



# The Right to Stay Alive?

## Citation

The Right to Stay Alive? (1998 Third Year Paper)

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# <sup>Vi</sup>~ The Right to Stay Alive?

Madeleine Blot  
Food and Drug Law

Recently, a close friend died of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. He was an otherwise healthy lawyer in his sixties who looked forward to retiring, after a long career of practicing law in New York, to spend time with his family and new grandson. Harry planned to retire during September of last year. He died on September 2<sup>nd</sup>

Harry was diagnosed with ALS in January of 1997. Although we were all aware that there is no known cure for the disease, we were told that it doesn't usually take its toll until three to five years after diagnosis. Harry exhibited no observable symptoms of the disease for the first several months of his illness. Combined with the fact that ALS was a disease which I had barely even heard of, this made it difficult for me to absorb the fact that Harry was really sick. By the summer, however, Harry had begun noticeably to deteriorate. And once the deterioration began, it moved at a pace more rapid than anyone could believe. It soon became necessary for Harry to use a cane to walk, and, within weeks of that, he was in a wheelchair. His voice was soon affected by the deterioration of his muscles, and the medication he was being treated with made him so drowsy and lethargic that it severely decreased his quality of life. Despite all of this, Harry came into work every day, sat at his desk, saw clients, and continued conducting business as usual — or as best he could - until practically the day he died.

There are currently twenty-five to thirty thousand Americans who suffer from ALS.<sup>1</sup> Compared to the millions of Americans who suffer from more well-known diseases such as cancer and AIDS, however, the numbers seem almost insignificant. ALS is an uncommon disease, which few people have heard of and even fewer understand. But to the person diagnosed with the illness and to his family and friends, the disease is quite real and equally unrelenting. While Harry was still alive, I learned a lot about ALS. I often talked with him about his condition and tried from whatever source possible to gather information for him. Harry was scheduled to participate in a experimental study for a new drug intended to slow the process of ALS. The FDA canceled this experimental program several weeks before Harry died.

Although I was not too familiar with the workings of the Food and Drug Administration, I, as many, had always heard stories about the red—tape associated with its drug review and approval process. I had heard about the cancer, and more recently the AIDS, lobbies that demanded a quicker and less controlled review process for new, potentially life-saving, drugs. I had heard the outrage expressed by terminally-ill patients and their families from whom access to new drugs had been delayed and, in some instances, ultimately denied. It wasn't until last summer, however, that I experienced the effects of the process first—hand.

The idea that terminally-ill individuals should be allowed special access to unapproved drugs is by no means a new concept. Nor is the technique of personalizing the FDA's review process with an example of how a close friend or family member paid for the lengthy and cumbersome process with his or her life. Although my purpose in this paper is to evaluate the question of whether

terminally-ill patients should have the right of access to whatever potentially life-saving drugs they choose, I did not begin this paper with my story about Harry as a technique designed to illustrate the callousness of the Food & Drug Administration. Although the effects of its new drug review process certainly appear harsh to people whom it has hurt, I would find it hard to believe that the FDA is trying to harm anyone.

On the contrary, I believe that an objective evaluation would probably show that - given the extensive number of decisions over which it has jurisdiction and the limited time and resources it has at its disposal - the agency is doing its best to be as fair, but also as careful, as it can. Because of its function, the FDA inevitably has forces pulling at it from many different directions, among which it is forced to prioritize. Equally, it is endowed with the very important duty of protecting human life, a job which must be taken seriously at all costs and which, if pursued negligently, could have serious consequences for the agency itself. Thus, although the length and detail of its review process do in fact produce some unnecessary suffering and even deaths, it would be naive to disregard all the suffering which the process eliminates and the lives which it saves. In its defense, FDA could point to all the harmful drugs that would have reached the market and harmed or even killed people, had its review standards been laxer. These are the stories that tend to go unpublicized.

Although some terminally—ill patients will try literally anything at the point where their situations have become desperately hopeless, most of the shocking stories of the FDA's callousness involve instances in which a drug, which was eventually determined to be safe and effective, was delayed from entering the market as a

result of the agency's approval process. The common criticism is that, had FDA acted quicker, many lives could have been saved.

What we have to remember in criticizing the FDA for these mistakes, however, is that our criticism is made with hindsight rather than foresight. We make our reproaches about instances such as this with the *retrospective* knowledge that a given drug turned out to be safe and effective. The only reason we know this, however, is because FDA took the time to determine it. If the same drug had instead turned out not to be safe and/or effective, would we have lauded FDA for rushing it into the market so that human beings could be used as guinea pigs to determine the answer? The point is that, given its function, duties, and liabilities, there is not much that the FDA can do differently in the area of improving access to even potentially life-saving drugs.

This harsh fact does not change the other fact, however, that there are still terminally-ill people out there living under excruciating and unbearable circumstances and dying perhaps needlessly, who, but for the length of the FDA's review process, might be cured, or at least successfully treated. Equally, it does not diffuse the anger and outrage of family members and friends who have lost someone close to them who might have been saved. So what do we do? I stated above that my goal in this paper is not to denounce the FDA or to suggest methods by which the agency's processes could be improved. The story of the battle between terminally-ill individuals and the FDA is one that has been told time and time again. Instead, my aim is to analyse and evaluate the issue of whether terminally-ill individuals should be given access to unapproved drugs from a different perspective, e.g. not as a battle at all.

Rather than weighing the duties of the FDA *against* the corresponding rights of terminally-ill patients, I would like to abstract the latter issue from the administrative context in which it usually arises and evaluate it as a discrete and separate matter. Thus, my plan is to evaluate the question of whether terminally-ill individuals have a fundamental right, independent of rules and procedures laid down by the legislature or its agencies, to have unqualified access to drugs which they believe could potentially save or prolong their lives. In this context, I will analyse the pros and cons of allowing terminally-ill individuals the choice of whether to take unapproved drugs as a matter in and of itself, without regard to the administrative complications that currently surround it.

While standing by my belief that FDA can't help infringing on the right of terminally-ill individuals, I will argue that the matter should be removed from FDA's jurisdiction altogether, and evaluated in a constitutional setting where it more properly belongs. Before I move on to a discussion of why I believe that the question of whether the terminally-ill should have access to unapproved but potentially life-saving drugs *should* be dealt with as a constitutional matter, I will briefly discuss why I believe that it *should not* be dealt with by the FDA.

#### **FDA Is Not the Proper Forum For Evaluation of Fundamental Rights**

Clearly, the FDA was established precisely to deal with issues concerning the human body, for which reason its members include skilled scientists from all different fields and for which reason it often consults with advisory committees comprised of doctors whose input might be relevant. The categories of food and drugs —over precisely which it is given jurisdiction — possess extensions,

however, which are vastly far-reaching. For this reason, decisions that touch on these categories call for all different types of questions and considerations to be addressed, from the most mundane to the most philosophical. To some extent, this should be acceptable.

Although the task of deciding which color additives should be allowed in cosmetics implicates questions of a different type and degree of importance than the question of whether a new medical device is safe to be used in human surgery, there is no obvious reason why FDA is not as equipped as anyone else to perform the appropriate benefit/risk calculations for each question and even answer the ethical issues which each demands to be answered. After all, wouldn't lay people be better advised, in deciding what foods and drugs to put into their bodies, to defer to the judgment of an agency whose members are equipped with medical and scientific knowledge that they do not even begin to possess. Is a bit of paternalism such a bad thing when it comes to matters involving our health? The prudent answer would probably be no.

There are certain properly labeled food and drug issues, however, whose seriousness and urgency is of such great magnitude that a decision to bring them under FDA's jurisdiction leaves the realm of prudence and enters that of the absurd. It is simply inappropriate to force certain types of issues to be evaluated by an agency which, despite how it internally prioritizes, must spend at least some of its time deciding what color lipsticks we can use. Although the question of where to draw a given line is never one that can be answered by an *a priori* analysis, my argument is that an appropriate place to draw the line that separates those issues which might not be considered appropriately left up to the discretion of



FDA from those which may be, might be around issues which involve intimate and literally life—and—death decisions.

To be clear, I am not arguing that governmental paternalism is *per se* a bad thing whenever it touches on an individual's freedom of choice; or even when the choice in question is a personal one that regards an individual's own body. I am stopping short of even reaching that issue. Instead, I am arguing that there should be recognized a special class of rights - which we might call the rights of the terminally—ill - that should be subject to independent rules and standards and evaluated on its own terms. Thus, implicit in my argument is the view that the terminally—ill comprise a special class deserving to be subject to different standards than the rest of us *in matters regarding which the fact of their terminal illness forces them to face different questions than the rest of us* do. Medical and health issues concerning the terminally-ill involve urgent, sometimes on-the-spot decisions, always of life—and—death proportions. More importantly, the terminally-ill often face more limited choices than the rest of us do because, as a result of their circumstances, *many choices have already been taken away* from them. Though death is certain for all of us, for individuals diagnosed with a terminal condition, it is imminent.

In his concurrence in a recent Supreme Court case regarding physician—assisted suicide, Justice Stevens made the point that the question facing terminal individuals who seek assistance in ending their lives is not whether *to die* but instead *how to die*, *Glucksberg*, 117 S.Ct. 2302, at 2307 (Stevens concurring) . This statement can be easily analogized to the situation at hand, regarding terminally—ill patients who seek to take unapproved drugs.

The question for them is not whether to stay alive but *how to stay alive*. I plan to save the philosophical analysis of the question of whether terminally-ill individuals should be allowed special access to drugs and medication until later in the paper. My reason for bringing up the analogy between my topic and physician-assisted suicide here, however, is not incidental.

Clearly, there are very strong conceptual links between the right asserted by terminally-ill individuals to have their doctors assist them in ending their lives prematurely and the right asserted by terminally-ill patients to have the choice of whether to take potentially life-saving, but unapproved, drugs. Both are based ultimately on the philosophical values of personal autonomy and freedom of choice. Both relate to excruciatingly personal issues. Both involve life-and-death decisions. And both fall very clearly under the extension of rights involving the terminally-ill, an essential feature which I believe binds them together more appropriately than any other feature which might place them in the extension of a different category.

Where these issues diverge, however, is with respect to the context in which they arise. Unlike the issue of whether terminally-ill patients should have special access to medications, the issue of physician—assisted suicide has been formulated, analysed and evaluated as a positive constitutional right. The question of whether the terminally—ill should have access to unapproved drugs, however, has been answered merely as a consequence of administrative decisions covering a variety of unrelated issues. The issue of physician—assisted suicide has been brought before the Supreme Court, twice recently, in response to state laws which prohibited it, as a matter of constitutional concern. On the other hand, although cancer and AIDS lobbies have been fighting for years

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to induce FDA to modify its procedures in order to provide victims of the diseases greater access to unapproved drugs, their cause has never been presented and ruled on as a constitutional matter.

Indeed, the closest the Supreme Court ever came to evaluating the right of the terminally-ill to have access to unapproved drugs as a constitutional matter was in the 1979 case of United States v. Rutherford, 442 U.S. 544 (1979) . The case involved a plea on the part of terminally—ill cancer patients to enjoin the FDA from banning their use of a drug called laetrile, derived from the kernels of seeds of most fruits, *Rutherford*, at 549, which purported to be a cure for cancer.

Although there was some mention of constitutional rights in the opinions of Court of Appeals and the Supreme Court, the latter ultimately and exclusively decided the issue as a matter of statutory interpretation and administrative law. Brushing aside any hint of constitutional concern, the Court accepted FDA's conclusion that Laetrile was not under any theory exempt from the requirement of section 505 of the Federal, Food, Drug and Cosmetic Act, 21 U.S.C.A. sec. 301 et seq. (FD&C Act), which provides that a new drug be proven safe and effective before it can be shipped in interstate commerce. To justify its acceptance of this conclusion, the Court points out that the construction of a statute by those charged with its administration is entitled to substantial deference, *Rutherford* at 553. Reasoning of this type resounds throughout the Court's entire opinion, as it dismisses the suggestion that the terminally-ill comprise a special class on the basis that the Federal Food, Drug and Cosmetic Act makes no special provision for drugs used to treat them. That conclusion, the Court holds, is clear from the plain language of the statute. The Court concludes that the question of whether the terminally-ill should as

a class be exempted from the reach of certain provisions in the statute is one that must be decided as a matter of legislative judgment and not as a matter of judicial inference, *Rutherford* at 558

However, rather than analysing the question of whether the terminally-ill *should* be exempt from certain provisions of the FD&C Act, the Court begs the question. It concludes that special exceptions *should not* be made for the terminally—ill by the circular reasoning that, as the statute reads, no exceptions *are* made. Thus, the Laetrile Court’s holding that the terminally—ill do not comprise a special class cannot be taken to mean anything more than that the terminally—ill do not comprise a special class, entitled to *exemption from the reach of the FD&C Act*. For, this is the only question that the Laetrile Court was dealing with. Rather than evaluating whether the terminally-ill should be recognized as a class worthy of constitutional protection, they determined simply that the language of the FD&C Act neither explicitly nor implicitly exempted them from its reach. Rather than deciding whether denying them access to a potentially life-saving drug was in conflict with their constitutional rights, the Court determined that FDA’s decision to ban the drug was not in conflict with its statute.

The Laetrile case may reasonably be construed as providing a negative answer to the question of whether terminally-ill

individuals have the right to have access to unapproved drugs.<sup>4</sup> My question however is whether the answer would have been the same if the questions had been phrased differently, so that the language of the constitution, and not that of the FD&C Act, would be the relevant guide to Court’s analysis of the issue. It may be true, as the Court points out, that ‘Mwjen construing a statute so explicit

in scope, a court must act within certain well—defined constraints, namely those imposed by the legislative purpose of the statute *Rutherford* at 551. It is also true, however, that positive laws cannot unreasonably constrain constitutional rights and that the Court has not only a right but a duty to set these priorities straight.

One might ask then, what is this right I am alluding to and on what do I ground my belief that the Supreme Court would be willing to recognize it? This is where the issue of physician-assisted suicide comes in so handy. One might argue that the Laetrile Court's seeming obliviousness to the constitutional implications of its statutory decision was strategically deliberate rather than misguided; that its choice to resolve the issue on purely statutory grounds stemmed from a reluctance on its part to disturb a longstanding administrative policy involving issues of considerable public controversy *Rutherford* at 554.

As I noted above, the Laetrile case was decided by the Supreme Court in 1979. Since then, however, the intensity of the 'public controversy' surrounding issues that implicate the rights of the terminally-ill has become much more pronounced and volatile, particular in the direction of favoring these rights. Since then,

we have had both the *Cruzan* case, which unqualifiedly granted the terminally—ill the right to refuse or be withdrawn from life— support, and the incessant pleas on the part of the terminally—ill themselves and a large segment of society that the right of the terminally-ill to end their lives with dignity be constitutionally recognized as well.

I am not saying that, were terminally—ill individuals to assert their right to unapproved drugs on constitutional grounds tomorrow, it is anything near clear that they would prevail.

Indeed, that is precisely the question which I intend to explore throughout the remainder of this paper. What I believe, however, is that the Laetrile case should by no means preclude this outcome; and that the current trend involving the rights of the terminally-ill is definitely moving in the direction of liberality.

As I find that there are strong analogical and conceptual links between what is known as the right to die and the right at stake for terminally-ill individuals who seek access to unapproved drugs, I believe that it will be enlightening to use the Supreme Court's recent discussion of the constitutionality of the former right to guide my analysis of the latter. As the two share a philosophical basis of justification, arguments raised for and against one will often be analogous to arguments made in favor of and against the other. Accordingly, for the purposes of analogy, I will call the right at stake in my topic the right to stay alive

I will begin by giving a brief description of the current legal status of both physician—assisted suicide and of the right to refuse or be withdrawn from life-support, both of which involve what is commonly referred to as the right to die. After this, I will discuss the current legal status of the right to stay alive. I will then discuss the relationship between these rights from several different perspectives, using the discussions laid out in recent Supreme Court opinions regarding the right to die to guide my evaluation of the right to stay alive. I will reserve my conclusion as to whether and/or to what extent the right to stay alive should be constitutionally recognized until after I have completed my analysis. At that point, I will revisit the question of whether it would benefit the terminally-ill in a *practical sense* to challenge their right to stay alive on constitutional grounds, rather than pursuing their current course of action and attempting simply to

reform FDA procedures. For now, however, my premise is that the merits of the right of the terminally—ill to stay alive should be evaluated on ethical and philosophical grounds, free of theoretically irrelevant administrative concerns. It is precisely this type of analysis which I will set out to do in the remainder of this paper.

#### **Current Legal Status of the Right to Die**

As mentioned above, the right to die has most recently been spoken of in the context of the debate over physician-assisted suicide. The right is asserted by and/or on behalf of terminally— ill individuals who urge that doctors be legally sanctioned to assist them (by supplying them with lethal medication) in ending their lives at the point where physical suffering and unbearable pain has made their lives intolerable. As asserted by respondents —four doctors and three terminally-ill patients - in the recent Supreme Court case Washington v. Glucksberg, 117 U.S. 2258 (1997) the right would be very specific and contained. It would not be interpretable to allow euthanasia, nor would it be recognized in individuals who were simply discouraged with their physical conditions. Instead, it would arise only in the most extreme and hopeless cases, where patients have been conclusively diagnosed as suffering from *terminal* conditions and where the pain which these illnesses cause is *unbearable*.

Despite the narrowness of the right which respondents in *Glucksberg* were seeking, the *Glucksberg* Court handed down a decision upholding the constitutionality of the challenged Washington state statute which expressly prohibited physician-assisted suicide. The argument in *Glucksberg* rested on substantive due process grounds.

In the companion case, Vacco v. Quill, 117 S.Ct. 2293 (1997) however, the Court upheld an identical New York state statute. The *Quill* petitioners challenged New York State's prohibition of physician-assisted suicide on equal protection grounds.

While the *Glucksberg* and *Quill* decisions clearly granted state legislatures the option of prohibiting physician-assisted suicide, it is important to keep in mind that the Court does not rule out the possibility that a state may legally decide to adopt this option. Although the decisions in both cases were unanimous, there were five concurring opinions (which were identical for the two cases), which seemed to want to leave open the possibility for change in this area. Recognizing the current volatility of this topic, even the majority ended its opinion by encouraging further debate on the issue at the state level. As of right now, however, only the state of Oregon has passed a statute allowing physician—assisted suicide.

Although physician-assisted suicide is still illegal in most states, the 1990 Cruzan decision not only recognized but constitutionally mandated another, supposedly more innocuous, right to die. This is the right to refuse life-sustaining measures or be withdrawn from life-support. First recognized in the case of *Cruzan*

*v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990), this right was popularized in the earlier New Jersey Supreme Court case of Karen Ann Quinlan, In Re Quinlan 70 N.J. 10 (1976)

The intuition underlying the right to refuse or be withdrawn from life-support is that human beings should have the option of being able to die a natural death, unimpeded by artificial life—sustaining devices and techniques. The right may arise under several sets of circumstances and may be implemented by several different methods. On the one hand, the right may effectively prohibit doctors from using on-the-spot medical life—saving



techniques, such as administering cardiopulmonary resuscitation. Equally, it may authorize a doctor to refrain from putting a patient on life-support or to withdraw a patient from life-support who has been determined to be in a persistent vegetative state or diagnosed as suffering from an incurable and irreversible

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condition

The right enunciated in *Cruzan* does not imply a default rule

of death where individuals would otherwise be kept alive by 'artificial techniques', but instead is wholly intention-based. An individual may evidence his desire not to be kept alive artificially by several methods. At any time, a patient may execute a living will, instructing any doctors who might be responsible for his treatment to refrain from all or any 'artificial' life-saving techniques. Living wills are probably the most effective means of conveying this intention because they provide written documentation of the individual's intention, which may be taken to imply that they are the product of reflective and competent analysis and consideration. This is particularly true in cases where a living will is executed while an individual is still healthy. Thus, living wills written in advance of illness or mental deterioration are probably taken as the truest and most reliable expressions of an individual's intent.

Despite the fact that a living will counts as written evidence of intention, an individual may verbally invalidate a living will at any time. Because of the strong disinclination on the part of doctors and society to opt against the use of life-saving techniques, a verbal *invalidation* of a living will expressing the desire *not* to be kept alive artificially will be honored. It is not as clear, however, whether a verbally-expressed intention not to be

kept alive artificially will override a living will which provides in whole or in part to the contrary. In fact, even in the absence of any written documentation, a verbal expression of the desire not to be kept alive artificially will not be the final word. Much scrutiny will be given to the competency of the individual making this statement, especially if he is already suffering from disease or illness.

Even more difficult, however, are cases in which a patient is unconscious or in a coma and his intention regarding the issue has not been documented. Some courts have allowed clear and convincing evidence of a patient's desire not to be kept alive artificially to

override the presumption of life that otherwise prevails.<sup>9</sup> This situation may arise where a patient who has otherwise always been competent and healthy becomes the victim of an accident or is struck with a quick and debilitating illness. If enough family members and friends attest to earlier statements made by the individual expressing a strong desire on his or her part not to be kept alive

artificially, courts will sometimes honor this intention.<sup>10</sup> Though the right to be withdrawn from life-support is unqualifiedly recognized in competent individuals, the *Cruzan* Court held that states may require the fairly rigorous standard of clear and convincing evidence to attribute this intention to an incompetent individual, *Cruzan* at 282.

Where a patient has never been mentally competent to make such a decision, courts will sometimes allow his intention to be inferred. Some courts will use a 'substituted judgment' standard, where it is determined what the intention of the incompetent person *would be* if he had an opinion on the subject. Some use the more

practical test of attempting to determine 'objectively' what would be in the best interest of the incompetent patient.<sup>11</sup>

Thus, at base, the *Cruzan* right to die is very narrowly construed. Often, doctors simply disregard living wills. Equally, courts are wary to enforce them unless the individual's intention is unarguably clear and unless the type of medical intervention which the patients opted to refuse is precisely that for which he has become a candidate. Thus, there is a gap between theory and practice with respect to both types of rights to die. While the *Cruzan* right to die is legally required, it is not always honoured. On the other hand, the legal prohibition of physician-assisted suicide has not completely stopped it from being practiced. Nor, as we have seen in the case of the infamous Dr. Kevorkian, has it stopped juries from acquitting doctors who engage in its practice. Ironically, however, as was reported in a recent New York Times article, there have been few... if any documented cases of terminally-ill patients using the legal means instituted by the state of Oregon to end their lives.<sup>12</sup>

#### **Current Legal Status of the Right to Stay Alive**

As I mentioned above, the only Supreme Court case that even referred to what I have called the right to stay alive was the 1979 Laetrile case. As I also mentioned, however, the Court's holding in that case turned entirely on a statutory interpretation of the Food, Drug and Cosmetic Act, 21 U.S.C.A. sec. 301 et seq., which continues to govern the law in this area.

As the Laetrile case noted, section 505 of the Act requires that all new drugs be subject to FDA's review and approval processes, which demand that the drugs be proven safe and

effective before they are allowed to enter the market. The approval process for the typical new drug takes between seven to thirteen years and consists of essentially four stages. First, the drug manufacturer must conduct preclinical research, e.g. test the drug on animals, in order to obtain clearance from FDA to proceed with its testing. If the drug passes the initial preclinical research test, manufacturers will then have to undertake three phases of clinical research on the drug, in which the drug will be tested on human subjects.<sup>13</sup>

Phase I is designed to test the safety of the drug. In this phase, the drug is administered usually to healthy subjects in increasing doses to test for adverse side effects. If no substantial adverse side effects are discovered, the drug enters Phase II, where its efficacy is evaluated. It is usually not until this stage that the drug is tested on patients suffering from the disease which the drug is intended to treat, and even at this point, only a small number of patients are allowed into the study.

If the drug is determined to be effective after this stage, it will then be tested in Phase III on many more patients suffering from the disease which it is intended to treat. Although hundreds, and even thousands, of patients will be able to participate in Phase III of the clinical research, the purpose of which is to detect adverse reactions and potential interactions of the new drug with

other medications,<sup>14</sup> some of these patients will be given placebos, and so will not enjoy the benefit of the new drug. In any case, a typical new drug must pass through these three stages in order to qualify to be submitted for new drug approval, the process by which FDA reviews the relevant data for approval purposes. The entire process costs between \$30 million and \$50 million.

Although, as the Laetrile Court pointed out, the FDA does not exempt the terminally-ill from the reach of its statute, it has, on response to avid lobbies on the part of cancer and AIDS sufferers, made certain concessions regarding its review and approval process for potentially life-saving drugs for diseases for which no other effective treatment or cure exists.

First, FDA has established a prioritized system of review, under which drugs are classified into three categories, determined by the importance of the therapeutic gain expected to be derived from them. Drugs intended to treat or cure diseases for which no other effective treatment or cure exists are given highest priority. Most likely for practical purposes, however, adherence to the priority schedule of review is not absolute. Review of Type A Drugs, e.g. those drugs considered to have the most important therapeutic gain will not trump *every* other obligation of the FDA. For instance, a 30 day safety review for a newly submitted IND

takes precedence over even a high priority NDA....<sup>15</sup> Equally, in response to the rise in number of drugs intended

to treat diseases for which no alternative treatments exists, FDA recanted its requirement that investigational drugs not be used for treatment purposes. Currently, FDA recognizes compassionate INDs, under which investigational drugs can be used for treatment on patients who meet FDA's protocol criteria. The criteria under which an investigational new drug would be allowed to terminally—ill patients was codified in section 312.7(d) (1), which requires that:

(1) the drug is intended to treat a serious or immediately life-threatening disease; (2) there is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population; (3) the drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and (4) the sponsor of the controlled clinical trial is actively pursuing

marketing approval of the investigational drug with due diligence (312.34(b) (1)) 16

FDA has allowed the efficacy of certain drugs intended to prevent terminal diseases to be established on the basis of surrogate endpoints (as opposed to clinical endpoints) , which recognize certain criteria as indicative of the drug's efficacy at an earlier stage than is required for most drugs. FDA has also allowed sponsors to charge money for investigational drugs, where

this is necessary to effect continued research of them.<sup>17</sup> In addition to allowing terminally-ill patients certain premarket access to drugs, FDA has instituted an expedited process for drugs intended to treat life-threatening diseases, defined as those diseases where the likelihood of death is high unless the course of the disease is interrupted. (sec. 312.81) . The procedures involve early consultation between FDA and drug sponsors (sec. 312.82) to determine a course of action most •in accordance with requirements for pre-market approval. After Phase I, FDA and the sponsor will seek to reach agreement on the proper design of phase 2 controlled clinical trials, with the goal that such research will be adequate to provide sufficient data on the product's safety and effectiveness, to gain market approval. After phase 2, FDA will grant market approval if it decides that the benefits of marketing the drug will outweigh the potential risks. If FDA allows the drug to be marketed at this point, it may seek agreement from the sponsor (sec. 312.85) to conduct certain postmarketing (phase 4) studies....<sup>18</sup> These expedited procedures reduce the approval process time on the average from eight to two years.

Congress has also instituted special provisions for drugs intended to treat orphan diseases, such as ALS, which are diseases

from which less than 200,000 persons in the United States suffer. Under the Orphan Drug Act, 96 Stat. 2049 (1983), Congress has required the IRS to provide tax credits for expenditures on clinical testing of orphan drugs, and required FDA to provide sponsors with written recommendations for necessary animal and clinical investigations and to encourage open label INDs for orphan drugs, which would allow sufferers from orphan diseases to have access to

the drugs for treatment at the investigational stage.<sup>19</sup> Despite all of the concessions that FDA has made for

terminally—ill patients with regard to its approval process, many are still not satisfied. It has been argued that FDA construes its criteria for treatment use of a new drug at the investigational stage quite strictly, despite the fact that the rules have been

substantially liberalized.<sup>20</sup> Equally, the idea of allowing surrogate endpoints for drugs intended to treat life-threatening disease, though in theory beneficial, results in many practical

ambiguities, which curb its use.<sup>21</sup>

Additionally, although FDA has designed procedures by which approved drugs can enter the market more quickly, there are still many drugs that are ultimately disapproved. Disturbingly, a 1980 study showed that only 22 percent of the deficiencies related to the applicant's evidence of safety and effectiveness. Thus, many drugs that may be substantially beneficial are disapproved on fairly

technical grounds.<sup>22</sup>

Even if the FDA adhered strictly to its liberalized standards for the terminally-ill, however, the concessions it has made are still discretionary. It is up to the agency to decide whether drugs and patients meet the criteria necessary to qualify for its special provisions. Thus, only a limited number of patients will in fact

gain access to not-yet-approved new drugs, and access itself will be limited and controlled. Many of the patients who do qualify to take part in experimental programs will be administered placebos rather than the actual drug. Equally, many patients will be conclusively denied access to drugs which have been disapproved on technical, rather than safety, grounds.

The special provisions set up for the terminally—ill continue to be looked on as 'exceptions', and do not have the status of unqualified rights. Thus, despite concessions on the part of Congress and the FDA, pre—market access for the terminally-ill to unapproved drugs continues to be discretionary, limited and controlled. Not only is it not guaranteed, but there are many patients to whom it will be denied. What the terminally—ill are entitled to as a matter of right is simply not the relevant issue.

### **An Argument for the Right to Stay Alive Based on Arguments for the Right to Die**

We see that, while there is fairly clear legislation regarding the legal status of the right to die, the legal picture of the the right to stay alive is a bit more fuzzy, in the sense that no case or statute addresses the issue as such. Regardless of how this right has been enunciated, however, it is clear that it is being urged. And being urged more and more strongly as time goes on.

Direct evidence of this are the numerous lobbies initiated by terminally—ill individuals themselves, which have aimed to persuade FDA not to interfere with their access to drugs that they want to take. Although recent AIDS lobbyists have been among the most vociferous, I have already mentioned that the terminally—ill have been fighting FDA on this issue since it prohibited their access to laetrile for cancer. I have also mentioned that, since then, the



amount and type of pressure being applied to FDA has arguably reached a new and greater degree. Anecdotal stories such as Harry's were evidently not enough to impress on FDA that its review process had to be changed. Even in the face of opposition, it held to its argument that it has a duty to protect everyone, including the terminally—ill, from potentially unsafe or ineffective drugs.

What it took to convince FDA that substantial reform was necessary was direct and personalized action on the part of AIDS sufferers themselves who were willing to do whatever it took to impress on FDA that they do not want its protection. *They* are the ones suffering from a dreadful disease, and so *they* were in the best position to perform the relevant risk/benefit analysis. It was *their* opinion as to what should and should not go into their bodies that counted, not anyone else's.

Along the same lines ran the more recent argument of the dietary supplement lobby, which, although not necessarily dealing with issues of life—and-death magnitude, expressed the same arguments with the same amount of vigor. In fact, the pressure applied by this lobby was so strong that it managed to have carved out of the Food and Drug law a distinct and virtually unregulated category for vitamins, which advocates believe to be beneficial to their health. Whether the object of the debate is dried—up fruit seeds intended to be a cure for cancer or a new drug purported to stop the progression of AIDS, the point is that there is an everincreasing emphasis in our society on personal autonomy and freedom of choice and against governmental paternalism. This is true in a general sense, but more crucially in specific situations that involve urgent, personal, life-and-death decisions.

As I have said before, the right to die and the right to stay alive are conceptually linked on both of these levels. In a more

general sense, they are both driven by the same underlying philosophical intuitions, namely that autonomy and freedom of choice should be given priority; but they also urge this system of priorities under the same types of circumstances. Advocates do not urge that the government mind its business as a *per se* rule, under *all* circumstances where decisions affecting health and the body are concerned. Their arguments do not reach the issue of whether *every* such decision should be decided in the purely personal realm. Instead, they are implicitly distinguishing normal situations from those that involve what I have described above as the rights of the terminally—ill, and urging that the latter be given the special treatment they deserve.

People want to be able to make decisions concerning their bodies, especially when these decisions will affect whether and how they live or die. This is precisely the intuition on which both the right to stay alive and the right to die are grounded. My question, then, is why the latter seems have made so much more headway in terms of being generally accepted than the former.

Although I stated above that the Supreme Court has recently upheld two state laws *disallowing* physician-assisted suicide as not unconstitutional, I also mentioned that it ended its opinion by encouraging debate over the issue at the state level. A brief look at the structure and content of both the majority and concurring opinions for the companion cases of *Glucksberg* and *Quill* will show a sympathy for — or at least a recognition of — the intuitive force of the right to die, on the part of all of the Supreme Court Justices, lurking behind the rigidity with which they dismiss the right.

In the first part of its opinion, the *Glucksberg* majority quickly decides that the right which respondents are asserting is not one that is traditionally constitutionally-recognized. It is

not a fundamental right. This is the first question that must be answered in a substantive due process analysis. If the answer is no, the case is essentially closed. The state must only show that its statute is reasonably related to a legitimate state end. If the right asserted does not meet the threshold requirement of being one that is protected by the constitution, there remains no further need for the Court to engage in part two of the due process analysis, which involves a balancing test that weighs the asserted right against possible competing government interests, and subjects the

statute to the most rigid 23  
state's scrutiny.

As just stated, the *Glucksberg* majority did in fact decide that what it strategically called the right to commit suicide [and have] assistance in doing so, *Glucksberg* at 2269, is both implicitly and explicitly disfavored by the constitution. Evidence of this was the fact that 'regular' suicide was traditionally illegal, and was legalized only as a conciliatory gesture towards the people left behind. Thus, in attempting to prove that the right to physician—assisted suicide is not a fundamental right, the majority essentially conflates the distinction between physician-assisted suicide and regular suicide, justifying its rejection of the right to the latter by appealing to our instinct to want to discourage the former.

After characterizing the right asserted by respondents in this very unsympathetic light, however, the *Glucksberg* majority goes on to perform a full—fledged due process balancing test, discussing the right asserted by respondents in the context of practically every conceivable competing state interest. Thus, despite its reluctance to admit that this right could in any way be construed as fundamental from history or tradition, the majority goes on to

afford it the same degree of analysis that it would a constitutionally-protected right.

If the majority felt compelled to weigh the right asserted in *Clucksberg* against competing state interests, we might wonder why it was so quick to deny the right any constitutional significance. The explanation is most likely that the volatility of the right and the heated debate which currently surrounds it induced the majority to make a conscious decision to cut it off at its roots, lest it open up a pandora's box. This was a good psychological move. By denying that the asserted right was one that could be construed to be constitutionally recognized, the majority relieved the state statutes that purportedly infringed on this right from being subject to rigorous scrutiny and required them only to have a rational relation to a legitimate state end.

Despite its initial reluctance to give any credence to the right asserted by respondents, the balancing portion of the majority's opinion suggests that its initial technical treatment of the issue is not reflective of its substantive opinion of it. In fact, the length and detail with which the majority argued against the right, and the almost naive formality and rigidity with which it initially dismissed it, might actually be taken to illustrate a recognition on its part that the right asserted by respondents *is* one that has some substance and force. Indeed, it might be that the majority regarded the right as so explosive that, short of requiring an unbridled recognition of it (which the majority did not want to do), the only choice it had was to contain it as tightly as it could.

The concurring opinions for *Glucksberg* and *Quill* possessed more of a realistic tone. Though each concurring Justice ultimately agreed with the majority that statutes prohibiting physician—assisted suicide should not be deemed unconstitutional, each also had no problem acknowledging the substance and importance of the right to die. The concurring justices also described the right more charitably as the right to die with dignity, *Glucksberg*, 117 S.Ct. 2302, 2307 (Breyer concurring) and acknowledged the importance of the characterization of a right to an evaluation of its merits. Hence, the concurring justices were not led ultimately to decide against respondents because they did not recognize the right being asserted by them, but rather because they all found various competing state concerns to override the right.

Thus, although the *Glucksberg* and *Quill* decisions do not advance the position of physician-assisted suicide *per se*, they do not in my opinion, do it much harm. Although the Court is not requiring states to make the option available to its residents, it is not disallowing them from doing so either. And while the opinions raise serious and important considerations against the legal sanction of the right to die, the tone at least of the concurring justices could even be seen as sympathetic.

Then we have *Cruzan*, the Supreme Court case which upheld the right of an individual to refuse life—sustaining measures and/or be withdrawn from life support. Here, we have the Supreme Court not only allowing states to make this option available to its residents, but actually requiring them to do so. Thus, the *Cruzan* Court gave official recognition to the idea that individuals should have at least the right to die naturally.

Respondents in *Quill* used this concession on the part of the Court to argue for the right to physician—assisted suicide. They reasoned that allowing what I will call the *Cruzan* right to die, while simultaneously disallowing the option of assisted suicide, constitutes a violation of equal protection, as some are granted the right to choose how to die, while other similarly situated people, are not.

In response to this argument, the *Quill* majority explains that the *Cruzan* decision was driven by concerns other than those of personal autonomy or a concession that individuals have the right to choose how or when to die. As the *Quill* majority contended, the justification for the decision was not nearly so deep. Instead, the *Quill* majority explains that the *Cruzan* decision was simply based on the time—honored common law rule that forcing unwanted medication on someone is considered a battery. Thus, history shows that we all have the right to refuse unwanted drugs or medical treatment, a right which is simply inapplicable to the issue of assisted suicide. In the case of assisted suicide, patients are *seeking* medication, not exercising their fundamental right to stay free of it. The Court also held, in line with the sentiment of the laetrile Court, that terminally-ill individuals do not comprise a suspect class. For that reason, the issue did not require heightened scrutiny.

Despite the fact that history did give the *Quill* majority a hook on which to hang its argument, even Justice Stevens points out the absurdity of the contention that the *Cruzan* decision was about a common—law rule of battery, *Glucksberg*, 117 S.Ct. 2302 at 2306 (Stevens concurring), as did the Supreme Court itself in Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833

(1992), when it alluded to its holding in *Cruzan* as one about personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power..., *Casey* at 857. Additionally, in *Cruzan* itself, the Court explicitly acknowledged that its decision stemmed from a belief that the choice between life and death is a deeply *personal* decision... (emphasis added), *Cruzan* at 262. Clearly, the *Cruzan* decision acknowledges the existence of certain boundaries passed which it is inappropriate for the state to tread. But why draw the line there, and not have it encompass the right to die by physician—assisted suicide? As Stevens points out, the relevant question with respect to the terminally-ill is how, not whether to die, *Glucksberg*, 117 S.Ct. 2302, 2307 (Stevens concurring). It is precisely this type of questioning which I believe the *Quill* majority feared.

Thus, as it did in *Glucksberg*, the majority cut the question off at its roots. Rather than trying to explain why we should be granted the right to refuse medical treatment which is necessary to keep us alive, but not be allowed to end our lives with peace and dignity at a point where death is a certainty, it was easier for the majority to distinguish *Cruzan* on historical grounds. In fact, the only substantive discussion in *Quill* of the conceptual distinction between the *Cruzan* right to die and the right to assisted suicide is the majority's discussion of the 'act/omission' or 'action/inaction' distinction.

As the Court explains, while *Cruzan-type* situations involve merely the refusal of artificial substances into the body for the purpose of not being kept alive unnaturally, assisted suicide requires the ingestion of foreign substances for the very purpose of

dying. As intuitively acceptable as this distinction sounds, it may be undermined by a fact which Justice O'Connor points out in her concurring opinion, namely that patients are already allowed to receive palliative care, 117 S.Ct.2258, 2290, (O'Connor concurring) . Under this option, doctors are permitted to administer potent doses of pain-killing drugs such as morphine which, although not intended to do so, almost necessarily have the effect of hastening death. Thus, even the theoretically clean—cut act/omission distinction deteriorates at a practical level. There is no clear—cut or mechanical formula by which we can determine the appropriate placement of the line which demarcates the point at which we have carried a right too far.

Though the *Glucksberg* and *Quill* opinions are facially formalistic, a deeper look at what they are saying shows a recognition of this insight. Although the majority in both cases speaks in terms of black-and—white distinctions, the opinions really seem to posit a type of moral spectrum, where not interfering with conventional medical treatment is at one end and ordinary suicide is at the other. The spectrum may be based on a kind of action/inaction distinction theory, under which the *Cruzan* right, which is exercised passively, would correctly be placed far from ordinary suicide. However, refusing life-saving treatment, even if it is considered artificial, cannot be put on equal footing with receiving conventional medical treatment, even though exercising the *Cruzan* right to die does not involve any *affirmative* action that will result in death. The fact that it can be characterized as passive, however, legitimately enables the *Cruzan* right to die to be placed far from regular suicide on the spectrum.



Assisted suicide, perhaps because of its unfortunate name, would fall closer in the Court's judgment to the other side, where regular suicide would be placed. Although the two acts are different not only in degree but in type (e.g. because for people who seek assisted suicide, *imminent* death is certain), on a formal level both involve the taking of steps that will cause death. Under this theory, the act of administering potent pain-killing drugs which may hasten death, but do not aim to do so, must fall somewhere in between.

The question then is where does the right to stay alive fall? Well, it depends on how we interpret the spectrum. If we choose to understand the spectrum as being based on an action/omission distinction, which might be a legitimate interpretation, then the right to stay alive - which involves the *taking* of unapproved medication - would clearly fall closer to the act side. Since a premise of a spectrum based on an act/omission distinction would be that any *action* which may or will result in death is less innocuous than passivity whose result is the same, we would have a legitimate basis to deny or at least curb the right to stay alive.

This would not be an unreasonable interpretation, as I think most would concede that there is some substance to the intuition that it is somehow more morally repugnant to do something that will prompt death than to *not* do something designed to delay death. The *Quill* majority describes the distinction as one between killing and letting die, a distinction which I believe captures a very real instinct and contains much rhetorical force. In practice, however, the distinction is not so clear. As Justice Scalia bluntly

points out in his *Cruzan* concurrence, starving oneself to death (by refusing life-saving hydration and nutrition) is no different from putting a gun to one's temple as far as the common-law definition of suicide is concerned, *Cruzan* at 296 (Scalia concurring)

In defense of the *Quill* majority, however, I would like to bring up another distinction which it finds important in distinguishing the refusal of life—support from assisted suicide. In justifying the former, the Court makes the point that, although the refusal of life—sustaining medical treatment may have the consequence of hastening an individual's death, dying is not the *goal* of the individual who makes this decision. On the contrary, the individual usually hopes to live, but simply wants to do so naturally. In the case of the individual seeking assisted suicide, however, the goal is precisely to die; death is what the individual is seeking. Thus, the Court looks beyond the nature of the act itself to the intention of the individual who requests it.

Under an action/inaction analysis, it is clear that the right to stay alive involves *doing* rather than *not doing* something. However, it does not involve doing something with the *intention* of hastening death. Thus, if we took the spectrum to be intention—based - with the intention to live on the top and the intention to die on the bottom — the right to stay alive would clearly be placed above both assisted suicide and the refusal of life—support. In fact, the right to stay alive would mark the upper boundary of the spectrum, as it is motivated by the most unrelenting will to fight death as strenuously as possible. Thus, we would construe it as the antithesis to regular suicide, which, because it is based precisely on the will to die, would occupy the spot at the bottom.

Thus, as we see, the placement of the various acts on the spectrum depends on what we take the basis of the distinction and comparison to be. While the general action/inaction distinction is an intuitively plausible basis for analogy, does it not make more sense, when we are dealing with issues of living and dying, to order the acts in question according to the extent to which each involves the will to live? Interpreting the spectrum this way, we would interpret the right to stay alive as the paradigmatic expression of an intention to live. In fact, we might even be committed to considering the right to stay alive more morally admirable than the common decision to undergo conventional medical treatment. After all, what could be more commendable than fighting to stay alive in the face of the bleakest odds? What could be more in line with the fundamental intuition to preserve life than the determination to try *anything* to accomplish this goal?

In attempting to explain why refusal of life-support should be allowed while assisted suicide is not, the *Quill* majority offers a range of distinctions between the two, some of which are artificial and some of which are more substantive. By doing so, it goes to great lengths to avoid admitting any essential link between the two, thereby obviating the need to engage in conceptual or psychological line-drawing. What I believe was truly motivating the majority, however, was the simple, and reasonable, intuition that refusal of life—support is simply more okay, according to the values which we take our constitution and society to embrace, than assisted suicide. Maybe it is because the latter involves activity while the former only involves passivity. More likely, however, it is because the former is not inconsistent with the will to live, while the latter by its terms explicitly rejects it. If I am right, then it seems

that an assertion of the right to stay alive, if formulated as such, should have some pretty strong constitutional footing. After all, because of notions that we take to be fundamental to our society, it would be hard to interpret our constitution to require, no less protect, an act that expresses an intention to die. On the other hand, it seems that a right which is based on an intention to stay live is one which we would hope that our Constitution protects as fundamental. As the *Cruzan* majority states it cannot be disputed that the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment, *Cruzan* at 262.

As I mentioned earlier, cries of autonomy and freedom of choice are rampant these days with respect to life and death issues. Equally, however, the Supreme Court itself has given certain of these rights a constitutional imprimatur. Thus, we have the Supreme Court construing the constitution to require that individuals have the choice of whether or not to be kept alive artificially. We have the positive pressure of a society that is looking to expand the province in which personal autonomy governs. We even have one state which has responded to this pressure by passing legislation allowing terminally-ill individuals to take their own lives. The fact is that society is becoming more and more intolerant of the government making decisions that concern how and whether we live and die. Evidence that this feeling is justified might be the fact that the people who are screaming the loudest are the terminally-ill themselves, and their loved ones. Who better to judge what feels most right and most comforting to people living under such dire circumstances than the people most intimately connected to the situation?

Without even reaching the merits of the various 'rights to die, however, it seems logical to concede that if we are going to allow *any* special privileges to the terminally—ill in matters of dying, there should not even be a question whether we should allow them special privileges with respect to matters of living. Stevens points out in his *Cruzan* dissent that choices about death touch the core of liberty... Our duty, and the concomitant freedom, to come to terms with the conditions of our own mortality are undoubtedly 'so rooted in the traditions and conscience of our people as to be ranked as fundamental', *Cruzan* at 343. But if the choice to die is connected so intimately to our liberty, then must not the choice to live be as well? Do not societal attitudes and the basic elements of our constitution imply, if not demand, recognition of the right to try to stay alive?

We might base an affirmative answer to this question on the right to privacy and personal autonomy arguments asserted and accepted in *Cruzan* and the abortion cases. The *Casey* case, which I referred to above - which confirms the decision in Roe v. Wade, 410 U.S. 113 (1973) that the right of a woman to choose abortion is a fundamental right - speaks of the Constitution's promise that ... matters, involving the most intimate and personal choices a person may make in a lifetime, choice central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment, *Casey* at 923. What could be more fitting of this description of protected rights than one which allows a person the choice of taking medication intended to keep him alive. Even more pertinent are the statements by the Court recognizing the freedom to care for one's health and person, freedom from bodily restraint or compulsion..., Doe v. Bolton, 410 US 179 (1979), 214, (Douglas

concurring), and the limits on governmental power to mandate medical treatment *or to bar its rejection*, (emphasis added), *Casey* at 857. *Cruzan* stands in part for the proposition that forced treatment may burden [an] individual's liberty interest, *Cruzan* at 288, (O'Connor concurring). However, to contend that prohibiting an individual from taking medication which he wants to take to attempt to prolong his life is different in type from forcing medication on him would again be to inappropriately inflate the practical weight of the action/inaction distinction. While the former is passive while the latter is active, both types of interference on the part of the government infringe on an individual's physical freedom, *Cruzan* at 287, (O'Connor concurring)

Without even having to appeal to concepts of bodily integrity and personal autonomy, however, it seems implausible that the Constitution would not be construed as protecting the right to try to stay alive at its most fundamental level. After all, with regular suicide on the opposite end of the spectrum of the right to stay alive, we may take the historical disapproval and disdain of the former, which the court dwells on at length in *Glucksberg*, to negatively imply a historical advocacy of the latter. Later in the paper, I will explore how the right to stay alive can be construed by a kind of negative implication from the Supreme Court's right to die discussions. For now, however, I will assume, on the basis of my analysis regarding what I take to be the underlying motivations for the Court's treatment of the various right to die issues, and on the basis the more explicit statements which I cited from the Court's abortion cases, that the Court could find a legitimate

historical/traditional basis to construe that the right to stay alive is worthy of constitutional protection.

Even if the right to stay alive were deemed to meet the threshold requirement of being characterized as fundamental, however, the substantive due process analysis does not stop there. As I mentioned above, if the Court were to make the initial determination that there is some substance to the right to stay alive, it would still have to proceed to weigh the personal interests at stake for the people asserting the right against any potential competing interests at stake for the government and society. In so doing, the Court would in effect have to make a determination as to which interests are more important on balance to honour. However, the burden at this point is shifted to the government - in this case the Legislature or FDA - to prove that its

statute serves a compelling interest.<sup>24</sup>

Although a substantial and vocal segment of the nation strongly urges an acceptance of the right to die, there are also those who vehemently oppose it. The concerns of these groups are discussed in the majority and concurring opinions for *Glucksberg* and *Quill*, and, as we see by the results of these cases, have been taken quite seriously, even by those justices who express a belief that there is some substance to the right. To extend my hypothetical constitutional analysis of the right to stay alive, I will dedicate my next section to identifying and evaluating the weight of government interests which both *have been* and *could be* asserted against the right to stay alive, if it were subjected to a due process balancing test.

Again, I will use the Court's discussion in *Glucksberg* to guide my analysis, as many of the objections raised against assisted suicide are analogously applicable to the right to stay alive. In discussing these objections, I will evaluate whether any distinction between the right to die and the right to stay alive would enable the latter to withstand the objection.

**The Right to Stay Alive vs. Possible Competing State Interests**

It pretty much goes without saying that the most forceful argument against allowing terminally-ill patients to choose to try unapproved drugs is that the drugs may not only be ineffective, but may actually be unsafe. This seems to be the main concern that was driving the opinion of the Laetrile court. Although, formally, its opinion was based on an interpretation of administrative law and procedures, it does, as does the *Glucksberg* Court, allude to several substantive government interests that might stand in opposition to allowing the terminally-ill access to unapproved medication. As the Court points out, it is the function of the FDA to protect not only healthy people, but sick people as well. Relying on the legislative history of the 1938 Act, the Court points out that Congress actually expressed concern that individuals with fatal illnesses, such as cancer, should be shielded from fraudulent cures *Rutherford* at 2475. Thus, rather than being exempt from the reach of the FD&C Act, the terminally-ill were among those deemed to need special protection against unapproved drugs.

On the other side of this very forceful argument, however, we have what is probably the most often-expressed and most forceful counterargument to this contention, namely the question of 'who cares'? If an individual is suffering from an illness for which there is no cure or treatment, then what he does have to lose by



trying a drug that may save his life? There is no down side, and the up side is huge. Safety and effectiveness lose their meaning when applied to people who are already dying. This sentiment was expressed by the Appeals Court in the Laetrile case which reasoned that [s]ince [terminally-ill cancer patients] would 'die of cancer regardless of what may be done'... there were no realistic standards against which to measure the safety and effectiveness of a drug for that class of individuals *Rutherford* at 2474, citing 582 F.2d 1234, 1236 (1978) . Construing this logic strictly, the case is pretty convincing. So convincing in fact that we might wonder how FDA could *ever* and *under any circumstances* justify keeping potentially lifesaving drugs from the market, or delaying their entry while the review process is being implemented. For, when imminent death is the only alternative, isn't even a potentially unsafe stab at a cure better than no cure at all?

If that were truly the extent of the question, then I believe that not many would have a hard time answering yes ~. However , we know that the situations with respect to which this question arises are not in fact nearly so black—and—white. As just stated, it would be difficult to justify 'protecting' someone, who was literally *about to die*, from a potentially unsafe, but potentially *life-saving* drug. However, the point at which a person is about to die is almost impossible to identify, except in retrospect. In fact, not all people who have been diagnosed with an incurable illness are even facing *imminent* death.

To use the example I began with, patients diagnosed with ALS, for which no cure or substantially effective treatment exists, may live up to three to five years from the date of diagnosis. This is true of AIDS and some types of cancer as well, for which the average life span after diagnosis may even be longer. Thus, by withholding

potentially unsafe drugs from the market, or limiting their availability, the FDA may be protecting these people, though not from eventual death, at least from giving up possibly several more years of life because an unreviewed drug turned out to have serious or debilitating side effects. Even if we were to provide that drugs to which the terminally-ill would have access at least be required to pass a phase I—type of safety test, as FDA’s compassionate access plan sensibly requires, patients would still have access to drugs whose combination effects would not yet have been tested. Thus, although the drugs would have been deemed safe in the abstract, in combination with other drugs, they might be harmful, or even lethal. If the terminally-ill had an unqualified right of access to unapproved drugs, however, they would not be required to have their trials of the drugs monitored.

Thus, it is not completely true that there would be no down side to allowing the terminally-ill access to unapproved drugs. For the reasons just stated, it could turn out that taking a new and unapproved drug would leave a terminally—ill individual in worse condition than he was from his original illness. If this happened, there would always be the regret that, if the patient was forced to wait, he might at least have had some more time to live under relatively normal conditions.

Equally, while he was waiting, a better form of treatment might have been discovered. As the *Cruzan* Court points out, there is always the possibility of advancements in medical science, *Cruzan* at 282, which could make one regret his decision to take a risk. For these and other reasons, the question of whether terminally-ill individuals should have access to unapproved drugs is not nearly as straightforward as some might imagine. Instead, it is clouded by numerous questions, some of which we can try to answer,

but some of which we simply cannot. At what point can we conclude that someone is terminally—ill? When, if ever, is it appropriate to give up hope? The only thing that is certain is that it is *not certain* that terminally-ill individuals have nothing to lose by not waiting. In fact, if their particular disease allows them to live long enough, they might even have something to gain.

Going back to my example, however, a person diagnosed with ALS could die within months. Because the life span after diagnosis varies so extensively from person to person, there is no telling when a person with ALS is about to die, except maybe when the disease has advanced to a point beyond which the success of any treatment would have already become quite unlikely. Thus, some individuals diagnosed as terminally—ill do not have the time to wait. In those cases, keeping drugs from them which have even the slightest chance of improving or even stabilizing their condition is in effect promoting their death. The problem is that these cases can usually not be distinguished *ex ante* from cases where the patient does have time to wait.

Basically, the decision of whether to allow terminally-ill patients premature access to certain drugs comes down to weighing the risks associated with both sides. On one side, we have the risk that the drug will not work and will actually worsen the person's condition and shorten or interfere with whatever time remains of his life. However, as any regime that provided for access on the part of the terminally-ill to unapproved drugs would likely require at least that the drugs be tested for safety, this is not very likely. The only real risk would be that the patient has a particular negative sensitivity to the drug or is taking one or more other drugs with which the new drug detrimentally interacts.

On the other side, we have the consideration that the person's days might be numbered anyway, though just how numbered is a question about which it is often difficult to speculate. On the positive side, we may be saving a lot of lives. Most people who suffer from terminal illnesses do not enjoy a very high quality of life as a consequence of their condition. Thus, a drug that decreased their quality of life, but added years to it, like chemotherapy, would likely be very much welcomed. It is true that a new and unapproved drug *might* take a greater toll on the health and quality of life of a terminally—ill individual than his underlying disease already has; it is also true that a terminally—ill individual could live for years without treatment, during which time a safer and/or more effective drug might come along and actually be approved. These risks should not be ignored.

Just given the odds, however, it seems that these scenarios would ensue much less frequently than would those in which lives of terminally—ill individuals would be saved by allowing them access to unapproved drugs. Equally, it seems clear, based on statements and outcries of the terminally—ill themselves, that any risks which might be associated with taking unapproved drugs are ones that they are willing to take.

True, the severity of their conditions may cause them to underestimate the risks of something purported to help them. Thus, they might not approach the benefit/risk calculation with as much scientific objectivity as would a doctor or the like. On the other hand, however, why shouldn't the pain and/or hopelessness which plagues the lives of the terminally-ill be a relevant factor to their benefit/risk calculations. Remember, granting the right to stay alive would not force the terminally—ill to take unapproved medication; it would merely give them the choice of doing so. If,

in their opinion, that measure seems warranted, who is to say that it is not? Why is a more removed perspective necessarily a better one? While there are clearly interests weighing against allowing the terminally-ill access to unapproved drugs, there are very forceful reasons to do so on other side. Though it is impossible to make a scientific determination of which interests are stronger, it seems that, all in all, the benefits associated with allowing the terminally-ill the choice to take unapproved medication which may save their lives outweigh the risks.

The same type of what if arguments presented against allowing the right to stay alive could easily be formulated into arguments against assisted suicide. However, there, the counterarguments may not be as strong, as the stakes are clearly much higher. If a drug which a terminally—ill individual experimented with turned out to have negative side effects, it is quite possible that the situation could be corrected. Equally, a medical breakthrough pertaining to his disease could quite possibly save him, even if he has prematurely taken ineffective medication. With respect to assisted suicide, however, there is literally no turning back. Once the right has been exercised, it cannot be retracted. Nor can the situation be rectified. Unlike the risks involved in granting the right to stay alive - which may not materialize and will probably be outweighed — the risk involved in granting the right to die is certain, calculable and irreversible. Whether we are talking about refusing life-saving medical treatment or about taking lethal medication supplied by a physician, the consequence of exercising the right to die is death.

On the other hand, giving the terminally-ill access to unapproved medications only presents a *slight* risk of the *possibility* of death - and it is intended to delay it. Thus, even

when we consider its worst possible downside, the right to stay alive comes out looking more innocuous than even the *permissible* Cruzan-type of right to die. To reiterate Stevens' observation, terminally-ill individuals do not have the choice of *whether to die*. They are already dying. Why not let people who are willing to experiment with unapproved drugs try to put off this fate as long as possible? Sure, an unapproved drug *may* have detrimental consequences. But, these consequences could not be as detrimental as those which ensue when a person refuses life—supports or is removed from a respirator.

Another objection which may be raised against allowing the right to stay alive is one that can be inferred from the Supreme Court's discussion of assisted suicide in *Glucksberg*. The concern there is that it is difficult to determine whether a given person is competent to exercise the right to assisted suicide. The same question can be easily applied to the right to stay alive. Whether a particular person is competent enough to make life and death decisions is not a question to which there is a simple yes-or-no answer. Even if it were determinable in an theoretical sense, it may be epistemologically difficult to determine in fact. Because no one, including doctors, can read people's minds, we have no definitive way of knowing whether a person's decision is the product of a reflective and informed analysis or instead sparked by a possibly fleeting whim. With respect to assisted suicide, however, the biggest threat of this public health concern, *Glucksberg* at 2272, comes from the fact that suicidal impulse is most often the result of clinical, and treatable, depression rather than that of a real and thought-out desire to end one's life based on the suffering that accompanies terminal illness, *Glucksberg* at 2272. Therefore, terminally—ill patients who experience this impulse *may* need to be

saved from themselves. As evidence of this, the *Glucksberg* majority points out that, in many cases, patients who are prevented from being allowed to end their lives eventually turn out to be grateful to be alive..., *Glucksberg* at 2272.

Although the specific threat of clinical depression does not arise in the context of the right to stay alive, the issue of a patient's competency is nonetheless quite relevant. Often, a patient whose physical state has deteriorated to the point where he would chose the option of trying unapproved drugs may not be in the requisite mental state to make such a sensitive decision. More relevantly, how do we ensure that a patient even understands the information on which his decision is based. It is difficult for anyone to understand abstract concepts such as actuarial probabilities, not to mention the medical jargon that might accompany an explanation of a drug's potential side effects. Thus, even if a person is competent in a psychological sense, he may not be competent in a practical sense. He may be making a decision on the basis of misperceived or misconstrued information.

Relatedly, we have the concern of potential coercion, which the *Glucksberg* majority also brings up. The worry there is that, if assisted suicide were a legally viable option, a terminally-ill patient might feel pressured to choose it on the inappropriate basis of financial or emotional considerations. With respect to the former, the Supreme Court fears that patients will feel compelled to end their lives prematurely, when the alternative is to live with extensive medical treatment and/or supervision which is placing a huge financial burden on their family. Because they are going to die soon anyway, and most often the greatest percentage of money spent on medical care is expended during the final days of a

person's illness, they might feel that it is right to spare their family that extra expense.

Equally, many terminally-ill individuals want to spare their family the agony of having to see them suffering unbearable pain. If not for their family and friends, they might be able to endure the pain of their illness. In combination with the pain that their loved ones feel on their behalf, however, the pressure might become too great to bear. Thus, terminally-ill patients might choose the option of assisted suicide, if available, in order to end the pain of their loved ones, even if they themselves would otherwise have been able to bear the pain.

While it may be noble for a terminally-ill patient to make a decision to end his life on the basis of one or both of these considerations, it does not accord with the idea of free choice and autonomy. Instead, it rings of coercion. The point is that the very existence of the option of assisted suicide may serve as a coercive force to choose it. The same concern - at least with respect to the idea of emotional coercion - easily applies to the choice which candidates for experimental medication would face if they were given unrestricted access to unapproved drugs. Even though a particular individual may not feel comfortable trying an unapproved drug, he might be subject to pressures from his family and friends who see him deteriorating and urge him to try anything.

Equally, he himself may feel pressured by the very availability of a choice. He might prefer to die a more natural death than to experiment with a bunch of new and unapproved drugs that could cause him physical pain or try his emotional state. He may be a fatalist, who believes that if he was meant to be saved by a particular drug, the review process for it would end before it is too late for him to use it effectively. If he were simply denied



access to unapproved drugs, he would know that there is nothing he could do to help himself. Given the option, however, he is presented with a very difficult choice which, regardless of which side he comes down on, entails a lot of what if's. Denying him the option would at least relieve him of one more difficult choice to face at an already confusing time in his life.

Another question that the *Glucksberg* court considers in its discussion of assisted suicide is the impact which a legal sanction of the option would have on the medical profession in general. In the court's opinion, the most detrimental way in which allowing physician-assisted suicide would compromise the ethics of the medical profession would be by undermining the traditional conception of the doctor as healer. How could patients be expected to retain confidence in their doctors if, instead of trying to improve their condition, they are agreeing to help them die? Clearly, that specific concern would not apply to right-to-live situations, in which patients are asking their doctors to help them stay alive. However, a doctor's belief that his terminally—ill patient should have special and premature access to medications may actually have a similar negative psychological impact on the patient.

In the case of assisted suicide, a doctor's *agreement* to assist a patient in ending his life may actually be a signal to the patient of what he interprets as the doctor's statement that all hope is gone. In a strange way, the same might go for the doctor who supports his patient's decision to try unapproved drugs. Although the ultimate goal is clearly to help the patient, the patient may take the doctor's acquiescence to his request as a signal from the doctor that his case is virtually hopeless. Thus, he may begin to lose faith himself.

While this might work to the psychological detriment of the patient, it is likely that, at that stage in the game, the patient would be used to the fact that the outlook is bleak. Thus, the only real harm that might arise would be if a patient took his doctor's *willingness* to provide him with unapproved drugs as a confirmation that his doctor thinks it would be a good idea. A request by a patient for unapproved drugs might merely be that patient's way of asking his doctor whether his doctor thinks that course of action would be advisable. By acquiescing, a doctor might inadvertently be endorsing a form a treatment about which he is actually ambivalent or even wary of; whereas, without as many choices and without as much discretion, the treatment process is much more straightforward. Although choice breeds possibilities for misunderstanding and misinterpretation, these barriers are clearly not insurmountable. Eventually, doctors would get used to having these additional options available and be able correctly to interpret their patients' desires as they do with respect to currently available treatments.

Another related concern is the psychological impact which a decision to give them special treatment might have on the terminally-ill. In *Glucksberg*, the court expressed the concern that allowing the terminally-ill the option of ending their lives would send a message to them that their lives are less valuable than the lives of healthy people. The same can be said for allowing the terminally-ill access to medication from which it is believed that the rest of us should be protected. To the individuals requesting the medication, the negative impact would not be great. In fact, it probably wouldn't be felt at all, for they are getting what they asked for.

The concern really arises with respect to that segment of the terminally-ill population which does not advocate the use of

unapproved medication. These people might be discouraged at the message that they perceive society to be sending. Why should they be less protected than the rest of us? Is the state of their lives truly that hopeless? Why should they be allowed to be guinea pigs for potentially unsafe drugs? What kind of commentary does that make regarding the importance with which society views the value of their lives? While viewing the terminally—ill as a special category of people deserving special treatment will obviously benefit those terminally—ill individuals who request to be treated that way, it may damage the morale of those terminally—ill individuals who want to be treated like everyone else.

Another common objection to the legal sanction of assisted suicide concerns the fear that doctors may be driven by economic incentives to encourage their patients to choose this option. This concern would be equally if not more relevant were doctors to be allowed to treat their patients with unapproved drugs. While doctors might not have too many economic incentives to encourage their patients to end their lives, it is possible that they would have incentives to try out new drugs on their patients. For example, a doctor in a research hospital might have worked on the development of a given drug, which it would then be in his best interest to market. Also, doctors or hospitals often have certain loyalties to particular manufacturing companies, whose drugs they would be inclined to promote. What better a forum for experimentation could they be given? If the right to live were granted, a patient's consent — and desire — to try unapproved medication would free the doctor or hospital of liability. Doctors would be able to effectively bypass the FDA review process, and experiment first-hand on willing human subjects. Equally, the results from these studies could be used to speed up the regular FDA

approval process for the drug, allowing it to become available sooner to people whom it may eventually benefit, but who have not yet become diagnosed as terminally—ill.

None of this sounds too bad - and indeed it would not be if the interests of doctors and patients were identical. The fact is, however, that, while many doctors will put their patients' interests first, many will be driven primarily by some of their own. Clearly, no rational doctor would want to jeopardize a patient's health. The problem with experimental drugs, however, is that it is not that clear what effect they will have on the human body. For that reason, it is likely that doctors will jump at the opportunity to try them out on willing patients. If they work, great. Then, they will get credit for helping to cure the patient. Their professional reputation will be benefited, and likely, they will attract more patients. If not, they have the law - and their patients' consent —behind them to free them of liability. If the right to stay alive were constitutionally-recognized, then doctors could not deny patients who requested unapproved but potentially life—saving drugs the opportunity to try out such drugs. Thus, while the success of a new drug would provide benefits to both the doctor and the patient, the failure of it would not entail any serious downside from the doctor's perspective.

There might be a downside to the patient, however. And because doctors might reap certain benefits from being successful in treating or implementing a cure for a terminal condition, we might have to worry whether they would take the potential risks to their patients seriously enough in weighing the benefits and risks of the situation. Doctors might become so zealous to cure~~ their terminally-ill patients that they would undermine the potential

risks associated with a particular drug and inflate the possibility of its success, even in their own minds.

Could this subtle and likely even unintentional manipulation be avoided? Possibly. But the efforts would have to come from doctors themselves, as decisions regarding the proper type and dosage of an unapproved drug are arguably better left to doctors than to the patients. It is this type of concern that likely underlies the intuition of those who are reluctant to let patients—even in conjunction with their doctors—take the matter into their own hands. Correspondingly, it is for this type of reason that proponents of the FDA believe that an independent agency, committed to determining objectively the risks and benefits of new drugs, is the most appropriate judge of which drugs should and should not be taken. The risks associated with leaving the issue up to doctors and patients might be great enough to justify the paternalistic aspect of FDA's function.

A related objection to allowing doctors to provide terminally—ill patients with unapproved medications is the concern that doctors might become somewhat desensitized to the value of human life. This concern is clearly more pronounced in the context of assisted suicide, where doctors would be authorized by law effectively to kill their failing patients. Though less extreme, the concern arises in the context of the question whether doctors should be allowed to treat their patients with unapproved drugs. As I said above, no doctor will want to be responsible for worsening his patient's physical condition. With a license from the legislature or the Supreme Court to experiment on their patients at the patients' request, however, doctors will likely become accustomed to a new set of ethical standards.

From one perspective, doctors may become more attuned to ethical concerns, as they will be put in the position of making decisions which previously they could rely on the FDA to make. Thus, a certain burden of responsibility will be shifted to practicing doctors. On the other hand, the decision of whether experimental drugs will be used for treatment would really and ultimately be up to the patient himself, as the bearer of the relevant right. Thus, a doctor who obtains his patient's consent essentially has a green light on the matter. Although he would still be expected to use discretion and prudence in advising his patient, there is not much room for a doctor to go wrong. When a person is facing imminent death, *any* option is likely to sound like a good option; indeed, from the patient's perspective, things probably couldn't seem any *worse*. For this reason, a patient might not be any more likely to blame a doctor if an unapproved drug were unsuccessful, or even harmful, than he would be if the doctor had treated him with an approved drug.

If there were truly no other available treatments or cures for a given disease, then I suppose no harm would really be done. Often, however, new drugs are produced as substitutes or improvements for other existing treatments. In Harry's case, there were already certain approved drugs on the market that purported to slow the progress of ALS. The experimental drug which he was scheduled to try was designed to be more effective. Thus, giving doctors discretion to treat their patients with unapproved drugs - even if the patient's consent is needed - might incline doctors towards recommending this option at the expense of more traditional and already-approved treatment. Even if the doctor were to explain to his patients that approved, but probably less effective, drugs were available, his mere statement that new and potentially more

effective drugs were available might legitimate this option in the patient's eyes.

Eventually, the line between approved drugs - which have undergone rigorous testing and evaluation - and unapproved drugs -which would have been subject to only the most minimal testing -could become blurred. Human beings would become guinea pigs in uncontrolled medical tests. It would be up to practicing doctors to determine which, among a vast number of drugs purported to treat or cure a given terminal illness, might be most effective for their patients, and to determine the point at which it should be concluded that a given drug does not work.

Even worse, as the Laetrile court also feared, the availability of new and unapproved drugs might cause patients, sometimes with the consent of their doctors, to put off conventional medical treatment. As the Court remarked, if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible *Rutherford* at 2477. While doctors would not become desensitized to *taking* human life in the way that they would if they were authorized to assist in their patients' suicides, they might very well become more careless about how they treat human life.

The final problem that the *Glucksberg* court brings up with respect to allowing assisted suicide is the fact that, even if we were to justify the act on a theoretical level, it would be practically impossible to confine the incidence of it to the narrow situations for which it would be authorized. For reasons I outlined in the beginning of the paper, I believe that this concern is justified. Again, how do we define terminal? How can we assess whether someone is in unbearable pain? The first of these

questions presents the biggest problem for the proposition that the rights of the terminally-ill should be evaluated as a discrete matter: how do we define the extension of terminally—ill and how do we ensure that our test will be strictly applied?

Clearly, this concern applies to my topic as much as it does to that of assisted suicide, as the common nexus of the concepts is that they both concern the terminally-ill. Since the *Glucksberg* Court laid a lot of emphasis on these types of definitional concerns in reasoning to its rejection of the right to assisted suicide, then what would make it change its mind if asked to recognized the right to stay alive?

My answer to this question is twofold. One, I do not believe that it is as difficult as the Court implies to fix an extension to the class of people for whom assisted suicide would be an option. While I agree that it would be hard to come up with a strict and formal mechanism for defining terminally—ill, I believe that we all have an intuition as to what should properly fall under that heading and what should not. Of course, our analysis of whether a particular person is terminally-ill could rest only on actuals, rather than hypotheticals, lest we would never be able to apply the label. (It would be impractical and self—defeating to factor in possibilities such as the chance of a sudden cure, which though possible would rid many diseases of their terminal character) However, I believe that an appeal to our ordinary, everyday usage of the term, which takes only realistic contingencies into account, would point us in the right direction. To give an example, Oregon has resolved the issue by confining its statute authorizing physician-assisted suicide to adult(s) of sound mind who ha(ve] been given less than six months to live in the opinion of two doctors. ~~25



Thus, in deciding whether an individual should be granted the right to obtain assisted suicide or the right to have special access to medication, our common understanding of the term terminally—ill, should be able to serve as a useful and likely sufficient guide. The problem of semantic open-endedness is not exclusive to the usage of the description terminally—ill, but is present each time we use language to formulate any rule or law. As a problem that we cannot escape, it is one that we have learned to deal with. I do not believe that the inherent vagueness and ambiguities of language present a great enough threat to justify abandoning the recognition of important rights.

Even if we were able to confine laws relating to the terminally-ill on a theoretical level, however, there remains the concern that affording special treatment to the terminally—ill in narrowly prescribed circumstances will lead in practice to an infinite regression. The *Glucksberg* court feared that allowing the option of assisted suicide to *certain people under certain circumstances* would promote similar, but more serious, types of restricted behavior. As evidence, the court pointed to the situation in the Netherlands, where legalization of assisted suicide has resulted in increased and uncontrolled instances of voluntary and involuntary euthanasia, *Glucksberg* at 2274. Taken to an extreme, any leaning in the direction of assisted suicide could begin to erode society's moral repugnance towards taking the lives of others.

While this specific consequence would not be entailed by allowing terminal individuals access to unapproved drugs, an analogous concern does arise. While granting the right to live would not harden society and doctors towards the taking of human lives, it could lead to a state of affairs equally capable of

getting out of control. As I mentioned above, once doctors are allowed to provide their patients with unapproved medication, it will be hard for them to draw the line between cases that do and do not warrant this type of *special* treatment. If a doctor sees that a given unapproved drug is having beneficial effects on a terminally-ill patient, he will likely be inclined to want to test the drug on patients with similar, but maybe not *terminal*, illnesses. Equally, he might get so used to treating patients with unapproved drugs that he will forego more conventional treatment for his patients, when maybe the latter would be more appropriate.

Additionally, there is potential for the situation to become unraveled on a broader level. While a law allowing special access to medication would be narrowly prescribed to apply only to *terminally-ill individuals* who suffer from a disease for which *no effective cure exists*, it would inevitably open the door to all kinds of claims from anyone from whom important drugs are being denied or delayed. Equally, it would be susceptible to the type of equal protection challenges enunciated in *Quill*, as it would grant *some people* the right to unapproved drugs while denying the right from others. Thus, the Supreme Court might be wary again to go down that road; for once the ball gets rolling in a certain direction, it is always hard to stop it. I believe that this fear was at the base of the Supreme Court's decision to rule against the *Glucksberg* respondents and its strong disinclination even to recognize the right to die as a right at all.

Thus, we see that, while it might be possible to establish the right to stay alive as one worthy of constitutional protection, it would still be up against a myriad of serious objections. Most of these objections, such as the question of competency, the potential for financial and/or emotional coercion, the possibility that the

ethics of the medical profession would be compromised, the concern that less-than-healthy individuals would believe their lives were being judged as less valuable than others, and the problem of confining the right both theoretically and practically were brought up in essence by the *Glucksberg* court to support its rejection of the right to assisted suicide. We have seen how they apply if not in a specific, at least in a general sense, to allowing terminally-ill individuals access to unapproved medication as well.

The other objections which I hypothesized and/or abstracted from actual discussions regarding the right of the terminally—ill to have access to unapproved drugs are the possibility that unapproved drugs may actually worsen a patient's already—grave condition and the concern that patients and doctors will decide to forego conventional treatment in favor of experimenting with unapproved drugs. While I have concluded that each of these actual and possible objections should be taken seriously, I believe that most of them are capable of being overcome by legitimate counterarguments. Although I agree that determining a patient's competency is not an easy matter, it is one that must be dealt with all the time where the paths of law and medicine cross. True, a patient suffering from a terminal illness will likely be in a particularly vulnerable and/or desperate state, but maybe the desperation that surrounds the situation should not be excluded from benefit/risk analysis. Equally, we do not have the specific concern regarding the right to stay alive, as we do with respect to assisted suicide, that patients granted the right will be in danger of being driven to exercise the right by an independent medical condition such as clinical depression. That specific objection is not relevant to situations where the right to stay alive would arise.

Alternatively, it might be possible to circumvent the competency problem by providing for a living—will type document in which a patient would decide before his illness advanced whether he would be willing to try unapproved but potentially life-saving drugs. Finally, even if an incorrect assumption were made as to a patient's competency, and he were allowed to exercise his right to stay alive where 'normally' he would not have, the consequence will almost certainly not be as grave as that which an exercise of the right to die would entail. Again, it is unlikely that unapproved drugs will cause death.

The concern of potential financial coercion, I take to be essentially inapplicable to situation at hand. However, I do believe that the possibility for emotional coercion presents a serious concern, and may actually compromise the personal autonomy which the right sets out to protect. Again, however, I do not believe that the potential for such coercion outweighs the benefit that would be derived from granting the patients the right to stay alive. I base this conclusion on two considerations.

First, I find it factually unlikely that there will be too many instances in which a terminally-ill individual will be resistant to using unapproved medications, but where his loved ones would nonetheless insist on promoting it. As we have seen, terminally—ill individuals are fighting bitterly and vigorously for access to unapproved drugs. I stand by the concern, however, that those who do not want the choice may feel pressured by its existence.

Secondly, however, I believe that the potential for emotional coercion is just as great, if not greater, with respect to *Cruzan* situations. Clearly, opting to be kept alive indefinitely by a respirator, when the option to die naturally is available, may seem

selfish to a person faced with the decision. Everyone knows that the former option would cause serious emotional and financial burdens to the individual's family and friends. However, the *Cruzan* Court saw the right at stake there to be more important than the competing possibility of financial and/or emotional coercion.

The same goes for the competency question discussed directly above, and the concern regarding the negative implications which granting the rights to live or to die might have on the ethics of the medical profession and/or society in general. All of these concerns were equally, if not more, applicable to the question of whether the *Cruzan-type* right to die should be honored. By the Supreme Court's positive decision in that case, however, we can infer that they were all apparently outweighed by the Court's belief in the validity and importance of the right.

Thus, although I stated before that establishing a right as fundamental is only half the *formal* battle of having it constitutionally-recognized under a substantive due process claim, realistically I believe that it is where the battle is truly won. Almost all of the objections that the court raised against allowing assisted suicide would apply to allowing refusal of or withdrawal from life-support. The only difference is that the latter is a right which the Court saw as worthy of mandatory constitutional protection, while the former was one which it was reluctant to recognize. If we interpret the spectrum of life—and—death decisions in the way that I suggested earlier, and take into consideration the societal and constitutional trends that have ensued since the time of the *Laetrile* decision, it would seem that the Court should be more psychologically inclined to accept the right to stay alive than any type of right to die, whether the latter be exercised actively or passively.

So what about the objections that would not likely have been raised with respect to the *Cruzan* right to die? These are the difficulty that would arise in attempting to confine and contain the right in question, in the *practical* sense that I described above, and the related concern that patients would exercise and doctors would comply with the right too liberally. Because the *Cruzan* right pertains to fairly well—defined situations, line—drawing is not too big a threat to its stability. A patient’s decision with respect to whether he wants to be resuscitated or put on a respirator is not easy to misunderstand. Equally, if we disregard the possibility of fraud or coercion, there are not too many situations in which the right could be taken advantage of. For these reasons, it was easier to grant the *Cruzan-type* of right to die without worrying that it would get out of control.

Though the concern that the right to stay alive, if honored, might be taken advantage of is not one that we can brush aside, I believe that the number of instances in which it would actually be abused would be far lower than the number of instances in which it would be properly and beneficially exercised. Although incentives other than purely their patients’ best interests do motivate doctors’ decisions, the interests of doctors and patients, though maybe for different reasons, actually coincide at most junctures. Thus, whether a doctor is motivated by a genuine and heartfelt concern for his patient’s well—being, or by a desire to strengthen his reputation and attract additional patients, or both, the outcome will be probably the same: he will want to take the course of action that will prove most successful for the patient’s health. Thus, while there would be a number of legitimate government interests against granting the right to stay alive, it seems that, in light of the Court’s 1990 *Cruzan* decision, they are not

insurmountable, nor compelling enough to cause the right to be denied. Again, if the right were to be recognized as fundamental, the relevant interests would have to weigh quite heavily in favor of the government in order for the government to be allowed to pass a statute which abridges the right. Equally, while it would be naive to suggest that the government would have no legitimate reason to want to curb the right to stay alive, I believe that any potential societal harm which granting the right to stay alive would entail would be considerably less than might follow from allowing any type of right to die, even the of the constitutionally—mandated *Cruzan* type.

Beyond raising *objections* that could be analogized to the right to stay alive, the *Glucksberg* opinion is useful in bringing to light a number of reasons why, in the Court's own language, the right to stay alive *should be recognized*. In my next section, I will discuss some reasons why the Supreme Court might actively want to honor the right to stay alive, which can be inferred from its discussion of its *reluctance* to honor the right to assisted suicide. While in this section, my goal was to show that the right to stay alive is capable of withstanding objections regarding the potential societal *harm* that it might entail, I will use my next section to discuss the potential societal *benefits* that would accompany the right, as implied by the Court's own reasoning in the right-to-die cases.

#### **An Argument for the Right to Stay Alive Based on Arguments Against The Right to Die**

In my first section, in which I discussed the relationship between the right to die and the right to stay alive, I concluded

that society's and the Supreme Court's attitudes towards the former indicate a trend that would tolerate acceptance of the latter. My general point was that, if we are willing to honor personal autonomy to the extent that we are willing to let people take (or omit) certain actions that will result in death; and if we are moving in the direction of actually allowing people to *take* their own lives prematurely, then certainly we have the requisite philosophical framework to justify giving people who are about to die the option of taking drugs intended to *save* their lives.

After concluding on this basis that the right to stay alive is at least one that should be constitutionally—recognized, I 'balanced' it against hypothetical competing government interests that would likely be raised against it. While I derived some of the possible objections to the right to live from common sense and from everyday life, I imported most of them from actual discussions of the right of the terminally-ill to have access to unapproved medication and the Supreme Court's balancing test discussion in *Glucksberg*. My purpose was to evaluate whether the particular nature of the right to stay alive would distinguish it enough from the right to die to enable it to withstand the objections to which the Supreme Court believed physician-assisted suicide succumbed. For this reason, I mentioned only those arguments from the *Glucksberg* opinion that I believed were relevant, either directly or by analogy, to right to live situations. On the whole, I concluded that, while many of the concerns that arise in the context of the right to die are applicable to the right to stay alive, the negative societal impacts would be less serious and less certain in situations involving the right to stay alive. Thus, the relevant objections, though not unfounded, would not carry as much weight



against the right to stay alive as they do against the right to assisted suicide.

To lend more support to my argument that the right to stay alive might be able to overcome competing government interests if formulated as such and challenged on due process grounds, I will now discuss several arguments made against assisted suicide which not only are not transferable to the concept of the right to stay alive, but actually support it by a kind of negative implication. I will attempt to show how several of the Supreme Court's arguments against the right to assisted suicide actually imply a societal and constitutional acceptance of the right to stay alive.

I mentioned briefly that the *Glucksberg* majority concludes that the right to die - or as they phrase it the right to commit suicide and have assistance in doing so — is not one that is even constitutionally—recognized. Again, the majority reaches this conclusion on the basis that the right is not one which can be located in history or tradition. To prove this, the majority embarks on a lengthy discussion of the evils of regular suicide and the vehement efforts made throughout history to prevent it. The Court points out that suicide used to be illegal, and was legalized only for the protection of the people which the suicide left behind. Thus, the Court concludes that the right which the *Glucksberg* respondents seek is not constitutionally recognized, no less constitutionally required.

Although the *Glucksberg* Court mischaracterizes - or at least characterizes to its advantage - the right in question to emphasize its relationship to regular suicide, its underlying point is not illegitimate. It is true that the values underlying historical efforts to prevent suicide are somewhat in discord with those that would underlie allowing physician-assisted suicide. It is probably

true that most of us would not want to make the general statement that suicide is okay. Nor would we want to condone a law that allows a doctor, even with the patient's consent, to enable a patient to take his own life.

It is this intuition which the *Glucksberg* majority captures in its first argument against allowing assisted suicide, namely that the state has an overwhelming interest in preserving human life. While the counterargument for this in the context of assisted suicide would be that situations involving *terminally-ill* individuals are distinguishable by type, proponents of the right to stay alive would not even have to go that far. Instead, the very legitimate intuition that we want at all costs to preserve human life is already a very forceful argument *in favor of* the right to stay alive.

While assisted suicide, and the *Cruzan* type of right to die, *allow* behavior counter to both our intuitions and our general societal goals, honoring the right to stay alive would not only be in accord with but would actively support this goal. People who seek unapproved drugs are asking for one last chance to try to live. They, and their proponents, are clinging to the instinct to preserve life even in the face of the most dire and hopeless circumstances. Ironically, everything which believers of the right to die stand for, believers in the right to stay alive stand against. Rather than giving up on life, they want to fight as hard as they can, and use whatever means possible, to stay alive. How then can we, a society purportedly committed to preserving human life, justify denying them the right to try to save their lives? How can the government interest in preserving life be strong enough to justify prohibiting people suffering from unbearable pain from taking their doomed lives even slightly prematurely, but not be strong enough to

protect people's efforts to try to stay alive? How can we let the FDA engage in *active* behavior (e.g. its lengthy review process) that will necessarily result in at least some unnecessary human deaths, while we deny the right to the terminally-ill on exactly this basis? Sure, we are allowed to refuse or be withdrawn from life-support; *but* the Court could not even bring itself to recognize this as a right of personal choice. Rather, it felt the need to characterize it as a kind of idiosyncratic implication of a historical common law rule.

The point is that the Supreme Court, and most likely society at large, is extremely disinclined to admit that allowing a person to choose to die is ever okay, whether the person himself concurs in the decision or not. It goes against all of our philosophical, ethical, religious, scientific etc. beliefs. The goal is always to try to find new ways to enable people to live longer. By the Supreme Court's own terms, then, it should be nothing less than admirable — and by the same reasoning necessary — to allow people to try any method they choose to preserve their lives. The people we are talking about are going to die soon anyway; they do not have to be protected from imminent death. What they are asking for, and what it would only be natural to grant them, is the right to try to stay alive.

The *Glucksberg* Court points out the efforts that have traditionally been and continue to be made to prevent people from taking their own lives. From that, it should follow that people have not only the right, but the responsibility, not to let themselves die. The Court also emphasizes the *state's* overwhelming interest in preserving human life. From that it should follow that the government should allow people all means possible to preserve their own lives. Thus, the right to stay alive presents a unique situation. Unlike other

asserted rights, such as the various types of rights to die or the right to abortion, some of which have been deemed weighty enough to overcome the government's primary interest in preserving life 26, the right to stay alive actually embraces this interest itself. It is true that there are safety concerns associated with allowing terminally-ill individuals access to unapproved drugs, but, again, because they are terminally-ill, the people who would be afforded this right do not have much to lose. Clearly, there is a point where an unreviewed - and so potentially unsafe - drug is more likely to be constructive than destructive in its effects. This point cannot be defined abstractly and absolutely, but must be identified on a case-by-case basis with reference to the intended recipient of the drug. If the harm which the drug might produce is less grave than the conditions under which the recipient is already living - or, conversely, if the good which the unapproved might do is greater than the harm which it might cause — then the logic of an argument based on a concern for health and safety deteriorates.

Thus, granting the right to stay alive is entirely consistent with the interest in preserving life. Hence, the right can find grounding not only in theories such as privacy, personal autonomy, bodily integrity etc., which have been used to defeat relevant government interests, but it has the additional force of actually standing for the significant government interest to which other important rights have been opposed, e.g. that of preserving life.

Along the same lines, the Court also fears that allowing assisted suicide would compromise the role of doctor as healer. The worry is that patients and society in general might lose faith in doctors and question their motives, if doctors are willing to participate in helping patients take their lives. As the traditional role of the physician is to help a patient stay alive,

it would be hard to justify allowing doctors *under any circumstances* to help patients end their lives. The idea is that it is counterintuitive for a doctor not to take steps to help a patient survive. Hence, we have the disinclination displayed on the part of courts to enforce the *Cruzan* right to die, even though that right is constitutionally required. In this light, it would only stand to reason that doctors be allowed to treat patients with any and all drugs that prolong their patients' lives. If a patient's condition is rapidly deteriorating, then there is no time to wait for FDA approval. Plus, the patients are asking to be saved.

It seems that a doctor's inability to provide patients with drugs that could potentially save their lives would be a viable basis on which patients could begin to lose faith in their doctors. It is not so much that patients would doubt their doctors' motives, for clearly it would not be a doctor's fault if he was legally prohibited from providing them with medication. It is more that the patient would begin to see his doctor as powerless, and **so begin** to lose hope himself. Some patients who suffer from terminal conditions look at doctors as gods. Even though they might remain confident that their doctors want to help, it is hard to see someone whom you depend on and look to for solutions in a helpless situation. The terminally—ill are aware that there are medications out there which might be successful in saving their lives but that these drugs are discouragingly just beyond their doctors' reach.

So, we have the Supreme Court upholding statutes that prohibit doctors from assisting their patients end lives of unbearable pain and suffering. We have courts that are loath to uphold 'legally valid' documents ordering the withdrawal of life—support. Yet, we allow people to die *who are dying to live*, where steps could be taken which might successfully save them. That doctors are

restricted from taking *any* measures which in their medical judgment might ameliorate a patient's already-terminal condition seems completely and totally inconsistent not only with our traditional conception of the doctor as healer, but with our legal and judicial attitudes towards the goal of the medical profession.

Thus, the very points raised by the Supreme Court to explain its rejection of the right to die could be easily used to support an argument for the right to stay alive. Although my last section showed that the right to stay alive was susceptible to several of the arguments made against the right to die, this section shows that, by the Court's own reasoning, allowing the right to stay alive would comport with some very fundamental and important societal goals. While there might be some legitimate government interests that run counter to granting the right to stay alive, these would likely be far less weighty than the very compelling government interests which the right embraces and which in turn necessitate the right. Hence, we have further evidence that, if formulated as such, the right to stay alive should be worthy of constitutional protection.

#### **Administrative vs. Constitutional Challenges**

Throughout this paper, I have been arguing that the terminally—ill comprise a special class of people deserving of special treatment; because they face different questions and alternatives than the rest of us face, they should be subject to different standards. I have argued that rights affecting the terminally—ill *qua* being terminally-ill (e.g. those involving life and death decisions) should be decided in a class of their own. On the basis of this reasoning, I have contended that the question of whether terminally-ill individuals should have special access to

unapproved medication is inappropriately, though incidentally, placed within the jurisdiction of the Food and Drug Administration. As I have mentioned, I believe that the issue should be abstracted from the administrative context in which it currently arises and analysed on its own terms as a separate legal and philosophical question. Along these lines, I attempted to outline what a hypothetical substantive due process claim of what I have called the right to stay alive might look like, importing into my analysis constitutional discussions from Supreme Court opinions concerning the analogous right to die. From this analysis, I concluded that based on its own reasoning in *Cruzan*, *Glucksberg* and *Quill*, the Supreme Court should be committed to recognizing the right to stay alive as one worthy of constitutional protection. I even contended that the right, because of the important and fundamental societal interests which it embraces and promotes, would have a good chance of withstanding competing government interests that would be launched against it as objections.

In spite of all of this, the terminally-ill continue to appeal directly to FDA to have their right to stay alive recognized. This may be because they take the 1979 Laetrile case to have been dispositive of any constitutional claims along these lines. As the Supreme Court did not address the constitutional issues alluded to in the Laetrile case directly, however, I do not believe that it would be committed to denying that the terminally-ill have constitutional rights at stake with respect to whether they should be given access to unapproved medications, that override the rules laid down by the FDA. Indeed, FDA - which is currently in the position of making rules that affect an infinitely diverse group of people living under infinitely different circumstances - might even be grateful to have this question taken off its hands. If the

right to stay alive was determined to be constitutionally—required, FDA would have no choice but to except terminally—ill people from the reach of its approval process rules.

That would work best for everyone involved; that is, if the Supreme Court did in fact look at the issue as I have hypothesized it would in light of its later *Cruzan* decision and current societal pressure towards an acceptance of the right to die. Even if the terminally-ill had a *chance* of winning the right to stay alive, no one could guarantee the outcome of a constitutional challenge. So, would there be a point in pushing the question into a constitutional forum? As I mentioned at the beginning of the paper, steps have been and are being taken under the current system to accommodate the rights of the terminally-ill with respect to unapproved drugs. The FDA has responded to cancer and AIDS lobbies. It has already made a number of concessions and seems open to further suggestions. In fact, there is currently a bill proposed for the 105th Congress concerning Medical Access Rights of the Terminally Ill which would further accommodate the right of the terminally—ill to obtain unapproved medication. Is it worth upsetting a process that is already moving in the right direction for only a possible victory? In that context, the answer does not seem as clear.

To avoid being guilty of begging the question that the right to unapproved drugs is one that should be constitutionally challenged as opposed to being left to the FDA, I would like to take a moment to expand on the analysis I proposed earlier to support this premise. The most obvious argument for removing the question of what drugs terminally—ill individuals should and should not have access to from the jurisdiction of the FDA is that decisions of that magnitude are simply *too important and personal* to be decided by an administrative agency established to address a whole gamut of



issues. Although individuals who seek special access to unapproved drugs can and have petitioned the legislature directly for help with their cause, the demand always concerns revisions and modifications of *FDA's* policies. The question is always clouded by administrative concerns.

It is not as easy as just saying, okay certain people can have access to certain drugs. FDA must fit this exception into its general rules, and draw lines around it rigid enough to keep out every other category of people and drugs over which it has jurisdiction. It is not free to consider the problem from an objective and absolute perspective. It must answer the question strategically, under the weight and influence of a number of other forces.

The very function which FDA was established to execute, namely to protect people from potentially unsafe food, drugs, cosmetics and devices, is inherently paternalistic. It is *FDA's* job to make sure that products on the market are safe for human consumption or use, and it is FDA which is held accountable if these products turn out not to be safe. The very exhaustive and rigorous review process to which it subjects new drugs, food, cosmetics etc. illustrates a philosophy on its part that a new drug etc. will be considered unsafe until proven safe. Because of the nature of its duties, however, it must act defensively in this area. Despite the inconvenience of having to wait a little or even a lot longer for certain products to enter the market, most would probably agree that in the normal course of events it is better to be safe than sorry.

The difference with terminally-ill individuals is that their situations do not represent the normal course of events. They do not have the time to wait. The choice for them is not between "safe" and "sorry", but rather between "potentially unsafe" or

definitely sorry. As the slogan on the ALS web page says, the terminally-ill do not want to be protected to death. Thus, their situations and entitlements must be evaluated according to a whole different set of rules. I mentioned earlier that the FDA has jurisdiction over a whole range of decisions, from the trivial to the very serious; the questions raised by situations involving the terminally-ill are not only of a different degree, but of a different type as well.

FDA does not have the time and resources to deal with the ethical questions inherent in this type of decision—making. Even if it wanted to allow the terminally-ill access to certain unapproved drugs, it would have to characterize this allowance as an *exception* to its general rules. It could not recognize the rights of the terminally-ill *as rights*, lest it undermine the validity of its protective and paternalistic function with respect to all other people under its jurisdiction. After all, if people have the right to choose what they will and will not put into their bodies, then no one and no decision concerning the ingestion of food or drugs should be subject to the discretion of the FDA.

It is precisely for this reason that the terminally—ill should be recognized as comprising a special class whose rights are evaluated as a discrete matter. It is under the category of rights of the terminally—ill where both types of right to die and the right to stay alive intersect and where they should most appropriately be evaluated. Sure, all of these rights possess predicates other than 'that they affect the terminally-ill' . The right to die is often linked with the right to abortion, in the more general sense that they both 'pertain to intimate decisions affecting the body' . And, as it stands now, the question of whether the terminally—ill should have access to unapproved drugs is

legitimately described as a 'food and drug' issue. In my opinion, however, the most *essential* feature of all of these rights is that they involve life-and-death decisions faced by people for whom death is imminent. For that reason, it should be this characteristic that sets both the interior and exterior limits of the class to which they most appropriately belong. That way, the context in which they are analysed will be neither too narrow nor too broad.

The context that surrounds FDA decision-making *will* inevitably be too broad, as FDA has only the latitude to make distinctions between types of *drug*; it cannot distinguish between recipients of the drugs under its jurisdiction on the basis of a philosophical rights analysis. And it should not have to. FDA cannot afford to be concerned with the question of whether it is morally correct to give the terminally-ill the chance to save themselves; it must concern itself with acting in accordance with its established function, namely to protect *all people* from potentially unsafe products. Thus, asking FDA to answer this moral question would be asking it to make a decision about which it must by its very nature be biased. This is not fair to either the agency or to the people whom its decision affects.

On the other hand, the Supreme Court's function not only allows it to but requires it to evaluate rights as rights, and to consider the nature of the person or group asserting these rights. Sure, the FDA may, at its own discretion or by force from the legislature, make some compromises in this area. If the right to stay alive were deemed worthy of constitutional protection, however, the battle would be conclusively won. It would not be a step—bystep process. It would not be subject to change or reconsideration. Instead, it would allow terminally-ill individuals access to the potentially life-saving drugs they so desperately seek, not as a

matter of administrative grace, but as a matter of fundamental right. After all, people falling under the category of terminally ill do not have time cut through red-tape.

As idyllic as this all sounds, however, there is no way to tell whether the Supreme Court would find the right to stay alive to be worthy of constitutional protection. Throughout the paper, I have assumed that the Supreme Court's wariness of allowing physician-assisted suicide as opposed to its more favorable response to allowing the refusal of life-support was at base driven by an intuitive sense that the latter just seems more morally okay. I attributed this intuition to the instinct shared by most of us that human life should be preserved whenever possible; that the more a given act accords with an intention to die, as opposed to an intention to live, the worse it is and the less it should be encouraged. Though I cannot read the minds of the Justices who comprised the *Glucksberg* and *Quill* majorities, it seems more likely that this moral instinct was responsible for the discrepancy between Court's treatment of the two types of asserted rights to die than the fact that the *Cruzan* right could be traced to a common law rule of battery. On the basis of this reasoning, I assumed that the Supreme Court would approach an analysis of the right to stay alive from a more psychologically favorable perspective. Equally, I concluded that the detrimental impacts on society which the Supreme Court genuinely feared would flow from allowing assisted suicide, though relevant to allowing terminally-ill individuals access to unapproved drugs, were either distinguishable or did not pose as a great of a risk in the latter case. However, either my assumption regarding the Court's underlying motivations, or my hypothesis regarding how it might balance the right to stay alive against competing government interests, or both, could be wrong.

If that were the case, then clearly proponents of the right to stay alive would be much better off pursuing the course which they are currently pursuing. Certainly, it would not help their position with the FDA if the Supreme Court were to declare that their right to unapproved medication is not one that is constitutionally-protected, or is outweighed by competing government interests. Perhaps, trying to reform the FDA's procedures, though more tenuous on a long-term basis, is the safer way to go, especially in light of FDA's favorable response to societal pressure to loosen its standards for the terminally—ill. Also, the FDA is allowed to respond to societal and political pressure in a direct way that Supreme Court is not. Thus, one reason why the right to stay alive has not been formulated and asserted as such might be that the downside of having a Supreme Court decision directly against it, in addition to the Laetrile case, would not be worth risking. Beyond this practical reason, however, there might be another strategic reason to keep the question within the jurisdiction to the FDA.

Earlier I argued that, *because of the seriousness of this question and the ethical issues that surround it*, an administrative agency *should not* have jurisdiction over it. As a sort of correlative counterargument, however, one might contend for the very same reason *that it should* be left within FDA's jurisdiction. My earlier contention was based on a belief that issues of great magnitude and ethical importance should not be evaluated within the constraints of an administrative setting, especially one that is bogged down with such a broad spectrum of issues. It might be countered, however, that the clinical and technical atmosphere of an administrative agency is just the place where volatile and sensitive questions should be decided; not because this type of setting is

germane to ethical discussion and debate, but instead precisely because it is not. One of the reasons I chose to compare my topic to the right to die is because both are currently very hot and much—debated issues. This is so because both deal with excruciatingly important and personal decisions whose consequences are of life-and-death proportions.

As sensitive as these issues are, however, they are equally explosive, with vehement proponents standing firm on either side. Thus, it is not likely that anyone would want to be in the position of making substantive judgments about their merits. In fact, the sheer volatility of the issue of physician—assisted suicide may have been another motivating force behind the Court’s rather odd treatment of it. Again, while the *Glucksberg* majority was quick to deny the substance of respondents’ asserted right, it felt compelled in any case to go on to perform quite a substantive analysis of the right; while it ultimately denied the right unqualified constitutional protection, it also encouraged debate over the issue at the state level; while the decision was unanimous, there were many concurrences.

The point is that pushing issues that are too hot to handle into environments that will extinguish rather than fan their fires might actually be a good strategic move. It could even have been that the *Glucksberg* and *Quill* Courts thought it made sense and/or was even morally appealing to allow terminally—ill people suffering from unbearable and unrelenting pain the option of ending their lives with whatever dignity has not already been taken away; nonetheless, the Court could understandably have been reluctant to take the step of construing our constitution as embracing the substantive ethical position that it is okay to engage in an act of self—destruction. Similarly, it might be more psychologically

difficult for the Court to give terminally-ill individuals - who are already in a weak and vulnerable state - the 'choice' of whether to take potentially dangerous medication, than it would be for the FDA change or loosen its administrative procedures for certain exceptional cases.

This is not necessarily because FDA would not be motivated by the same substantive ethical considerations. It might believe in the moral correctness of the move; or it might be motivated by the force of societal pressure, or both. The point is that, whatever its motivations might be, it would not have to spell them out as would the Supreme Court. The issue would merely have to be *decided* rather than having to be *evaluated*. Equally, an exception made by FDA would not be as final, nor would its implications be as important or vast, as a decision handed down by the Court. FDA could decide to allow terminally-ill patients access to potentially life-saving drugs on a trial or an experimental basis. Its decision would not be taken to set a potentially far-reaching precedent. Thus, it is not unreasonable to take the view that volatile issues might be better received in settings that allow a decision to be made in favor of these issues without forcing a major statement to be made.

One might say that this view was tested in the case of Heckler v. Chaney, 470 U.S. 821 (1988), in which prisoners who had been sentenced to death by Oklahoma and Texas state courts attempted to have FDA enjoined to intervene in their executions. The theory was that the use of drugs for lethal injection to effect the death penalty contravened the FD&C Act, both as an instance of misbranding and as an unauthorized use of a new drug.

According to the first theory, use of drugs for lethal injections violated the misbranding provision (352(f)) of the FD&C

Act, which prohibits unapproved use of approved drugs. As the drugs in question had not been approved for the purpose of being used in lethal injections, the FDA should hold prisons in violation of the statute for using the drugs to effect executions. Alternatively, the prisoners argued that the drugs should actually be considered new drugs, because the purpose for which they would be used is not the one for which they were originally intended. Under this theory, the drugs would be subjected to the long and tortuous review and approval process, which I described in the beginning of the paper.

The prisoners' plan did not work. The decision turned primarily on questions of administrative law. The Supreme Court held that FDA's decision not to take enforcement measures along the lines that the prisoners suggested was presumptively unreviewable, and that the particular circumstances of the case did not undermine that presumption. Somewhat reminiscent of the *Laetrile* case, the Court did not really reach the issue of whether it would or would not be appropriate for FDA to intervene in the administration of issues such as the death penalty. The only analysis to this effect was offered by the FDA Commissioner himself, who expressed that, even if the agency did technically have jurisdiction in the area, it might not be appropriate for it to interfere with this particular aspect of the criminal justice system, *Chaney* at 824.

On the basis of the same reasoning asserted by the prisoners in the *Chaney* case - and coming full circle — one might try to push the issue of assisted suicide into the jurisdiction of the FDA as well. One might argue that the pills which doctors would supply to terminally-ill patients to assist them in ending their lives are being used for an unapproved use. Or, along the same lines, one might argue that FDA could finally be the one to stop the ever-acquitted Dr. Kevorkian from using his suicide machine — an



intravenous machine which administers lethal drugs 27 — on the basis that his usage of it in assisting patients' suicides constitutes an unapproved use of a human medical device according to section 360 of the Federal Food, Drug and Cosmetic Act. Equally, as the prisoners in *Chaney* argued, one could contend that this suicide machine is misbranded as the intravenous device is not labeled as being designed for the purpose of putting people to death.

These would certainly be cases of cutting the ethical underpinnings of hugely volatile issues off at their roots. Equally, if FDA were to decide to disapprove the uses of the above— mentioned drugs or medical devices, it would effectively insulate the issue from moral attack. That is not to say that opponents of the decision would not assert ethical arguments against it; but rather that any moral objections would lose their force and relevancy when posed against a purportedly 'non-ethical' decision.

Opponents would have to resort to a different line of attack to be able to defeat the decision on its own terms. This task would not be impossible, or even difficult. Clearly, the statutory question of whether either the use of drugs for lethal injection or the use of intravenous machines for euthanasia violated the FD&C Act would turn on an interpretation of the word use. Those who supported the death penalty or assisted suicide would surely be able to come up with interpretations of the language of the FD&C Act broad enough so that it could reasonably be construed as permitting the particular uses in question. For instance, one could argue that intravenous devices were designed for the purpose of administering drugs to human beings in liquid form. As Dr. Kevorkian uses his machine for that immediate purpose, it is irrelevant what his ultimate goal may be. In fact, identifying the

use of a medical device by its ultimate purpose could at the outer limits yield quite absurd results.

If Dr. Kevorkian's use of the machine constituted a new use, would the use of devices as innocuous as I.V. machines in the course of treatment for every new disease constitute a new use of the device? Would doctors or hospitals have to clear it with FDA every time they used an I.V. machine in any different course of treatment? Would every surgical instrument, for instance, have to be approved for use in *every type* of operation for which it is needed? Certainly, there is a difference between the immediate or primary purpose for which a drug or medical device is designed and the ultimate purpose which it may be employed to effect. In any case, the point is that, regardless of what types of technical and semantic statutory arguments might or might not be made, the placement of controversial ethical issues under the jurisdiction of the FDA would certainly change the tone of the debate over these issues from what it is now. It might be strategically sound to attempt to have an ethical viewpoint implemented on the basis of an essentially unrelated technicality, if it worked. This would be like convicting Mafia figures for tax evasion because we cannot and are scared to get them for anything else. However, my personal opinion remains that this indirect type of approach is for the most part inappropriate.

In general, I believe that issues that are ready and meant to be decided favorably will be decided favorably in their appropriate settings. If the risks which they pose for individuals and/or society are shown to outweigh the benefits, then maybe it is correct to decide against them at the current stage of the game. Of course, we run the risk that the somewhat arbitrary nature of due process balancing tests makes them susceptible to bias, or even misjudgment.

However, a system that balances philosophical and ethical concerns a little unscientifically must be better than one that does not (explicitly) balance them at all. Pushing ethical decisions into administrative settings masks, rather than extinguishes, substantive moral judgments. The decision will be just as morally-motivated, only it will illegitimately be insulated from direct moral attack. Even on a common sense level, would we really want the Food and Drug Administration making decisions about capital punishment? Wouldn't we feel more comfortable, whether we agree with the ultimate decision or not, knowing that the question of whether there *should* or *should not* be capital punishment was decided in a setting designed precisely to consider that type of decision?

Of course, whenever there is an issue about which one feels strongly, one cannot help but hope instinctively that it be decided in favor of one's view, even if it means that the decision has to be made on the basis of a technicality. Speaking in the abstract though, most would probably appreciate that, while they would like the end result of having a decision in their favor based on inessential considerations, they would feel uncomfortable with the means of arriving there.

As a general rule, I do not believe that important decisions should be made on the basis of unrelated technicalities. However, I might be able to justify an exception to the rule when and only when there is no other way for the right decision to be reached. After all, I do believe that it would be better to convict Mafia figures of tax evasion than to not be able to convict them at all. However, this type of reasoning is clearly heavily value—laden, as few would admit that a view which they advance was wrong. This might explain my inclination to want the right to stay alive to be advocated *on its merits*. After my hypothetical analysis of the right, I

concluded that the right to stay alive is one worth honoring, as long as it does not get out of control. For this reason, I cannot help but believe that it *would* prevail in a constitutional setting. As of right now, however, I am confident that those terminally—ill individuals who *have* been able to cut through FDA's red-tape to obtain the potentially life—saving drugs which they seek do not care that it was an administrative agency and not the Supreme Court who made the decision to accommodate them. With this, I would also agree.

#### **Conclusion**

As stated, the conclusion which I have reached is that what I have called the right to stay alive is a right which should be recognized within certain prescribed limits. I think it is correct to give terminally—ill individuals the choice of whether or not to take potentially life-saving drugs, which have not been approved by the FDA. However, my personal opinion on the subject is not what is relevant, nor is it the purpose of this paper to advocate the conclusion to which I have come. What I am arguing is simply is that the question of whether terminally-ill individuals should have access to unapproved drugs is one that I believe should be answered on a philosophical and ethical level.

Based on the analysis above in which I discussed the relationship between the right to stay alive and the right(s) to die, I believe that the Supreme Court should by its own terms be committed to honoring the former. I attempted to illustrate this from several different perspectives. First, we could use the spectrum metaphor, whereby a legal acceptance of the right to stay alive would be justified by the legal acceptance of similar, but less innocuous, rights, e.g. the *Cruzan* right. The contention would

be that if the Supreme Court *requires* that terminally—ill individuals have the right to refuse life—sustaining methods; if it has not conclusively ruled out physician-assisted suicide and even encouraged debate on the topic; if one state has already legally sanctioned assisted suicide; then it only stands to reason that we should not interfere with a right based on the desire to try to stay alive.

Thus, we have a legal basis from which to analogize to the justification of the right to stay alive. We have the philosophical values of freedom of choice and personal autonomy on which to base

it. We have positive societal forces pushing for it. And we have the moral intuition that it just seems right to give people every opportunity to try to prolong their lives. On the basis of all this, I concluded in my first section that the current societal and Supreme Court views of the right to die should imply an acceptance of the right to stay alive and a recognition of it as fundamental.

In my next section, I concluded that the right to stay alive might also be able to withstand a substantive due process balancing test. Although I acknowledged that the right would be susceptible to many of the objections made against the analogous right to die, I concluded that it was distinguishable from it in that it would be better able to withstand or dodge these objections. I also posed some hypothetical objections against it, which would not apply to the right to die. Though I appreciate the gravity and legitimacy of government interests that might compete with the right to live, I believe on the whole both that the benefits would outweigh the risks and that the values which underlie the right are ones that accord completely with our moral and societal goals. In this light, it would be hard to come up with a government interest compelling enough to weigh against the right.

I based this last conclusion on my analysis of the *Clucksberg* and *Quill* Courts' *objections* to allowing assisted suicide. There, I argued that the reasons which the Court gave for being disinclined to allow the option of assisted suicide should by implication commit it to wanting to require that terminally—ill individuals have the option of taking potentially life—saving drugs. The idea was that precisely the same values which the Court denounced assisted suicide as standing *against* are those which allowing the right to stay alive *stand for*, particularly the notion that human life should be preserved. If, as the Court seems to be implying, an intention to live is more morally desirable than an intention to die, then allowing dying people the right to try whatever medications they can to save their failing lives has to be something that we should encourage, at least in theory. Thus, not only can an acceptance of the right to stay alive be justified on the basis of arguments made for the right to die, it can also be justified on the basis of arguments made against it.

In many of the same respects, both the right to stay alive and the right to die have strong philosophical and emotional appeal; equally, however, they both *oppose* interests that are philosophical and emotionally appealing as well. With respect to assisted suicide, these opposite forces leave me ultimately in a state of ambivalence. With respect to my topic, however, though I am also pulled in both directions, I find myself leaning more towards advocating an acceptance of the right than a denial of it. I suppose this is because, in case of a mistake, assisted suicide has a graver and more irreversible downside.

My next analysis took a step back to the very premise of my paper. In this section, I attempted to explain why I believe that, like the issue of assisted suicide, and the *Cruzan* issue, the right

to stay alive should be formulated as a positive right and evaluated in a constitutional setting. I discussed the pros and cons of keeping the issue within the jurisdiction of the FDA, and mentioned how the FDA's control could technically be extended to cover right to die issues as well. Ultimately, however, I concluded that the FDA is not the appropriate place for issues concerning *any* of these rights to be decided, precisely because I believe that rights relating to life-and-death decisions which must be made by the terminally-ill, should comprise a special category of rights that is subject to its own rules and standards.

True, the FDA *is* making some efforts to accommodate the rights of the terminally—ill, and true a constitutional challenge might fail. However, despite FDA's concessions, the current state of affairs for the terminally-ill in this area remains tenuous and unsatisfactory. As I mentioned earlier, there have been extensive lobbying efforts for big diseases such as cancer and AIDS. And while all terminally—ill people ultimately benefit by any administrative and/or legislative reform that these efforts achieve, other rarer, less recognized diseases do not have the lobbies such as this, and thus could easily get left behind.

I started this discussion by admitting that it is not as simple as saying that people who are dying should be allowed to do whatever they can to stay alive, since they have virtually nothing to lose. At base, however, this is not far from the truth. I know this from my experience with my friend Harry, which induced **me** to appreciate the real extent of the urgency, desperation, and helplessness that accompanies terminal illness, especially when no really effective treatment exists.

The last time I saw Harry, I mentioned to him a doctor who I'd heard had treated ALS patients with what might be called an

alternative approach to medicine. This doctor linked ALS with diabetes and ultimately pinpointed allergy as the original source of both.<sup>28</sup> Having gone through childhood with a host of allergies myself, I was quite familiar with the rather strange reactions that foods and chemicals could produce. I was also familiar with the skeptical attitudes of doctors who never thought that an issue could be that simple. After having been diagnosed and tested for all kinds of medical conditions, I finally realized that the best doctor was my mother, who managed to cure me of virtually all of my symptoms by changing my diet or environment.

For this reason, I was very hopeful that this doctor's alternative theory would provide at least some help for Harry. Ironically, Harry told me that, all his life, he had been considered a borderline diabetic. He also said that his doctor was not opposed to alternative treatments, and encouraged whatever help he could get. Harry took the name and phone number of the doctor and expressed a strong interest in contacting him. Unfortunately, he weakened and died within less than a week of my visit, and so was never able to follow through with this, or any other type, of alternative medication.

Although I will always wonder, my feeling is that by the time of my last visit with Harry, his disease had already progressed to a point beyond which there was not much hope for return. However, the experience made me wish that more information was available regarding potential treatments for terminal diseases and that one could find it at a kind of central location. It might be ambitious to expect doctors to provide patients with — or even know about — every proposed possibility for treatment pertaining to the diseases which they treat. However, it seems quite counterintuitive, to say the least, that doctors should be prevented from experimenting with



*mainstream* treatment possibilities, if their patients desire them to do so.

I was also glad to hear that Harry's doctor was willing to try anything to save his life; but I was discouraged to learn later on, that there were some things which he was prohibited from trying. The point that my experience with Harry impressed on me is that situations involving terminal illness are truly of a type all their own. Although I could have reasoned to that conclusion in an abstract sense at any time, I don't think it really hit home until I saw it for myself. Terminally—ill individuals face questions that differ in degree and type from questions which the rest of us face. It is for this reason that I do not think it would be arbitrary to hold them to different rules. After all, they are playing a different game.

I spent the bulk of my paper discussing the relationship between the right to stay alive and the right to die. What really brought these issues together for me, however, even more than their conceptual similarities, was the central role that both of them played in Harry's death. Harry died immediately after exercising his *Cruzan* right to refuse life—support. Ironically, the same person who was denied the option of trying to stay alive with potentially life—saving medication was allowed to make a decision that caused his death. I am the first to say that my topic leaves us with many questions that need to be answered, but I will conclude by leaving open to consideration the one which I see as most pressing: does what happened with Harry make any sense?

We might not want to give people the right to die, but shouldn't we at least give them the right to try to stay alive?

1 ALS Advocacy, pages.prodigy.com/ALSPROD/index.htm (last modified December 10, 1997)

2 Throughout the paper, when I speak of the terminally-ill having access to drugs which have not yet been approved by the FDA, I am assuming that the drugs would at least be put through an initial safety test, to determine that they do not have any obvious and significantly harmful side effects. Even if the terminally-ill were entitled to obtain unapproved medication as a matter of right. I believe that this minimal testing would be acceptable and necessary.

3 Washington v. Glucksberg, 117 S.Ct. 2258 (1997)

4 Although I am discussing the right of the terminally-ill to have access to unapproved drugs, the same arguments can be made for their access to disapproved drugs, which have been disapproved on the basis of lack of effectiveness, or on other bases not related to safety.

5 Cruzan v. Director. Missouri Dep't. of Health, 491 U.S. 261 (1990)

6 In describing the terminally-ill as a class worthy of special protection, as I have and will continue to do from time to time throughout the paper, I am not arguing that the terminally-ill comprise a suspect class in the equal protection sense. This suggestion was rejected in *Quill* and it is not my intention to evaluate that determination. What I am arguing is that that certain fundamental rights, like the right to stay alive may attach to the terminally-ill *because they are terminally-ill* on substantive due process grounds. In singling out the terminally-ill as a special class, I am not saying that we would not *all* have the right to stay alive (if it were recognized) in a latent sense. However, it is more germane to speak of this hypothetical right as being exclusive to those who are currently terminally-ill because only they have reached the stage at which the right would appropriately kick in.

7 Waggoner, Lawrence W, Alexander, Gregory S. & Mary Louise Fellows, Family Property Law, 2<sup>nd</sup> ed. (1997), p. 496

8 Death by Default, James Lindgren, *Law and Contemporary Problems*, Vol. 56: No. 3 (1993)

9 *Id.*

10 *Id.*

11 *Id.*

12 No One Rushing In Oregon To Use New Suicide Law, *New York Times*, March 15, 1998.

13 Hutt, Peter Barton & Merrill, Richard A., Food and Drug Law, The Foundation Press, Inc. New York: 1991.

14 Hutt, atp. 554

15 Hutt,atp.531

16 Hutt, atp. 554

17 Certain provisions of the Food, Drug and Cosmetic Act were amended by the Food and Drug Administration Modernization Act of 1997. The 1997 Act provides for expanded access to investigational new drugs and medical devices.

18 Hutt, at pp. 560-561

19 Hutt, atp. 566

20 Hutt, at p. 566

21 Hutt,atp.519

22 Huttatp. 534

23 Since advocates of the right to stay alive would be asserting the right against the FDA, or indirectly, the Congress, the applicable amendment would be the Fifth, rather than the Fourteenth Amendment, as it is the Fifth Amendment which guarantees that no person shall be deprived of life, liberty or property without due process of the law, *United States Constitution*, by the Federal Government. The Fourteenth Amendment guarantees this privilege against the States.

24 The substantive due process cases which I have referred to have involved challenges to *state* statutes, where the statute is subjected to rigid scrutiny when it is found to infringe on a fundamental right. It is possible that the Federal Government or a Federal Agency would be given more deference with respect to statutes which they promulgate than the states are given. However, there are many cases where Federal statutes have been subject to rigorous scrutiny under which they must be proven to be based on a compelling government interest. To reiterate, this paper is intended to explore the issue of whether the terminally-ill should be given access to unapproved drugs from a philosophical and normative perspective. I am basing most of my support for this right on pertinent Supreme Court opinions because it is the Constitution which defines our rights, and because I believe that that the Constitution can and should be construed as protecting the right. As this is intended to be more of a hypothetical philosophical exercise than a strict constitutional law paper, however, I am not as concerned with outlining the specific mechanics and procedures by which a constitutional challenge could be launched and of the technical treatment it would be afforded by the Court.

25 No One Rushing in Oregon to Use New Suicide Law, *New York Times*, March 15, 1998.

26 The life at stake in the abortion cases is the life of the unborn fetus.

27 Smith, Wesley J., Forced Exit, (Random House, Inc. New York: 1997).

28 Null, Gary, No More Allergies, Gary Null Association (1992), at pp. 50-5 1.

