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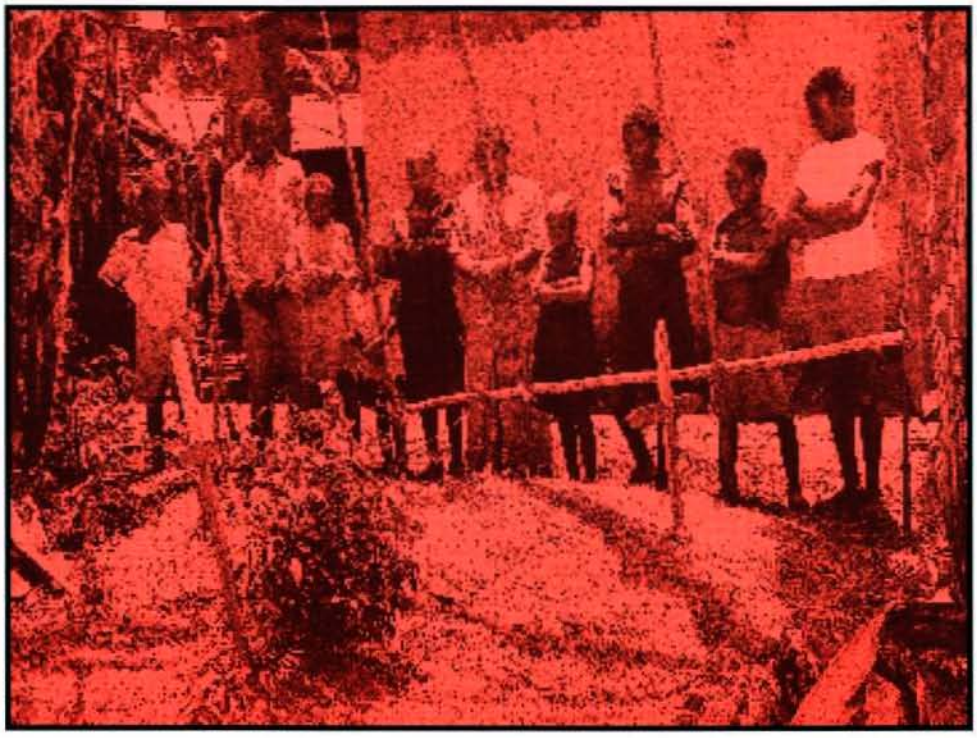

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THE ETHICS OF VOLUNTARILY STOPPING EATING AND DRINKING: A SURVEY OF MASSACHUSETTS PHYSICIANS

Richard A. Norton, M.D.

Summary:

A survey of 144 Massachusetts physicians showed that just over half (51.3%) have cared for patients who refused food and hydration and then died. Mean survival was about twelve days, 6 days while conscious, and 6 days comatose. Only a small minority (6.3%) favored assisting suicide, but a majority (60%) favored allowing a competent patient who is terminally ill to refuse feeding and hydration.

Patients may decide to fast and avoid fluids as a reasonable alternative when there is a terminal illness and severe suffering. Skilled nursing is helpful for the special needs of these patients, especially mouth care. The ketonemia of fasting helps alleviate some of the emotional distress.

Voluntarily stopping eating and drinking can be defended on an ethical basis: It is entirely consistent with the autonomous right of a patient to accept or refuse treatment.

This management deserves further consideration, and is ethically superior to physician-assisted suicide.

The national debate about physician-assisted suicide is still with us and will doubtless continue. Meanwhile, many physicians oppose assisting suicide, while the general public cautiously supports it.[1,2] The national Hospice movement provides outstandingly good care at the end of life, but most patients are referred for care very late in their terminal illnesses, so the opportunity to reduce suffering is less than ideal.[3,4] Largely overlooked in this debate is a method of reducing suffering which has many advantages over physician-assisted suicide: voluntarily stopping eating and drinking. It is defined as the active discontinuation of all oral intake by a patient who is physically capable of taking nourishment by mouth.

Although competent, terminally-ill patients have occasionally refused nutrition and hydration, often apparently by instinct, there is considerable lack of understanding on the part of some physicians about the clinical course of a patient who insists on doing this. It has occurred to recent observers that refraining from all oral intake might be a good alternative to physician-assisted suicide, although many of those in medical practice may not recognize this.[5-8]

Methods:

I mailed a questionnaire to 30 physicians at the New England Medical Center in Boston as a pilot study. The responses to this mailing showed that the instrument did produce the information that I needed, and it did not need major revision.

The main survey involved mailing questionnaires to 432 physicians randomly selected from a list of those practicing in Massachusetts[9], except that physicians at the New England Medical Center were not included. In the questionnaire I inquired about their experience with patients who voluntarily stopped eating and drinking, and I asked about their attitude toward this as compared with physician-assisted suicide.

Results:

The U.S. Postal Service was able to deliver 385 of the 432 questionnaires, and one physician's widow notified me of his recent death. The 144 replies form the basis of this paper. This was a 37.5% response rate to the mailing.

Table 1 shows the survey results.

Each physician was asked whether he or she had ever been approached by a patient with a request for assisted suicide. About one third (34.7%) had had such a request. Two thirds had never been approached.

How did physicians react to this request? Only 6.3% were warmly in favor of assisting suicide, with 17.4% mildly in favor, 20.8% unsure or neutral, and 58% mildly or strongly opposed.

By contrast, how many of these physicians have seen patients who refused food and hydration and then died? The number was 74 or 51.3%. How many days passed before coma intervened? The average was 5.18 days. And how many more days passed before death occurred? The average was 6.03 days.

When asked whether they would consider advising a patient to to refrain from eating and drinking as a method of dying, about a quarter (25.7%) favored this approach, but 50% were opposed, and the remainder left the question blank. The written comments from several respondents indicated that they thought this was "too slow and painful" a form of dying.

A second question about the reasonableness of voluntarily stopping eating and drinking was posed in the context of how to respond to a patient who is asking for assistance with suicide: "Would you consider talking with this man about giving up eating and drinking?" Thirty-nine respondents (27%) replied in the affirmative, 61 (42%) in the negative, and 39 were unsure (27%), with 5 replies blank (3%).

Table 1: Questionnaire Results on Voluntarily Stopping Eating and Drinking

		Number	Percent
1. Have you had patients who requested assistance in dying?	Yes	50	34.7
	No	89	61.8
	blank	5	3.5

2. (a) Have you seen patients who refused food or hydration and then died:

Yes	74	51.3
No	66	45.8
blank	4	2.7

(b) How many days passed before coma intervened? (average) 5.85 days

(c) How many more days passed before death occurred? (average) 6.03 days

3. How do you feel about the decision of an 85-year-old woman with a severe stroke to refuse food and water? [Please check one on this continuum.]

a) Yes, certainly	86	60.0%
b) Yes, mildly in favor	24	16.7%
c) I am unsure or neutral	21	14.5%
d) No, not a good idea	8	5.6%
e) No, firmly opposed	1	0.7%
blank	4	2.7%

4. Are you in favor of giving a patient with advanced, metastatic carcinoma a prescription for enough barbiturate to end his life? [Please check on this continuum.]

a) Yes, certainly	9	6.3%
b) Yes, mildly in favor	23	16.%
c) I am unsure or neutral	22	15.3%
d) No, not a good idea	51	35.4%
e) No, firmly opposed	34	23.6%
blank	5	3.5%

5. Would you consider talking with this man (in question 4) about giving up eating and drinking?

a) Yes	39	27%
b) Unsure, maybe	39	27%
c) No	61	42%

Discussion:

The response by a third of physicians that they had indeed been approached for help in suicide was surprisingly high. If this sample is representative, then nearly 5000 of the 14,000 practicing physicians in Massachusetts have had to deal with this request on a direct basis at some

time in their practice.

In the past, before the introduction of intravenous fluid therapy, most terminal illnesses ended "naturally" with the patient taking little or no food or water. Coma was expected, with death soon after. We need to consider whether all terminal patients really should have intravenous fluid therapy administered routinely, or whether this is an unnecessary intrusion and an unwanted prolongation of suffering.[10]

Not many years ago it was considered mandatory to continue all treatment measures as long as the patient was alive. The tide of public opinion and judicial decisions has now largely relieved the medical and nursing professions of this burden. Artificial nutrition and hydration have their place in the care of very sick patients, but there comes a time when withdrawal is ethical and proper. [11]

How much suffering does voluntarily stopping all oral intake actually bring to a patient? Refusing food alone leads to a gradual loss of weight, energy, and eventually the shutdown of vital functions. The brain requires a constant source of glucose to survive, but the heart can get along on a wider variety of energy sources, such as fatty acids. The ten Irish Hunger Strikers in the 1960s stopped eating, but they continued to take water and other fluids. All ten died. Their relatively long survival, an average of 60 days, reflects this unrestricted hydration.[12]

Refusing all fluids leads to renal failure, and this results in a rising serum sodium level and a rise in creatinine. Coma comes from the effects of these changes on the brain, and then cardiac failure follows from further biochemical changes. Death comes in a few days to a few weeks.[13] This experience is very similar to that of patients who elect to discontinue renal dialysis. Cohen and his coworkers found that the average survival after cessation of dialysis was 9.6 days, and most of the deaths (11 of 18) were "good" by their criteria.[14]

A known side effect of fasting is that the burning of fat stores in the body leads to an increase in circulating ketones, and these substances affect the brain by producing a degree of euphoria. Individuals who fast regularly, such as members of religious orders, have come to expect this state. It can lessen the discomfort of the terminally ill. In addition to ketonemia, other biochemical alterations appear to improve comfort, such as beta-hydroxybutyrate and endogenous opioids such as beta-endorphins.[15]

Other changes that patients experience during fasting and avoiding fluids include some beneficial effects of dehydration in the terminally ill patient:

1. Decreased urine output resulting in less incontinence and less need for toileting.
2. Decreased production of gastric fluids resulting in less nausea and vomiting.
3. Decreased pulmonary secretions resulting in less need for suctioning.
4. Diminished incidence of edema and ascites. [1, p. 2724]

Gert and his coworkers have contributed a great deal to our understanding of the moral basis of voluntarily stopping eating and drinking as compared with physician-assisted suicide. Their comment on voluntarily stopping eating and drinking: "[Dying] is usually painless; it takes long enough for the patient to have the opportunity to change his mind, but is short enough that significant relief from pain and suffering is gained." They point out that rational refusal of food and fluids "is not killing but, at most, allowing to die."[17]

McCann and others carried out a 12-month study of 32 terminally-ill, competent patients in a comfort care (cancer) unit of a long-term care facility in Rochester, NY. Twenty patients (63%) never had hunger, and 11 (34%) only initially. Symptoms of dehydration could be alleviated with small amounts of food, fluids, ice chips, and lubrication of the lips. "We found that patients with terminal illness can experience comfort despite minimal if any intake of food or fluids."[17] Mogielnicki et al commented that McCann's findings support this approach as an alternative to euthanasia or physician-assisted suicide.[18]

Miller and Meier underscore the moral superiority of terminal hydration over assisted suicide

or euthanasia, but they also point out some drawbacks, such as the uncertainty about the length of survival.[19]

Some have argued that if a physician cooperates with a patient who voluntarily stops eating and drinking, it is the equivalent of physician-assisted suicide. I would argue that this is very different. Voluntarily stopping eating and drinking begins with the patient's autonomous refusal of food and water, rather than starting with a request for the means to carry out suicide. When the illness is terminal and the suffering is unbearable, then the work of the physician is to provide comfort. The duty to rescue becomes the duty to minimize suffering. This is different from killing the patient. It is in the category of "allowing to die."[20]

Some physicians will argue that many Americans lack the courage and inner strength to undergo fasting and dehydration; instead, they need to have immediate help in dying quickly, and this should be provided by physicians. I would argue that instead of giving in to this demand, there is a reasonable and ethical alternative. It does not subvert the long-established dedication of the medical and nursing professions to preserving life when possible and making the dying process tolerable.

The patient seeking assistance from a physician for a suicide places that physician in a precarious moral position. Will the physician commit an act which is contrary to the moral training of most humans ("Do not kill"), condemned by the Hippocratic Oath, and illegal under the laws of 49 of the 50 states? Many of the physicians in the present survey expressed in their written comments a concern that physician-assisted suicide was not a good route to follow.

By contrast, a patient in a terminal illness who decides to refuse food and fluid is express-

Author Biography

Richard Norton is now retired from New England Medical Center. This study was carried out during a fellowship in Medical Ethics at the Division of Medical Ethics, Department of Social Medicine, Harvard Medical School. He would like to acknowledge the department and Dr. Walter Robinson who provided generous support.

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MDMA vs. Prozac: Arguments Surrounding the DEA's Listing of Schedule I and Schedule III Drugs

Erin Loew

Introduction

MDMA, more commonly known as Ecstasy, has recently become a popular drug among young adults at raves and on college campuses nationwide. Ecstasy is currently listed as a Schedule I drug on the Drug Enforcement Agency's list of substances, which means that it can not be used for medical purposes, research or recreational use. The Schedule I listing of MDMA is a controversial issue. This paper will explore whether Ecstasy should be moved to the DEA's Schedule III listing. In addition, this paper will consider why Prozac, a drug with similar effects, is legal for adults and children, while Ecstasy is not, especially since both of these popular drugs have adverse effects and high potentials for abuse.

Much disagreement has occurred not only between anti-drug crusaders and proponents of drug legalization, but within the psychiatric community as well.[1] Some claim that Ecstasy has potential therapeutic benefits as a serotonin re-uptake inhibitor, while others are wary of its potentially harmful side effects. Unfortunately, not enough information has been collected to determine the true nature of Ecstasy, including both its positive and negative effects. In a similar fashion, the anti-depressant, Prozac, has not been fully researched, despite its legal stature and popular, ever-increasing use. Both drugs are mood altering, chemically synthesized substances that change serotonin levels in the brain. Even though Prozac is available legally through medical prescription, both Prozac and Ecstasy are used recreationally to enhance feelings of happiness and pleasure.[4]

History of Ecstasy

In order to understand the controversy surrounding MDMA, it is necessary to investigate its history. MDMA was first developed in 1914 by a German pharmaceutical firm, Merck, as an appetite suppressant. It was never manufactured in Germany, but in 1953 it was brought to the United States. The U.S. Army tested Ecstasy, along with many other psychoactive compounds, on animals to see if it could be used by the military as a toxic, "brain washing" substance.[11] Ecstasy was never administered to humans and remained a relatively unknown drug until the Seventies. MDMA was used by psychotherapists who were especially impressed by the drug's ability to induce "profound states of empathy, one of the strongest predictors of psychotherapeutic outcome." These psychotherapists were also struck by MDMA's ability to help people "open up and talk honestly about themselves and their relationships, without defensive conditioning intervening." Reportedly, "for several hours, anxiety and fear appeared to melt away, even in subjects who were chronically constricted and apprehensive." MDMA was hailed as a "penicillin for the soul." It was believed to be capable of treating a large variety of mental disorders, including post-traumatic stress, depression, relationship difficulties and phobias.[11]

Initial efforts were taken to restrict the amount of information available on Ecstasy to the American public. In an attempt to keep Ecstasy away from recreational users, most knowledge about the drug was limited to a few psychologists and pharmacologists.[11] Unfortunately, it was difficult to keep the wonders of Ecstasy a secret for long.

MDMA filtered through to the fringes of society, where it was known as a predominantly homosexual drug.[3] During the late 80's, however, the use of MDMA soared as it entered the lives of college students and adolescents at astonishing rates. The recreational use of Ecstasy evolved small groups in private situations to larger groups of people in public. Ecstasy quickly became known as a popular party-drug.[4]

Apprehension among parents and civic authorities was quickly aroused. The rave parties were sighted as evidence of uncontrolled, dangerous drug abuse. The DEA subsequently created an emergency ban in 1985, making trafficking of MDMA punishable by fifteen years' imprisonment and a $125,000 fine.[8] Several highly publicized hearings were held after the ban became effective to determine the future of Ecstasy. Several psychologists, researchers and lawyers gave testimonies in support of the therapeutic benefits of Ecstasy. The Multidisciplinary Association for Psychedelic Study lobbied extensively for the legalization of MDMA under research purposes.[16] Numerous Ecstasy supporters claimed that the drug was safer than heroin and cocaine, did not confuse like marijuana, stupefy like LSD or wire like cocaine.[3] The DEA administrative law judge ruled that MDMA could be used safely under medical supervision, recommending its placement under Schedule III.

Despite such support for Ecstasy, the DEA director overruled the federal judge's decision and, in 1986, permanently classified Ecstasy as a Schedule I substance. This ruling was largely based on a study done by the physiological brain researcher, Dr. Charles Schuster, in which rats experienced brain changes after large, frequently repeated doses of MDA, a chemical derivative of MDMA. The DEA focused on the word *potential* rather than on the word *high* when describing misuse. Although, due to an effective court challenge filed in September of 1987 by the Harvard University psychiatrist Lester Grinspoon, Ecstasy was unscheduled for a brief period. Grinspoon argued that MDMA did not have a high potential for misuse, but rather a low or medium potential. In addition, he claimed that there was accepted safety for Ecstasy use under medical supervision.[14] He wanted to see Ecstasy and other similar drugs available for experimental research in psychiatry, which could "be an important area of study in psychiatry." However, after only six months, the DEA surpassed Grinspoon's views and succeeded in moving Ecstasy back to the Schedule I listing. The agency based this decision on a lack of published information about the therapeutic benefits of Ecstasy.[1]

Subsequently, MDMA's therapeutic community nearly discontinued all use out of an unwillingness to break the law and jeopardize professional careers. While most psychologists stopped using Ecstasy in their treatments, America's youth continued to increase their use despite the drug's illegal status. As a result of the high media attention, public awareness of Ecstasy increased, along with the manufacturing and marketing of this drug. Media reports covering the psychotherapeutic benefits and the "fun drug" reputation of MDMA created the unintended consequence of attracting America's youth to yet another psychoactive drug. Ecstasy became a substitute for cocaine as the recreational drug of choice at college campuses nationally.[11] Ecstasy is still considered a niche drug, failing to even register on the government's drug surveys. The number of Americans who take it monthly remains less than one percent.[3] Despite these overall small numbers, the spread of Ecstasy use among American youth continues to cause much alarm.

The disputed nature of MDMA remains controversial among judges, government officials, psychiatrists, and the general public alike. As a result of Ecstasy's unusual history, not enough research has been able to be conducted. Therefore, not enough information about its true side effects exists. Ecstasy's popularity has soared, while accurate information about the medical and psychological side effects remains low. Much federal money has been used to test the functional and structural injury to animal neurotransmitters caused by Ecstasy, but experimentation on humans has received much less government support. The MDMA treatment model has not been given a fair opportunity to test its safety and efficacy in healing psychological ailments.[11] Testing on human subjects would be far more beneficial in understanding the complete workings of Ecstasy. In order to try to comprehend why such disputes surround Ecstasy,

all available information, both in support of and against Ecstasy, should be closely evaluated.

Benefits of Ecstasy

Once Ecstasy enters the blood stream, it causes the nerve cells in the brain to immediately release all of the stored serotonin, independent of the usual electrical signal. MDMA floods the brain, overwhelming the serotonin receptors, and preventing the reabsorption of the serotonin. As a fast-acting substance, the time for initial effects to occur ranges from 30 to 60 minutes, with a peak taking place after only 90 minutes and lasting for about 8 hours.[16] Reportedly, Ecstasy does not have any of the hallucinogenic effects of other illegal drugs, because users are able to retain control, while their minds are able to wander.[3]

MDMA's claim-to-fame has long been its ability to increase self-awareness and feelings of empathy. It relaxes inhibitions and enhances communication. Ecstasy supposedly helps reduce defensive barriers, while cultivating communication.[11] Endearingly termed the "hug drug," Ecstasy reportedly makes people loving, friendly and self-assured.[8] Rick Doblin, founder of the Multidisciplinary Association for Psychedelic Studies, believes that MDMA has a "special ability to help people make sense of themselves and the world, and can lead people to inner truths".[3] Ecstasy reportedly gives its users feelings of confidence, happiness, verbal ease and emotional intimacy. One interviewed psychiatrist explained that a "five-hour session [with Ecstasy use] can be equivalent to five months of regular therapy".[8]

Proponents of MDMA for psychiatric use argue that it can truly help people suffering from a range of mental problems including depression, addiction, anxiety, family problems and schizophrenia. It can serve as an effective part of psychological treatment, invoking insights into past life events, without the need to repeat the experience.[6] Many patients who seek psychiatric guidance find it difficult to express their deep, inner thoughts with a stranger, and many also struggle with troubling instances from their past. Richard Ingrasci, a Boston psychiatrist, claims that once you give a patient MDMA, "you're hearing all kinds of stuff you haven't heard before. That's when the therapy really takes off." He noted that six of his patients were able to recall and discuss being sexually molested as children only after taking MDMA.[10] According to the psychiatrist, George Greer, a person taking MDMA can, "think about things, talk about things that normally would be too frightening to deal with".[19] Therefore, Ecstasy could be very helpful in breaking the patient-doctor barrier, allowing a higher, more beneficial level of psychological recovery to take place.

Supporters claim that MDMA is not habit-forming or addictive, because its euphoric side effects decrease with use, while its negative side-effects increase with use. These unwanted effects occur with greater frequency than those experienced with more commonly abused drugs like cocaine. When a level of tolerance for Ecstasy develops, increasing the dose of MDMA will not create the desired effects.[14] George Ricaurte, a Johns Hopkins neurotoxicologist, argues that "the vast majority of people who have experience with MDMA appear normal, and there's no obvious indication that something is amiss".[3] Furthermore, Ecstasy is less likely to cause violence, less addictive than cocaine or tobacco, and less deadly than heroin. New York's Bellevue Hospital psychiatrist, Julie Holland, remarks that she "does not see people whose lives have been ruined by MDMA," unlike many other legal and illegal drugs.[17]

Harms of Ecstasy

The federal government has spent time and money discerning only the negative effects of Ecstasy, as opposed to the potentially therapeutic effects. Even though most evidence is inconclusive, much supports the claim that Ecstasy is, in fact, harmful. Computer images of the brain activities of Ecstasy users reveal that they have fewer serotonin receptors in their brains than non-users. By forcing the serotonin out of the brain cells, these cells' shapes are changed, possibly permanently.[3] Ricaurte claims that "even one dose of MDMA can lead to permanent brain damage in humans." Other studies have consistently shown that MDMA produces a clear but acute depletion of serotonin.[11] Such evidence supports the claim that use may lead to depression and memory loss, but this work is not conclusive.[8] Serotonin axon

terminals are able to regenerate, but the time allotted for complete recovery varies from person to person and may be quite extensive. Unfortunately, it is still unknown whether this recovery is normal or slightly impaired.

Ecstasy may be considered physically non-addictive, but some users have shown clear patterns of psychologically compulsive behavior.[11] Some people report a need to increase their use of Ecstasy in order to mimic the psychological effects obtained from their initial use. The Federation of American Scientists claims that MDMA can "inspire use of more than one session a week and more than one tablet a session".[17] Such evidence suggests a degree of tolerance heightened with every intake.[5]

There are many other possible adverse effects aside from the serotonin neurotoxicity threat, which currently receives the most concern from the scientific and medical communities. These other problems include elevated heart rate, hypertension, reduced appetite, dry mouth, dilated pupils and energy elevation.[5] An additional risk, common to many illegal drugs, is a lack of purity and potency in drug sales. Adulterated Ecstasy is sold throughout the black market. An estimated low forty-percent of "Ecstasy" is pure MDMA, resulting in even greater potential harms.[11]

Harmful psychological effects also have a potential to develop, including euphoria, panic disorder, depression and impaired judgement. According to an article in *Life*, one user of Ecstasy claimed that the drug merely intensifies whatever mood its user is feeling prior to intake. This view stands in direct opposition to psychiatrists and their treated patients, who argue that Ecstasy enables people to become calmer and express their feelings openly. Advocates of Ecstasy claim that the shy become outspoken and the depressed become happy and energetic. On the other hand, according to opponents, the depressed become even more depressed.[8]

The deputy director, Robert S. Mueller, asserted that Ecstasy is "quickly becoming one of the most abused drugs in the United States." From just 1997 to 2000, United States Customs reported an increase of Ecstasy tablet seizures totaling close to nine million.[17] If the supposed dangers of Ecstasy do actually exist, then Ecstasy users need to be educated about these hazards and the claims about the safety of Ecstasy need to be relinquished.

Testing of Ecstasy

Due to Ecstasy's Schedule I status, no studies to test the efficacy of MDMA in psychological therapy treatment have yet been approved by the United States government. A few experiments have been conducted outside the country, but despite their encouraging results, the American government remains apprehensive towards showing any support of MDMA. One such experiment conducted in Switzerland indicated high levels of treatment response in mental patients.[11] A more specific experiment is taking place in Spain, where rape victims are currently being treated with MDMA to cure post-traumatic stress disorders.[3] More similar experiments need to be developed in order to prove the benefits of Ecstasy in the psychological treatment realm. Unfortunately, many scientists claim that it is extremely difficult to get the necessary government approval for MDMA testing. This inability hinders anyone except the wealthy, powerful and biased pharmaceutical companies, from conducting research.[10]

Comparing Ecstasy and Prozac

When considering whether Ecstasy is safe to use medically, it is advantageous to compare it with a similar but legal drug. The commonly prescribed drug, Prozac, is closely related to Ecstasy. Today, around five million people take Prozac to combat depression, totaling in sales close to an astonishing four billion dollars a year.[4] Both Ecstasy and Prozac change the serotonin levels in the brain by inhibiting the re-uptake of serotonin. The main difference between these two drugs concerns the manner in which the serotonin is released. Prozac merely prevents the serotonin, which has naturally been secreted, from being taken back up into the cells, while Ecstasy actually *shoves* serotonin from the brain cells.[3] This difference is the reason why Ecstasy has been praised as a faster acting and, therefore, a better drug. For Prozac-treated patients suffering from depression, it may take four or more weeks for the drug to become effective. In addition, Prozac-treated patients may need to keep

taking Prozac for at least six months to prevent the depression from returning.[20]

History of Prozac

Praised as a wonder drug, Prozac first entered the market in 1984. Advocates claimed that it was the safest anti-depressant available. The Food and Drug Administration officially recognized Prozac as a drug suitable for the treatment of depression and obsessive-compulsive disorders. Apart from these federally approved treatment modalities, Prozac has been used to treat a wide range of additional problems. These disorders include panic attacks, premenstrual tension, premature ejaculation and chronic back pain.

Prozac never had to face any of the stigmas that overwhelmed Ecstasy. Prozac entered the market when the number of people suffering from depression and obsessive compulsive disorders was quite high. By this time, mental illness had become more common throughout American society. A safer drug treatment was greatly needed and Prozac was able to satisfy this necessity. Psychiatrists and their patients were eager for the invention of a new drug like Prozac that would work easily and effectively without many adverse effects. Initially, Prozac was solely manufactured as an adjunct to psychotherapy. Following the conventional distribution guidelines of American industry, under the authority and approval of the FDA, Prozac was chemically synthesized, mass- produced, and distributed. It was also highly publicized by the media and by its manufacturer, Eli Lilly, through attention-grabbing advertisements.[15]

Prozac's success has possibly depended on a lack of information and from the pressures of the pharmaceutical industry. As depression becomes an increasingly common disease, the pharmaceutical industry continues to persuade the public into regarding many disorders as depression. Coincidentally, the American dependence on drug therapy continues to increase, as evidenced by the growing levels of Prozac use. This over-reliance on Prozac may be unjustified. Even though it has never been revealed, "when clinician-based disease-specific rating scales have been used by researchers Prozac has been shown to work for depression, but when patient-based, nonspecific quality of life instruments have been used, it has not been shown to work".[12]

Testing of Prozac

Like any drug, problems can occur when a drug has not been fully tested by the government and medical authorities, but is available to the public. Even the most commonly prescribed medications, when used over long periods of time, can cause dependency and unwanted effects. A written listing of possible side effects is packaged with every drug prescription ordered today. In addition to the worry concerning adverse drug effects, the problem of adequate testing raises much concern. The FDA has been known to release drugs onto the pharmaceutical market before long-term safety studies have been concluded.[2]

One predicament with Prozac is that it has never been tested on children. It has only been proven safe in adults, despite numerous side effects and withdrawal problems. The manufacturer of Prozac, Eli Lilly, is unable to market Prozac as a remedy for children, but it is legal to prescribe Prozac to children.[13] Although all antidepressants have not been specifically approved for use by patients under eighteen years of age, more than 500,000 children use them.[15] Between 1995-1996, the number of children taking Prozac and other anti-depressants rose by an astonishing 80 percent, totaling in 785,000 SSRI prescriptions for children ages six to eighteen.[7] This sharp rise in Prozac use may or may not be warranted. The difference between age groups should be explored, especially because children may suffer from worse side effects than adults.[20]

Prozac is currently over-prescribed by psychiatrists to patients of all age levels and all socioeconomic backgrounds. Many patients that may not be truly clinically depressed or suffer from true obsessive-compulsive disorders are given Prozac at an overwhelming rate.[4] According to research from IMS America, 28 million Americans took antidepressants in 1996, but only 16 million actually suffer from mental disorders treated with antidepressants.[15] Clearly some people are able to receive the pleasurable effects of Prozac legally, while others receive the same effects illegally through the use of Ecstasy.

Prozac vs. Ecstasy

Some doctors argue that Prozac merely restores a person's capacity for pleasure, which would naturally exist if the person were well. However, Ecstasy creates a "fake" pleasure immediately. This enjoyment is sought after by recreational users of Ecstasy and by a few patients of psychotherapy. Yet it is still similar to the pleasure obtained by Prozac users. Unfortunately, both Ecstasy and Prozac have entered the black market, a dangerous buying ground. Ecstasy is sold on the unregulated black market simply because of its illegal status. On the other hand, Prozac has entered the market, because many people who are not clinically depressed are unable to receive prescriptions but greatly desire the drug's effects.[4]

If the vast increase in Prozac use has not caught the FDA's attention, then why has the increase in Ecstasy use caused such alarm? Why can a pill like Prozac be used to make a person feel better, if a pill like Ecstasy can not be legally used? The facts surrounding both Prozac and Ecstasy are inconclusive, so why is the distribution and usage of one favored over the other?

Many hypotheses can be drawn as to why Prozac has been treated so differently from Ecstasy. One strong reason stems from the different manners in which each drug has entered into American life. Inevitably, much suspicion will surround any drug that was initially tested as a brain-washing substance for the government. An air of infamy would undoubtedly surround such a drug. The following phase of Ecstasy, characterized by its association with a few fringe psychotherapists and homosexuals in the Seventies, increased skepticism of the drug. Due to the stigma surrounding mental illness and homosexuality, the cynical views about MDMA worsened. Clearly, MDMA grew up in a negative light. Its use truly blossomed when it reached the reckless youths of the American Generation X. Ecstasy supposedly never entered the lives of the upright, responsible, mature Americans. Ecstasy was largely seen as only a drug of the mentally ill, homosexuals and young ravers.

Unlike Ecstasy, knowledge about Prozac did not slowly leak out over time. No secrets or uncertainty surrounded Prozac. It entered American life in full blast, praised by the medical community, rather than in a controversial manner like Ecstasy. The two drugs also varied in the acceptability by the therapeutic community. In general, Prozac had the full support from psychiatrists and pharmacologists. MDMA, on the other hand, was not accepted by all sectors of the psychiatric treatment community, most likely because it became available during a time when drug therapy was not commonly used in psychological treatment. In addition, according to Howard Simon of the Partnership for a Drug-Free America, because the long-term impact of Ecstasy is unknown, "it makes sense to err on the side of caution".[9]

The scenarios in place today position Prozac in a psychotherapeutic, controlled environment that is supported by the psychiatrist-patient community and the government. In opposition, Ecstasy is positioned in an unmonitored, stimulating party atmosphere that is feared by government authorities and many citizens. Furthermore, the intended use of Prozac is at regular intervals in a home environment for the purpose of medical treatment, whereas, the current intended use of Ecstasy is mostly at odd hours in a loud dance club environment for the purpose of having fun. Both drugs increase feelings of happiness, yet Ecstasy's effects are "euphoric" rather than "slightly better than well," and Ecstasy's effects are immediate rather than gradual.[4]

However, these effects should not necessarily be viewed in a negative light. In fact, most Americans favor quick fixes over gradual resolutions, but most Americans also trust their government and medical authorities. Since these power figures do not approve of Ecstasy use, neither does the general public. It is highly unlikely that Ecstasy will ever reach Schedule III classification, especially because an effective, approved drug like Prozac already exists. If the history of Ecstasy had been different, I wonder if Ecstasy would be the Prozac of today.

Since it is impossible to change history, I can only question today's situation. The exorbitant levels of Prozac prescriptions, especially for children, raise much concern. There is a high possibility that Prozac is being both medically and recreationally abused. I feel that Prozac's legal status should not

automatically guarantee its safety and uncontrolled freedom of prescription, especially because it has not been tested to a complete extent. There is a high possibility that ill effects of long-term Prozac use may exist, especially because this drug has only been available for a relatively short period of time.[18] Like Prozac, Ecstasy must also be further explored. Despite substantial media coverage and millions of federal dollars spent investigating the neurotoxic effects of Ecstasy, complete understanding of the medical and cultural impact of this drug remains indefinite.[11] Research using pure, pharmaceutical grade MDMA on human subjects must be conducted to reach the truth.

The government and medical authorities do not seem to want to recognize the potentially harmful effects of Prozac, a federally-approved drug. They also do not seem to want to recognize the potentially beneficial effects of Ecstasy, an illegal drug. The lack of conclusive information on Ecstasy and Prozac makes it extremely difficult to decide whether their benefits outweigh their consequences. I believe that until definitive answers to my questions can be concluded, no one, who could benefit from the psychotherapeutic use of MDMA, should be denied it. I recommend Ecstasy's transfer to Schedule III, despite a likely resulting increase in use. To this day, the legal/illegal choice has not been effective. Criminalization has had "little deterrent effect on the recreational user population, while substantially reducing its therapeutic use".[14] Andrew Tatarsky, a psychologist specializing in substance abuse problems, explains that a "pragmatic approach starts by acknowledging that people will continue to use these drugs, whether we like it or not; honest education about risk and compassionate treatment based on clinical experience are the best antidotes".[9]

All legal and illegal drugs face the potential for misuse. Restrictions, guidelines and strict monitoring have been instituted to make the use of legal prescription drugs as safe and effective as possible. MDMA could enter the legal realm of prescription drugs, just like Prozac. Research could then be conducted, enabling mental patients to be treated with a fast-acting, effective drug. Legislation can help diminish the recreational problems of Ecstasy use by decreasing availability and increasing cost. However, legislation should not prevent Ecstasy's potential therapeutic benefits from being attained. MDMA is a potent, immediate-acting antidepressant and there is no drug like it available in psychiatry.[9] Until unbiased, researched information can undeniably prove that MDMA is unsafe under all circumstances, especially medical ones, I do not approve of the DEA's current classification of Ecstasy.

Author Biography

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AIDS IN HAITI: TRANSCRIPT FROM TUFTS UNIVERSITY EPIIC SYMPOSIUM

Paul Farmer, MD

FARMER: I am very grateful to the Tufts community. It's good to be back here. I just want to focus on two pressing problems, neither of them solved of course. And just two of the dozens of problems facing the destitute and those who are likely to become the destitute sick. And so I'd like to just use these examples from infectious disease, realizing of course that infectious disease is simply one of many plagues in the world today.

There are the plagues that were mentioned of substandard housing, no education, no clean water, inadequate food supplies, no food security. These are really the underpinnings of what we see in terms of infectious diseases. The numbers are surprising to some people. HIV and tuberculosis are the two leading individual pathogens causing adult deaths in the world today. And of course one of them has been around for a long time, and the other one is new having risen through the ranks of infectious killers to eclipse tuberculosis as the world's leading infectious cause of adult death. And that has happened all in the space of one generation. I remember being in medical school at the time the virus was identified, and to see all this devastation occur in the space of less than 20 years has been disturbing and revealing. Disturbing for obvious reasons, revealing because HIV like many other diseases reveals these social fault lines of poverty, gender inequality, racism, which although not central to academic inquiry yet need to be because these are again the social fault lines that determine the shapes of epidemics in the world today. I'm not going to spend a lot of time reciting figures, don't worry. I will move directly to some examples. But the scope of the plague I'll discuss first, HIV is just enormous. And now we're debating whether it's really 40 million people living with HIV. I've heard the figure 65 million several times this past month. The point is it is spreading rapidly, with the majority of new infections occurring in the most resource poor settings. It says here, developing world, and there's really no term that describes adequately the various components of the developing world because after all some of them are in the third world or in the affluent countries like our own, affluent and inegalitarian. But there's no getting around the fact that HIV is most concentrated among the poor and in places were poverty and gender inequality and racism marginalize large groups of people.

And so one of the questions that has been too little asked and asked too tardily is, how exactly do social inequalities exacerbate an epidemic like this? Because I believe that could be the primary

cofactor if you will for the advance of HIV. Social inequalities are the primary cofactors. And the impact in parts of the world have been profound as you can see just in looking at AIDS orphans. The idea that there could be 12 million orphans on a single continent is really going to be the cause of enormous suffering and disruption even if everything was improved radically right now. Even if all new infections were to cease suddenly, we're already left with a really cataclysmic problem in some parts of the world. The impact of HIV on other existing problems has also been profound. For example, what has happened to tuberculosis control in those settings most affected by HIV? In African countries, even some that are more wealthy than others like Zimbabwe or South Africa, the impact of HIV on tuberculosis has really reversed gains in tuberculosis control in much of the world. And the finally the most sobering rebuke to optimism is probably the impact on life expectancy and the reversal again of major public health gains all in the space of the last generation.

So the big question that comes up at least for those engaged in direct service is well really what could be done? And there have been a long series of debates inside the public health world, those concerned with HIV, about what should be the priority interventions. And this debate has been sometimes fruitful but sometimes not. And some of you know the sort of polarized version of the debate right now. And certainly over the last couple of years has been, do we invest in prevention, or do we invest in treatment of HIV. And I'll be arguing today that that bipolar opposition is artificial and probably a big mistake and has stymied to some extent an open and progressive debate about what should be done. Prevention and treatment are part of a continuum of engagement. Prevention obviously being our top priority. Avoiding HIV infection, preventing HIV infection prevents all of these long lists of tragedies of that I've mentioned to you from losing a parent to HIV to having someone who is not HIV infected but is in contact with someone else who has tuberculosis. People who are affected by HIV in all sorts of ways, not directly by living with the illness itself but also indirectly through increased risk of tuberculosis, again increased risk of diarrheal disease. You lose your mother in some of the poorest parts of the world, many of the poorest parts of the world, and your chance of survival drops very, very significantly as a child. So to lose your mother is often a lethal event for a child without HIV. And then of course there's this central problem, is HIV prevention going to be enough as it is currently construed to protect vulnerable populations? I think already we know the answer is no. Current prevention does not include a vaccine, and so it is reliant upon education which is very effective for some people who can take the fruits of education and use them to alter their own lives. But there are lots of other people who cannot use the fruits of education to alter their lives. And to use language from social theory and I should be shot for doing so, the agency of poor and marginalized populations is very restricted. That is, their ability to make choices is very restricted. So there is a trend inside HIV prevention where you have basically people like me exhorting people who live in poverty to use condoms, avoid risks, say no to this that and the other thing. Easy for us to say, but not so easy to implement if you're struggling for survival and to feed your children. And we know this lesson, we know it in our bones. We know it's not good enough the methods that we have now, the HIV prevention methods. We have to keep moving that agenda forward. We have to continue to educate, especially adolescents, at the same time we also have to be realistic about who is going to benefit from these interventions, and who is less likely to benefit. And that's a very important debate that is just now happening I would say in the international HIV community. It's really the last couple of years that people have been honest about saying, well you know the methods that we have so far are really just not good enough. And then there is another problem which is that an exclusive focus on prevention let's say, does ignore an ever growing number of people who are living with HIV. We had a panel in central Haiti, Gender Inequality, Poverty and HIV, and one of the panelists got up and said, I ardently support HIV prevention but I already have HIV, and so how do I fit in? And this was in the mid-90s when we were just starting to see the impact, and I mean just starting, at the very cusp and the impact of some of the new therapeu-

tic advances in HIV care. The impact of these advances was even more profound than we suspected. People who have access to these medications are much less likely to be in the hospital and of course to die. And this has been seen not just in the United States but also in Brazil and in a lot of European countries and in some parts of Asia. So for our group, Partners in Health, and I'm actually not the executive director anymore, I was the founding director, but for same group of people working together, an ever enlarging group of people working together, this was a very troubling issue for us back in 1995 and 1996 because we started to see this and we knew that we would be challenged as a social justice organization to act on this bit of data. And we looked for leadership, and again I hope it's OK for me to use this word leadership, when we looked for leadership on this issue it was very hard to find. Because the question was well what do we do now that we, A, know these medicines could help many people living with HIV, and B, also live and work in settings of enormous poverty, and we know that these medicines are costly. I'm sure that it'll be central to our discussions here today. So that was our big challenge, and I'll show you what we did do. And now of course when you look at something retrospectively you kind of neaten it up, but it wasn't experienced by me personally or by my coworkers in Haiti as a neat and clear strategy, we were simply trying to do a good and equitable job in taking into account all these new discoveries. So what we did in surveying the situation and by the way, HART means highly active retroviral therapy, basically the cocktails, the antiretroviral agents that have revolutionized care in some parts of the world. Well first of all we found two major roadblocks everywhere we went. And also an almost defeatist attitude about the roadblocks I would say, not so much among patients and activists but among experts. And some of whom were convinced and are still convinced, and I respect this opinion, that these roadblocks could not be avoided, could not be overcome. One of them was lack of infrastructure. That is, the HIV was causing the most trouble in those areas without infrastructure which is very true. And the second was the cost of the drugs. Just to give you some numbers and these change rapidly now, early on in this debate it was felt that more than $10,000 per patient per year without lab tests was going to be the expenditure on these new medications. Now there could have ensued and there did ensue in certain circles a very brisk debate about these two issues from early on. The first debate would have been, OK, if we don't have infrastructure how do we build infrastructure in those places that need it most, and the second was if the drugs are too expensive how do we lower the cost of the drugs and how do we have some strategy for making sure that the drugs go to populations who need them most. And I would argue that that debate did not happen until very recently on a global level. Haiti is as you know, I shouldn't say the poorest country but the most impoverished to quote a friend of mine, a Haitian with whom I spoke last Friday. The difference between poorest and impoverished is that the word impoverish reminds you that this is a historical process. It takes time and I would say to some extent ill will to create and sustain poverty. It's not the natural condition of humans in the modern world I would argue. And I'm going to show you how in one area it did happen. And no matter how you look at these figures, you can just see these are terrible public health indices. This of course reminds us that we need to be concerned with setting priorities. And again that's another area where you can suddenly find yourself in a debate where it's regarded as irrelevant. The impact that these medications could have when there are so many needs unanswered in Haiti. So our group again was faced with a difficult problem. We knew that we wanted to work in all the public health conventional arenas, and we have been, which is of course vaccination, oral rehydration, salts, improving living conditions, access to decent nutrition. And we had to struggle as a group, as a small group, to not go into this either/or situation where we said well we could only do this, we could only treat HIV if we shortchange other efforts. We have tried to avoid that logic and I'll show you what we did in Haiti. First of all, back to the question of creating poverty over time. [slide] This is the valley, I'm actually heading back there tonight. This is the valley where we've been working since 1983. But this is not a natural body of water, it's a reservoir from a hydroelectric dam,

and it's not unimportant to the local people there who lost their land to the hydroelectric dam, it's not unimportant that this was a dam signed into existence in Washington, D.C. It was, when it was completed one of the tallest buttress dams in the world, and the amazing thing for me as a graduate student working there and as a medical student, was to hear the stories told by people living there how they lost their land on the day the water rose. And the first day I heard that I thought it must be exaggerating poetic license, but in fact there really was no resettlement plan and many people fled the valley when it was flooded. I mean literally on the day it was flooded. And so they went up into hills and they live in conditions that they refer to as indecent poverty. [slide] And this to quote a Haitian expression, this is a house that can fool the sun but not the rain. It has a dirt floor, in the rainy season, a mud floor, and thatch roof and is regarded as completely unacceptable by the millions who live in these conditions and globally by the hundreds of millions who live this way. Believe me they also know what Nike footwear is, they also know that there is, they know through radio and other things what the rest of, how the other half lives. And just as they do on that one side of the tracks in Mission Hill [Boston] know just what it's like on the other side, so too it is globally that these inequalities are experienced in a new and more pressing way by those living in such destitution. And so we ended up building a clinic in the middle of this squatter settlement and as you might imagine we were overwhelmed and are overwhelmed by just the demand for provision of services. And this was all spelled out for me in sort of a warning by one of my Haitian coworkers. He said, well go ahead and ask the villagers what they want, if you want to do that. But they're all going to tell you they want a hospital. They're not going to say we want vaccines, oral rehydration salts in a health post. They're going to say we want a hospital. And sure enough they did. They said, we're already sick, we need a hospital. Well we built a hospital and I make it sound like it was easy, it was very difficult as you might imagine. And it involved collaboration of people, not just within Haiti but throughout the States and we even had some small amount of support from Europe as well. This was all private funding through Partners in Health by and large. Or through church groups, progressive foundations, individual donations. And at the same time that we were doing the public health work we were also seeing the first impact of HIV in this area. First case of HIV in the central plateau of Haiti, 1986, someone from that area. So again significantly later than then urban epidemic which was very tightly tied to the American epidemic, and as time went by we introduced the first serologies, the basic HIV tests in the area and began intensive prevention efforts, meaning we developed culturally appropriate videos, handbooks, talks throughout the region, in schools, in churches, making condoms available, etcetera. So we did that part of the work and continue to do it, but the impact on the epidemic was difficult to discern. And so when in 1995 AZT was shown to block transmission of HIV from mother to child we went through this again painful process of deciding whether or not we would buy this expensive drug and put it on the formulary of the hospital, which we did. And something very interesting happened. In the women's health clinic, in the prenatal clinic, there was suddenly a great deal of interest in testing for HIV. Again it makes sense in retrospect, introducing a new therapeutic actually helped our prevention efforts because it gave people a reason to want to be tested, in this case during pregnancy, and a lot of interesting testing ensued. Of course, suddenly we had lots of negative HIV tests because most of the women who were tested were not HIV infected, and that was a chance for us to continue to push prevention and counseling in prevention in a very new way. So in 1997 we followed U.S. guidelines. Again we couldn't find a lot of leadership in the international public health community, because we went to the international public health gurus and said what do we do around post exposure prophylaxis for victims of rape? Because we saw our first cases of rape in 1992. It was a long story, I won't go into it but that doesn't mean there wasn't a lot of rape before but that it hadn't come to our attention until then. And so we said, well what are we going to do in these cases? And also we had as does every healthcare facility professional injury, that is needlestick accidents, accidents in the operating room, etcetera. So we introduced a three

drug regimen for people who are victims of rape or professional injury. And then in 1998 still without much in the way of leadership from the international community, what do you do in these poorest of settings with these new medicines? We started expanding our antiretroviral therapy in patients with HIV, with AIDS, who weren't responding to other ministrations; for example, to inexpensive antibiotics, to treatments to control diarrhea, etcetera. And we called it DOTHART because we were using directly observed therapy, that is we were having community health workers deliver the medicines just as we did with tuberculosis but using a different set of drugs, in this case antiretrovirals. And we now have about a little over 120 patients who are receiving this and some very interesting things ensued again. First of all, the reason we used TB infrastructure is because we couldn't get funding to build new infrastructure. So it wasn't out of some shrewd planning or brilliance on our part, we just didn't have any money. We were getting turned down and still are getting turned down by the way for this project, and so we had some interest from donors, guess who, from patients and students in the United States. Patients with HIV here who were saving unexpired medications, and this is a called a recycling project, and some students here that really gave us a boost. We knew that we had to rely on buying the basic drugs, and we did at some cost. But we also had some, at least some cheerleading from patients here and from students here and that helped a lot. But the reason we used this infrastructure is because it's the one we had and we didn't have money for new staff. So we called them accompagnateur, which really isn't a Haitian word, it's a French word, but it went well in Haiti, and it sort of got taken up. And one of the surprising discoveries was that the accompagnateur really provided something very special to the patients. And that was solidarity, again almost nothing written on that in the medical literature, public literature. But it seemed to me that that would be the only word that could describe what was happening. We require that the accompagnateur go to the patient's house once a day, not twice a day even for those that are usually twice a day regimens. And we find accompagnateurs who were going to visit the patients five times a day, and sitting down and making coffee for the patients or spending times babysitting their children. And again this was a natural process that we saw and see emerging even now. And the impact on the patients of the meds was profound. I'm just going to give you some examples to speed this up a bit. On patients who we have tested with first [world?] type diagnostics which is viral load, the impact of this program has been very profound with 86% of those tested having no detectable virus in the peripheral blood. I would add that this is significantly better than many U.S. programs, probably most U.S. programs. In one study in Atlanta of a very good project, very good infrastructure, about half, we have about twice the rate of suppression that was registered there. And there were many other things that were surprising to us. One was the good impact on staff morale. So what do you think it's like to be a doctor or nurse with a large cohort. We have 1500 patients with HIV. What do you think it's like to be a provider, social worker, nurse, community health worker, and say I'm sorry, these medicines are too expensive for you even though you're right, they are causing very reduced rates of death in the first world or among the privileged in your country, you're too poor for this treatment. That's very demoralizing. Of course that's not the language that doctors and nurses and social workers use, but the message was really tantamount to you're too poor to treat. And a number of patients said that, what they're telling us is that we're too poor to treat. Get back to the patients' message. So how big a project is this, is it as small as it looks? Well probably not because the big question is what fraction of patients with HIV actually need antiretroviral therapy? And it isn't the majority I would argue. In the United States it's true that a lot of patients are not on therapy, but a lot of patients don't need these drugs yet, it's really going to be the subject again of much debate. What fraction of the patients will most benefit from the drugs and have the least in the way of adverse affects? And my own guess is that the proportion will creep down, maybe not down to 10 or 15% which is where we are but down below 50%. And this is just speculation as a provider. So we don't think we're that far off from providing universal coverage to a population in which 5% of

all adults are infected with HIV. We're getting there, even with very limited resources. So we argue that this is a compelling method of delivering antiretroviral therapy for several reasons. One of them, and this is the one that's brought up most often in international public health, is the prevention of acquired resistance to the drugs. That is, if someone's getting directly observed therapy they're not usually missing doses, and even making sure that once a day is observed seems to have a very profound impact on the impact of the drugs. And also as you can see it's inexpensive if the deliverers of care are community health workers. You can't have, or expect in a place with no physicians or nurses, to have physicians and nurses delivering this care. And that's another long-term struggle, is equity of access to physicians and nurses. In the short run, however, it's only community health workers who really fill this gap in our view. And of course this also prevents the sale of these drugs on the black market. Another very compelling part of this is what do the patients say? And I'll just add here as I often do that the patients we work with have asked me repeatedly, please use our names, our faces and our words whenever you can in your speaking, 'cause we can't go to Tufts, we can't go out of the, actually we tried to have one of the patients come to a conference last fall and he was turned down for a visa to enter the United States.

Anyway, let me close by turning back to tuberculosis, but as I do so I would say right here you have I think where we are now in this global struggle for leadership really on responding to a new problem. With the right kind of support from the international bigwigs with whom we work and we were just on the phone on the way over here with U.N. Aides, someone from U.N. Aides who strongly supports the idea that Haiti, the poorest country in the hemisphere, he's from Brazil, strongly supports the idea that Haiti should have access to this global fund, and you guys have heard about the global fund which could make a lot of money available not just for AIDS but for tuberculosis and malaria. Well to do that you have to have some sort of network where you don't exclude the public health leaders of that country. And I can't be here and not mention that again we have an aid embargo on Haiti which is right now the freezing of aid to the poorest country in the hemisphere on the grounds of some political dispute. This is frozen really by the United States, by the State Department, and this is causing enormous problems for work like ours which is really not political work, which is public health care, but we're just as affected as you might imagine as the Ministry of Health, because we work closely with the Ministry of Health, where they are the people responsible for the health of the Haitian people. An image that will trouble you, this is from the Pan American Health Organization, in what country is the cost highest, well in the poorest country. Again these are clearly not rational responses to a new epidemic of this support. An access to drugs remains the big challenge along with building human infrastructure, because what I've described to you is human infrastructure, community health workers, not building new hospitals and labs and doing viral loads and CD4 counts in Haiti, but making sure that the drugs are used wisely. Now, we have an experience with tuberculosis which I'll show you, and it started with what I've called the transnational case, that is a case of someone who was working in Peru, an American who became sick, came back to a teaching hospital at Harvard and was diagnosed and died from multi-drug resistant tuberculosis. If you look at Massachusetts TB cases, in the 2000 data, 72% of all cases in this state are diagnosed in the foreign born, so it's not, it shouldn't be unusual to hear the expression transnational case because most cases here are transnational. Same thing in Western Europe. Low risks in one part of the world, high risks in the other, in the era of globalization. Assuming that these will not impact each other profoundly is an error. So as time goes by and HIV incidence drops in affluent settings and it rises in others, most HIV cases will be transnational as well. So there are general messages from this. And looking in the literature we could find lots of cases like this, that originated in Peru and were diagnosed, this is not HIV but multi-drug resistant tuberculosis, and diagnosed in affluent and low incidence settings in Europe. So what happens if you do transnational case finding and you go to the place where this case originated, this case at a Harvard teaching hospital. We met people like this

woman who dying in a public hospital of multi-drug resistant tuberculosis. Now you know this is an airborne disease, it's not like HIV. So here with this illness the question of double standards is posed even more poignantly. Double standards for the rich and the poor. And let me just show you how this is the first sweep through these areas of northern Lima. We found and confirm literally hundreds of cases of active untreated pulmonary multi-drug resistant tuberculosis. Imagine what this means inside the families. Now what do you do? Well again, from the World Health Organization it says DOTS is our only hope basically. What is DOTS, directly observed therapy. S means short course chemotherapy for tuberculosis, that's based on two drugs, they happen to be named Isoniazid and rifampin. And to what two drugs is every multi-drug resistant strain by definition resistant? The same two drugs. So giving people with MDR TB the short course chemotherapy doesn't work, and we have proof of that. And so once asked the question, well, here this is a map, also from the World Health Organization, it says Epidemiological Forecast, and if you see it's raining multi-drug resistant tuberculosis on Colombia, see the little storm clouds. In Peru it says TB is being defeating by a model DOTS.

Something else is going on here and that is aggressively pushing forward a very sound strategy for some places, but what happens when you give people with documented multi-drug resistant TB short course chemotherapy, well basically they don't get better. It won't surprise them, I was going to say I don't think it would really surprise anybody, whether you're a clinician or not. Now here's the real reason, and this is where we need to go I think with our debate today, and this is the real reason that, this is again from the World Health Organization, it says it's just too expensive to do this, and it draws attention away from the main tasks at hand. Now how many times have you heard a very similar statement about HIV? If we put energies and resources in treating people with HIV we are going to shortchange prevention. We're going to shortchange what we need to be doing to save the most lives. Now, this is our dilemma or our times, of the modern world, the global era, whatever you'd like to call it. Having double standards for rich and poor people or nations is going to become increasingly problematic, it already is problematic, of course, as I've showed you with these two examples. But there are some things that can be done. For example organizing accompagnateurs again. These are community health workers this time in Peru, to deliver the care in the patients' homes. These are young people, unemployed, from the same neighborhood, and could they do a good job delivering the services? You bet they could. It began in 1996, this is one of the accompagnateurs, and that's by the way what someone with untreated tuberculosis looks like, like a specter. But the cure rate, again hats off to the community health workers using very stringent criteria is over 80%. And this is supposedly untreatable patients with an untreatable disease. But what about the drugs? Well that was the crux. What do we call this first of all? We couldn't call it tropical DOTS because it was taken by a candy, so we called this DOTS Plus and we tried to make, to mend, to patch up any arguments with the World Health Organization and the Global International Health authorities and said, look let's work together to see if we can have a sensible way to dropping drug prices. And that's where we are today with HIV drugs. With the World Health Organization, Medicins en Frontiers, and other countries really affected by this disease we formed something called the Green Light Committee sitting in the World Health Organization which evaluated projects as to whether or not they could use the so-called second line drugs and then dispersed the drugs, sold the drugs basically at a reduced price, and again this is working with the pharmaceutical industry and generic manufacturers as well, not just generics but also big pharma, and look at the percent decline in prices over just one year. That's a decline in a prices with an increase in control. And that's of course what you want. You want to increase control over the drugs and not have them available willy nilly in the market. You can go into a rural market in Haiti and see people selling ampicillin, and we don't want that to happen with TB drugs. We don't want that to happen with HIV drugs, but there is a way to move this forward. And as you can see I've tried to show that there are a set of very similar barriers and also concerns around these

two diseases which again are very major players in international health. And taking on these dilemmas and concerns aggressively and say, we need to find a solution to this problem and not merely to say it's really too complicated, too expensive, not feasible in the areas most affected. That's going to be I think the challenge for international health and for people interested in the health of the poor basically. This is an equity issue as it has been for a long time. I think this is where we're going: And it's a very strange place, the modern world, because we have more and more tools that can really alter the course of these diseases that we're describing. Either they can prevent them or alter the course. And yet we don't have an equity plan as a global society. We don't have a plan that says, how can we use the fruits of science in an equitable manner so that those who need these interventions most will have untrammeled access to them? And without a plan, and this is probably true, certainly not just true for infectious diseases but all the major developments in medicine, but many in public health and engineering as well. Without an equity plan we're stuck with a growing outcome gap. And people who are Luddites who don't want to develop new technologies, they'll say, well you see we can't develop all these new technologies, let's just stop. But we would not say that because these new technologies can have a profound impact in populations living in poverty as well if there's an equity plan. Well I look forward to discussing with you the equity plan, and I thank you very much for honoring me with this award. Thank you.

[END OF TAPE]

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The Ethics of... Food?

Sarah Hatoum

The term "genetically modified," to most people, might bring up Technicolor Spiderman-type images of DNA strands replacing one another and solemn white-jacketed scientists injecting strange substances into hapless creatures. Try and mix those images with dinner and the idea seems intuitively wrong. This is a recurrent problem concerning the public perception of genetically modified foods, in that many do not understand what goes on behind the "scary" terms. This general discomfort for genetically modified organisms (GMO), even among those who are informed, make most companies hesitant to claim that they use modified ingredients. There is yet to be concrete evidence against the consumption of GMO, yet does this allow for the fact that we do not know that we are eating it?

The Food and Drug Administration (FDA) orders that all food products to be released into the market have a basic nutritional label. Yet, it claims that there is no need to label whether or not foods have genetically modified ingredients since they have not been proven to be harmful, despite many educated claims that we ***do not*** know this for sure. Still, the FDA seems to consider the right to know what the daily percentage of vitamin C is in cereal to be more important than whether the corn ingredient in it is from a plant containing a bacterial gene making it resistant to insects. I think that genetically modified crops, which can be designed to have much higher yields, have the potential to be a savior of starving and diseased populations all over the world, but it seems that taking away a basic right to know what you are eating is unfair to all those who feel uncomfortable about the idea. The typical American consumer would probably be surprised to learn that he has almost definitely already been exposed to genetically modified foods in one form or another. In fact, more than 50% of foods on the shelves of grocery stores across the nation have genetically modified ingredients[1], yet they are all completely undifferentiable from ingredients with non-altered foods. Taco Bell taco shells sold in supermarkets used to contain a genetically modified corn ingredient called StarLink that was unapproved by the FDA for usage in food because it has been linked to being a possible human allergen.[2] Although upon this discovery all the products were recalled, it makes many wonder what else is out there.

Recently the question of whether or not we want to be eating foods that were constructed and fashioned by researchers is in the forefront. Farmers and breeders across the nation are adamant about making use of the science behind Dolly, the ewe cloned in Scotland. Already there are approximately 100 cloned cows in America, and farmers see them as an enormous benefit to the industry. Each, though, costs a huge amount of money to produce, and now that some clones are starting to produce milk, their owners are becoming all the more insistent to make the investment worthwhile.[3] The only thing preventing them from doing so is an informal request from the FDA that states that more research needs to be put into the issue.

Still, not all are so worried. A National Academy of Science panel claims not to be worried and calls the food safety concerns "overblown" and complications to be unlikely[3]. Many of these experts say this is a no risk situation since a clone is "just a normal animal." Japan is expected to lift the ban on cloned animal products as scientists in Japan have agreed that there is no difference between a clone and a "normal" animal. Even the Catholic Church is putting its support behind continuing this field, as Bishop Elio Sgreccia, Vatican Director of Bioethics and Vice-President of the Pontifical Academy of Life (PAL) has pointed out the potential benefits of genetic modification as whole to humanity. That does seem to be the case as a great deal of research and money has even gone into producing pharmaceuticals in milk.[4]

Despite this lack of concern about the safety of these products, should we still demand that all containers with milk from clones be marked? Will a marking on a meat packet from a cow that was created in a laboratory unfairly effect what is potentially a great market? Yet don't we still have the right to know, regardless?

Despite worries and calls for more research, estimates are that clone cow byproducts will be in the market place by 2003, with pig products not far behind. The question is whether the public will accept this, and maybe more to the issue, whether the public will know or will they consume these products as easily and as unsuspectingly as they did with the genetically modified foods currently found in their pantries?

Many countries have taken decisive stances in favor of the labeling and tracing of genetically modified foods, especially those in the European Union who have been practicing this since 1997 and who, this July, passed a proposal to even further regulate GMO. America has

yet to do so, and in fact has been known to criticize the EU for their firm stance on the issue by claiming that economically, the idea is a bad one, since the consumer will have to deal with the additional costs of tracking and labeling. Still, the fact that a survey conducted by ABC news in June 13-17, 2001 claiming that 93% of those polled were in favor of labeling illustrates how in favor the American public is of putting health before wallet. Pressure on the U.S. government is now well on its way. Oregon is at the forefront of this campaign with an initiative claiming a mission "to create a national grassroots consumer campaign for the purpose of lobbying Congress and the President to pass legislation that will require the labeling of genetically engineered food in the United States." Registered voters in Oregon will decide what their stance is on this issue on November 5, 2002. This will most definitely not be an issue kept in Oregon, as California has already shown an interest in following suite. The rest of the country is no doubt going to be affected by this controversy, with everyone having to make a decision pretty soon, because it doesn't seem like it will take too long before the ballot is in front of each of us.

[1] Pence, Gregory E. "The Ethics of Food." Lanham: Rowman and Littlefield, 2002.
[2] Burros, Marian. "Labeling Foods With Designer Genes." The New York Times 3 Jan. 2001.
[3] Gillis, Justin. "Cloned Food Products Near Reality: Items Could Reach Shelves by 2003." The Washington Post 16 Sept. 2002: A01.
[4] Pollack, Andrew. "Biotechnology Venture Hits Unexpected Snags." The New York Times 23 Nov. 2001.

In the News

Bush Proposes Cuts in Medicare Payments

The Bush Administration is proposing deep cuts in Medicare payments for drugs and medical devices. For example, the reimbursement rate for the procedure to insert a battery-operated pacemaker would be cut from $29,360 to $12,102, or 59%. Patient advocates have joined providers in opposing the cuts, which they say will reduce access to needed medical services. "Hospitals will not be able to continue providing chemotherapy at the proposed rates. Patients will have less access to care," said Dr. Edward Braud, president of the Association of Community Cancer Centers. Government health officials contend that the new rates are based on actual claims submitted by hospitals, but a spokesman for the Advanced Medical Technology Association says hospitals tend to underreport the price of high-tech services.

Democrats Push Generic Drug Bill

After failing to reach a compromise with Senate Republicans on a Medicare prescription drug benefit, Democrats are attempting to force through the House a bill that would provide greater access to generic drugs. The bill closes some of the loopholes that allow brand name pharmaceutical companies to keep their patents longer. Brand name drugs are more expensive than generic drugs, and the costs of prescriptions has been a rising complaint among senior citizens. The Senate has already passed the legislation.

Americans Fear West Nile Virus

Fear of contracting the West Nile Virus has only become prevalent throughout the US within the last few years. Originally transmitted by mosquitoes, West Nile Virus can cause encephalitis and meningitis, as well as mimic the type of paralysis caused by polio. The war against this virus has been targeted at killing the mosquitoes where they live with insecticide. In addition, workers in the US and other countries are infusing ponds with a bacterium that enters the bodies of mosquito larvae, destroying their stomachs.

For most people, West Nile poses little danger. In areas in which the virus is present, fewer than 1% of mosquitoes carry it, and of those bitten, fewer than 1% will become seriously ill. According to epidemiologists, about 1 in 150 infected individuals develop encephalitis or meningitis, with the elderly and those with compromised immune systems at higher risk.

Although the odds of contracting West Nile Virus through a mosquito bite may be slim, a small percentage of the nation's blood supply may also be contaminated with the virus, increasing the risk of becoming ill with this potentially fatal disease. Several cases of the virus have been detected in patients who have recently had blood transfusions, and researchers are currently testing if the virus can in fact be transmitted in this manner.

Federal health officials are nearly certain that the West Nile virus can be and has been transmitted through blood transfusions. In order to decrease the risk of contracting the virus from the nation's blood supply, officials are thus hastening efforts to develop tests to detect if the virus is present in given blood samples.

This new threat also places a burden on physicians' decision making with regard to patients who may need blood transfusions, as well as whose blood is used in minor surgery. Although clinicians have been increasingly critical about how much blood is used, they may feel even more pressured to use blood only in dire cases. Patients facing elective surgery might also consider donating their own blood in advance.

From the Editors

How does one happen to learn about bioethics? Bridging several academic and professional disciplines, bioethics boasts its importance in all lives. Yet, one must think critically about how people become involved in the process. So often at conferences or meetings, we hear of a need for public education, or for public expression about issues confronting us. Yet, if people do not know the science or the philosophical background, how can they be expected to constructively contribute? Most commonly, community groups and organizations use proxies. However, the majority of their constituents likely remain in the dark.

We have adopted parts of a model called "Education for Active Citizenship" developed by the Tufts University College of Citizenship & Public Service for the development of a seminar on contemporary bioethical issues, leadership strategies, and connections to public policy. At the core of this model is an intuitive way for students to learn more than the basic science or basic philosophical arguments for or against technology. Often, these issues are too complex to "choose a side." Ethical, religious and cultural, and political perspectives all contribute to allocation of funds and the passage of regulations. In this mode of education, students are exposed to fundamental science as well as how they can overcome problems by focusing their energy on policy creation. Additionally, all students contribute to an overall citizenship project as part of their grade. Our ultimate goal rests with the students' understanding of how bioethical issues arise, and their translation of that knowledge into careers such as biologists, policy makers, lawyers, or physicians.

In designing a curriculum, we brainstormed the major bioethical controversies of the present day, and then made connections between them and general policymaking, active citizenship, problem solving, and leadership. The target audience of this class was not upperclassmen with previous natural or political science knowledge, but first-year undergraduates. Thus, everyone was primarily even in regards to science and policy backgrounds. In constructing this course, we realized the relative inexperience of many of the students with regard to major contemporary bioethical issues, and thus created a survey course that maximized exposure while allowing development of skills. At the end of the term, students are expected to have a solid understanding of policymaking pertaining to science, as well as a toolbox of skills that they can apply to any interdisciplinary topic in bioethics.

While currently awaiting feedback by evaluative methods, we have some insights to offer vis a vis curriculum implementation. On written faculty feedback, students reacted positively to various media (video, PowerPoint, Internet) as well as various pedagogical methods in contrast to either straight lecture or free discussion. One concern that we are currently testing and exploring is the students' retention of basic scientific knowledge, which prefaces each class topic. As a survey course, scientific specialization is not among our goals; however, the lack of depth into the details of each bioethical argument may hinder precision in either discussion or application.

Through this seminar, we are giving our students bioethical exposure and a repertoire of thinking tools, which they normally would not obtain until possibly professional experience demands it. By sharing this information with our students now, we hope that we are creating more active citizens for the future, and a group of people who can spread the knowledge to others. Meanwhile, we are gaining perspective into the education of people on bioethics, a goal that bioethicists commonly share. To educate, one must expose a topic, integrate previous beliefs with new knowledge, personalize the issues, and inspire commitment to action. While it may be difficult to create a mass-education plan for society as a whole, we are satisfied with this model of education, believing that it will inspire our students to educate others.

Class Topics: Our Model

Introduction to Ethics and Policy Making
Genetically Modified Organisms/Foods
Genomics and the Human Genome Project
Two Bioethical Case Studies: Gene Therapy & Xenotransplantation
Stem Cells
Hype & The Media
Domesic Bioethics Policy
Bioterrorism and Science Policy after 9/11
Cross-Cultural Bioethics
AIDS & National and International Health Policy
The future of medicine and healthcare

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