, society should attempt to finance medically indicated and clearly beneficial health care services beyond the basic level.*

This is in deference to the sanctity and inherent value of each and every human life.

3. *If providing a particular medical treatment to a given patient or class of patients beyond the basic guaranteed level would seriously compromise society’s ability to finance the basic and reasonable level of health care services for all citizens, then the medical treatment in question may be considered an*

38. Allen E. Buchanan, *Is There a Right to a Decent Minimum of Health Care?*, in *INTERVENTION AND REFLECTION: BASIC ISSUES IN MEDICAL ETHICS* 525, 525–26 (Ronald Munson ed., 8th ed. 2008).

39. KEANE, *supra* note 5, at 5.

40. CATHOLIC BISHOPS OF THE U.S., *supra* note 22, at 2–3.

41. KEANE, *supra* note 5, at 8.

“excessive expense for the community” and need not be provided.

Ethically, this principle is grounded in a commitment to the common good.⁴² It also provides a criterion for determining what qualifies as “excessive expense for the community,” a concept which has not been defined thus far.

4. *In order to maximize the number of health care services which can be funded overall, providers of health care services should pursue cost-reducing efficiencies which do not compromise quality of care, and should act in accord with a standard of “fair compensation” in pricing their services.*

At this point the notoriously high cost of drugs comes into consideration. Such costs could conceivably limit prescription drug benefits to only those drugs included in the basic package. If drugs are developed and produced in a way that is not cost efficient, or if drugs are priced beyond what constitutes fair compensation for development and production of them, then a situation may be *artificially* created in which some prescription drug benefits could be excluded as constituting “excessive expense for the community.”

In his book *Catholicism and Health-Care Justice*, Philip Keane devotes a section of the sixth chapter to “The Cost of Prescription Medications,” noting “[t]wo special factors . . . relative to the cost of drugs.”⁴³

42. *Id.* at 17 (“In general, the most complete notion of proportionality in health care ought to include the theme of the common good, and some decisions for health-care rationing may be made so as to act in favor of the common good.”); *Sullivan, supra* note 36, at 395 (“For example, today’s expensive and increasing health care costs and the number of the uninsured, the financial status of people to pay for long term life support is increasingly a moral concern as it adds to the burden of family and society. One may object to this financial status criterion, which will likely invoke feelings of ‘choosing money over human lives’ or valuing money over life. This need not be the case. It is not the financial concerns *per se* that is at issue, but the benefit of one life versus the benefit of other lives. *One human life is not so valuable that it warrants extreme expenditures to the disproportionate detriment of others.*” (emphasis in original)).

43. *Id.* at 174–75.

The first factor is that “a significant part in the cost is related to drug manufacturers spending large amounts of time and money developing similar and even redundant drugs so that they can compete with one another in the marketplace.”⁴⁴ Hence “[m]illions of extra dollars can be spent to develop competitive drugs that do very little that is new, and these costs are passed on to the patients.”⁴⁵ Keane suggests setting some limits on competitive research.⁴⁶ For example, “[s]tate regulatory agencies might limit the providers in their states to the use of no more than two or three similar products for a given condition, thus limiting the incentive for the drug manufacturers to develop too many drugs for the same purpose.”⁴⁷

The second factor noted by Keane deals with the enormous cost to develop drugs:

Even with regulatory schemes that restrict the number of drugs developed, vast sums of money will be spent on research for and development of new drugs. Most drug companies in the United States employ a two-tiered approach to the pricing of their drugs. In the United States, the drugs are priced to recover the cost of the research that was done to develop them. Some of this cost is recovered through government grants, and some through direct charges to the consumer; in either case the consumer ultimately pays for the drugs. When the companies sell the same drugs to other countries, a different pricing structure is often used, which pays for the cost of producing the drugs but not the cost of the research to develop the drugs in the first place. The result is that U.S. manufacturers frequently sell their products in other countries for far lower prices than they charge in the United States. One regularly reads accounts of U.S. citizens who live near the U.S. borders journeying to Mexico or Canada to buy prescription drugs.⁴⁸

Keane’s response to this situation is twofold. On the one

44. *Id.* at 175.

45. *Id.*

46. *Id.*

47. *Id.* at 175–76.

48. *Id.* at 176.

hand, Keane thinks that “lowering the price of drugs is a socially responsible action on the part of the drug companies” in countries having “very limited economic development and sometimes terrible health problems.”⁴⁹ On the other hand, he contrasts this situation with “countries with highly productive economies.”⁵⁰

Admittedly, “[s]ome of these countries are involved in research to develop new medications, and they bear some of the costs associated with this research.”⁵¹ But, according to Keane, it is the case that “the United States, and in particular drug consumers in the United States, are asked to bear a disproportionately high share of the research and development costs related to new medications.”⁵² Thus Keane proposes that “[i]t would seem more just to develop a formula that would cause all of the world’s productive economies to share equitably in the cost of developing new drugs.”⁵³

Keane suggests that “U.S. drug manufacturers might develop two pricing structures for products they sell outside the United States, one for poorer countries and one for richer countries.”⁵⁴ According to Keane, “[s]uch an integrated approach would also have the effect of lowering drug prices for consumers in the United States, at least to some degree.”⁵⁵

The point to be drawn from Keane’s discussion is this: addressing factors contributing to the high cost of drugs is a prolegomenon to factually and ethically sound determinations of what drugs our society can and cannot fund.

How do the guiding principles we have proposed apply to the case of long-term care resident Joe? Joe’s cardiologist advises him of the availability of a new drug that would likely prolong his life another six months but would cost \$60,000.

49. *Id.*

50. *Id.* at 177.

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.*

During those six months Joe would have a reasonable quality of life physically while being able to take part in activities valuable on a personal level (e.g., celebrating his sixtieth wedding anniversary, seeing the birth of another great-grand child, preparing spiritually for death).

Further, let us consider the hard case in which Joe's medication would not make it into the basic package of health care services guaranteed to him because of its limited life-prolonging effects.

In deference to the sanctity and inherent value of every human life, we should try to find a way to finance the medication that is medically indicated and clearly beneficial for Joe. This may well involve the larger project of an honest examination of the current high cost of drugs, and whether means can be found to reduce these costs without compromising quality of care. This is necessary so that the availability of pharmaceutical resources can be maximized.

Only after such attempts have been made could we make an ethically sound judgment to deny the drug to Joe. In other words, only after such attempts have been made could we feel comfortable ethically with depriving patients of medically indicated and clearly beneficial drugs beyond those in the basic health care package on grounds of excessive expense to the community.