BIOETHICS OUTLOOK

Plunkett Centre for Ethics in Health Care

Volume 18 Number 2 June 2007

End-of-Life Care Revisited

Recent Debates Have Raised Some Important Foundational Questions

Daniel Sulmasy ofm

In this issue

In our first article, Daniel Sulmasy ofm identifies three ideas which have emerged in recent debates about the use of life-sustaining treatments which, in his words, 'seem to deviate from established, traditional forms of Catholic argument'. Dr Sulmasy makes the ideas explicit and responds to the forms of argument which they employ. His intention is to 'further honest discussion of the ethics of life-sustaining treatment' among faithful Catholics.

In our second article, Helen McCabe considers the ethical challenges to medical practice associated with contemporary collaboration with pharmaceutical companies. She considers how far a market-oriented enterprise can be consistent with a professional practice which is oriented to the 'benefit of the sick' in ways which are distributively just.

A number of claims made in recent discussions about Catholic teaching and the use of life-sustaining treatments raise important and very serious theological, philosophical, and medical questions that have received almost no direct attention or examination.

Some recent forms of argument seem to deviate from established, traditional forms of Catholic argument. Yet the nature and extent of these deviations from tradition have not been apparent to most commentators. Some recent claims have been based upon over-simplified understandings of clinical and economic reality. Still other claims appear to be based upon novel philosophies of medicine that have not been made explicit. In this brief article, I make some of these questions explicit for the sake of furthering honest discussion of the ethics of life-sustaining treatments among the faithful.

Intending Death?

Claim 1: *When one discontinues the use of a feeding tube in a patient who is in a persistent vegetative state (perhaps better termed "post-coma unresponsiveness"), and that person has left*

no advance instructions asking that this be done for a morally legitimate reason, then one must be intending that person's death as a means of relieving his or her suffering and therefore committing euthanasia.

This form of argument has been very prominent.[1] However, there is an underlying, unrecognized premise at the argument's heart – that the proper moral principle by which to analyze the act of withdrawing a life-sustaining treatment is the rule of double effect. This rule has assumed an unprecedented prominence in Catholic circles in recent years, due to the influence of what has been called the "New Natural Law Theory." According to this theory, which effectively removes ontological considerations from natural-law thinking, everyone must act for one of a small number of reasons called "basic goods," and one may never act directly against one of these basic goods. These theorists recognize that, in real life, however, one is constantly facing choices in which one good must be sacrificed so that another can be realized.

According to this theory, one may tolerate an act that goes against a basic good (e.g., undermines respect for life or marriage) only if this bad result is an indirect, unintended side effect of acting to promote another basic good. That is to say, the rule of double effect applies in all of these situations. Therefore, in a feeding tube case, the New Natural Law Theory directs the patient's loved ones to ask themselves, "What good am I trying to accomplish here?" If they answer, "Relieving the patient's suffering," they will violate the rule of double effect. Since the feeding tube itself does not appear to be doing any harm, the only way to relieve the suffering of the patient is by way of making the patient dead. Therefore it is concluded that the act is morally impermissible.

However, the story is complicated because commentators who would require feeding tubes for patients suffering from post-coma unresponsiveness are not the only ones who use the rule of double effect in this situation. Some who argue that it is permissible to withdraw feeding tubes from such patients also invoke the rule of double effect in doing so. To make the argument work, however, they are forced to conclude that the treatment is of "no benefit", so that even the most minimal burdens caused by the feeding tube can be considered disproportionate. Of note, this seems to entail the judgment that life itself is not a good, since the effect of the treatment (maintaining life) is judged to be of no benefit. Justifiably, this has upset orthodox Catholic sensibilities, since it seems to denigrate the value of human life.

I argue, however, that both sides of the debate are mistaken, because they have framed the problem using the wrong principle. The Catholic moral tradition has for several centuries relied upon the casuistry of withholding and withdrawing extraordinary means of care as the proper framework for analyzing such cases, not the rule of double effect. The moral theology of forgoing extraordinary means of care was developed independently of the rule of double effect and this rule was never invoked in its development or justification. Instead, the traditional understanding of forgoing extraordinary means has been based upon the principles of "physical and moral impossibility".

These principles are based upon the understanding that although negative precepts ("Do not commit adultery") bind absolutely, positive precepts ("Fast on Ash Wednesday") are always limited in a finite world. They are limited by physical impossibility (what cannot be done) and so-called "moral" impossibility (that which is beyond what a reasonable person can be expected to do or to bear in carrying out a duty). The intention of a person who refrains from fasting (say, because of age or infirmity) is not to denigrate the value of penance and self-mortification; it is, rather, to say, "I have done all that the Lord requires of me, given my finite physical, psychological, social, financial, and spiritual resources. Fasting is beyond me, and I can forgo this otherwise obligatory duty".

The forgoing of extraordinary means of care emerges from this form of moral analysis. One has a positive duty to sustain one's life, but this duty is limited. One need not do everything conceivable to sustain one's life. And when a person forgoes a life-sustaining treatment under this analysis, one cannot conclude that that person has the intention of causing death.

When a faithful Catholic withholds or withdraws a life-sustaining treatment, the moral object of the act, the intention-in-acting, is to forgo a treatment that is demanding more than one can reasonably be expected to bear. The intention is fulfilled when the treatment is stopped. In so doing, one foresees death following, but death is not within the scope of one's intention. Whereas the outer limits of judgements about when this is permissible are determined by the community of believers, decisions about what is extraordinary will always depend upon the individual case – the constitution of the patient as person integrally considered; the nature of the condition and its treatment; and the clinical, social, and economic conditions, among others.

The traditional criteria for judging that a treatment is extraordinary (i.e., morally optional) have been either that it is futile (physical impossibility) or that it is more burdensome than beneficial (moral impossibility). Burdens have included not just pain but also the broad range of physical, psychological, intellectual, financial, social and spiritual resources of the person, including such traditional notions as horror or repugnance at the state in which one will be left by the treatment (e.g., after amputations).

Some commentators have argued that the ordinary/extraordinary means distinction is merely an application of the rule of double effect, but this is not true historically, and in fact makes no sense when applied to many situations in which there is clear consensus among the faithful that treatment would be "extraordinary" or morally optional.

One important difference is that, under the rule of double effect, only the positive and negative effects associated with the action itself count in the proportionality assessment. When this is applied to withdrawing life-sustaining treatments, this means that the only benefits and burdens that count are those bad effects caused by the withdrawal of the treatment (e.g., shortening life) and the benefits resulting from stopping the treatment (e.g., relieving pain and side effects caused by the treatment itself and capping the treatment's costs). This sets an almost impossibly high standard. Unless death is just minutes away, the treatment itself would need to be torturous to the patient for one to view its withdrawal as a good proportionate to the bad effect of shortening something of so great a value as life itself. However, under the analysis proposed by the extraordinary-means tradition, the burdens of the disease itself, not just the burdens of the treatment, count in the proportionality considerations.

For example, Cardinal John De Lugo wrote in the 17th century that one had no obligation to prolong one's life by dousing oneself with water if one were being burned to death and water were reasonably available, but only in a supply great enough to prolong one's burning to death, not enough to extinguish the fire. The pain caused by the condition itself (i.e., being on fire), which the treatment (water) only prolonged, and not just the suffering caused by water itself (which in this case is not a burden but rather a source of temporary relief) counted in the evaluation of benefits and burdens.

Many commentators who analyze cases of the withdrawal of life-sustaining treatments under the rule of double effect appear to overestimate the burdens caused directly by treatments such as ventilators. This is the only way they could use this rule to justify the claim that the positive effects of withdrawal are proportionate to the negative effect of shortening life. This might work theoretically, but in real life most life-sustaining treatments do not themselves cause much suffering. Rather, they tend to relieve some symptoms and to prolong the suffering associated with the underlying condition – much like the water in Cardinal De Lugo's case.

For example, if a patient is comtaose, he or she will not feel the discomfort of having an endotracheal tube. So the directly intended good effect of stopping the ventilator cannot be the relief of the suffering caused by the ventilator. If the patient is awake, the discomfort of ventilation is often preferable to feeling the discomfort of shortness of breath. In both cases, it is generally the suffering caused by the disease, not its treatment, that constitutes the true burden. Thus, under double-effect analysis, stopping the ventilator in most cases will be euthanasia, since the aim would appear to be to relieve the patient from a state of suffering that is being prolonged by the machine. The only way this could be accomplished would be by means of making the patient dead, and so it would not be allowed.

However, according to the traditional Catholic analysis, stopping ventilator treatment in a patient dying of a painful cancer would be the morally permissible forgoing of an extraordinary means of care. The burdens of the disease count in the equation (e.g., the pain caused by the cancer). The intention is not to make the patient dead, but to stop a treatment at a point at which the burdens of this disease and its treatment are greater than what one could reasonably be expected to bear in carrying out one's duty to preserve one's life.

Extraordinary Means: Whose Point of View?

According to the traditional Catholic analysis (which was developed centuries before the legal concept of substituted judgment was invented), when family members or religious superiors make a judgment for the patient, they are acting on the patient's behalf and assuming the patient's point of view. The tradition has never focused on the family's motives and belief as the central moral concern. The proposed analysis that some are now urging changes this, however, by making the central moral question, when patients cannot speak for themselves, "What basic good is the family member attempting to realize by way of his or her act?" The Catholic tradition, by contrast, asks the family to assess whether the patient could be presumed to have met the reasonable limits of what would be necessary in carrying out his or her duty to preserve the gift of life. This difference is so subtle that it largely goes unnoticed, but in reality the shift is monumental, and changes the whole character of the analysis.

The Cost of Care

To complicate matters further, the way that claims about the financial costs of treatments have been bandied about in recent discussions appears to draw upon an insufficient understanding of the actual clinical and economic reality. Traditional analysis has allowed consideration of costs to enter into judgments about whether treatments are extraordinary either because (a) the patient has decided to forgo a treatment as an act of charity or (b) because the treatment is prohibitively expensive. But recent discussions seem dominated by a somewhat oversimplified understanding of the costs of certain types of treatment. Tube feeding is assumed to be cheap. However, tube feeding involves far more than the cost of the nutrient solution.

First, little attention is paid to the fact that no one ever gets to the point of being in post-coma unresponsiveness without millions of dollars having already been spent in hopes of recovery. It takes six months of intensive care just to make the diagnosis! Second, the additional costs of caring for patients – such as special beds, nursing care, supplies, testing, pump, electricity, hospitalizations for complications, and so forth – are never considered in discussions of the costs involved in supplying tube feeding.

On the other side of the equation, many treatments that seem more technologically sophisticated than tube feeding have become much less expensive than many commentators seem to appreciate. It has been estimated that the annual cost of feeding tube supplies for home treatment (adjusted to 2005 dollars) is about $12,000 per year.[2] This is relatively cheap, but it does not count any costs for nursing home care (which would bring the cost to $868,000 per year[3]), nor does it count the labor costs if treatment were given at home (estimated at $87,000 per year[4]). This

is roughly comparable to the annual cost of continuous ambulatory peritoneal dialysis (CAPD) at home, which is about $17,000 per year for supplies[5]; $28,000 if one includes labor, electricity, testing, and other factors.[6]

Some developing countries such as Malaysia have reduced the annual cost of the supplies for CAPD to as little as $7,000.[7] Both tube feeding and CAPD can be done at home. Both involve placing a tube through the abdominal wall to replace a lost physiological function. Patients die in similar time frames after discontinuing dialysis or feeding tubes (about two weeks).

If one of the main arguments in favor of declaring feeding by tube to be ordinary and obligatory is its low cost relative to other treatments and relative to the wealth of developed nations, then CAPD would also have to be considered in principle ordinary and morally obligatory for all patients in renal failure, even those suffering from post-coma unresponsiveness. Similarly, ventilators can now be used at home, oxygen can be delivered via oxygen concentrators, and the price of this treatment is thought to have come down considerably from the $77,000 per year estimated in 1997.[8] A year's worth of antiretroviral drugs for HIV costs substantially more than this.

The point is that the church must be extremely careful at the reasoning being invoked to conclude that feeding tubes are ordinary and morally obligatory in any particular clinical circumstance. It does not seem to me that the magisterium has explicitly decided to revoke a 600 year-old tradition of moral reasoning in favor of a new method for analyzing such cases. And if this new method of analysis is used in the case of feeding tubes, the precedent-setting implications are potentially astounding, given the propensity for life-sustaining treatments to become increasingly available and less expensive relative to the economies of the developed world. A rash move in this case threatens to make Catholic servants of technology, when the point of technology ought to be its service to the human person.

The Nature of Human Suffering

Claim 2A: *It cannot be argued that, if patients are in the condition of post-coma unresponsiveness, feeding tubes cause them any pain. Since, by virtue of their brain damage, such patients cannot be said to suffer from the treatment, the only intention one could have in discontinuing feeding-tube treatment would be to make them dead by way of a judgment that they are unworthy of life.*

Claim 2B: *If their feeding tubes are discontinued, patients in post-coma unresponsiveness suffer miserably from the pangs of starvation and die with parched tongues and cracked, bleeding lips. It is a cruel and inhumane to make a person suffer so.*

Recent arguments about the use of feeding tubes in patients who suffer from post-coma unresponsiveness raise significant questions about the nature of suffering, the human person, and Catholic teaching. Some people, in arguing that feeding tubes are always ordinary and morally obligatory in cases of post-coma unresponsiveness, have used both of the arguments above. The arguments do not appear in the same paragraph, but have been invoked by the same source. When they are placed side by side, it is easier to see that these arguments are internally inconsistent. One cannot argue both that tube feeding must be continued because such patients lack the neurological substratum for experiencing suffering and also that tube feeding cannot be discontinued because the patients will thereby experience intense suffering.

Additionally, the clinical descriptions of such deaths are medically misguided. Most persons who die of chronic illnesses stop eating at the end of life, and dehydration is generally a contributing cause of such deaths, whether resulting from cancer or tuberculosis. While there is a tendency towards dry mouth (often exacerbated by the injudicious use of oxygen), this problem can be treated with ice chips, sips of water, or gentle mouth swabbing by nurses or family members.

Also, it is unclear whether feeding tubes help relieve the sensation of hunger. They provide no taste or smell or oral sensation, and since the nutritional solution is usually dripped into the tube continually to avoid the side effect of aspiration pneumonia, feeding tubes do not provide a sensation of satiety – the patient's stomach is never full. Thus, discontinuing the tube would not deprive a patient of a sensation of satiety. Finally, the question exists whether any of these physical sensations can be cognitively appreciated by a patient who lacks function in the cortex of the brain.

But such contradictions and clinical mischaracterizations aside, these arguments raise much deeper and serious questions for Catholics about the nature of human suffering. Do we believe that a person in post-coma unresponsiveness cannot suffer? Provided that the diagnosis is relatively certain, it would seem that there could be no cognitive appreciation of such sensations as pain or thirst. But does this mean that the patient is not suffering? Certainly, in ordinary English, it would appear grammatically correct to say that a person is *suffering* from post-coma unresponsiveness. And no sane person would every say that he or she wished to be in such a condition. But if a person, integrally considered, is in a state in which he or she is deprived of conscious interaction with the physical world, but not yet dead and united with the One, True, and Eternal Source of all life and all goodness – is this person not in a state of suffering?

As Pope John Paul II wrote in *Salvifici Doloris*:

> *Suffering is something which is still wider than sickness, more complex and at the same time still more deeply rooted in humanity itself. A certain idea of this problem comes to us from the distinction between physical suffering and moral suffering. This distinction is based upon the double dimension of the human being and indicates the bodily and spiritual element as the immediate or direct subject of suffering. Insofar as the words "suffering" and "pain," can, up to a certain degree, be used as synonyms, physical suffering is present when "the body is hurting" in some way, whereas moral suffering is "pain of the soul". In fact, it is a question of pain of a spiritual nature, and not only of the "psychological" dimensions of pain which accompanies both moral and physical suffering. The vastness and the many forms of moral suffering are certainly no less in number than the forms of physical suffering.*[9]

It would seem that the church, when considering the use of life-sustaining treatments in patients with post-coma unresponsiveness, must be particularly careful about making judgments that depend upon assumptions about the nature of human suffering that might narrow the field of what we, as Christians, understand about the nature of human suffering. We must, above all, never endorse the notion that any of the essential features of human beings can be reduced to brain states. Persons who suffer, suffer as persons in their totality.

What Is A "Medical" Act?

Claim 3: The use of feeding tubes is an act of basic human caring, and is not a medical act.

This argument is commonly invoked by those would declare feeding tubes in post-coma unresponsiveness an *a priori* ordinary means and therefore, in principle, morally obligatory. However, one can raise serious questions about whether this line of argument can bear the freight that has been loaded upon it.

It is obvious that feeding is associated with caring, beginning with the relationship between mother and child. Eating is associated with love in the Scriptures, from the multiplication of the loaves and fishes to the post-resurrection appearances of Jesus at Emmaus and shores of Lake Tiberius. And it is clear that the emotional significance of feeding tubes, and their symbolism, make the decision to withhold or withdraw feeding

tubes particularly stressful for family members, even compared with the stress of forgoing other treatments.

No one doubts that only a physician can perform a percutaneous endoscopic gastrostomy (PEG) and insert a tube to be used for feeding. In this sense, it is clearly a medical act. Some argue, however, that once the tube is in place, its use becomes nonmedical, obligatory, ordinary care.

This argument deserves more attention than has been given to it.

First, logically, this would imply that withholding a PEG tube would be morally permissible, since its *insertion* is a medical act, whereas discontinuing its use once it is in place would be prohibited, since its *use* is *not* a medical act. This would be the first instance of a Catholic teaching that there is a morally relevant distinction between withholding and withdrawing care. The tradition has always consistently held that the same criteria apply to withholding as apply to withdrawing life-sustaining treatments. This would be another departure from tradition.

Second, there seems to be, on the basis of this argument alone, no principled reason for distinguishing between post-coma unresponsiveness and any other clinical condition. It would seem that one ought to be prohibited from discontinuing assisted hydration and nutrition for any and all patients if the act is not medical and represents basic human care. If this intervention is necessary in order to show respect for the dignity of the person who suffers from post-coma unresponsiveness, then it also ought to be given to other patients, who have no less dignity and are no less worthy of similar respect. This, of course, would have the absurd conclusions that no one dying of a chronic illness could have a feeding tube withdrawn.

Third, unless it is totally ad hoc, the general form of the argument being advocated here must be something like the following: that whenever a medical device has been inserted or attached to a patient, and a layperson can be trained to use it, the use of the device becomes nonmedical and in principle ordinary and morally obligatory once the procedure has been completed. Under this argument, a person who has undergone a leg amputation and the attachment of a prosthetic limb would be obliged to use that prosthetic limb and crutches even if his or her other leg were later amputated because of life-threatening gangrene. It would be wrong, according to the argument, to forgo the use of the prosthesis in order to accept life in a wheelchair. Even though, given the new condition, using a wheelchair might be much easier and would render the patient more mobile, the use of the prosthesis and crutches would be required because the use of the prosthesis had become nonmedical and morally obligatory. Such a conclusion seems odd in the light of common sense and Catholic tradition.

So perhaps the form of the argument should be modified in such a way that the medical device in question would have to be life-sustaining in order to be declared nonmedical and morally obligatory. But then support with a home ventilator would, in principle, be considered nonmedical and morally obligatory and could never be discontinued, because, as with a feeding tube, although the ventilator's use might be initiated through a medical act, it can be used by laypeople trained for that purpose, it is attached to the person, and it is life-sustaining. Yet since the time of Pope Pius XII, the paradigmatic example of a potentially extraordinary means of care has been the ventilator. Therefore, this cannot be the correct form of the argument either.

So perhaps the argument must be amended to say the act becomes nonmedical when the substance delivered to the patient by a layperson via an indwelling device is something all human beings need in order to survive. Again, however, this formulation will not distinguish a ventilator from a feeding tube, since, at least in some cases the gas-exchange capacity of a ventilated patient remains normal and it is only the ability to breathe that is impaired, so the patient is

treated with room air via the ventilator. Everyone needs air. Therefore, unless the ventilator is supplying additional oxygen, it could never be considered extraordinary and could never be stopped. And once again, this fails to square with the *sensus fidelium*.

Perhaps one might construct the argument so that an act becomes nonmedical when the substance delivered to the patient by a layperson via an indwelling device is something that all human beings commonly need in order to survive *and* one that can be delivered to the patient without using any additional device. This might appear to distinguish the ventilator from the feeding tube. But this argument will not work either. One needs at least a syringe to deliver the nutrition via a PEG tube, and if the patient cannot breathe, one needs at least an Ambu bag to deliver air to him or her. The need for an extra device would not distinguish medically assisted nutrition from medically assisted ventilation.

As a last resort, one might ask: What if the trached patient were able to breathe on his own – would you remove the oxygen from the room? The answer is clearly no; that would be a direct act of killing. Taking away someone's supply of oxygen is not analogous to a failure to provide food. The killing/allowing to die distinction classifies the former as killing and the latter as allowing to die.[10]

Taking the oxygen out of the air that a dying person is breathing is killing and is always wrong. Failing to provide food is allowing to die. Doing so is sometimes wrong and sometimes morally permissible. It is wrong not to feed a baby who can eat. It is not wrong to refrain from force-feeding someone dying of cancer who has lost his appetite.

The proper parallel is not between air and food, but between breathing and swallowing. The analogous medico-moral issues concern the intervention aimed at assisting persons who have lost these functions. If that is so, then just as there are reasonable limits to the obligation one has to replace the lost function of breathing via a ventilator machine or an Ambu bag, there are limits to the obligation one has to replace a lost ability to swallow with a pump machine or a syringe. So there seems to be no principled way to define a medical act in such a way that feeding tubes are classified as "nonmedical" while other treatment modalities that are initiated and prescribed by physicians remain classified as "medical."

In any event, why does this odd foray into an idiosyncratic interpretation of the philosophy of medicine require a dogmatic definition from the church? The concepts of "health," "disease," "therapy," and "medicine" are also hotly debated in the philosophy of medicine. Is the answer to the medical/nonmedical question of such import that the church must define which acts are, when performed by medical personnel, in fact not medical?

Perhaps more importantly, the whole argument is irrelevant from the points of view of traditional Catholic teaching. The tradition has never considered the question of whether something was "medical" to be a criterion for distinguishing ordinary from extraordinary means of care. Very commonplace acts, such as traveling to a healthier climate, eating certain kinds of food, or even eating itself have all been considered, in the proper circumstances, "extraordinary means" under traditional analysis. Does the church think it is important (a) to define this distinction between the medical and the nonmedical and then (b) to alter the tradition and make this a decisive factor in distinguishing ordinary from extraordinary means of care?

Does the symbolic value of a feeding tube itself carry the weight of the argument? Is the symbolic meaning of eating in the Gospels carried by the physiology of nutrient absorption, or by the interpersonal human experience we normally consider part of sharing a meal? What would the implications of such a dogmatic declaration be for our Eucharistic practices? Would we thereby say, of a person who cannot swallow but is awake and alert, that it would be preferable to deliver a small bit of the consecrated bread or wine into the feeding tube than to place a drop of

the consecrated wine on the person's tongue? Which would we consider truer to the sacramental meaning of sharing in the Body and Blood of Christ? These questions ought to be carefully considered before any formal dogmatic pronouncements are made concerning the use of feeding tubes.

Serious Examination is Needed

In this brief article, I have considered several underlying questions raised by recent discussions about life-sustaining treatments within the church. These are not the surface questions that have dominated media coverage, political lobbying, and polemical discourse about these issues. In my judgment, these questions require serious examination in advance of any formal dogmatic resolution of these hotly disputed questions.

Br. Daniel P. Sulmasy, OFM, MD, PhD, is Chairman, John J. Conley Department of Ethics, St. Vincent's Hospital, Manhattan, and Professor, Medical Ethics, New York Medical College, Valhalla, NY.

This article is reproduced with permission from *Health Progress,* the official journal of the Catholic Health Association of the United States, Vol 87, No.4, July-August, 2006, pp.50-56.

Footnotes

1 The arguments outlined in this section are presented in much greater detail in Daniel P. Sulmasy, "End of Life Care and the Rule of Double Effect: Some Clarifications and Distinctions," *Vera Lex*, vol.6, nos. 1 and 2, Winter, 2005.

2 P. Reddy and M. Malone, "Cost and Outcome Analysis of Home Parenteral and Enteral Nutrition," *Journal of Parenteral and Enteral Nutrition*, vol. 22, no. 5, September-October 1998, pp. 302-310.

3 Susan L. Mitchell, et al., "Tube-Feeding versus Hand-Feeding Nursing Home Residents with Advanced Dementia: A Cost Comparison," *Journal of the American Medical Directors Association*, vol.5, no.2 (supplement), March-April, 2004, pp. S22-S29.

4 Melvin Heyman, et al., "Economic and Psychologic Costs for Maternal Caregivers of Gastrostomy-Dependent Children", *Journal of Pediatrics*, vol. 45, no. 4, October 2004, pp. 511-516.

5 A.F. De Vecchi, M. Dratwa, and M.E. Wiedemann, "Healthcare Systems and End-Stage Renal Disease (ESRD) Therapies – An International Review: Costs and Reimbursement/Funding of ESRD Therapies," *Nephrology Dialysis Transplantation*, vol. 14, no. 6 (supplement), December 1999, pp. 31-41.

6 David W. Johnson, et al., "Cost-Savings from Peritoneal Dialysis Therapy Time Extension Using Icodextrin," *Advances in Peritoneal Dialysis*, vol.19, 2003, pp. 81-85.

7 Lai Seong Hooi, et al., "Economic Evaluation of Centre Haemodialysis and Continuous Ambulatory Peritoneal Dialysis in Ministry of Health Hospitals, Malaysia," *Neprhology*, vol. 10, no. 1, February 2005, pp. 25-32.

8 Mary A. Sevick and Douglas B. Bradham, "Economic Value of Caregiver Effort in Maintaining Long-Term Ventilator-Assisted Individuals at Home," *Heart & Lung*, vol.26, No.2, March-April 1997, pp. 248-157.

9 John Paul II, Salvifici Doloris, 1984, section 5, available at www.vatican.va/holy_father/john_paul_ii/apost_letters/documents/hf_jp-ii_apl_11021984_salvifici-doloris_en.html.

10 Sulmasy, "Killing and Allowing to Die: Another Look," *Journal of Law, Medicine & Ethics*, vol. 26, no.1, Spring 1998, pp. 55-64.

Paying attention to the Pharmaceutical Industry

Helen McCabe

If we are paying attention to the American health care context, we will notice that, notwithstanding the robust nature of the pharmaceutical industry in that nation, the poor often struggle, as they do in much poorer nations, to obtain the pharmaceutical benefits that Australians enjoy and have come to expect. And if we are paying particular attention to the operations of the pharmaceutical industry itself, then we will also notice that our good fortune in respect of access to medicines is less sure than it once was. We only have to consider, as managers of pharmacy budgets do every day, the marked increase in the cost of medicines in order to wonder as to the sustainability of Australia's Pharmaceutical Benefits Scheme (PBS) and the possibilities it has allowed. And if we also consider the influence the pharmaceutical industry itself now has on the operations of the PBS, then questions of sustainability become even more urgent. So, paying attention to these developments is a wise thing to do.

Keeping a weather eye on the operations of the pharmaceutical industry has occupied several commentators over the past decade, one of whom is the recently retired editor-in-chief of the *New England Journal of Medicine*, Marcia Angell. In her new book, *The Truth About the Drug Companies*,[1] Angell recounts a tale of pharmaceutical industry involvement in profiteering, collusion, political corruption and exploitation of public finances. It's a worrying tale to be sure. Ray Moynihan and Alan Cassels tell another disquieting story in their book, *Selling Sickness*.[2] They provide factual evidence which supports the charge that the pharmaceutical industry has been busy convincing both the worried well and the medical profession of the existence of a new array of dubiously-defined 'diseases' amenable to pharmaceutical remedy, such as 'adult attention-deficit disorder' and 'female sexual dysfunction'. As well, both John Abraham[3] and Ken Harvey[4] point to the effects of global trade regulations on pharmaceutical costs; they say that these arrangements now threaten our ability to ensure equitable access to affordable, safe and effective pharmaceutical resources.

So, what are we to make of all this? If these commentators are right, then where did things go astray and what does it mean for us, ethically-speaking?

The goals of health care

When we think about engaging in health care activity, we are properly guided by such ethical goals as health, life, healing, and keeping company with those who suffer illness and disability (what Aristotle would call the 'good of friendship'). At least, it is these moral goods which are pursued by those who engage in what they understand to be a healing vocation. Yet, as is obvious, they are not the *only* goals that can be pursued: profit-making, for instance, emerges as a serious contender for the hearts and minds of those engaged in health care activity and pharmaceutical companies represent clear instances of profit-seeking enterprises.

Of course, it is reasonable to argue that there is nothing wrong with profit-making of itself, that commerce is a legitimate activity and that, in order to continue to develop necessary

medicinal remedies, it is also necessary to procure, firstly, a reasonable profit. And, to be sure, research, development and innovation are all activities requiring significant financial support. However, while this is so, certain ethical anomalies necessarily arise when the pursuit of profit becomes the *primary* goal of the industry's activity, pursued for its own sake, so that it takes precedence over the pursuit of health and healing. In other words, goals like health serve as a moral guide whenever we engage in health care activity whereas profit-making, for its own sake, takes us off course in ways that undermine our mission.

For instance, research priorities that are oriented to boosting profits differ from those oriented to curing illness so that attention to the problems of the wealthy (e.g. infertility at age 50) often take precedence over those of the poor (e.g. malaria). Or, if profit is the guiding force, then health care resources will be distributed according to 'willingness to pay' or 'consumer choice' and not human need. Or, when profit rules, the price of medicines will be determined, simply, by 'what the market will bear'. When the market operates competitively, prices *might* be contained (although a careful dose of regulation rarely goes astray in this respect); however, when companies form a monopoly or engage in collusion, then prices escalate, such as has occurred in relation to medicines.

The Pharmaceutical Industry

Marcia Angell explains that the average price of one commonly-prescribed pharmaceutical agent in the United States is $US1,500 per annum and that older Americans are often taking up to 6 different prescription medicines at any one time (costing $US9,000 annually). This adds up to an enormous number of profitable sales for the pharmaceutical industry; Angell reports that in 2002, global sales of pharmaceuticals reached, in total, the sum of $US400 billion.

The pharmaceutical industry defends itself against accusations of greed by claiming that defences are worth considering. However, as Angell points out, the amount spent on research and development by pharmaceutical companies is dwarfed by that spent on marketing and administration, whereas most of the research drawn on by these companies is undertaken in the publicly-funded American universities and the National Institute of Health. In addition, these publicly-funded research departments, in forming partnerships with pharmaceutical companies, have been convinced by the industry to engage in the kind of research that is more likely to result in financial gain than in cure of illness. That is, for both the industry and research academies, the goal of research has often shifted from health to profit.

As well, we are told that much of the innovation these companies claim to engage in does not materialise in new and/or better treatments for illness. Instead, we simply gain a range of so-called 'me-too' drugs which contain the same active ingredients as drugs which already exist on the market. So, the 'me too' drugs are simply re-packed (and more expensive) formulations of existing (cheaper) drugs, such as anti-hypertensive agents, marketed as 'new and improved' treatments for hypertension. This kind of behaviour undermines the credibility of the pharmaceutical industry's claims to innovation and, therefore, to some of the patents they are granted.

To the extent that the industry is innovative, then it is so inasmuch as it sometimes 'diagnoses' a new set of 'illnesses' in need of pharmaceutical remedy. This occurs in one of two ways. Firstly, in relying on questionable research findings, the industry has successfully extended the definition of illness by changing the parameters of what medical science has understood to be within a normal range. Secondly, the industry has 'invented' new 'illnesses' by re-describing a range of normal human conditions as medical diseases. For instance, shyness has been re-described as 'social anxiety disorder' and normal pre-menstrual symptoms have been reduced to a disease-entity: so-called 'pre-menstrual

dysphoric disorder'. Having done this much, the pharmaceutical industry then offers a pharmaceutical solution, sometimes in the form of old drugs re-packaged and re-marketed.

The pharmaceutical industry and government

We might assume that the operations of the PBS can at least ameliorate the effects of these developments. However, policy changes and altered trade agreements over the last decade would suggest that the protective function of the PBS is now less sure. For instance, in recent years, the pharmaceutical industry has been granted a more persuasive role in determining approval of and funding for medicines under the PBS and has, as well, successfully lobbied for changes in regulation so as to

- hasten the approval process of new pharmaceutical agents at the expense of ensuring the previous standards of efficacy and safety;
- provide significant disincentives to reject approval of new medicines, including on the grounds of public safety;
- grant patents so as to postpone the 'entry' of cheaper, generic medicines into the market;
- relax the regulatory standards in which to conduct research and development; and
- relax the rules around approving new medicines which are no more therapeutically effective than existing medicines.[5]

Overall, it can be seen that, whenever the goal of health care activity moves too nearly to that of profit and too distantly from that of health and healing, we find ourselves struggling to uphold the integrity of those whose vocation it is to serve the sick. It would be a shame if the blessing that is the PBS became a mere 'cash cow' for investors.

To the extent that this has occurred, then the profit-seeking objective of the industry has taken precedence over not only the goals of health and healing but, also, efficiency.[6]

Footnotes

1 M. Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*, 2004, Random House, New York. For a concise overview of the book, see *The New York Review of Books*, Vol. 51, No. 12, July 15, 2004. Available at: http://www.nybooks.com/articles/17244 Accessed on 9th October, 2006.

2 R. Moynihan & A. Cassels, *Selling Sickness: How Drug Companies Are Turning Us All Into Patients*, 2005, Allen & Unwin, Sydney.

3 J. Abraham, 'Pharmaceuticals, the state and the global harmonisation process', *Australian Health Review*, 2004, Vol. 28, No. 2, pp. 152-9.

4 K. Harvey, 'Patents, pills and politics: the Australia-United States Free Trade Agreement and the Pharmaceutical Benefits Scheme', *Australian Health Review*, 2004, Vol. 28, No. 2, pp. 218-26.

5 J. Abraham, op. cit.

6 Reprinted, with permission, from *Health Matters*, official journal of Catholic Health Australia, Iss.39, December, 2006, pp 18-20.

Dr. Helen McCabe is a Research Associate of the Plunkett Centre for Ethics.

Bioethics Outlook is a quarterly publication of the Plunkett Centre for Ethics,
a joint centre of Australian Catholic University & St. Vincents & Mater Health, Sydney
Telephone (02) 8382 2869 Facsimile (02) 9361 0975
Editor: Bernadette Tobin Layout: Linda Purves
Subscription is $90 (Institutions), $50 (Individuals) and $25 (Students/Pensioners)
+ 10% GST and $10 overseas airmail

Plunkett Centre for Ethics, St. Vincent's Hospital, Darlinghurst, NSW 2010

ISSN 1037-6410 www.acu.edu.au/plunkett/centre/