

THE THORNY BUT PERVASIVE PROBLEM  
OF PERMISSIBLE DEATHS

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Few legal drugs are used as ubiquitously as Tylenol, the popular nonprescription analgesic known by the scientific name of acetaminophen (paracetamol in the UK). Although the use of acetaminophen is advocated for a number of mild-to-moderate pain conditions such as headaches and arthritis, it is less well-known that in large doses acetaminophen can be lethal. In fact, acetaminophen liver toxicity, often from an intentional overdose, causes more than 450 deaths annually in the United States, and this number appears to be on the rise (Bridger, Henderson, Glucksman, Ellis, Henry & Williams, 1998; James, Mayeux & Hinson, 2003; Larson, 2007). While there is little doubt that this number could be substantially reduced by restricting access to the drug, such as removing its nonprescription status, or even removing the drug from the market entirely (as happened with the painkiller Vioxx), the fact is that regulatory authorities like the FDA must view this number of deaths as being acceptable in light of the enormous overall clinical benefits the drug provides. (After all, if they didn't feel this way, they presumably would do something about it). This example illustrates the concept of "permissible deaths", a thorny ethical issue that regulators and policy makers must deal with in a great many settings.

The problem of "permissible deaths" is hardly unique to the regulation of drugs; there are many other instances where this nasty issue shows up. For example, Generals conducting military campaigns must decide how many combatant deaths on either side are tolerable, as well as decide how many unavoidable innocent civilian deaths are acceptable ("collateral damage") (Alexander, 2001; Arya, 2007).

Similarly, safety engineers must strike a balance between the cost of a safety feature and the number of lives saved, since, for instance, relatively few people would be willing to buy a car costing \$300,000 no matter how safe (Viamonte, Ball & Kilgore, 2006). Likewise, adding numerous extra safety features to nuclear power plants, to commercial aircraft or to invasive medical equipment could conceivably make these products too expensive to be affordable.

This issue even comes up in surgery. In high-risk procedures such as cardiac surgery, how many deaths are acceptable? In 1998 the British General Medical Council, the regulatory agency that monitors British doctors, charged that two heart surgeons under their scrutiny were

guilty of operating on children despite knowing that their fatality rates were unacceptable (Treasure, 1998; Bolsin, 2002). This naturally raises the issue as to what an acceptable death rate might be and how such a rate should be determined. (In some states like New York where the fatality rates for all heart surgeons are publically available, one unintended consequence has been for heart surgeons to simply refuse to take on very high-risk cases for fear of adversely affecting their "batting average".)

Another medical situation concerns permissible deaths related to the use of medical equipment. For instance, patient-controlled analgesia (PCA) machines that allow patients to self-administer morphine after painful surgical procedures are inherently risky. While potential benefits of this technology include superior pain control, automatic electronic documentation and improved utilization of nursing resources, unfortunately, unanticipated flaws in the design of these machines can sometimes lead to adverse drug events such as overdoses, and even death (Lin, Vicente & Doyle, 2001; Vicente, Kada-Bekhaled, Hillel, Cassano & Orser, 2003). One particularly notorious unit is the Abbott Lifecare 4100 PCA Plus II machine. In 1997 three deaths that occurred while patients were connected to this

device were documented. Investigations revealed that part of the problem was an unfriendly user interface that made user errors more likely. Unfortunately, despite being amply notified of this problem, the manufacturer was unwilling to upgrade the unit to a safer design, claiming that there was no problem with the unit in the first place that could not be handled with proper user training. In the end no design change was ever implemented and the unit remains in occasional clinical use to this day (Doyle, 2007).

Clearly, complex technologies like automobiles and nuclear power plants offer personal and social benefits at a price that necessarily produces occasional injury and death. Still, when government regulators license drugs or medical devices, they implicitly require that the perceived benefits exceed the perceived risks. In the case of drug products, when this relationship is no longer obvious, the drug may be withdrawn (as happened to Vioxx) or its indications restricted (as happened to Celebrex). In the case of medical devices like PCA machines, when preventable deaths or injury have occurred the FDA may require that the device be recalled from clinical service so that safety

upgrades can be instituted. But, as in the case of the Abbott PCA machine, this is not always the case.

Another example is the Bjork-Shiley Convexo-Concave heart valve, an early-generation artificial heart valve that would occasionally fail catastrophically due to fracture of a strut (Blot, Ibrahim, Ivey, Acheson, Brookmeyer & Weyman, 2005). As many as 480 deaths have been estimated to have occurred as a result. Since only a relatively small fraction of the approximately 80,000 implanted convexo-concave valves actually failed, not all valves were removed and replaced, given that the comparatively small risk of valve fracture must be balanced against the not insubstantial risk and cost of the surgery needed to replace the valve.

Complicating this matter is the fact that according to a US government lawsuit, the maker of the valve, Shiley Inc., issued false reports to the FDA both to obtain initial approval of the device, as well as to keep the valve on the market. For instance, Shiley did not inform the FDA that in some cases they polished, rather than rewelded, cracked valve struts in order to make them look normal in appearance. In 1986 the FDA stopped sales of the

valve. By 1990 there were 100 lawsuits pending against the manufacturer.

Although the Bjork-Shiley Convexo-Concave heart valve is an example of a product that the FDA acted on, sometimes authorities do not take action. Failure to mandate a recall of medical devices that harm patients may occur for several reasons. First, the remedy may be so expensive as to be impractical. Second, the medical device may involve an old design that is approaching the end of its life cycle anyway. Third, regulatory agencies with limited resources must prioritize their goals, with the result that medical devices that injure or kill only a small handful of people may not get the regulatory attention that victims and their families would otherwise like. In such cases, legal remedies may be the only option available.

### **Just War Theory**

Just War Theory is a field of academic activity that studies the notion that armed conflict can and should meet specific criteria regarding the right to go to war ("jus ad bellum") and regarding the proper conduct of war once hostilities have begun ("jus in bello"). For instance, the

Catechism of the Catholic Church (Holy See, 2000) lists four conditions for "legitimate defence by military force":

- The damage inflicted by the aggressor on the nation or community of nations must be lasting, grave, and certain.
- All other means of putting an end to it must have been shown to be impractical or ineffective.
- There must be serious prospects of success.
- The use of arms must not produce evils and disorders graver than the evil to be eliminated. The power of modern means of destruction weighs very heavily in evaluating this condition.

Implicit to such considerations is the notion that military leaders must make every effort to plan their actions so as to reduce the chance of unintended injury or death, as well as to minimize accidental property damage. While accidental strikes against friendly or neutral forces is obviously undesirable, unplanned collateral damage against enemy civilians and civilian facilities is usually also taken to be abhorrent.

With the advent of advanced computer modeling techniques, military authorities are now able - at least in some scenarios - to arrive at precise numeric estimates for various kinds of collateral damage. This brings us once again to the question of exactly how many deaths are permissible in a particular situation. Not surprisingly, such considerations have occasionally resulted in substantial controversy.

### **Doctrine of Double Effect**

The "doctrine of double effect" (Saini, 1999; McIntyre, 2004) is a principle of ethics first espoused by Thomas Aquinas in his *Summa Theologica* that states that it is sometimes permissible to cause a harmful side effect in bringing about a good end result even though it would not be ethical to cause such a harm directly in order to bring about the same good result. According to the Stanford Encyclopedia of Philosophy (2004) the doctrine "is often invoked to explain the permissibility of an action that causes a serious harm, such as the death of a human being, as a side effect of promoting some good end".

As a case in point, the Stanford Encyclopedia of Philosophy (2004) provides the following example: "A doctor who intends to hasten the death of a terminally ill patient by injecting a large dose of morphine would act impermissibly because he intends to bring about the patient's death. However, a doctor who intended to relieve the patient's pain with that same dose and merely foresaw the hastening of the patient's death would act permissibly."

### **Putting it All Together: Invoking Moral Theory**

I would like to now spend some time discussing how moral theory might be applied to the scenarios described so far. Moral or ethical theory can be approached from many viewpoints (Beauchamp & Childress, 2001; Lawlor, 2007). The deontological approach to morality (from the Greek word *deon*, or duty) is based on specific obligations or duties. These can be positive (such as to care for our family) or negative (such as not to steal). This approach is also sometimes called nonconsequentialist since these principles are held to be obligatory regardless of any good or bad consequences of that might result. For example, it is wrong to deliberately kill even if it results in great benefit.

In this particular context, the concept of the "Categorical Imperative" developed by the 18th-century German philosopher Immanuel Kant is particularly relevant (Secker, 1999). Kant said that we must treat people as an end, and never as a means to an end, by which he intended that we should always treat people with humanity and dignity, and never use individuals as "mere instruments" as a means to our own happiness. Another version of the Categorical Imperative is: "Always act in such a way that the maxim of your action can be willed as a universal law."

Other deontological approaches include "duty theory" (defining duties to God, duties to oneself, and duties to others) and "rights theory" (concerned with rights that all people have, and which the rest of us must respect) (Beauchamp & Childress, 2001).

It seems to me, however, that the various deontological approaches available to us are not particularly helpful in analyzing the "permissible death" problem. This is, I believe, because they are intended to provide guidance against the causing of deliberate injury or harm, but do not help us very much in the setting of

unintended harm, which is the case for the “permissible death” problem. This leads us to consider whether a different category of moral theories, consequentialism, might be helpful to us.

In contrast to the various deontological approaches to morality, the consequentialist approach determines moral responsibility by weighing the consequences of one’s actions (Beauchamp & Childress, 2001). According to the consequentialist view, correct moral actions are determined by a cost-benefit analysis concerning the consequences of an action. Several subtypes of consequentialism have been proposed: (1) the view that an action is morally correct if its consequences are more positive or favorable than negative to the person performing the action (*ethical egoism*), (2) the view that an action is morally correct if the consequences of that action are more positive than negative to everyone except the person doing the action (*ethical altruism*), and (3) the view that an action is morally correct if the action’s consequences are more positive than negative to everyone (*utilitarianism*). It is this last view that I would like to discuss in more detail.

## Utilitarianism

Some philosophers might argue that a utilitarian approach would best fit most of the "permissible death" scenarios described above. They might even hold that it would form the basis for public policy in such matters. This possibility is discussed next.

Utilitarianism is a school of moral philosophy frequently identified with the writings of Jeremy Bentham and John Stuart Mill (Gillon, 1985). In more recent years it has undergone a number of refinements, such as "Preference Utilitarianism", advocated by Professor Peter Singer (Jamieson, 1999). Classical Utilitarianism advocates the principle of providing "the greatest happiness to the greatest number" as the basis for assessing the morality of various actions, while "preference utilitarianism" advocates the principle of meeting the preferences of the greatest number of people. Thus, good variously consists in providing maximal happiness (or satisfying people's preferences) and the rightness of an action depends directly or indirectly on its yielding such outcomes.

However, while Utilitarianism has had a strong influence of the intellectual landscape of recent philosophical discourse and, in particular, in ethical theory, it is often seen to falter when it is applied to questions of social or individual justice. In particular, Utilitarianism sometimes violates common-sense notions of justice. Because Utilitarianism seeks to maximize the total amount of a particular "utility" (like happiness or preferences) over an entire society or social group, it seeks whichever arrangement achieves maximum utility. But such an arrangement might be achieved by distributing benefits and burdens in a way that violates common notions of justice.

Perhaps the best known example of how Utilitarianism sometimes violates common-sense notions of justice is the often-cited scenario where killing one individual would save the lives of many. Under the classical Utilitarian ethical model such action would be appropriate. (Such a situation arose in the 1968 movie "The Magus", where the mayor of a small Greek village under WW II German occupation is ordered by the Nazi Commandant to personally kill three Greek freedom fighters responsible for the death

of German soldiers. If the mayor refused, the Germans would kill both the freedom fighters and all the villagers.)

Another example: The use of slaves might greatly help maximize the *net* happiness in a society, but common-sense notions of justice almost always take slavery to be wrong (with apologies to both Aristotle and Thomas Jefferson, two great intellectuals who were unapologetic slave owners).

Another serious criticism of Utilitarianism is that under the goal of maximizing happiness or some other utility, the wishes and desires of sadists and perverts are lumped in with the wishes and desires of everyone else when an overall determination of utility is made. By espousing a system in which the satisfaction of *all* desires are to be maximized, Utilitarianism can end up violating our intuitive precepts of natural justice.

A final issue, especially in the context of the "permissible death" problem, is that the application of Utilitarianism in this specific setting requires that some kind of calculus be set up that assigns specific values to various lost lives and injured parties and weighs them

against various forms of benefit. In practice, this is not a practical task.

Such issues lead the philosopher John Rawls and others to take the position that we must reject Utilitarianism and instead develop a genuine understanding of what is right and wrong as a basis for making ethical decisions. What is needed, Rawls argues, is moral theory with justice at its core (Rawls, 1971). Unfortunately, Rawls' moral theory, at least as I interpret it, also seems to be unhelpful in dealing with the "permissible death" problem.

As noted earlier, a unifying theory of ethical action that could be relied on to provide precise guidance in all the circumstances identified above would be very helpful. Unfortunately, it appears that no such universal approach is readily apparent. Instead, as with the approach the Catholic Church has taken in the case of "Just War Theory", every situation must be judged on its individual circumstances.

## **Conclusion**

In conclusion, the concept of "permissible deaths" remains a thorny ethical issue that one encounters in a great many settings, covering issues as diverse as the regulation of drugs and medical devices to the debate about acceptable collateral deaths during the conduct of a "just war". Unfortunately, however, there is no single ethical theory that can be universally relied on to provide practical guidance in all such settings.

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(See also an online commentary at  
[http://www.catholic.com/library/Just\\_war\\_Doctrine\\_1.asp](http://www.catholic.com/library/Just_war_Doctrine_1.asp))

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