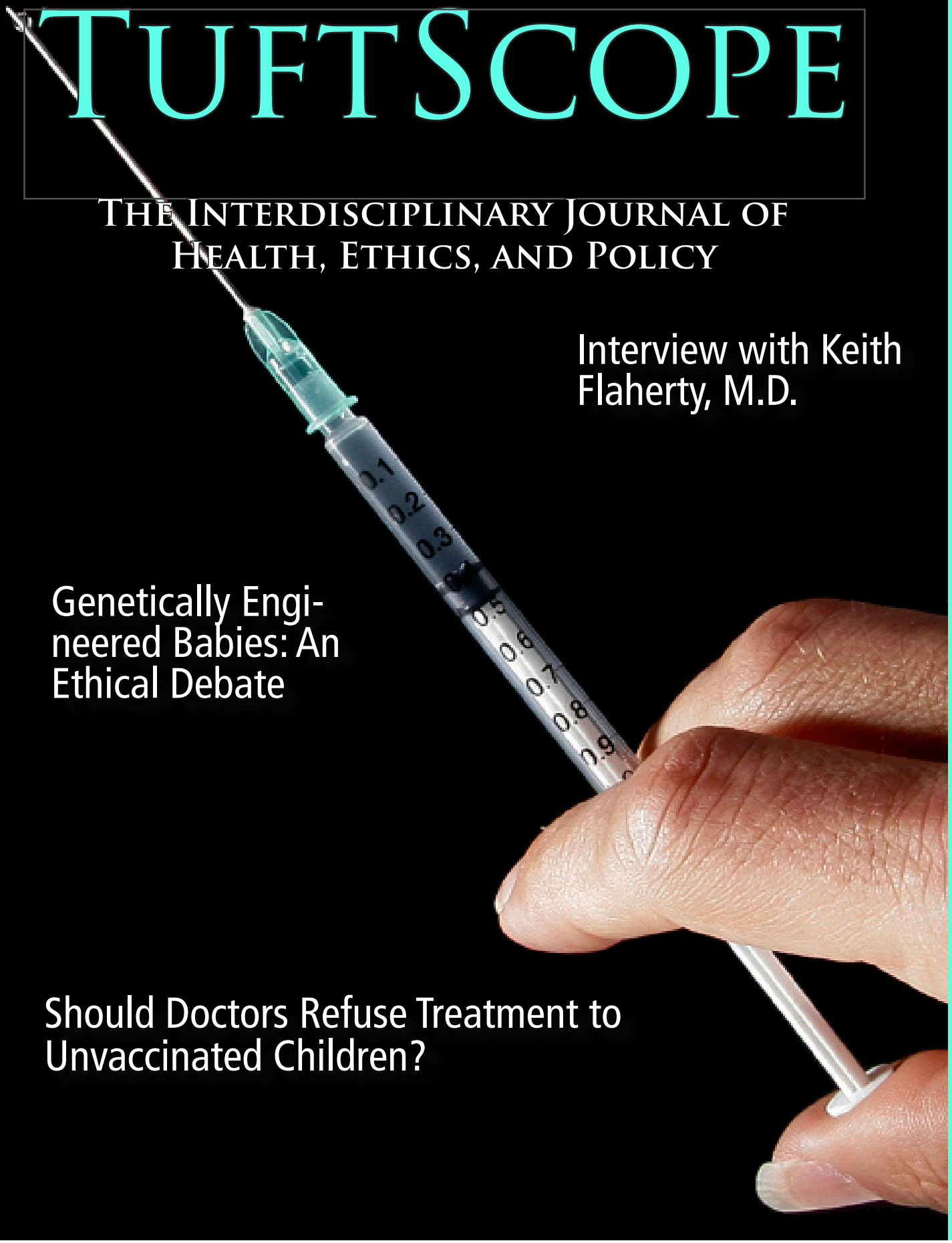
TuftScope

The Interdisciplinary Journal of Health, Ethics, and Policy

Interview with Keith Flaherty, M.D.

Genetically Engineered Babies: An Ethical Debate

Should Doctors Refuse Treatment to Unvaccinated Children?



TuftScope

The Interdisciplinary Journal of Health, Ethics, and Policy

JOURNAL HISTORY

Since 2001 *TuftScope: The Interdisciplinary Journal of Health, Ethics, & Policy*, has provided an academic forum for discussion of pertinent healthcare and biosocial issues in today's world. The journal addresses different aspects of healthcare, bioethics, public health, policy, and active citizenship. It is operated and edited by undergraduate students of Tufts University and is advised by an Editorial Board composed of Tufts undergraduates and faculty. Today the journal is one of the few peer reviewed undergraduate published journals in the country.

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Cover Image: In this issue *TuftScope* explores the intricacies of vaccination in American culture and healthcare. Cover image courtesy of Wikimedia Commons.

LETTER FROM THE EDITOR

Tenth Issue in the Books

Dear Reader,

The Spring 2011 issue represents the last publication of the 10th volume of *TuftScope*. It comes less than a full month after our publication of our first winter issue, and is replete with both outstanding staff and original articles.

TuftScope's managing editor David Gennert was privileged to interview Dr. Kevin Flaherty, the Director of Clinical Research Trials at Massachusetts General Hospital in Boston. Dr. Flaherty has been a leader in developing the next generation of cancer treatment drugs, deemed targeted therapies, for the past decade. Dr. Flaherty was showcased in a six part series in *The New York Times* over the last year, yet was still able to find the time to give a very engaging interview to *TuftScope*.

The Spring 2011 edition covers a wide variety of pertinent health topics. Sarah Gardner and Neha Wadekar examine the ethics behind genetically engineered babies and surrogacy, respectively. Laura Corlin and Emily Clark each look at different aspects of drug regulation: how FDA drug approval leads to increased prices and drug dumping. Elena Pellicer adds another chapter to *TuftScope*'s continuing examination of soda taxes, writing on a form of a soda tax that will improve public health beyond just reducing soda consumption.

Finally, one editorial board member of *TuftScope*, Emily Clark, will be joining us in graduating from Tufts this May. Emily is off to DC to work as a policy communications intern at The Global Health Council in DC . As for us, Lauren-Elizabeth will be continuing her studies at Tufts in pursuit of a MPH, while Max will be joining the Department of Computer Science at Brown University to pursue his Ph.D. It has been a pleasure to serve *TuftScope* during our careers at Tufts, and we look forward to seeing what the future holds for *TuftScope*. However, none of our achievements over the past years would have been possible without the help of many individuals at Tufts. We would especially like to thank Professor Harry Bernheim for his invaluable advice and support, the TCU Treasury office for their commitment to *TuftScope*, the dedicated members of the *TuftScope* staff and, of course, the Tufts community, whose support makes *TuftScope* possible.

Sincerely,

Lauren-Elizabeth Palmer & Mark Leiserson

EDITORIAL

Are Radiation Levels in TSA Body Scanners Too High?

Lori Fingerhut

In March of 2010, the Transportation Security Administration began widespread employment of full body scanners in major airports. Currently used by some seventy-five to eighty national airports, the scanners provide added security because of their ability to detect both metallic and non-metallic items that may of threat, such as include weaponry and explosives. Since their inception, there has been much speculation about the safety of full body scanners because of the possible risks produced by the radiation used. While the TSA has stated that the scanners pose no threat to an individual's health, many doctors, scientists, and lawmakers are calling for further investigation to ensure that this is actually true.

Two forms of advanced imaging technology are utilized by the TSA: a millimeter wave unit and a backscatter unit. The millimeter wave unit uses electromagnetic waves to create an image while backscatter units use small doses of ionizing radiation. According to the TSA, the amount of energy from cell phone radio waves is more than a thousand times greater than the amount produced by the millimeter wave imaging units. Under even greater scrutiny, though, are the backscatter imaging units. Similar to the millimeter wave units, the TSA has maintained that the levels of radiation administered by the backscatter units are less than the amount of radiation a person would come across naturally. The amount of radiation an individual receives from a single backscatter scan is equal to radiation exposure from two minutes of flying on an airplane. Meanwhile, after scanner use became more extensive, it took little time for researchers to begin voicing concerns about the doses of radiation emitted by the scanners, especially relating to the possible increased risk for some of developing cancer.

David Brenner, director of Columbia University's Center for Radiological Research, explains that his biggest concern is not the dose of radiation emitted by these machines, but instead the number of people who will be exposed. According to Brenner, it is statistically probable that due to the large number of people who travel, some will develop cancer as a result of the radiation, especially children and those who fly often. While the risk to a single individual may be small, the risk to the population as a whole could be appreciable. Brenner further indicated that the most likely type of cancer to develop as a result of this radiation is skin cancer.

At the University of California, San Francisco experts have also voiced concerns about the radiation in full body scanners. Of particular concern to researchers at UCSF was the fact that the safety of the scanners had not been sufficiently shown, especially amongst high risk groups. These groups include children and frequent flyers (the same groups mentioned by Brenner), as well as immunocompromised individuals and the elderly.

Not all radiology specialists, however, share the same concerns over the safety of backscatter full body scanners. Professor of Radiology Mahadevappa Mahesh of Johns Hopkins University School of Medicine explains that the radiation of a single medical x-ray is equivalent to around one to two thousand scans from backscatter machines. Dr. Mahesh does advocate for the continual maintenance and testing of the scanners, however, to ensure that the radiation dose remains unsubstantial.

The TSA has recently fallen into mucky water regarding the maintenance and retesting of radiation levels in the backscatter scanners. At the beginning of this year, the TSA had yet to report any data on the state of their scanners. On March 11, 2011, the TSA stated that it would be retesting all airport backscatter body scanners. This comes after some reports indicated that the levels of radiation might have been as high as ten times the previously believed amount. The agreement to release results came only after lawmakers pressured the TSA into providing reports for the scanners. The TSA also has a history of negligent monitoring of their x-ray machines. A CDC report from 2008, for example, indicated that the amount of radiation used for luggage scanners was more the levels permitted.

While the levels of radiation emitted by backscatter full body scanners is supposed to be tiny, there is nothing that says the machine cannot malfunction and emit more than the desired amount. Lawmakers and scientists, alike, are concerned about the unresponsiveness of the TSA to their call for reports, and their irresponsibility in ensuring the continuous safety of their machines. The TSA indicates that the reports that came out (that indicated higher levels of radiation than expected) reflected math mistakes. As of April 15 2011, however, the TSA has yet to publish any further records of inspections of their scanners.

The debate continues among doctors, physicists, and lawmakers as to the safety of backscatter full body scanners. Some doctors believe that any added radiation correlates with an added risk of cancer, and thus the chance is not worth taking. Others, however, maintain that levels are small compared to natural radiation exposure. Meanwhile, everybody is still waiting for the TSA reports about the state of their machines, and thus official response to allegations of higher than expected radiation levels. Until then, if traveling, there is always the full body pat-down option.

References for this editorial can be found at

TuftScopeJournal.org

Lori Fingerhut is a staff writer for TuftScope

EDITORIAL

Cannabis and Psychosis

Ariel Lefland

People have used cannabis, or marijuana, for thousands of years. Now, cannabis is the most widely used of all illicit drugs. Subjective experience from use of the drug ranges from relaxation and mood alteration to hallucination, and paranoia. These reactions are caused by changes in the brain as a result of cannabis' active ingredient, delta-9-tetrahydrocannabinol (THC), acting on receptors in areas such as the substantia nigra, hippocampus, cerebella cortex and cerebral cortex. There are several known effects of cannabinoid use such as harmful addiction and respiratory disease. However, research is now being conducted to determine if cannabis is linked to another harmful disease—psychosis.

The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition defines psychosis as a disorder mostly characterized by delusions and hallucinations. A well-known form of psychosis is schizophrenia. The disorder, which literally means, "split mind" is a severe psychopathology characterized by emotional withdrawal, disturbances of thought, hallucinations and delusions. Approximately 1% to 2% of the United States population, or 2.2 million people, is estimated to suffer from the disorder. Geneticists have determined that schizophrenia has a genetic component; concordance rate between monozygotic twins is 48%. It is, therefore, important to understand the relationship between the use of cannabis and the occurrence of psychotic disorders such as schizophrenia.

"...suggested using cannabis as a teenager or young adult inreases the risk of psychosis."

Studies have clearly indicated a correlation between and the occurrence of psychosis and use of cannabis. Researchers, however, disagree on whether cannabis leads to the onset of psychosis or if psychotic symptoms precipitate cannabis use. Patients who self-medicate psychosis with cannabis provide one gray area for investigators. Furthermore, researchers are still unsure of whether "skunk" and other potent forms of the drug contribute to a higher risk for developing psychosis later in life. For studies that rely on self reported data, confounding variables come into play, clouding results. Thus, research to date remains somewhat inconsistent. Correlation does not show causation, warranting further study to determine the precise relationship between psychosis, especially schizophrenic-like behavior and symptoms, and the use of cannabinoid. This paper will review the current information on this relationship and the ways in which society is interpreting the implications of the scientific data. Although research has not yet produced definitive results, most studies thus far have shown increased risk for schizophrenia in cannabis users when compared with infrequent users or non-users of the drug, especially for individuals with a predisposition for the disorder.

A 2007 review study collected data from 4,804 longitudinal and population based studies. Investigators examined suicidal thoughts, anxiety, and affective disorders, such as depression, separately. Although results of the review suggested an increase risk of any psychotic disorder in individuals who used cannabis more frequently, there were less consistent findings. Non-causal explanations were not fully addressed. There was a substantial confounding effect for both psychotic and affective outcomes.[7]

A separate review study conducted by Denghardt and Hall aimed to look at vulnerable individuals' risk in particular. Through an examination of longitudinal studies with a population sample of adolescents and young adults, potential confounders such as other drug use, and personal characteristics were controlled. Biological plausibility was also examined. The results from six studies conducted in five different countries suggested more conclusive results. Researchers found that cannabis use predicts an increased risk of schizophrenia diagnosis or of reporting symptoms of psychosis. Additionally, results seemed to not be a result of cannabis use to self-medicate previously existing symptoms of psychosis. Increased risk was more likely to be a result of personal or family history of schizophrenia.

BBC recently commented on a December 2010 report that suggests using cannabis as a teenager or a young adult increases the risk of psychosis. Published in the British Medical Journal (BMJ), the ten year study was conducted in Germany and tracked 1,923 people from the general population who were between 14 and 24 years of age at the baseline. To determine the causal relationship between psychotic disorders and cannabinoid use, researchers performed a prospective population based cohort study. Investigators followed-up with participants at several points during the ten year time period, including 3.5 years after the start of study (T2) and 8.4 years after the baseline reports (T3). For participants with no lifetime psychotic symptoms and no reported lifetime use of cannabis at the baseline, incidence of cannabis use over the period from baseline to T2 increased the risk of developing psychotic symptoms later observed from T2 to T3. Results also suggest that continued use of cannabis can increase the risk of persistent psychotic symptoms over the period from T2 to T3. By impacting on the persistence of symptoms reminiscent of psychotic disorders, cannabis use may be a dangerous risk

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psychotic symptoms.[4]

An editorial by Wall and Denghardt published in the British Medical Journal in response to this study and other similar investigations found that research points to cannabis precipitating schizophrenia in vulnerable people because of personal or family history for the disorder. In a prospective double blind provocation study, researchers intravenously exposed participants to tetrahydrocannabinol. Researchers found cannabis triggers both the positive and negative symptoms of schizophrenia in a dose dependent manner in both healthy individuals and individuals diagnosed with schizophrenia. Another study found patients with schizophrenia who use cannabis have more psychotic symptoms.

Furthermore, participants classified as regular cannabis users increased their risk for developing schizophrenia by two or three fold. Hall and Denghardt also illustrated that 7 in every 1000 cannabis users are likely to develop symptoms. However, there is an increased risk for regular cannabis users (14 in 1000). A dramatic increase in risk exists for people with a family history of psychotic symptoms. It is estimated that 1 in every 10 individuals that fall under this category are likely to develop schizophrenia as a result of cannabis use.[5] Such alarming statistics show the importance of studies focused on determining the exact relationship between cannabis use and schizophrenia.

There are important implications that must be taken into consideration as a result of these studies. One possible way to battle this problem is to prevent adolescents from using the drug. A modeling study estimated that between 2,018 and 4,530 young people need provention from regularly using the drug in the United Kingdom to prevent any cases of schizophrenia. For those who use the drug less frequently, the estimate is four to five times greater; 10,000 to 23,000 individuals must be prevented from taking the drug. A second way in which people can take results of these studies and apply them is through education.

Adolescent use of cannabis is associated with poor education outcomes, increased use of other illicit drugs, increased risk of depression and poor social relationships in early adulthood. If young people and adolescents are educated on the risks of illicit drugs, especially cannabis, the prevalence of psychosis that is related to cannabis use may be decreased. It is questionable whether or not government policy and classification of cannabis has a positive effect on decreasing cannabis use.[4] It is interesting to note that about four years ago in July 2007, the British government considered reversing their policy on cannabis. Cannabis had been downgraded from a class B drug to a class C drug. "Weak" evidence on cannabis' causal relationship to psychosis convinced many that the government need not reverse the decision.[6]

Hall and Denghardt further explored the implications of scientific findings on the reuse of cannabis as a contributing cause of the onset of psychosis. They compared analyses of similar evidence for the harmful effects of other addictive substances such as alcohol, tobacoo, and amphetamine. Researchers concluded that evidence for the causal relationship between cannabis use and psychotic symptoms was as strong as evidence for heavy alcohol use and amphetamine use and psychosis in young adults. Researchers concluded similarly; cannabis use should be discouraged in adolescents and young adults. People must be informed of the potentially hazardous consequences of cannabis use. Caution must be used when considering more lenient legal policies.[7]

The effects of cannabis use on the development of psychosis later in life is an ongoing research subject. As the most widely used illicit drug, cannabis must be properly regulated to keep all individuals safe from its potentially harmful effects. Whether the risk is greater in young people or people predisposed to psychotic disorders, cannabis poses dangers to all who abuse it. Research that aims to find the exact causal relationship expressed by clearly established correlations are important steps in the process of properly regulating and using this drug, in addition to knowing the ways in which cannabinoids affect the structure and function of the brain. Psychotic disorders affect millions of people around the world. This research is not an issue that should be taken lightly. It is important that scientists and officials and administrators alike properly understand the biological bases behind the disorders that drugs such as cannabis may cause.

Parents Prefer Genetic Testing

By Mark Leiserson

A recent study has shown that parents are likely to have their kids genetically tested for adult diseases, providing evidence that parents generally believe the benefits of early genetic testing outweigh the costs.

Testing for common genetic diseases is becoming more and more mainstream as associations between genetic traits and disease continue to be found. However, this study only examined diseases with prevention strategies, as the utility of genetic testing non-preventable diseases continues to be questioned. In the study, parents were given the option of applying a genetic test to their children that could detect different preventable, early-onset adult diseases. Generally, the benefits of providing such a test to those with a genetic susceptibility to a disease with prevention strategies is the ability to take early preventative steps. The associated costs are "invasion of privacy and psychological discomfort".

Future studies will be required to determine the generalizability of these results, especially since the "offer of child genetic testing was hypothetical, and participants received incentives for completing online surveys". In addition, studies of children's attitudes towards genetic testing should also be conducted.

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ORIGINAL ARTICLE

Rethinking Soda Taxes

Elena Pellicer

Obesity is one of the most prevalent public health concerns facing the United States. According to the Center for Disease Control and Prevention's report, in 2007-2008 68% of American adults aged 20 and older were either overweight or obese.[7] Obesity directly increases the risk of developing diabetes, cardiovascular disease, stroke, some cancers, hypertension, and more.[7] In response, politicians and academicians have proposed food taxes in the form of either a "Fat Tax" or a "Soda Tax" as the most realistic means of battling this epidemic. So far, the debate has focused on the regressive nature and legality of these taxes. Less attention has been paid to how the revenue generated would be spent; I explore a strategy that uses this revenue to study a primary care model of obesity intervention.

The logic behind the study is as follows: a long-term solution for obesity necessitates a lifestyle change; lifestyle changes are most effective when independently arrived at by a patient and maintained by an educated support system; primary care medicine is appropriately structured for this type of care but lacks the time and resources to do so; it is the insurance driven fee-for-service system that undervalues primary care, pointing out that no data supports primary care as the most effective type of obesity intervention. Therefore, as an amendment to current Soda Tax proposals, I propose a revenue-spending package that funds a single-state pilot program to test the long-term efficacy of adequately funded primary care obesity interventions. My proposal is based on the economic theories of Arthur Pigou, whose approach to taxation is particularly applicable to the American obesity epidemic.

"...unlike many fattening foods, soda has little to no nutritional value to justify consumption."

EXISTING SODA TAXES AND THEIR INHERENT FLAWS

Dr. Kelly D. Brownell and New York Governor David Patterson are two of the best recognized proponents of food taxes. Brownell, a renowned obesity expert and director of the Rudd Center for Food Policy and Obesity at Yale University, proposed the first Fat Tax in the early 1980s. Brownell's proposal has since evolved into a Soda Tax, a more politically palatable option because unlike many fattening foods, soda has little to no nutritional value to justify consumption. Governor Patterson proposed a Soda Tax in 2008 as part of a statewide proposal aimed at preventing obesity. Though rejected by legislature, Patterson continues to adapt the proposal and advocate its implementation.

Both Dr. Brownell's and Governor Patterson's proposals lack specificity in regard to revenue spending. In 2009, Brownell and colleague Dr. Frieden published an article in the *New England Journal of Medicine* calling for "a penny-per-ounce excise tax on sugared beverages".[3] Citing results from previous studies, they predict their tax would reduce consumption by 10%, ultimately "reduc[ing] the risk of heart disease and other conditions".[3] However, Brownell's proposal only briefly mentions the "considerable revenue"[3], discussing it in light of the current economic downturn.

Governor Patterson's proposal for a Soda Tax is nearly identical to Dr. Brownell's, and equally vague. Initially he declared that the revenue would fund obesity prevention programs in New York State. However, according to The Lancet, "officials confirm that the projected $14 billion budget shortfall this year…presented a new opening for this type of tax" [11], implying Patterson intentions to redirect the revenue towards deficit reduction. This new direction lacks both specificity and any mention of obesity prevention.

The effects of both versions of this tax depend solely on the punitive value of the tax without considering more intensive interventions. This could have political implications, as Dr. Brownell's own poll of New York residents "found that 52% supported a soda tax, but the number rose to 72% when respondents were told that the revenue would be used for obesity prevention".[3] Unfortunately, Patterson's revenue redirection ignores these numbers and even with this information, Brownell too failed to incorporate the revenue into any specific plans to prevent obesity. Both of these proposals fail to demonstrate obesity related spending of taxpayer's money, threatening the longevity, and thus effectiveness of the taxes.

PIGOU'S ECONOMIC THEORY

A better approach would adhere to the principals set forth by renowned 20th century economist Arthur Pigou. Pigou defined economic externalities as costs or benefits that affect even those who do not partake in the original action.[1] Externalities can be divided into positive externalities that benefit the greater population, and negative ones that harm the greater population.[1] He used smoking as an initial illustration

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to both compensate for and prevent the negative effect.[1] The reasoning being that the preventative efforts from the revenue would compensate for the broad negative effect on society, adding to the individual punitive effect of the tax alone. Addressing the societal effect results in a more just tax because, in the case of obesity, the not-obese would equally benefit from improved health care and decreased insurance premiums. The American excise tax on tobacco is an excellent example of a Pigovian success. Tobacco tax revenues are largely devoted to anti-smoking education campaigns. These campaigns have added to the economic disincentive to individual smokers and resulted in a 21.4% decrease in smoking prevalence over the last 44 years. [12, 13]

Through a Pigovian lens, it becomes clear that the "cost" of obesity affects society as a whole, whether by decreasing national productivity or increasing healthcare costs paid through taxation or higher insurance premiums. This "cost" is applied regardless of weight, health or consumerist choices, making it a perfect negative externality. A Soda Tax would help correct this discrepancy, charging only those who continue the unhealthy behavior. However, to create a true Pigovian tax, the revenue needs to compensate for the broader social "cost" by improving treatment and, as a result, contributing to the long-term prevention of obesity.

THE CATCH-22 IN CURRENT OBESITY CARE

Obesity is a behavior-based disease that requires long-term efforts to improve unhealthy lifestyles. Lifestyle change is extremely difficult to achieve and even quick fix solutions like diet pills or surgery are often unsustainable when not accompanied by a lifestyle change. Primary care medicine is the field most often associated with long-term, preventative intervention. Dr. Kelvie Johnson, a pediatrician from Olympia, WA, points out that lifestyle changes are far more successful if the patient "decides to change instead of having the change imposed on them".[8] However, guiding a patient to this sort of realization can be a lengthy process and requires time that is not readily available to Primary Care Physicians (PCPs).

Currently, the national average for primary care visits is between 12.8 and 16.5 minutes per patient.[9] Many obesity cases demand extra time in order to develop a relationship with patients, earn their trust, and help guide them towards the realization that a lifestyle change needs to occur. There is also the factor of co-morbidities, other diseases that commonly accompany obesity and can take up a substantial portion of a visit, leaving little time for the equally important counseling on how to improve the root problem of obesity.

The current fee-for-service system that America uses to pay physicians significantly undervalues primary care, as has been noted in numerous journal articles including the New England Journal of Medicine [14], Journal of General Internal Medicine [2], and New York Times.[4] By not paying Primary Care Providers (PCPs) adequately for hours spent on weight related visits, insurance companies limit the time PCPs devote to patients and create a disincentive to providing preventative medicine, especially for complex, weight-related cases. In their defense, many insurance companies argue that they will not fund this type of obesity care until PCPs can demonstrate a more statistically significant effect on obesity reduction. Looking at it from an insurer's perspective, this is a valid concern. While there have been promising studies and pilots that demonstrate the effectiveness of PCP intervention [5,10], none have looked at a representative sample of the American population or subsidized primary care to enhance treatment options. To date, there is no data to support primary care as the most effective means for treating obesity. The appropriate roles for therapeutic counseling directed by PCPs, pharmacologic therapies, and at the extreme, surgical interventions in obesity treatment and prevention still remain in question and need to be clarified before obesity policy can be most effectively implemented.

To break the Catch-22 cycle of inaction due to lack of knowledge, I propose spending the revenue from a Soda Tax to determine whether or not primary care directed treatment is, in fact, more efficacious than its alternatives in long-term obesity reduction. While the initiative for this type of study could be taken by any state, let us consider a state like New York where potential revenue has already been calculated: "A penny-per-ounce excise tax would raise an estimated $1.2 billion in New York State".[3] My proposed pilot would subsidize primary care obesity interventions in New York and track patient progress to ultimately evaluate the program's efficacy. By both treating patients as well as working towards a clearer understanding of the most effective obesity intervention, this pilot would better satisfy Pigovian criteria.

THE PILOT PROGRAM

I propose that this program incorporate ideas put forth by Dr. Kelvie Johnson as a representation of PCP services that are currently limited by the fee-for-service based funding. Dr. Johnson identified "integrated physical activity and nutrition education programs for the whole family; motivational health coaches; and more frequent and longer visits with these patients" [8] as the most important resources for effective primary care intervention in weight loss. I found additional support for these types of methods in a pilot program for childhood obesity that successfully used "group education with peers" and a "patient empowerment readiness model," to lower children's BMI.[10]

Physical activity and nutrition education programs that include whole families provide vital health knowledge while simultaneously developing an internal support system, improving the likelihood that a weight-loss program will be adhered to in the long-term. Even for healthy children, these programs hold an important preventative value that if started with younger generations are more likely to evolve into social norms.

Motivational health coaches allow for more constant tracking of a patient's progress and encouraging input from an outside source. Johnson remarked, "from a primary care standpoint, if we had health coaches that could work with motivational interviewing and help people stay on track that

“ The obese and overweight population in America cost us over $200 billion in anual healthcare spending.”

could be huge”.[8] Coaches utilize a technique known as “motivational interviewing” that leads patients to discover their own drive through tactical interviewing techniques, a vital component of achieving the important lifestyle change. With this funding, coaches could be integrated into a primary care practice’s staff and become part of the standard of care for obesity.

Finally, the request for frequent and longer visits would enable PCPs to spend more time on the therapeutic counseling side of obesity care while still having time to address the more clinical aspects and co-morbidities. Lengthier visits enable both acute treatment and long-term prevention, both of which are key in reducing obesity’s overall effect on Americans.

CONSIDERING THE STAKEHOLDERS

The obese and overweight populations in America cost us over $200 billion in annual healthcare spending.[6] We need to move forward establishing the best practices for treatment and prevention of obesity while also considering the most effective applications of taxation to achieve these goals. The proposal I have put forth presents a pilot program that would produce revenue, treat patients, and help clarify questions on best practice. I believe that this approach will result in the best outcomes for the most people: doctors being appropriately paid and valued for their contributions, patients receiving the necessary interventional care to make lasting changes, taxpayers feeling less cheated by the system, a healthcare system less strained by rapidly increasing diseases rates, and ultimately a healthier and more sustainable society.

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Soda Taxes: A Recurring Theme

TuftScope has explored the issues concerning a proposed soda tax in the past. For more information check out the Oppossing Viewpoints article from the Fall 2009 edition of TuftScope. In this article, Lauren-Elizabeth Palmer and Jeremy Nowak debate the question, “Should sugar in beverages be taxed to improve public health?”

OPPOSING VIEWPOINTS

Should doctors refuse treatment to unvaccinated children?

***Virginia Saurman** argues that doctors should have the right to refuse treatment to unvaccinated children, as they put vaccinated children at risk. **Eriene-Heidi Sidhom** counters that ultimately parents have the right to care for their child's health as they see fit.*

YES

Doctors should have the right to refuse to treat children whose parents refuse to get them vaccinated. There are those who believe that some vaccines cause more harm than good, such as that the MMR (measles, mumps, rubella) vaccine is responsible for autism. This fear has no scientific support since British surgeon Andrew Wakefield's 1998 study in the Lancet journal was retracted in February 2010.[1] Based on a study of 12 patients, Wakefield claimed there was a link between the MMR vaccine and an autism-like disorder. An investigation into Wakefield's methods revealed fraud and conflicts of interest. The results of his study corresponded with plummeting MMR vaccination rates in the UK, and an increase in cases of measles causing 100 hospitalizations and 3 deaths.[2] Wakefield's license to practice medicine in the UK has since been revoked. Unfortunately, the damage caused by this paper, the anti-vaccine movement's propaganda, and Jenny McCarthy's belief that her son's autism was caused by an MMR vaccine has only ensured that this fear remains alive.

The problem with this belief is that it not only endangers the unvaccinated child, it endangers other children who have yet to be vaccinated (because they are too young), those who cannot be vaccinated (because their immune systems are compromised), and those who have been vaccinated. Why is this so? A vaccine campaign is only effective if 95% of the population in a given area has

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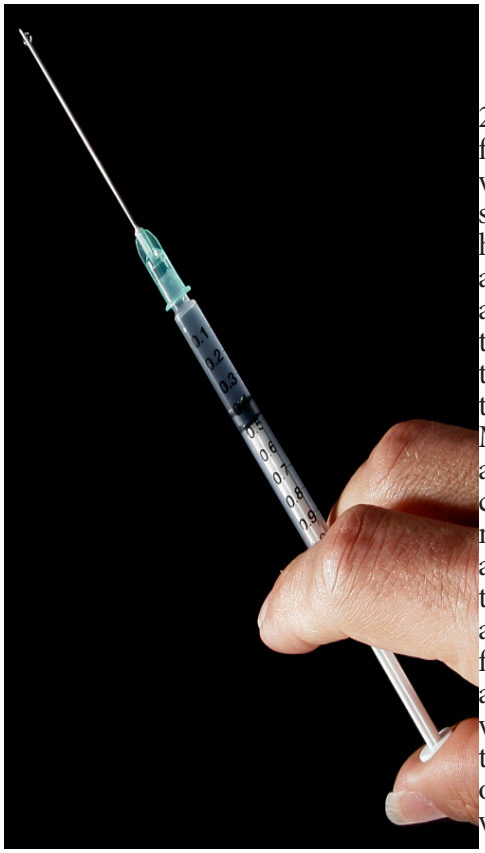

NO

Jennifer and Ronnie Prine are the parents of a 20-year-old son who has suffer a severe reaction to his DPT vaccine at 7 months old. Due to seizures that began 14 days after his vaccine he has regressed and now at 20-years-old he is at a six-month's level. Due to the family's negative experience they do not want to vaccinate their 11-year-old daughter.[1] Most states have laws which allow parents to exempt their children from vaccinations: a medical exemption is issued if an immunization could injure the child or a family member; a religious exemption is issued for members of religious sects against vaccinations, like Jehovah's Witnesses and Christian Scientists; a conscientious objection can be issued for a variety of reasons and allows parents to have more control over which vaccines are administered to their children.[2] Additionally, in 1990 the federal government established the Vaccine Adverse Event Reporting System (VAERS) to determine the risks of different vaccinations and the time between the vaccination and the appearance of symptoms. Recently, despite these state-approved exemptions, some pediatricians have decided to not treat unvaccinated children.[3] This decision on the part of physicians is taking away parents' fundamental rights while evidence for the associated risks still exists.

A physician's decision to refuse treatment to unvaccinated children puts well-meaning parents in an unfair position: while caring for their child's health, they are putting them at risk by preventing them from receiving

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YES

received the vaccine. Not every person who receives the vaccine is actually immunized against diseases like MMR. However, they are not infected because everyone around them has been immunized against the disease. Safety in numbers actually prevents epidemics from occurring. If the proportion of the population that has received a vaccine falls below 95%, there is a far greater chance that a disease can gain a foothold and sicken people. A disease like measles has been shown to have a 90% successful infection rate in patients who are unvaccinated.[1]

The anti-vaccination philosophy has more than individual consequences; it is a danger to public health to refuse to immunize children against diseases like MMR. The effects of these poorly informed decisions can be seen not only in the UK, but also in California where 40% of the schoolchildren in the Bay Area are not vaccinated. In 2010, the number of cases of pertussis increased to four times the prevalence in 2009. This disease is characterized by coughing attacks that cause the victim to gasp for breath when the fits end. When the vaccine was introduced in 1940, cases declined until the twenty-first century. As of 2010, there were 7297 reported or suspected cases of pertussis. Whether the high percentage of unvaccinated children is directly linked to this pertussis epidemic remains to be seen, but the situation is worrisome nonetheless.[1]

Parents who thus insist that their child remain unvaccinated are putting their children at risk, the children at their pediatrician's clinic at risk, and their child's classmates at risk. It is only logical that a pediatrician would want to limit his other patients from exposure to such risk. The American Academy of Pediatricians has previously considered it ethical for pediatricians to refuse to treat patients whose parents refused to get them vaccinated.[3] According to David Cronin, MD, of the Medical College of Wisconsin in Milwaukee, "it's entirely appropriate for a physician to refuse elective treatment to any patient.

NO

standard medical care. Supporters of state laws that allow for exemptions from vaccinations believe a parent should not be coerced into making medical decisions by their pediatrician.[2] Furthermore, by the Liberty Clause of the Fourteenth Amendment, parents have a fundamental right to the upbringing of their children.[4] However, when physicians refuse treatment they are effectively taking away the parents' choice in the health of their children which also makes the informed consent necessary to the medical procedure superfluous.[3] Even the informed consent which currently exists is limited because under the US National Vaccine Injury Compensation Act of 1986, physician and vaccine manufactures are not liable for any injuries or death that results from the vaccine.[5] Therefore, by physicians refusing treatment it is effectively taking away the parents' choice in their children's medical treatment which is both a violation of their fundamental rights as well as the standard legal procedure of informed consent.

Despite the fear that a lack of immunization will pose a threat to other children, those who don't receive immunizations are required to take further precautions. For example, students who claim exemption are not allowed to attend school in the event of an outbreak of a disease for which they are not vaccinated. Additionally, the exemptions can be suspended in an emergency.[6] Furthermore, the Centers for Disease Control survey states that in the states which allow for conscientious choice exemptions do not a higher rate for vaccine preventable diseases. Therefore, despite fears of a dangerous outbreak there is not definitive proof that mandatory vaccinations are essential for protecting public health.[4]. Although vaccinations are not necessarily mandatory, the influence of a physician may cause the parent to feel that their child needs to be vaccinated despite their own judgment. Therefore, parents who do not wish to have their children vaccinated should not feel obligated to do so, because precautions are taken and with these current precautions there is no evidence of increased risk to other children.

Finally, parents' fears for the risks that vaccinations pose are not unfounded. On average, VAERS receives 12,000 to 14,000 reports annually of hospitalizations, injuries and deaths due to vaccinations.[4] During the period from 1991 to 2001 reports of death ranged from 1.4% to 2.3% and life threatening illnesses ranged from 1.4% to 2.8%.[3] The National Childhood Vaccine Injury Compensation Program was established by the Federal government to reimburse parents whose children were permanently disabled due to a vaccination; as of 2007, it has paid over $1.5 billion in damages to families.[7] Furthermore, the lack of studies and scientific proof of the safety of vaccinations is also a cause of worry to parents. In fact, vaccination is the only medical procedure which does not require the industry-standard, double-blind, placebo-controlled safety studies.[5] The lack of scientific evidence for the safety of vaccines which contain well-known neurotoxins and carcinogens, as well as the living examples thousands of children annually

YES

Being a physician does not entirely obligate one to provide care to 'all comers'."[3]

So what can be done about people who for one reason or another refuse to get their children vaccinated? An effort must be made to further compel them to vaccinate their children. A pediatrician can attempt to educate skeptical parents on the necessity and safety of vaccinations, but only for so long. "By four months, if I can't help you come to terms with the scientific fact that vaccines are helpful, then I've done my job educating you," explains Andrew Lieber, MD, of Rose Pediatrics in Denver, CO (which has some of the lowest vaccination rates in the nation).[3] Every day these children go unvaccinated is another day they spend potentially risking themselves and others. There needs to be legal pressure to ensure children are vaccinated. Currently only two states have laws mandating that children attending public schools must be vaccinated in order to attend public schools, with no exceptions, and these are West Virginia and Mississippi.[1] The remaining 48 states should adopt similar laws to safeguard the health of their citizens. When there is no scientific evidence supporting anti-vaccination claims, personal belief must take a backseat to maintaining the health of the public.

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NO

who suffer from the damages of adverse reactions are legitimate reasons for parents to question the administration of vaccines. Accordingly, physicians should take the required informed consent more seriously and should not view it as a mere formality. Furthermore, a refusal to sign an informed consent should not be met with a refusal to treat.

As of 2001 the American Academy of Pediatrics reported that 23% of physicians stated they "always" or "sometimes" refuse to treat children unless they receive all the proper shots, and this number has only increased in recent years.[8] As more physicians refuse to treat children who have not received their immunizations, vaccinations will effectively become mandatory, removing the parents' fundamental rights and making informed consent a mere formality. Even if a legitimate risk is posed by a parent refusing to have their children vaccinated, according to Samuel Katz, MD of Duke University, refusing treatment is still unethical because the wrong party is being punished: it is the parent who is refusing; the child still deserves proper medical care.[8]

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Same Drug, Different Price

Laura Corlin

Recently, there has been much debate on issues involving women's health at the national level. Beyond debates in Congress over funding such initiatives as Planned Parenthood (which, incidentally, is not allowed to use federal dollars for abortion due to the Hyde Amendment),[1] other agencies have dealt with a range of issues including mental health, breast cancer, and reproductive health. Among these topics, an important recent announcement by the Food and Drug Administration (FDA) has caught the attention of many. For years a compunded drug has been used to prevent pre-term births in women. This drug was recently replaced by an FDA approved drug, Makena. Makena costs significantly more than the previous version of the same drug. Because pre-term births are most prevalent in women of lower socioeconomic standing, many physicians and healthcare advocates are up in arms about this problem.

The FDA released their position on the issue, stating that "FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality."[2] Essentially, this decision was meant to allow a cheaper version of a drug used to prevent pre-term births to continue to be sold, despite recent approval by the FDA of an essentially identical drug: Makena (hydroxyprogesterone caproate).

Both the cheaper version and the newly approved Makena version of the drug are used to prevent pre-term births. Pre-term babies , especially those who are born after less than seven months of gestation, are susceptible to a wide range of potential problems, since their organs are not fully developed at birth. Some of the risk factors for preterm births are multiples (twins, triplets, etc), mothers who smoke during pregnancy, have experienced chronic stress, or have folic acid deficiency during pregnancy.[3] The results of pre-term birth can be difficult as these infants not only tend to weigh less, they are also at risk for many serious conditions such as respiratory problems, physical abnormalities, and developmental and learning disabilities. Depending on how premature an infant is and what medical care is available, these infants are also at an increased risk of death within their first year of life.[4]

On February 3, 2011 the FDA approved Makena for the use by women who have already had at least one pre-term baby. For these women, Makena is seen to be a safe and effective drug in preventing pre-term birth. The decision to allow the sale of the cheaper version of Makena followed oon after this controversial FDA approval. Makena was given "seven years of exclusivity under the Orphan Drug Act" which

should have allowed it to be sold without marketing competition during this time.[5] Issues arose due to the exorbitant cost of Makena, priced at $150 per dose, from KV Pharmaceutical of St. Louis. The previously available compound drug had been priced at only $10-20 per dose.[3] The drug is administered as a weekly injection resulting in a price difference of hundreds of dollars per pregnancy.

The FDA responded to the outrage expressed over the unfairly cost-prohibitive nature of Makena. Opponents of this decision pointed out that the new price change would be especially problematic for the women most at risk of needing the drug, since pre-term babies are more likely to be born to mothers of low socioeconomic status.[3] Acknowledging the criticism and potentially harmful competition, Greg Divis, the CEO of KV Pharmaceutical stated that, "we reduced the list price of Makena by nearly 55%. We are providing additional discounts to Medicaid and health plans and have expanded our patient assistance program… Eighty-five percent of patients will pay $20 or less per injection. Those whose financial need is greatest won't pay anything at all."[7] While it has yet to be seen whether KV Pharaceutical will actually follow through with ensuring fair access to a potentially lifesaving drug, this rather unprecedented series of events brings up two larger and interrelated issues.

APPROVAL AND PATENT PROCESSES

The first issue is whether the FDA approval and the related patent processes should be modified to better account for off-label uses of drugs and potentially cheaper generic versions of needed drugs. Understanding this issue requires a brief discussion of the long development process of new drugs. It involves both pre-clinical laboratory trials and three phases of clinical trials. Pharmaceutical companies might initially investigate several thousand compounds and run preclinical trials on several hundred of these for each new drug eventually approved.

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phases differ from early phases, where the purpose is mainly to determine whether the drug works by expected pathway, to more advanced trials where the industry is examining side effects and safety at a population level. In total, from the early development of new drugs to their final approval, it typically takes 10-15 years and around $800 million.[8] Despite this lengthy process, the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) approves several new and generic drugs each day.[9] These new drugs continue to be evaluated with long-term studies.

Due to the time and costs expended in developing drugs, pharmaceutical companies seek patents and exclusivity whereby other manufactures cannot develop and market generic versions of the drug for a specified amount of time. Patents are valid for 20 years. This does include several of the development years so once the drug is on the market there may be a substantially shorter amount of time before generic drugs can be developed. Exclusivity rights for marketing vary from a few months to seven years.[10] These protections are in place to help encourage companies to invest in the development of drugs. Once the patent and exclusivity are lifted, generic equivalents can be developed and marketed in competition with the original drug. These generic drugs are much more easily and cheaply developed because their basic science and safety have already been established in the development of the trade name drug. Given the fact that less time and money go into the development of generic drugs, it makes sense that these should typically be much more affordable for consumers.

The drug that had previously been given to women to prevent pre-term births was a compounded or "off-label" drug and, therefore, did not have to go through the long process of FDA approval. Compounded drugs still require a prescription from a physician, but they are not approved by the FDA for the specific use for which they are prescribed and are not allowed to be marketed for their off-label use. Typically, these drugs are approved for other uses, in other dosages, or in different forms (such as pill compared to liquid). Sometimes the compounded drugs contain different inactive ingredients from generic or brand name versions of the drug but have the same active ingredients. Physicians retain their role as the "gate-keepers" of off-label drug use. Still, off-label prescribing happens frequently, particularly in some specialties such as oncology, pediatrics, and obstetrics. Additionally, these compounded drugs are typically covered differently by insurance companies than generic or brand name drugs, although this varies by insurance provider.[11]

While the case of the drug preventing pre-term births has seen quite positive outcomes as is typical with the use of off-label drugs, there is very little systematic research on this. Patient outcomes can vary and patients may be placed in dangerous circumstances if physicians prescribe compounded drugs that have unexpected actions. Professional ethical guidelines about off-label drugs suggest that providers only prescribe these drugs when there is enough evidence in the literature to suggest that the drug will have the intended effect and that it is in the best interests of the patient. Since 2007, the FDA has gained power and the ability to oversee the use of off-label drugs from post-approval studies, requiring public registration of industry studies of drugs, and restricting the use of drugs shown to have a negative effect on people.[12] The problem with this limited oversight mechanism is that it requires people to get sick or have adverse consequences from the off-label use before the drugs are more tightly regulated as opposed to proving the drugs are safe and effective for use first, as is done with typical medications. This tends to put an unfair burden of responsibility on the consumer rather than on the industry to report adverse symptoms of medicines.

UNFAIR BURDEN ON THE PATIENT

The idea of an unfair burden on the public underlies the second major issue brought up by the recent approval of Makena and the subsequent FDA decision to allow pharmacies to continue giving women the compound version of the drug. Preterm births are a clear example of the unfair and preventable aspects of health disparities. There is no reason that one racial group should be more affected than another by the problems associated with pre-term births. However, the data shows that while one in eight babies are born prematurely and are at risk for a range of physical and emotional problems in life,[13] African-American women are 1.6 times more likely to have premature babies than Caucasian women and 2.5 times as likely to have very premature babies compared to Caucasian women.

The cost of a pre-term birth, greater than the cost of a semester at Tufts, is also ten times more than the cost of a term birth.[14] This also represents a large cost to our society both in terms of lost potential of children who have to deal with physical and developmental disabilities and for the associated medical expenses.

While there remains a long way to go to reduce the health disparities associated with pre-natal care, it seems that both the FDA and pharmaceutical industries have taken important steps towards making safe, effective, and affordable medication available to women to prevent pre-term births. By making the series of controversial decisions that it did, the FDA made an implicit statement about the value of preventative care.

Our society places great value on down-stream care – in the development and administration of medicines for people once they become sick compared to trying to prevent people from becoming sick in the first place. However, this drug to prevent pre-term births falls somewhere in the middle since it is for women who have some risk factors but is designed to prevent a host of severe medical complications for the fetus. Hopefully, the acknowledgement by the FDA that this drug and its alternatives need to be available to women of all socioeconomic classes represents a shift towards placing greater value on equitable, preventative care.

References for this article may be found online at

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FEATURE INTERVIEW

A Discussion with Keith Flaherty, M.D., Practicing Oncologist and Director of Clinical Research Trials

David Gennert

Photo of Keith Flaherty, M.D.

Dr. Keith Flaherty, M.D. is an oncologist at Massachusetts General in Boston, MA, and is a leader in the development of a new wave of cancer treatment drugs known as targeted therapy. He has been involved in clinical trials for breakthrough cancer treatment drugs for nearly ten years and has published over 15 papers that investigate the molecular mechanics of cancer development and proliferation. The New York Times ran a six-part series from February 2010-January 2011 highlighting targeted therapies and Dr. Flaherty's involvement in their clinical trials and the treatment of patients.

As a brief background, can you give an overview of the history of clinical research trials during the past 50 years?

Basically, for the past ten years and a little bit before that, too, there has been this transition point in cancer drug development from an era which was the era that produced what we term "chemotherapy," the set of drugs– there are about 40 of them– that are in practice, used in practice to varying degrees, all of which have common features, and it took about from the '50s with the earliest chemotherapy-type drug, up until even the early '90s– the little last trickle of new chemotherapy type drugs. And while chemotherapy has a famous reputation for harming normal cells, the reality is that every chemotherapy drug that ever made it in the world are ones that had some margin, not a big margin, but some margin of killing cancer cells more than they kill normal cells.

There were drugs that were thought and/or hoped that were safe that in humans turned out not to be safe. People died as a consequence of receiving those drugs. That wasn't lots and lots of drugs and/or people, but still, it happened. One of the things is that it created much of the environment in which we do clinical trials and research now for new cancer therapies. A lot of rules and regulations– and by "rules" I mean, not laws but how the process goes in hopefully an ethically sound way, and then also regulations that are federal regulations that generally the FDA sets in motion– are just statements, mandates that we all must follow because the FDA doesn't just govern the approval of drugs, they govern the whole process of drug development.

The point is, that starting in the '70s, into the '80s, and particularly by the '90s, there began to be this increase and acceleration in terms of the molecular understanding of cancer. And it wasn't until the '90s that it first began to be conceived as a way of actually developing drugs and therapies that would actually counter cancer at the molecular level.

Your area of focus when it comes to drug development is the new system of "targeted therapy." Can you describe what that is?

So that all sets the stage for this whole generation of what's happening in cancer therapies and what will continue to happen forever, which is the elaboration of so-called targeted therapies–drugs that target a specific thing. Sometimes you're targeting a specific enzyme that's mutated, and overactive, or turned on by mutation. That's been one of the big successes of the past ten years– drugs that work in that way– and there's a handful of them now that are standard FDA-approved therapies. You can't find, for every cancer, a set of key enzymes you can easily make drugs for. There are some that we wish we could make drugs for, but we still can't. The technology just doesn't exist. That doesn't mean it won't, but there is a lot of work to be done. And also, there's no cancer that is just one mutation, there is a whole complex series of events, and we think, just like with HIV [drug research], that we're going to have to counter multiple things, and we're still just in chapter one of countering individual things right now.

We can develop so-called targeted therapies, and they work, but they only work for some period of time before resistance emerges. We would love to cure it, absolutely, and we have instances where it is being cured, even with some targeted therapies used in the right setting, but the first project is just to try to build what HIV [research] did, but recognizing that HIV is one disease, cancer is a larger number than that.

The drugs we use definitely have a bigger so-called therapeutic index now– they don't have the same effects of poisoning normal tissue. It doesn't have no side effects, but they're not conventional chemotherapy drugs with a rather

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narrow window. The risk that we kill someone with these types of therapies is vanishingly small.

We're moving increasingly, as more and more targeted therapies prove themselves to be useful and get approved, to become a standard element of cancer therapy, moving gradually away from this risk profile that's inherent in the disease.

To give readers an idea of the process of drug discovery, could you describe from your end, as director of clinical research trials, the process of working with a pharmaceutical company?

All that I said about the understanding of cancer and research development happened outside [private] companies. This is a public enterprise. It is publicly funded research that generates all the knowledge we're talking about. There is not a single cancer target that's been identified by a company. All targets are identified by publicly funded research. Target identification is, which is to say understanding the biology of cancer, an incredibly inefficient process.

So what companies do is they take things that have been nominated as targets, generally nominated multiple times, so it is becoming convincing that something really is a potentially important molecule to aim at, and then they will develop the drugs. How much credit they should get for that is a very viable question, in terms of how much money they should be able to make off this process or how much they should be justifiably able to charge for these drugs. They always argue that it's not the development of any given drug that they're trying to recoup the money on, but all the failed drugs that were developed in parallel.

Someone like me who takes care of patients, but got into oncology because I was interested in trying to close the gap in terms of unmet need, I do clinical trials because it is a means to that end. There is a variety of roles one can play in this process. You can be more active or more passive in the process in terms of how you deal with companies and engage companies. I am pretty active in the sense that I do a lot of work that is in the earliest phases of drug development, which is the most ethically charged. It's taking an established scientific concept created by a number of individuals, labs, and institutions, and part of what I do is follow that road and be connected with the scientific world well enough, following scientific literature and beyond that, to try to keep up with the moment in terms of what things are looking sufficiently solid that it really is something that could be a significant hope in terms of a new potential therapy. Then I will seek out companies that are developing drugs in that area. I will seek them out and try to convince them to work with me to do clinical trials from that early point of something entering human development for the first time. And then of course, if it's panning out over time, I want to stick with it, because then there are more and more questions to try to address in the context of the complexity of the cancer.

There are requirements and regulations about how you study safely and what animals species, how many of them, and how long, what doses are given. All of this is judged by the FDA before they give the green light to move into humans. I rely on that. If I'm meeting a company for the first time and getting to know the scientists and doctors who work in that area, I can't know that they think the way I do. I have my own sense of risk-rewards balance– reward being efficacy, risk being toxicity– and I can't trust that they inherently have that. The FDA is the referee of that. The companies show me their evidence and data, if I'm going to be putting anything in humans, so I very much rely on the FDA to make the call about if something is OK to move forward.

So working with companies is this building of mutual trust. Mutual in the sense that they have to trust when I get my hands on their drug, I will use it wisely and carefully and be a good and careful doctor. I won't be reckless and ignore someone who is having a serious problem that might be related to the drug and march on and ultimately have something terrible happen. They have that kind of issue about who they work with. There's this mutual dependency.

Has a pharmaceutical company ever approached you with a project to research or a clinical trial and you have just said "No," that you don't want any part of it?

Yeah, it happens all the time. I'm in the position where I'm pretty well known for this sort of early drug development piece particularly. So I get those offers all the time, where I have to say 'This just doesn't look good.' Sometimes the science is super, because it was produced by fantastic scientists and I know the data, and I know that this is an area to be interested in, but they come marching with their orders, which happens every week or two, and they'll come in the door with a drug that's meant to target that, and I'll look at their evidence, and I look at it and I say 'Thanks but no, thanks.' And they'll move on.

They're not going to give up just because I won't work with them. Can they always find somebody who will agree to participate in that trial and put that into humans? Pretty much. Worldwide? Absolutely. Even in the US, pretty much. It's created a recent ethical dilemma about the US and Europe, who are pretty much on the same standing in this regard, but Eastern Europe has become a known playground for drugs of concerning background, in terms of the level of evidence to take them forward.

You had mentioned earlier how there are some treatments that just extend a person's life maybe six months, a year, or so.

Right, we really don't know. We really never know from the individual how long they can extend their life, because we don't know how long they were supposed to live in the first place. And then we don't know for even a population of people. You can look at the results of a clinical trial that were done in thousands of people. You can say 'extended survival' with an average was four months. Some people will look at it and say 'extends survival by four months.' No, no it doesn't. In some people, it extends survival by zero. In some people, four months, in some people, 12 months, and in some people, they are still kicking four and five years later having had that

drug. But then you go into your clinic to offer that therapy that's now FDA-approved, and what do you tell someone in terms of what they're going to get, in terms of benefit? You can tell them the range; you can summarize the statistical distribution of outcomes.

There is a bell curve, people will live varying amounts of time. You can describe that bell curve in the absence of therapy, and now you can describe the bell curve for lung cancer treated with chemotherapy X and Y, or targeted therapy Z. Some people get no benefit, some people get modest benefit, some people get heroic benefit. That's not true for every therapy. There are some therapies where nobody gets heroic benefit. It's somewhere between zero and modest. It is this fundamental lack of understanding about statistics, describing distributions and the variability that is inherent in the world, in biology for sure, that people oftentimes get lost on.

People hear all the time about the "cure for cancer" being developed. But if these drugs, for example, extend a person's life one year on average, do you think the public needs to reevaluate what they're expecting from cancer research?

Sure. Yes is the bottom-line answer, but to go back to the problem with the distribution of outcomes, it turns out that Herceptin, which is a targeted therapy that was one of the earliest approved, extends survival by a range of times, but doesn't cure anybody in the metastatic breast cancer setting. So, in breast cancer, it can make a difference, but it doesn't cure people.

Understand, and this is where much of society focuses and I understand why, on metastatic full-blown cancer that's all over the place That's where people think about the issue and challenges of dealing with cancer in that situation. Remember, even metastatic testicular cancer can be cured– wiped out, even in the big-tumors-all-over-the-place situation– but there are others that can't be touched with available therapies. There are metastatic diseases you can't do a damned thing about with available therapies, so there is a spectrum, to be sure.

But the point is, that none of us, myself included, are interested in sitting back and waiting for cancer to show up in the full-blown metastatic state and then trying to wrestle with it then. We're interested in trying to cure it. That's the way cancer drug development works. It's a societal agreement. It's the whole operation. It's everybody involved– doctors, patients, their overseers. When I say 'society's agreement,' there are probably some people in Des Moines who aren't aware of what rules and regulations govern this process. Maybe more people need to be informed about it. We try to inform people, like patients, who walk in the door. I have yet to meet a patient who is savvy about this entire process we've been talking about So when someone walks in the door, and we're serving their options with them, and if there's this available option that's good and they have done that and it didn't work, and now they're out of those options, I have to explain to them what I just explained to you, this testing era for it because here's what's known or not know about it so far.

If you're focusing a trial on a drug that has been projected to extend life six months or a year, or that's what the estimate was, is your approach in the trial different than if it were a drug that was projected to be more efficient?

We can't project that. [Let's say] the drug's been in trials up to a certain point for melanoma, and we're getting the sense that people are living longer that we thought they would. By 'getting the sense,' I mean we haven't tested that yet, just this group of people received this drug, and [by calculating] their survival distribution, they seem to be doing better than the average. We could be getting lucky. We could just have happened to pick 30 people unintentionally who happened to live longer from their melonoma. Sometimes you have this sense that the projection is based on what you've observed. But you have a certain amount of confidence or non-confidence based on the number of people you treated, the characteristics of them in terms of how bad the disease was.

Then if you're going to try to test it, the issue is 'Are there are instances in which you need to test it or not test it?' Meaning that it looks so good, it looks so much better than available therapies, then you don't need to test that. The answer is yes. In the area of targeted therapy, the FDA has approved drugs on the basis of phase 2 trials, meaning non-randomized trials. B-RAF drugs likewise get that kind of treatment. Because it looks too much better. You can't do a phase 3, unless you believe at the outset that there is so-called equipoise, which is to say that you think the outcome is most likely the same between the two groups. You're randomizing them between treatment A and treatment B, and you can't do that if you know that treatment A is better than treatment B.

You can't know that one is going to be better and do that. That's not a problem. That's a problem solved. If the FDA doesn't agree, then you yell at them a bit. This came up with the B-RAF story, and it's been coming up. A new drug comes along, it's quite safe, we know that early on, and it's looking pretty damn effective. The drug just gets approved on the basis of phase two. It's happened multiple times. More often than not in the era of targeted therapy.

One of the things that the Times article didn't delve into is that this is quite a global issue. Would it be appropriate for a drug, a new kickstart, to get approved in the US and not anywhere else? Is that ethical? In a grand society way, to have privately approved drugs? Because we have different levels of proof needed here than elsewhere. Whether its ethical or not, it happens. It absolutely happens, that some drugs don't get approved elsewhere because the regulatory authorities in that place value a therapeutic index differently. They want more efficacy or less toxicity, or they want some bigger separation than what is available with a given therapy.

It was becoming clear in discussions between the company and the regulatory bodies– [in] the US and Europe and Australia – of 'What do we need to show? What evidence do you need to see?' in advance of doing it. Basically, the US had its answer, different European countries had their answers, and Australia had its own. And so they got different answers, which creates a situation of maybe you have to do a phase three randomized trial to satisfy some people or countries

and not others. Because I was centrally involved in the development of this drug, I got asked about this many times along the way, and my answer would be 'For what I need to know about a therapy, we're good. We know what we need to know. We don't need a randomized trial. This is a terrible disease, available therapies are terrible, and this is an advance, period. And, I think, I don't know, that the FDA would agree with that and it would become an available therapy for me and my patients here.' But I couldn't say, and as I was hearing feedback coming from other corners of the world, that that would be true elsewhere. Would I have a problem going to bed at night with the idea of endorsing a development plan that wouldn't get the drug the same chance of being made available because the trials weren't done? Yeah, I would have a problem with that. Why are Americans somehow more deserving than other people in other parts of the world? This gets complicated pretty quickly in terms of trying to come with a single way of judging [a new therapy].

We've been hearing a lot about end-of-life care and options lately. As an oncologist, I'm sure these scenarios arise all the time. What are your thoughts on what should be legal, encouraged, or even prohibited, as it relates to end-of-life care? How far do you feel ethically comfortable to go, in terms of leaving a morphine drip on or some other measure to all but kill a patient?

I go that far routinely Which is to say that my stance, and I think it's a common one, is to have no limit in terms of stopping suffering. By that, I mean if there is a symptom that I can improve, I improve it. Some people then say 'If someone's suffering, ending their life could be a way to stop that suffering.' I've never done that, and I can't envision doing that, but you absolutely can raise the issue that a morphine drip is somewhere in between that. It's good for pain, it's good for shortness of breath, and that if someone's got excruciating, terrible pain, and a little bit of morphine won't do the job, and a fair amount of morphine won't do the job, you keep going to try to get the pain to reasonable level. And in doing so, someone is now comatose. I would say that's OK, completely OK, because the alternative is that they be in excruciating pain, and I feel as though I would not be serving my purpose as a physician in my view if I let that state of affairs be.

Does that ever result in someone not living as long? We talked before about not knowing how long a [cancer patient] will live. Well we don't know that when people are actively dying, right then and there, meaning they will be dead in hours to days. Do I know that I shorten someone's lifespan by six hours? I don't know that. Might I have? Absolutely. Am I OK with that? Absolutely. The standard I have to serve is my own internal standard. There is no standard. There is no law about this. That is, that I will not hold myself back, I will not stop giving narcotics, I will not give less narcotics in the face of cancer pain because I would be concerned that it would shorten someone's life by a day or a few days.

I have discussions with patients about what my stance is, as it becomes reality. It's hard to have these conversations, to be honest. How much of this discussion can you and I get into now? But having a discussion with cancer patients who have a finite lifespan– which is to say a 95% likelihood that they're going to die of this cancer; maybe they will respond to therapy so well that they're cured, which happens 5% of the time– when do you have the discussion about how we are going to manage, as you get increments closer to, dying. This whole distribution of potential survival for that one individual sitting in front of you. I've done this, and those conversations have very little staying power for those patients. They will feel differently about things as they march eventually, at different paces, towards a confrontation with end of life. That's when it becomes quite real, when someone's sitting in the office having this conversation when they're feeling perfectly well and then when the circle of events comes around. None of us are that bright. This is not an entirely intellectual conversation; it's an emotional one, and it's a combination of the two. It starts hitting chords that don't get hit in life until one is in that situation. It comes up with cancer patients all the time. It's not so simple. It's a murky area.

Do you and you colleagues tend to engage in social media or other internet-based communication or collaboration?

Scientifically, yes. On topics of our understanding of disease and the like, yeah, it happens all the time. That comes up increasingly now, trying to come up with ways that aren't just emailing about individuals, but more systematically, [and it] has become a much more common way of communicating. There are other ways to create ongoing dialogue in various wikis, posting comments, but not in the blogging kind of way. And sometimes we have scientific collaborations or communications that are password protected on sites of that nature.

That has been multiplying from what I've seen, but in my own field and my national/international community of colleagues and those who I collaborate or communicate, it's become fairly standard practice. It used to be medical conferences where it would be in-person [dialogue], but those conferences would happen every so often, and you would have to travel there, and so this is a much more fluid way. It hasn't supplanted the conference world, partly because my children will have an easier time doing this, but for many of us, there's a different type of communication that happens face-to-face.

Compared to where we are now, in terms of the flow of information, I would say it's a totally different game. There's this acceleration in terms of how we evolve hypotheses, test them, then recycle and modulate our model of how we think about, in this case, melanoma. How do we subdivide the disease into meaningful, discreet, biologic entities in cancer? In cancer, you can make the statement that it's not all one beast. That's much of what my career is– getting lab-based investigators back and forth so that they understand what's happening or not happening in the clinical trial, and likewise so that I'm informed by what they're doing.

EDITORIAL

Childhood Obesity and the Built Environment

Brian Wolf

To eradicate childhood obesity, a conscious effort among citizens across America is needed to create programs and environments that will produce healthy alternatives for nutrition and physical activity. Currently, overweight children and adolescents are at risk for numerous adverse health outcomes that range from type 2 diabetes to high cholesterol, which are normally associated with adults. In addition, the relationship of the built environment (e.g., man-made physical structures and infrastructure of communities) to childhood obesity has grown exponentially. Careful structuring of built environments, such schools and homes, is necessary to prevent childhood obesity. However, these built environments need to be supported by policies and programs that promote and effect beneficial changes.

Various studies have been conducted in California on the relationship between the built environment and childhood obesity. A large proportion of California children live in low-income, multiethnic, inner-city neighborhoods; reports have concluded that these children are at particularly high risk for obesity. Inner-city residents are forced to depend on convenience stores that tend to have a smaller selection of healthful foods. The increased availability and affordability of energy-dense foods, such as fast food and sugar-sweetened beverages, particularly in low-income neighborhoods has led to the increasing rates of obesity among children. Due to urban sprawl and poor community design, biking and walking in some communities is sometimes impossible, which eventually leads to a decrease in levels of physical activity.

A report was recently conducted on the community-level risk associated with childhood obesity in East Los Angeles, a community with one of the highest rates of childhood obesity in Los Angeles.[1] This report took into consideration the number and location of food establishments near schools, the availability and quality of fresh produce in local grocery stores and the quality and utilization of local parks. Although the parks in East Los Angeles were found to be welcoming and aesthetically pleasing, parks and other recreational facilities were few in number, small in size, and located on the outskirts of the neighborhood. Consequently, these recreational environments are inaccessible without transportation. These findings again highlight the demand for thoughtful community design to guarantee that communities provide safe parks for recreational activities through safe crosswalks, walking paths, and bike paths. In East Los Angeles, there were 62 grocery stores and "only 18% sold fresh fruits and/or vegetables of good quality."[1] Also, only four of the grocery stores that sold fruits and vegetables were within walking distance of a school. These findings recommend the need to increase the accessibility of healthy foods near schools. Public health educational campaigns and home and school interventions are needed to promote healthier life choices. An increase in active surveillance (community-based research) is needed for research that addresses problems of obesity and is encouraged in future research.

The availability of parks and recreational resources are necessary to decrease the levels of childhood obesity. The results from a report on this topic suggest that children with better accessibility to parks and recreational environments are less likely to acquire an increased BMI.2 Of the 12 Southern California cities studied, many children had a lack of access to local parks; more than half of the children had no parks within 500 meters of their homes. While many neighborhoods do not have the space to create new parks, investments in sidewalks and street trees that promote walking, jogging, biking, and informal play appear warranted. The creation of safe sidewalks and the planting of street trees partially substitute for new parklands by, hopefully, increasing physical activity and complementing additional recreational programming.

The ban of sugar-sweetened beverages (SSB) in the school environment appears to be a credible way of reducing the intake of unhealthy beverages. Since California's 2003 ban on SSB sales at public schools, the students in schools implementing a SSB ban consumed significantly less SSB than before the ban was implemented.3 While there has been no significant change in adolescent obesity prevalence, the substantial decline in both childhood obesity and adolescent sugar sweetened beverage consumption has the potential to lead to a decline in obesity prevalence among adolescents in future years.

A study on school nutrition policies offers more information on how to address childhood obesity in the school environment in Los Angeles middle schools.4 Through community-based participatory research, school and community officials are able to come together to institute obesity-related school policies. The collection of information took place when trained observers visited settings to collect data through active surveillance to help make more informed decisions on health promotion efforts. The layout of the cafeteria, food offerings, and conversations with teachers and students helped researchers better understand the school environment. Based on the observers' findings, some policies were not implemented, such as posting of nutritional information for cafeteria food and providing a variety of fruits and vegetables. The reasons for these two policies not being implemented included cafeteria understaffing and costs. Unfortunately, there are insufficient funds to implement all the necessary changes.

Through education and the opportunity to make healthy choices, it is hoped that people will make the right choices culminating in a healthy and productive lifestyle. Encouraging

individuals in a community to participate in healthy lifestyle choices is an important step in reducing childhood obesity. However, further reductions in childhood obesity can only be achieved if there is a continued and sustained effort of parents, teachers, legislators and children to make healthy lifestyle choices. In the home environment, parents need to be more aware of the influences they have on their children. In the school environment, education about healthy eating habits and proper physical activity practices needs to be promoted and strengthened in classrooms, cafeterias, and physical activity spaces. The public health community must continue to raise awareness to stop the shocking increase in childhood obesity. Without a concerted effort to implement these changes, today's obese children will be tomorrow's obese adults.

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Childhood Obesity: A Recurring Theme

For more information about childhood obesity check out the Fall 2010 edition of TuftScope. Read Mark Leiserson's interview with Mayor Curtatone of Somerville and Eriene-Heidi Sidhom's evaluation of Michelle Obama's "Let's Move" campaign. Or check out the Winter 2011 edition and see Awesta Yaqubi's original article, "Childhood Obesity in the U.S."

FDA Approves Non-Surgical Aneurism Treatment

By David Gennert

The FDA has given "Premarket Approval" to the Pipeline Embolism Device, manufactured by ev3 of Menlo Park, California, for the treatment of brain aneurisms without the necessity of open surgery. Aneurisms are bulges that develop in blood vessels due to blood pressure pushing against a weakened portion of a vessel. Aneurisms in the brain are particularly common, with one of the more frequent locations being at the base of the brain in the internal carotid artery, which is the one of the main blood suppliers of the brain. If left untreated, aneurism can bulge enough to impinge upon surrounding brain tissue, causing neurological symptoms, or they can rupture, causing a life-threatening hemorrhage.

The device is a metal mesh tube that is inserted through a blood vessel in a patient's leg into the carotid artery near the site of the aneurism. Once in place, the device is expanded against the neck of the aneurism, which limits blood flow to the aneurism. This lack of blood flow causes blood left in the aneurism to clot and the aneurism to shrink over time, both of which help reduce the risk of a ruptured aneurism. Past methods of treating brain aneurisms mostly included surgical procedures, which had the potential of causing serious complications, such as damaging surrounding brain tissue, disease recurrence, and stroke. According to the clinical studies, 70% of aneurisms treated remained blocked by the device without significant narrowing of the artery at that location after one year following the insertion procedure. The device has been approved in Europe and has been on the market outside the US since July of 2009. According to the parent company of ev3, Covidien, it will become available at existing clinical sites in the US shortly.

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EDITORIAL

Understanding the Potential Health Hazards from the Nuclear Disaster at Fukushima

Mark Leiserson

By now, Fukushima Daiichi, the name of the Japanese nuclear power plant struck by a tsunami on March 11th of this year, is as notorious as Three Mile Island and Chernobyl, the sites of the world's previous worst nuclear disasters. However, despite the quarter century since the Chernobyl accident that exposed 34 million people to nuclear fallout[1], public knowledge of the dangers of radiation exposure from nuclear fallout continues to be relatively sparse. What is more, even nuclear experts are unclear about the long-term effects of accumulated radiation[2]. While the situation on the ground at Fukushima is still in flux, meaning the types and extent of radiation leaks could still change, this essay will examine the potential health hazards of the malfunctioning Fukushima nuclear plant. First, I will present an overview of the types of radiation that can be released from nuclear fallout and their subsequent risks. Then, I will explain what are currently thought to be the most likely risks specifically from Fukushima.

Fallout from a nuclear power plant such as Fukushima produces four main types of radioactive elements. The first is radioactive iodine. Radioactive iodine has a half-life of only 8 days–meaning that half of the radioactive iodine loses its radioactivity every 8 days. Consequently, the radioactive substance degrades to its non-radioactive form within a few months[3]. The other three elements, cesium-137, strontium, and plutonium-238, have half-lives of around 30, 29, and 90 years, respectively[4]. As a result, an area that is contaminated with any of these three radioactive elements can be expected to remain dangerous for hundreds or thousands of years, unless the elements are actively identified and removed.

Exposure to any of these products of nuclear fallout results in irradiation. The dangers of extended irradiation are extreme and well-known, though the consequences depend on the severity of the dose of radiation. For example, the current maximum radiation dosage allowed for emergency workers at Fukushima is 0.25 sieverts (to understand the scale of a sievert, the radiation from a CT scan is 0.01 sieverts). At three times that level, vomiting and hair loss is expected. At higher levels such as 3 sieverts, half of people who experience full-body exposure for a few hours will die within weeks[5]. Only people at a nuclear power plant at the time of a breach may encounter such sustained, high-levels of radiation. For most civilians, exposure is more likely to be piecemeal.

The dangers of accumulated exposure, or a number of small exposures over time, are much less well-known and understood. An increased risk for developing cancer is the main consequence, but because the prevalence of cancer is so high–around 40% of any group of people is likely to develop cancer at some point in their lifetimes [2]–it is difficult to measure the magnitude of the increase in risk. As a result, scientists still dispute whether accumulated radiation exposure follows a model where any increase in exposure corresponds with a proportional increase in cancer risk, or whether accumulated exposure increases the risk of cancer whenever it surpasses certain fixed thresholds. In the case of Chernobyl, where thousands were subject to multiple small doses of radiation over time, there simply has not been the rampant increase in cancer and mortality that scientists first feared after the nuclear meltdown.

"...it is unclear if there are more areas of high-concentration that have not yet been detected."

However, Chernobyl did provide nuclear safety experts with a different lesson: the largest increase in disease in those exposed to radiation from Chernobyl was a huge spike in the incidence of thyroid cancer[3]. The reasons for this spike have been researched and are now well-understood. The thyroid requires iodine, and is unable to differentiate between radioactive and normal iodine. Iodine is often taken into the body via food such as milk and vegetables, all of which were contaminated by radioactive iodine as a result of the Chernobyl meltdown. As a result, with excessive amounts of radioactive iodine being taken into the body via food, many individuals' thyroids began using radioactive iodine instead of normal iodine[3]. Over time, the thyroids' continued irradiation led to a huge increase in the incidence of thyroid cancer. However, scientists believe that the intake of radioactive iodine is preventable, both by avoiding foods that have possibly been contaminated by radiation, and also by taking potassium iodide pills, which flood the thyroid with normal iodine[3].

For Fukushima, the main risk to date has been radioactive iodine contamination. Since radioactive iodine degrades so rapidly, the main risk is of thyroid intake as explained above. Thankfully, both of the recommended steps for reducing the risk of radioactive iodine intake have been adopted at Fukushima. High concentrations of cesium-137 have been

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found in two spots up to 25 miles away from the reactors, but it is unclear if there are more areas of high-concentration that have not yet been detected[6].

However, it is important to note that, at this time, "environmental levels of radiation outside the 20-km evacuation zone around the power plant are currently far below levels that warrant concerns about human health"[2]. The main sources of radiation from the Fukushima plant have come from radioactive steam produced by efforts to keep the fuel rods cool, which prevents a large-scale meltdown as occurred at Chernobyl, and the release of radioactive water that did not directly reach the fuel rods. Most of the radiation released has been sent out to sea, by prevailing winds in the case of the steam and by intentional dumping by the Japanese authorities. As a result, in order to prevent the intake of radioactive material, fishing will come to a standstill in that area of Japan until radiation levels return to normal.

Consequently, the current situation at the Fukushima Daiichi power plant does not seem to pose any imminent health risks to those not involved in the cleanup. While cesium-137 and radioactive iodine have been released in the surrounding environment, precautions have been taken, including evacuation, distribution of potassium iodide pills, and a moratorium on the consumption of food-products in the area. Therefore, at this time, it seems that the preventative measures taken by the Japanese authorities will limit the public health problems from the damage to the Fukushima nuclear power plant.

References for this editorial can be found at

TuftScopeJournal.org

Cardiovascular Damage in Children

By Eriene-Heidi Sidhom

In a study conducted as part of the Project Health Schools in Michigan, children as young as 10 years of age were exhibiting symptoms of cardiovascular damage. In a first study, with 1,104 students, 16% of students had low HDL cholesterol levels and a second study with 1,276 students showed children with poor cardiovascular fitness. Additionally, these findings correlated with other risk factors: a low HDL cholesterol level correlated with higher BMI and at least two additional symptoms of metabolic syndrome (high LDL and triglycerides, elevated blood pressure or abdominal obesity).

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Americans under Medicaid Unable to Access Adequate Healthcare

By Alex Sakers

Under Obama's health care bill, Medicaid plays a vital part in providing health insurance, and thus access to healthcare for many uninsured Americans. Medicaid aims to reimburse doctors, dentists, hospitals, and other healthcare providers enough to ensure that its recipients have the same access to care as the general population. However, as payment rates have been cut in many states, many with Medicaid are finding it hard or impossible to find doctors and specialists to accept their insurance. For example, Kim Hardy, an OB-GYN in Lafayette, LA reported that Medicaid pays $1,000 for the same level of prenatal care that private insurance pays $2,400. The increasing disparity in reimbursement between Medicaid and private insurance has been driven by the need to control the Medicaid budget while accommodating the surge of people now insured under this program; it is expected that the number of people covered under Medicaid will surge from 56 million to 76 million in the next 10 years. Already, over 20 states have cut payments to healthcare providers by 15-20%. With each cut, it becomes harder for Medicaid enrollees to find specialists to provide the care they need. For example, Nicole Dardeau described her Medicaid card as "a useless piece of plastic" after being unable to find an orthopedic surgeon to treat three herniated disks in her neck that keep her from being able to work. Stories like hers are far too common; sadly Medicaid simply does not afford the same level of healthcare to its enrollees as private insurance.

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ORIGINAL ARTICLE

Pre-Exposure Prophylaxis (PrEP): Current Concerns and Future Considerations

Nicole Stenquist

The release of the first anti-retroviral (ARV) drugs in 1986 for the treatment of HIV-1 infection signaled an important point in the fight against the HIV/AIDS pandemic. More recently, mounting evidence has suggested that the use of ARV drugs as prophylactics could prove effective in preventing HIV infection in high-risk populations. Results from two recent studies, the iPrEx and CAPRISA trials, provided evidence for the effectiveness of pre-exposure prophylaxis (PrEP), although a number of questions and concerns remain that must be addressed before the scientific community considers PrEP as a preventative strategy at the population level.

INTRODUCTION

According to the Joint United Nations Program on HIV/AIDS (UNAIDS) 2010 HIV/AIDS Progress Report, an estimated 33.4 million people worldwide are infected with HIV; the current incidence rate stands at 2.5 million infections per year.[12] Although the advent of generic pharmaceutical companies in the beginning of the new millennium led to a significant decrease in ARV prices and an increase in access to treatment, 14.6 million infected individuals worldwide continue to live without antiretroviral treatment (ART) [12], exacerbating the disease burden through continuing transmission and premature morbidity/mortality of patients. Motivation to test the effectiveness of ARV drugs for PrEP in humans arose over a decade ago, stemming from data from several animal trials, as well as efficacy trials that tested ARVs for preventing mother to child transmission (PMTCT). Preliminary results from the iPrEx and CAPRISA studies are encouraging, although evidence from successive studies must be attained before PrEP will be recommended for use in clinical settings.[1] Issues in both adult and adolescent populations concerning drug safety, feasibility, acceptability, patient adherence, and resistance development must also be addressed adequately if PrEP is to become available for use in occupational settings as a biomedical prevention for HIV infection.[10]

The iPrEx Study

The iPrEx study, sponsored by the US National Institutes of Health (NIH), the Bill & Melinda Gates Foundation, and J. David Gladstone Institutes, looked to determine the safety and efficacy of once-daily oral co-formulated TDF/FTC (or Truvada) as an HIV prevention intervention in 2,499 men who have sex with men (MSM) and transgendered women who have sex with men.[1,3] Each participant was randomly assigned to one of two treatment arms, active or placebo. Participants received risk-reduction counseling, monthly HIV-tests, condoms, and treatment for simultaneously occurring sexually transmitted infections (STIs).[3,11] Participants who seroconverted during the course of the treatment discontinued treatment and were referred immediately to appropriate medical care.[11] Upon completion of the study, investigators reported a statistically significant 42% reduction rate in HIV seroconversions in the active drug arm compared to the placebo arm.[9]

CAPRISA 004

While evidence for the efficacy of oral ARV-based prevention has existed for over ten years, evidence of the effects of ARV microbicide gels on HIV transmission did not materialize until the release of the CAPRISA study results in July 2010. Considering the persistent economic, social, and political inequities among men and women in most developing countries, investigators recognized the need for a "woman-controlled substance" for HIV prevention.[4] A total of 889 HIV-negative, at-risk women in KwaZulu-Natal, South Africa were enrolled in the study to determine the effectiveness of a microbicide gel containing 1% Tenofovir (TDF) as a prevention strategy against HIV-infection.[4] Findings indicated a 54% protection rate in woman who applied the gel as prescribed, twelve hours before and after the coital act, 80% of the time [4]. The projected implication of this trial is that the use in South Africa alone could prevent 1,323,000 new HIV infections and 800,000 deaths over the course of the next 20 years [4]. Although results from both the iPrEx and CAPRISA studies are promising, they mark only a preliminary step in the emerging field of HIV/AIDS research. Furthermore, several recently published studies and reviews call attention to a set of questions, concerns, and gaps in research pertaining to both adult and adolescent populations that must be addressed systematically before the initiation of a global PrEP rollout can even be considered.[9]

RESULTS

Preparatory Behavioral & Safety Studies: Feasibility, Acceptability and Adherence

Recognizing that adherence patterns depend heavily on the mode of delivery and are influenced considerably by users' attitudes towards the product, investigators report a need for comprehensive studies looking at drug acceptability and feasibility patterns across MSM, heterosexuals, and adolescents populations.

According to the AIDS Vaccine Advocacy Coalition's "PrEP at CROI" review, there is a lack of data on social and behavioral trends in MSM, such as frequency of sexual activity and "consistent" condom use in these high-risk populations.

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Table 1. Summary of Prophylaxis Studies

Study	Methods	Primary Findings
Saftey and Side Effects		
First Safety Study of Daily Tenofovir for HIV Prevention Among MSM; the Centers for Disease Control and Prevention[8]	Phase II safety study enrolled 400 HIV-negative MSM in three cities across the US. Each participant to one of four study arms either immediately after enrollment or nine months following enrollment in order to contrast any risk behaviors between those receiving pills, whether placebo or active drug, and those not[8]	No significant adverse effects.[8] Besides reports of rare events with kidney function and bone mineral density (BMD) declination, study investigators reported minor side effects of nausea and loss of appetite.[8] Investigators also reported no significant evidence of increases in risk behaviors among participants in the active arm, although they noted the experimental setting in which the study was conducted. Participants received counseling throughout the study, something to which patients in a clinical setting receiving the drug may not necessarily have access.[8]
SubStudy of the First Safety Study of Daily Tenofovir for HIV Prevention Among MSM[9]	184 MSM randomly assigned to oral TDF or placebo	A small but statistically significant reduction in BMD in participants taking the active drug compared to those receiving the placebo was reported [9]. Investigators describe the need for further examination of this phenomenon before a final assessment of its implications can be provided. A sub-study of the VOICE trial, an ongoing study involving close to 2,000 heterosexual women in South Africa, also addresses the issue concerning BMD and will provide additional insight as to its significance upon the release of the study results.[9]
Preparatory and Behavioral Studies: Feasibility, Acceptability and Adherence		
MTN 001; Craig Hendrix (John's Hopkins University[9]	Enrolled 144 South African, Ugandan, and American women who had received PrEP in both gel and oral forms	Results showed a 93% pill adherence rate and an 83% gel adherence rate. In terms of preference, investigators found that while American women favored the oral form, African women showed no partiality, although they reported satisfaction from the "added sexual pleasure" from the gel microbicide.[9] Chief investigator Craig Hendrix reported gel concentrations in the vaginal tissues that were 100-times greater than oral concentrations in vaginal tissues. In addition, he observed that oral concentrations in the blood were 20-times greater than gel concentrations in the blood. Investigators also note the possibility for gel forms of PrEP to hold more "tolerance" for missed doses.[9]
ATN (Adolescents Medicine Trials Network for HIV/ADIS Interventions) 082 (ENROLLING)[10]	99 young American men between the ages 18-22 who have sex with men (YMSM) [10]. Each young man was administered either once-daily TDF/FTC, daily placebo, or no pill at all.	Upon study completion, investigators hope to identify any contrasting adherence patterns in the three study arms, as well as the presence of behavioral disinhibition or other observable behavioral trends. They expect to gain valuable information on both the acceptability and feasibility of oral TDF/FTC among this population, as well as potential aspects of "PrEP protocol" to be include in the future PrEP efficacy studies designs.[10]
MTN (Microbicide Trials Network) 004 (completed 2009, results pending)[10]	Looked at the safety, tolerability, and "systemic absorption" of 3% Viva gel in young, sexually active female participants.[10] Participants received either 3% wt/wt VivaGel, VivaGel placebo, or the hydroxyethyl cellulose placebo gel, all of which they applied vaginally twice a day for 14 straight days	
Microbicide Safety and Acceptability in Young Men (ONGOING)[10]	Examined acceptability and safety trends of a rectal microbicide in young, ethnic MSM [10]. This is an ongoing 2-stage longitudinal study with a clinical and behavioral evaluation, along with an acceptability and adherence trial. These are followed by a randomized control trial in which participants are receiving either an active microbicide or a placebo [10].	

Authors argue that this "knowledge gap" slows dramatically the development of "effective new prevention programmes," making it difficult to identify possible "PrEP users" for inclusion in future studies.[9] The review also draws attention to the grave need for programmes focused on reducing stigma. The authors noted the difficulty in estimating demand quantities for PrEP due to the sensitivity associated with conversations between health care providers and at-risk individuals concerning sexual history.[9]

The ongoing VOICE trial (MTN 003), a combined behavioral and efficacy study involving close to 2,000 participants, compares two topical PrEP interventions (TDF gel vs. placebo) to three oral groups (TDF, TDF/FTC, and placebo). Investigators hope that these results will not only support the findings from the CAPRISA study, but will provide significant insight on oral vs. topical preference patterns. These trends in adherence, drug concentration levels, and missed-dose tolerance will influence considerably PrEP delivery strategies.[5]

One review published in the 2010 edition of Journal of AIDS addresses the substantial importance of the development of preparatory behavioral studies focusing specifically on at-risk adolescent populations.[10] According to these authors, trials designed to collect data on feasibility, acceptability, and adherence trends of at-risks adolescents are truly lacking despite the degree to which they could affect future HIV transmission rates and the burden of the epidemic. The authors address the need for the development of behavioral trials using coitally independent vs. coitally dependent PrEP that look specifically for potential effects that this difference might have on adherence patterns.[10] Identifying coital independence and dependence will be essential in guaranteeing PrEP efficacy in adolescent populations because of the tendency for regimen neglect. The release of the results from both studies will provide necessary information for the designing of future adolescent-focused PrEP behavioral and efficacy trials.

Adherence to PrEP regimens among all at-risk populations will have a tremendous impact on the effectiveness of pre-exposure prophylactics and its overall contribution to reducing the burden of HIV. The ways by which individuals on treatment view the drug in terms of ease of administration, comfort or discomfort, efficiency, and status among family and community members will determine their observance patterns to the prescribed regimen. Therefore, distinguishing the feasibility and acceptability trends characteristic of each specific at-risk population of HIV negative individuals is essential. Experts must develop strategies that cater to the attitudes and opinions specific to each population in order to ensure maximum adherence rates. Extensive studies that examine these distinctive characteristics must be conducted.

Resistance Development

Although evidence from the iPrEx and CAPRISA studies suggests significant efficacy rates for preventative mono and co-formulated therapies, the development of drug-resistance remains a clinically important complication. Authors from several commentaries and reviews address this issue as it applies to PrEP, as well as the current debate regarding a simultaneous rollout of ART and PrEP in high-burden regions.

Authors of one commentary published in the Journal of AIDS in 2010 discuss one small study in which no signs of TDF resistance appeared in individuals who received two weeks of TDF monotherapy.[7] They note several recently designed mathematical models for predicting HIV resistance incidences that predict that less than 1% of expected seroconversions during TDF regimens would develop strains resistant to TDF.[7]

One review published after the release of the CAPRISA trial results calls attention to the role that dosing strategies play in the development of drug resistant strains of HIV. Questions regarding the effects of intermittent vs. daily dosing strategies on drug-resistance development remain unanswered. Although the designs of three ongoing studies, the IAVI E001, IAVI E002, and HPTN 067, address this issue by looking at the pharmacokinetics of intermittent oral therapies, authors note the need for the development of large-scale trials comparing drug-resistance incidences in both dosing strategies.[5]

At the recent Conference on Retrovirals and other Opportunistic Infections (CROI), one young researcher presented the results of her study. She and colleagues designed three mathematical models to identify potential effects of a simultaneous rollout of PrEP and ART.[9] The models, which looked at ART alone, PrEP alone, and ART with PrEP, calculated the number of new infections and resistance incidences in each scenario.[9] Results of the study showed that a joint rollout of ART and PrEP would have the biggest "prevention impact" out of all three scenarios.[9]

Strict adherence patterns, efficient drug regimens, and stringent prescription regulations remain important in averting the growth of drug-resistant strains.[7] Monotherapy TDF and co-formulated TDF/FTC are two of the most desirable ARVs for PrEP, mainly because of several pharmacodynamic properties of TDF, including its long half-life and ability to achieve high concentrations in genital tissues.[10] Because TDF is used as the predominant drug in antiretroviral treatment, experts fear the continued surfacing of drug-resistant strains with additional use of TDF for PrEP. [7,9] Exposing the virus to the same drug with such frequency presents ample opportunity to develop resistance. Therefore, experts need to continue to address the production of new ARVs and the development of clinical efficacy trials for these ARVs as a top priority, looking to stay ahead of the growth and transmission of drug-resistance strains of HIV. Frequent diagnostic testing in those receiving PrEP will monitor HIV resistance, ensuring that high-risk HIV-negative individuals involved in efficacy trials remain negative. Identifying seroconversions as early as possible will lessen the chances for the development and transmission of drug resistant strains.[7]

Treatment vs. Prevention

With recent reports of data demonstrating efficacy rates of PrEP, a lively debate regarding the relative importance of ART vs. PrEP has surfaced. Willard Cates, author of "After CAPRISA 004: time to re-evaluate the HIV lexicon," addresses

the "compartmentalized terminology" that has come to define the ART-PrEP discussion today.[5] Elly Katabira, President of the International AIDS Society, discusses the compelling need for the AIDS community to recognize "treatment" and "prevention" as one concerted effort.[6] In his presentation at CROI 2011, Bob Grant, chief investigator of the iPrEX study, stressed the significance of "messages" that portray PrEP as the "bridge to universal access to treatment".[9] All three experts maintain the stance that without this necessary cohesion between the two concepts, universal access will not be achieved, and the HIV burden will remain as it stands today. Several reports also highlight the need for an accurate cost-effectiveness assessment of the relative benefits of working towards large-scale PrEP implementation programs.[2]

Establishing a more "integrated" approach for discussing PrEP is a necessity if it is to become the primary method for fighting HIV transmission. As argued by Cates, existing terminology used to define PrEP leads to the compartmentalization of the prevention strategy based on modes of delivery with microbicides referring to topical delivery, and PrEP to oral.[5] This classification method leads to divided "scientific" discussions and meetings, resulting in further segregation between the terms. Both topical and oral PrEP methods work towards the same goal, and the integration of both terms with one another will be important in allowing the scientific community to continue to progress towards commercial release and use of the drugs.

ART generally results in what Mr. Katabira describes as "undetectable viral loads" in patients that maintain strict adherence to their prescribed regimens.[6] This depletion in viral load diminishes significantly the risk of HIV transmission during the coital act, and has the effect of serving as both a treatment and a prevention mechanism.[6] Katabira's take home message on the importance of the concept of ART as prevention correlates directly with Bob Grant's vision of PrEP as the bridge to universal access to ARVs. PrEP will ensure HIV-prevention in myriad populations of at-risk individuals while simultaneously reducing the number of individuals in need of ART, while ongoing ART will continue to deplete viral loads in even the most acute cases around the world, reducing the risk of transmission.[6] This scenario will not happen without universal dedication to the development and implementation of PrEP behavioral and efficacy trials. The creation of even a rudimentary cost-effectiveness model will allow experts to assess the potential economic benefits of a large-scale PrEP rollout. The investment in PrEP regimens for at-risk populations, particularly adolescents, could lead to fewer ART expenses to be paid in the future.[7]

CONCLUSIONS

The preliminary evidence on the potential effectiveness of chemoprophylaxis against HIV has brought the HIV/AIDS field one step further in its efforts against the HIV pandemic. Nonetheless, this new data has raised important questions and concerns relevant to the safety, efficacy, and rationale for using ARV drugs to prevent HIV transmission. The number of unanswered questions that have emerged and the diversity of at-risk groups to which they apply further complicates this issue. Understanding the attitudes and economic and social trends of the targeted populations will be critical in ensuring optimal adherence rates in all PrEP users, particularly adolescents. Biological, psychosocial, and cognitive aspects of each population must be considered, requiring the development of extensive pharmacokinetic drug profiles to ensure appropriate dosing and use in each at-risk population.[10] Monitoring and tracking closely all PrEP users will be crucial in preventing drug-resistant strains from developing. Avoiding drug resistant strains during the experimental phase is also critical in order to then implement large-scale PrEP use, as the development of HIV-resistant strains early on during efficacy trials will compromise drug effectiveness.

In order to continue to make significant progress in the field of ARV based prevention, experts must establish a more integrated approach to defining PrEP drugs and forms of delivery, as well as accept the position of PrEP as the link to universal access. Experts in the field must continue to communicate and collaborate as they work towards universal access through ART and PrEP delivery.

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ORIGINAL ARTICLE

Wombs for Rent: A Bioethical Analysis of Commercial Surrogacy in India

Neha D. Wadekar

The practice of commercial surrogacy in India has developed into a profitable industry that operates within the free market. The surrogate mothers are generally impoverished, uneducated women from Indian villages, who engage in surrogacy for a variety of reasons. Because of the few government regulations on the surrogacy industry, the interests of the intended parents, the surrogacy clinics, and the brokers and agencies tend to be served before the interests of the surrogates themselves. An analysis of the practice through the lens of medical ethics examines if commercial surrogacy in India violates the four prima facie principles of non-malfeasance, beneficence, autonomy, and justice. Upon this analysis, recommendations can be made as to how and if the commercial surrogacy in India should be changed or regulated in the future.

INTRODUCTION AND BACKGROUND

The practice of commercial surrogacy has grown into an international industry since 1978, when Drs. Robert Edwards and Patrick Steptoe facilitated the birth of Louisa Joy Brown, the first baby conceived through in vitro fertilization (IVF), in Oldham, England.[1] India has consistently been at the forefront of surrogacy technology during its 30-year existence, beginning with the birth of the world's second IVF baby, nicknamed Durga, in Kolkata, India just several months after Louisa Brown was born. Today, commercial surrogacy in India has become a profitable industry with an estimated value of $445 million per year.[2]

Surrogacy is a last resort for infertile couples trying to conceive a child who is genetically related to them. Infertility is widely defined as the inability for a couple to become pregnant after one year of unprotected intercourse, and it can affect both men and women.[3] Worldwide, an estimated 40.2-120.6 million women aged 20-44, living in a married or consensual relationship, are unable to conceive after one year of trying. Of these women, only 12-90.4 million are likely to seek medical help.[4] The highest rates of infertility are reported in developing countries, due to untreated pelvic infections, sexually transmitted infections (STIs), hormonal imbalances, and traumatic complications with past childbirths.[5] Until the recent advent of artificial reproductive technologies (ARTs), the only available option for an infertile couple to have children was to adopt them.[6]

As both medicine and technology advanced throughout the 1980s and 1990s, various ARTs were invented to help couples identify and correct, or circumvent, the source of their infertility. Women's treatments included hormone injections and intrauterine insemination (IUI), while men could depend on artificial insemination (AI) and intracytoplasmic sperm injections (ICSI).

There are several different types of surrogacy. Traditional surrogacy utilizes an embryo conceived via IVF that is implanted back into the female within the intended couple. This article focuses on gestational surrogacy, the kind that is practiced in India for profit. Gestational surrogacy is the most expensive and invasive infertility treatment, and is generally viewed as a final effort for infertile couples.[7] In gestational surrogacy, the embryo is conceived through in vitro fertilization (IVF), generally using the egg and sperm from a prospective couple, although donor eggs and sperm may also be used. The success rates of IVF vary greatly depending on factors such as age, cause of infertility, and weight. For example, in 2006, the U.S. had average IVF success rates of 39% in women under age thirty-five, 30% in women age thirty-five to thirty-seven, 21% in women age thirty-seven to forty, and 11% in women forty-one to forty-two.[8] If the IVF is successful, the egg is fertilized, and the resulting embryo is implanted into the womb of the surrogate mother, who carries the child to term and delivers on behalf of the intended parents. Commercial surrogacy, as opposed to altruistic surrogacy, occurs when the surrogate mother is compensated for her efforts, usually according to the guidelines of a previously decided agreement. [9]

Opinions concerning ARTs vary greatly between countries around the world. Gestational surrogacy ignites a particularly heated debate. Many countries, Australia, China, the Czech Republic, Denmark, France, Germany, Italy, Mexico, Spain, Switzerland, Taiwan, and Turkey, for example, have entirely banned surrogacy. In 1991, France defended its position by declaring, "the human body is not lent out, is not rented out, and is not sold."[10] Other countries such as Belgium, Finland, Guatemala, Greece, the Ukraine, and India have minimal regulations regarding surrogacy. In the United States, the legality of the practice varies by state. In India, the surrogacy industry exists in a liberal market economy, where private agencies run and manage the practice with little government interference.[11]

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THE REALITY OF COMMERCIAL SURROGACY IN INDIA

Commercial surrogacy in India is part of a larger trend known as medical tourism, in which foreigners travel to India to receive different types of medical treatments, primarily cardiac care, joint replacement, or cosmetic surgery, for relatively low prices.[12] Commercial surrogacy has specifically been renamed reproductive outsourcing. India attracts crowds of medical tourists due to its English-speaking medical staff, its technologically advanced medical care, and its low costs, The few regulations and little government interference in the industry makes India a more hassle-free location for infertile couples seeking commercial surrogates than developed nations like England or the United States.

India legalized commercial surrogacy in 2002.[13] Currently, the Indian government has no official, enforceable laws to monitor or regulate the industry. In 2005, the Indian Council for Medical Research (ICMR) formulated guidelines for the surrogacy industry, but these suggestions focus on ensuring that the surrogacy process does not "tax the [intended] couple's endurance physically, emotionally, or economically."[14] Specific sections of the document are dedicated to ensuring the protection of the unused embryos, the children born of surrogacy, and the intended parents, but there is no such section for protection of the surrogate mothers. The regulations provide no means of enforcement. Because the surrogacy industry in India remains laxly regulated and decentralized, few files and no central registry exist to document the various outcomes of the procedures, the names and nationalities of the intended parents, or information about the surrogates. This poses a challenge in attempting to regulate commercial surrogacy, since estimated numbers and projections about the industry vary greatly.[15]

The dawn of the surrogacy industry in India is widely attributed to the work of one woman, Dr. Nanya Patel. In 2003, Dr. Patel orchestrated the surrogacy of a woman from Anand, Gujarat, a rural dairy community with a population of approximately 150,000 citizens. The woman wanted to serve as a surrogate mother for her infertile daughter who was living in the United Kingdom. With Dr. Patel's help, the woman gave birth to her own grandchild as a gestational surrogate, and this event fueled a media frenzy. Dr. Patel was inundated with requests for surrogacy, and she decided to create a business. Dr. Patel currently runs the Akanksha Infertility Clinic in Anand, where forty-five local women serve as surrogates in rotation. At any given time, between twenty and thirty surrogate women are pregnant.[16]

The Akanksha Clinic serves as a typical example of the many surrogacy clinics in India. The clinic physicians, nurses, and brokers actively recruit women from the neighboring villages to serve as surrogates. The clinics generally follow a set of informal rules when selecting a surrogate: the woman should not be older than forty, should be medically fit with a healthy uterus, should be married with at least one child, and must have her husband's consent. In reality, the majority of surrogates are poor, with a median family income of approximately 2,500 rupees (sixty dollars) per month.[17] While a few surrogates completed high school, most never graduated from middle school, and some illiterate surrogates can only sign their consent forms with a thumbprint. The women work a variety of jobs ranging from housewives to farmers and tailors. Their husbands tend to be contract workers, farmers, or unemployed.[18]

The success of India's thriving commercial surrogacy industry stands in stark contrast to the standard of healthcare that these surrogate women are accustomed to. The rural poor in India have fewer than four doctors for every 10,000 people. According to the 2005 Reproductive and Child Health Facility Survey, fewer than half of India's primary health centers have a labor room or a laboratory, less than one-third stock essential drugs, and only one-fifth have a telephone connection. The growth of private health care in India has fueled the migration of skilled healthcare workers to urban centers or abroad, leaving the rural poor with few or no quality healthcare options.[19]

To ensure the safety of the fetus in the surrogate's womb, many clinics require that the women spend the duration of their pregnancy living in a surrogacy hostel. Reporters and researchers are rarely allowed access to the clinics or the surrogates, so gathering information about the surrogates' lives and attitudes has been difficult. Generally, the hostel rooms have eight to ten single beds fit into a small space. The women have little to occupy their time, as they cannot climb stairs or use the elevators without the nurses present. Their husbands are allowed to visit, but are forbidden to stay the night to ensure that the surrogates do not have any sexual relations during the pregnancy. Some clinics offer the surrogates activities to pass the time, such as English and computer lessons to help make the women better candidates for surrogacy again in the future by improving their communication skills.[20] The nurses monitor every moment of the surrogates' daily lives for nine months, so the clinic directors can assure their clientele that their women are, as Dr. Patel explains, "free of vices like alcohol, smoking, and drugs."[21]

In the United States, surrogacy costs approximately $80,000, including medical costs and surrogate fees. In India, the same procedure costs around $12,000, usually paid to a medical tourism agency or a surrogacy broker. In the award-winning documentary Made in India, the filmmakers explore the distribution of this money, finding that between the agency and the clinic directors, the Indian surrogate women are left with a small percentage. While clinics claim to pay surrogates between $5,000 and $7,000, several of the surrogates who were interviewed in the documentary stated that they only received a portion of their money, sometimes as little as $1,000.[22]

A PRINCIPLED BIOETHICAL FRAMEWORK

The practice of commercial surrogacy in India raises complex moral and ethical questions. Experts from various fields of study have presented different ethical analyses and proposed numerous solutions to the practice. This paper addresses commercial surrogacy as it is currently practiced in India as a bioethical dilemma. As described by bioethicist Professor Ben Mepham, bioethical dilemmas initially appear unsolvable, and are often characterized by several features. Firstly, such dilemmas often have valid reasons for both supporting and opposing a particular course of action. Secondly, the ethical acceptability in determining a course of action to deal with

a bioethical dilemma depends heavily on scientific evidence, which may be complex, incomplete, and/or debatable. Finally, in such cases, a decision must be made by and for society as a whole, in which many individuals may oppose the opinion held by the majority of scientific experts.[23] The practice of commercial surrogacy in India fits all three criteria, and can therefore be defined as a bioethical dilemma.

The four prima facie principles of bioethics were developed by the medical ethicists Tom Beauchamp and James Childress in the United States, with the goal of helping doctors, nurses and healthcare workers deal with the ethical problems that they inevitably faced when treating their patients. Beauchamp and Childress built upon Oxford philosopher David Ross' suggestion, proposed in the 1930s, that ethical principles needed to be prima facie, or conditional, so that a stronger or more compelling principle could overcome a weaker one in a particular situation. Beauchamp and Childress believed that decisions in medical ethics should be handled on a case-by-case basis, by applying the prima facie principles to each situation.[24] The four principles of bioethics are:

1. Non-malfeasance: to cause no harm.
2. Beneficence: to effect a cure.
3. Autonomy: to respect patients' independence.
4. Justice: to treat patients fairly and without discrimination.

These principles are intended to provide a general guide to dealing with bioethical issues that transcends the boundaries of culture, nationality, religion, and other existing ethical frameworks. Because they are conditional, the principles are characterized by a need for balance, which allows multiple important factors to weigh into the final chosen course of action. In the case of commercial surrogacy, many different stakeholders must be taken into account: the intended parents, the child, the healthcare workers, the brokers and agencies, and the surrogate mother herself. In some cases, a complex issue such as commercial surrogacy may create a double effect in which an action that may have unforeseen harmful effects to one set of stakeholders may simultaneously cause many beneficial effects to another set of stakeholders.[25] According the criteria of the double effect, a practice having foreseen harmful effects that are inseparable from the good effect is justifiable if the following is true:

- That the nature of the act is itself good, or at least morally neutral.
- That the agent intends the good effect and not the bad either as a means to the good or as an end itself.
- That the good effect outweighs the bad effect in circum-stances sufficiently grave to justify causing the bad effect and the agent exercises due diligence to minimize the harm.[26]

APPLYING THE BIOETHICAL PRINCIPLES TO COMMERCIAL SURROGACY IN INDIA

Non-malfeasance

The biomedical principle of non-malfeasance is based on the 4th century Hippocratic oath. It states that to "cause no harm" includes not to kill, not to cause pain, not to incapacitate and not to deprive of goods. In the United States this principle is considered fundamental and absolute. However commercial surrogacy in India has the potential to cause both physical and psychological harm to the surrogate and the fetus. If surrogacy were illegal, the mother would never take this risk; no potential fetus would be at risk. However, the commercial surrogacy industry in India ignores this fundamental risk by its very existence.

"Despite the risks involved, surrogates have no one to hold accountable should something go wrong."

Gestational surrogacy is a complex medical process that can cause a great deal of potential physical harm. Since the surrogate is not genetically related to the baby, her body must be prepared for artificial pregnancy. The embryo transfer itself is not very complicated, but the process of preparing the surrogate for that transfer and the weeks after, require a great deal of medical attention. Birth-control pills and hormone shots are required to control and suppress the surrogate's natural ovulation cycle, after which estrogen shots are given to help build her uterine lining. After the embryo is transferred, daily progesterone injections are administered until the surrogate's body finally believes and realizes that she is pregnant and begins to sustain the pregnancy. The side effects of all these medications can include hot flashes, mood swings, headaches, bloating, spotting, uterine cramping, breast fullness, light-headedness, and vaginal irritation.[27]

Despite the risks involved, the surrogates have no one to hold accountable should something go wrong. As one surrogate told researcher Amrita Pande during an interview, "we were told that if anything happens to the child, it's not our responsibility but if anything happens to me, we can't hold anyone responsible."[28] There is no one accountable for the surrogate's welfare- not the brokers, nor the doctors, nor the intended parents. In India, should the doctor make a mistake so the surrogate is injured or even dies from the procedure, the surrogate's family cannot hold the doctor liable. The fact that there is nothing the surrogate can do in the case that she is harmed creates conditions in which the surrogacy industry in India could potentially take unnecessary shortcuts and risk the surrogate's health without fear of legal repercussions.

The surrogate faces more than physical harm. She also may be harmed psychologically through the process of gestational surrogacy. Removing a newborn child from its birth mother is inherently psychologically harmful. Some in the field of commercial surrogacy claim that the bond between

causes the surrogates in developing countries.[30]

Surrogate mothers also face high levels of social stigma and ostracism in India. This social stigma may be due to several contributing factors. Surrogacy is a practice that involves the bodies of poor women, which in India's socially conservative culture, is cause enough for disparagement. The surrogate mothers are treated as disposable objects, and the surrogacy industry highlights the "unnatural" aspects of pregnancy and reproduction. In addition, many Indians associate surrogacy with paid sex-work, and this comparison to prostitution further stigmatizes the surrogate women.[31]

Surrogate mothers face another type of potential psychological harm that stems from their social position as inferior and powerless within the complex of gestational surrogacy. Surrogate mothers typically engage in commercial surrogacy for three reasons. Some surrogates may have primarily altruistic motives. That is, a woman may feel compelled to become a commercial surrogate for a paying couple out of her pure desire to help them, and she takes the pay as an unimportant added benefit. Some women become commercial surrogates due to immediate financial pressures that the pay of surrogacy can alleviate. Finally, some women may not want to become surrogates but may do so as a result of external pressures. In Pande's interviews with forty-two surrogate mothers as well as surrounding family members, friends, and clinic workers, she found that the women often cited their own children as their primary reason for becoming commercial surrogates. Their wishes to send their children to school or pay for a good wedding would only be possible with the money they earned from their reproductive labor. Any and all of these reasons for engaging in commercial surrogacy in India, if viewed under the biomedical principles, commercial surrogacy in India may apply undue pressure on the women to consent.

Beneficence

Beneficence, or promoting the well being of others, is widely interpreted to mean acting in the best interest of the patient. It considers the opposite of malfeasance. In the case of commercial surrogacy in India, the patient is the surrogate mother undergoing treatment. The intended parents can be considered the client. In examining beneficence in the overall practice of commercial surrogacy, the client appears to benefit.[32] The surrogate mother undergoes a risk that she need not encounter at all, in exchange for her fee. Therefore, the question that needs further examination is whether benefits for the surrogate mother are promoted and awarded equal consideration throughout the surrogacy process.

Ethicists have attempted to answer the question of what benefits commercial surrogacy can provide to a poor Indian woman. Casey Humbyrd argues that in order to rule that commercial surrogacy is harmful to the surrogate mothers, the psychological harm of surrogacy must outweigh psychological harm of poverty.[33] Jennifer Parks lists the following ways in which surrogacy benefits the surrogate mothers: it provides economic relief, it provides the resultant effect of being able to care for their families, it ensures their freedom to use their bodies as they see fit, their freedom of choice, and their freedom to contact.[34] These defenses highlight the positive aspects of commercial surrogacy that promote the well-being of the surrogate women involved.

Numerous anecdotes exist that emphasize the benefits of commercial surrogacy to surrogate women. Marie Claire, a popular women's fashion and lifestyle magazine published an article that told the story of Najima Vohra, who earned $5,500 for being a surrogate mother. Her current job, helping her husband collect scrap metal, pays $1.20-$1.45 per day. With her money, Vohra plans to purchase a brick house to replace her family's mud house that washes away each year during the monsoons. She also will invest in her husband's business and pay for her daughter's education.[35] Stories like Vohra's imply that surrogacy is a quick fix: an easy way for poor women in developing countries to make a great deal of money to help their families.

Surrogates sometimes receive more than just monetary benefits from their participation in the surrogacy industry. Another surrogate mother featured in Marie Claire is Rubina Mondal, who traveled from Kolkata to a surrogacy clinic in Gujarat because her young son had a hole in his heart and surrogacy was the only way for her to make enough money in time to pay for his surgery. The client involved was an American woman named Karen, who called Rubina weekly for updates throughout the pregnancy. Karen and her husband purchased an apartment for Rubina and her family, and gave them money for groceries, and send the, clothing. In the last weeks, Karen moved in with Rubina for support, and was by her side during the delivery. Rubina plans to attend Karen's son's first birthday party in the United States. In some cases, like Rubina's, the surrogates can form lasting and beneficial relationships with the clients.[36]

A number of surrogacy hostels provide English and computer lessons to the resident surrogate mothers. These lessons can prove to be valuable for the women later in life, after their temporary employment as surrogate mothers ends. The surrogacy clinics also teach the women a great deal about maternal health, since most of these women had such poor quality healthcare before becoming surrogates.[37]

Autonomy

Autonomy is the right of an individual to self-determination. In the context of commercial surrogacy, this "right" is defined in numerous ways. The medical field defines autonomy in more complex terms as, "self-determination that is free from both controlling interferences by others and personal limitations preventing meaningful choice (such as inadequate understanding or faulty reasoning). Having the capacity to act with autonomy does not guarantee that a person will actually do so with full understanding and without external controlling influences."[38] This definition calls into question many different aspects of the commercial surrogacy that is practiced in India, and whether the surrogates' autonomy is truly respected and preserved.

Before pregnancy

Proponents of commercial surrogacy argue that the freedom to procreate and the freedom to contract are the most

important aspects of a surrogate mother's autonomy. As long as these rights are not violated, the surrogate's autonomy is preserved.[39] However, in the case of commercial surrogacy in India, the right to procreate and the right to contract are not always upheld to their intended standards. Philosopher and ethicist Elizabeth Anderson argues that the interest protected by the right to procreate is that of being able to create and sustain a family life with some integrity. Although commercial surrogacy in India helps to create one family life, it potentially can destroy another.[40] After her nine-month job is over, the Indian surrogate mother could potentially return to a disgruntled husband, neglected children, and a society riddled with stigma towards surrogates and the practice of surrogacy. In addition, the freedom to contract that is, in theory, intended to preserve the autonomy of Indian surrogate women, is constrained in reality. The surrogacy contracts "command the surrogate mother to conform her emotions to the interest of the other parties to the contract." In addition, the contracts restrict the surrogates' behavior and make demands upon the surrogates' emotions. Because surrogacy in India currently operates within a laissez-faire system, surrogacy arrangements tend to favor the healthcare providers, surrogacy agencies, and intended parents at the expense of the surrogates and their communities.[41] Surrogate women have little to no voice throughout the process, not even in drawing up the contract, and the practice of commercial surrogacy consequentially infringes upon their autonomy.

"The contract allows the surrogate no time to change her mind or object to handing over the infant."

The key points of the medical definition of autonomy ask whether surrogate women in India are free *from both controlling interferences by others and personal limitations preventing meaningful choice*. In the surrogacy industry in India, many external controlling forces exert influence upon the surrogate women. For example, most of the surrogate women are poor, uneducated, and lower caste, and are made to feel vastly inferior to surrogacy doctors, clinic workers, and the intended parents. As a result, the surrogates follow instructions and commands with few questions or complaints, because they presume that the doctors and clinic workers know best. Living within India's traditional patriarchal society, the surrogate women lack control over their own finances and the money they are able to earn, which could further contribute to feelings of inferiority. Everyone around them has the monetary control, from the intended couple that determines the fee, to the clinic directors who distribute and control their pay, to their husbands at home who take their money.[42]

The poverty and desperation the surrogate women and their families face calls into question whether the surrogates make autonomous decisions to engage in the practice in the first place. In many clinics, the doctors, nurses, and clinic staff who benefit monetarily from the practice of surrogacy actively travel into the impoverished surrounding communities to recruit young women to become surrogates. Some surrogates report that they enter into commercial surrogacy contracts due to pressure from their husbands or in-laws who need money.[43] It is important to note why and how these women decided to become surrogates in the first place. Desperate poverty, clinic recruitment, and familial pressure are all factors that influence and coerce women into becoming surrogates, and infringe upon their ability to make autonomous, informed decisions.

During and after pregnancy

The surrogate mothers must forgo their autonomy throughout the surrogacy process. After a woman presents herself to a surrogacy clinic as a candidate, the clinic screens her and either approves or denies her application. If selected, the surrogate waits to be matched with an intended couple. The surrogate has no say in who the intended parents are. Many clinics do not permit the intended parents and the surrogate mother to meet, in circumstances similar to a closed adoption.[44] The women must sign a binding consent form that lists the procedures they will undergo and the amount of compensation they will receive. The forms are generally written in English, a language most surrogates cannot read or understand. The clinic workers and nurses translate what they deem to be the most important points for the surrogate, and she signs away her reproductive rights.[45] As currently practiced, commercial surrogacy in India has the potential to occur without the autonomous and informed consent of the surrogate mother. After the delivery, the surrogate mother, or a nurse, hands the newborn over to the intended parents. The contract allows the surrogate no time to change her mind or object to handing over the infant. Given their average family income, it can be presumed that most surrogates do not have the means to seek legal council, and therefore have no opportunity to contest the terms of the surrogacy contract.

Justice

Justice, perhaps the most difficult medical principle to define, is the concept of fairness and equality in the distribution of scarce health resources and the decision of who will receive what treatment. For both medical interventions and research, justice occurs when the burdens and risks are spread equally to all parties involved. When examining justice from the surrogate's point of view, it is important that the principles of medical ethics not be violated during the process of commercial surrogacy in India.

One source of injustice that affects the surrogate woman in India is the international double standard regarding the practice of commercial surrogacy. Most developed nations have banned commercial surrogacy on the basis that it violates women's ethical rights. As France states, "the human body cannot be lent out, rented out, or sold." Does a French woman's body deserve this protection more than the body of

an Indian woman? Is the Indian woman's right to live under the protection of the principles of medical ethics any less than the right of any other woman?

Even within the practice of commercial surrogacy a hierarchy exists and injustice abounds. With the creation of in vitro fertilization, it became possible for a woman from a developing nation to have a baby intended to grow up in a developed nation. The practice abounded. According to Amrita Pande, "In gestational surrogacy, the parents no longer care about the surrogates genes. Not surprisingly, gestational surrogacy allowed the surrogacy market to go global. It was now possible for a South Korean couple sitting in Los Angeles to hire a surrogate from a little village in western India to have a child for them."[46] In India, even within the practice of commercial surrogacy, women of higher caste receive better wages for the same work than women from lower castes, further emphasizing the social inequalities that exist in the population.[47]

CONCLUSION

In the future, commercial surrogacy in India can take one of four paths. It can continue to exist in a loosely regulated environment, in which case the surrogate women are the most likely to be exploited and denied the basic medical ethical principles. The Indian government can pass laws to regulate the industry, requiring a central registry of surrogate women and intended parents, creating minimum payments for surrogates, and creating agencies to inspect and help maintain a quality standard of care. Furthermore, this regulation should also provide protection and non-binding clauses for the surrogate mothers, in case they suffer during the surrogacy process, either physically or mentally. India could follow in the footsteps of countries such as England by making gestational surrogacy legal, but only in altruistic cases. In these circumstances, the coercion of money would be removed from the practice, but surrogacy technology would still be utilized. Finally, India could implement a ban on commercial surrogacy.

Despite it's economic advantages, I believe that commercial surrogacy inherently violates the bioethical principles to which Indian surrogate women should be entitled. In a country such as India, with a free market economy, and combination of public and private healthcare sectors, a moderate or regulated version of surrogacy would be difficult to achieve. I believe that it is crucial to preserve the rights and dignities of these Indian women, and that commercial surrogacy in India must be banned in order to end the potential exploitation that is occurring.

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The Drug-Resistant Bacteria in Supermarkets

By Emily Clark

A study published today in the journal Clinical Infectious Diseases raises cause for some alarm about the state of food safety and agriculture in the US. 47% of the meat and poultry samples that researchers tested from supermarkets contained Staphylococcus aureus bacteria, and more than half of these were resistant to at least three classes of antibiotic. Staph bacteria can cause skin infections and food poisoning, and pose a danger if meat is not cooked properly or if there is cross-contamination in the kitchen. However the exact risk that this finding poses to consumers is not fully clear yet. These bacteria aren't one of the three drug-resistant organisms that the government looks for in retail supplies of meat, and so researchers suggest that it probably should be better tracked. The FDA is the branch of authority responsible for making sure that US consumers are safe from dangerous food products. Still another concern raised is that the widespread use of antibiotics in livestock ends up causing antibiotic resistance in humans, and there is evidence that the source of these bacteria were from the animals themselves. Therefore in the long run, this may be a question not just of food quality standards but also of agricultural practices more generally.

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SCIENCE REPORT

Pesticides, Parkinson's and Power

Jessica Seaver

"A reliable rule of thumb is that chemicals that kill wildlife, especially birds and mammals, will also harm humans."[9]

Pesticide use around the world has been widely debated and protested throughout the 20th century. Rachel Carson's Silent Spring brought the issue to the public in the early 1960s and the contention has only grown since then. Though the health risks of pesticide exposure compile an exhaustive list, one in particular has come to the forefront in the past decade: Parkinson's disease. A greatly studied condition in the scientific world, Parkinson's disease (PD) has proven to be elusive in its exact causes. However, studies have shown that it is characterized by degeneration in the nigrostriatal pathway and subsequent decreases in the levels of dopamine. So what is the connection between pesticides and Parkinson's disease? Recent research has shown a link between exposure to certain pesticides and the development of PD-like symptoms as a result of decreased dopamine. The continued use of known hazardous chemicals in the agriculture industry illustrates Michel Foucault's concept of "biopower," for the system is knowingly affecting the health of its citizens for the sake of the population as a whole. The increased prevalence of Parkinson's disease in those exposed to pesticides can be seen as a calculated risk in the process of easily maintaining agriculture output in the United States. In this paper, I will first briefly describe Parkinson's disease and the research showing a connection between PD and pesticide exposure. I will then outline Foucault's idea of "biopower" and examples of its use in history. Finally, I will illustrate how the continued use of dangerous pesticides demonstrates the modern implementation of "biopower."

Parkinson's disease is a neurological disorder with symptoms that include tremor, rigidity (muscle stiffness), akinesia (difficulty initiating movement or lack of movement), and postural instability or difficulty maintaining balance.[4] As stated above, the condition has been linked to neural degeneration, specifically in the area of the brain known as the substantia nigra. The substantia nigra maintains numerous connections with motor centers and produces a neurotransmitter called dopamine. With the loss of cells in this area, the dopamine that normally relays messages to motor areas no longer functions correctly.[4] This decreased motor efficacy results in the symptoms outlined above. Typically, PD is considered to be a condition associated with aging, as the average age of onset is around sixty years.[4] However, the symptoms emerging in those exposed to certain pesticides do not seem to be dependent upon age.

The neurotoxicity of pesticides has been addressed in countless pieces of literature as well as formal studies over the past few decades. In Silent Spring, published almost fifty years ago, Rachel Carson explains that, "Both types of insecticides, the chlorinated hydrocarbons and the organic phosphates, directly affect the nervous system…"[3] She describes many examples of workers who have been affected, with symptoms ranging from tiredness to loss of memory to paralysis. In America the Poisoned, written twenty years later, Lewis Regenstein describes similar symptoms resulting from exposure to a pesticide called leptophos. "The workers…suffered partial paralysis, blurred vision, dizziness and other severe neurological disorders."[9] These are just two examples of historical evidence pointing to the dangers of pesticides. So with this continuous accumulation of literature illuminating the harmful effects of pesticides, one would hope that the Department of Agriculture would implement a policy banning such chemicals. However, Pesticide Toxicology and International Regulation, released in 2004, contains a chapter entitled "Occupational Aspects of Pesticide Toxicity in Humans." This section outlines the most common pesticides used more recently in the agriculture industry and the resulting adverse effects. An example is that of organophosphorous compounds, chemicals that can cause such symptoms as convulsions, tremor and coma.[5]

The connection between Parkinson's disease and certain pesticides is commonly thought to relate to a substance called methyl phenyl tetrahydropyridine, or MPTP. MPTP was first discovered during a botched attempt to synthesize a homemade mind-altering drug. After injecting the substance, unaware that its chemical composition was not as expected, the users were admitted to the hospital with what looked like advanced PD.[4] Paraquat, an herbicide used frequently in the U.S., shares a similar chemical structure with MPTP and has been studied for its connection with PD.[5] Brooks et al., conducted a study in 1998 that showed a significant, dose-dependent decrease in dopaminergic (dopamine-producing) neurons in the substantia nigra in response to paraquat exposure in mice.[2] As would be expected, the loss of these neurons resulted in reduced motor function. This study, along with many others showing similar results, is solid data substantiating anecdotal evidence of illness and suffering going as far back as Silent Spring.

With this information, it would seem that the Department of Agriculture would have no choice but to take pesticides with paraquat (along with many other chemicals linked to PD) off the market. However, this is not the case. An article released by the National Institutes of Environmental Health Services explains that, "Paraquat use has long been restricted to certified applicators,"[1] indicating that it is still utilized in at least the professional world. Though the chemical is listed

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under the "restricted use" section, clearly there still remain workers in the agriculture industry who are handling it and are thus being exposed to its harmful physical effects. The absence of interference on the part of the U.S. government illustrates Michel Foucault's idea of "biopower."

Foucault's concept of "biopower," put simply, is control over a person or group. He connected this notion to things like sexuality, racism, and nuclear war to illustrate the key factor of state intervention in the lives of citizens. As Paul Rabinow explains in Biopower Today, "At its most general, then, the concept of 'biopower' serves to bring into view a field comprised of more or less rationalized attempts to intervene upon the vital characteristics of human existence."[8] Specifically with regard to general health of the people, Foucault argued that administrative power was inherently bound to control over their physical lives. Adriana Petryna elaborates on this point in Life Exposed by saying that, "Health was recast in the service of the state; the capacities of individuals were to be maximized inasmuch as those individuals lived, labored, and reproduced within a given territory and ruling apparatus."[7] Under the idea of "biopower" are two repercussions pertinent to the continued use of harmful pesticides: hierarchy and the redefining of suffering.

Embedded Foucault's "biopower" is a consequent formation of hierarchy. In his own writings, Foucault references racism in U.S. history and the Holocaust as byproducts of such hierarchies. Both rested on the principle that one group was inferior to another and was treated in a way that reflected such a belief. Within the issue of poisonous pesticides is the same type of notion, specifically regarding the health of U.S. agriculture employees. Their general welfare is being exploited in order to provide consumers with food at the lowest production cost possible. The system is, to use Rabinow's phrasing, intervening upon essential traits of these workers, in this case those of physical health and well-being. The government deems it acceptable to sacrifice them in the name of meeting consumer demand.

The government's approval of physically harmful pesticides in farming illustrates an inherent redefining of suffering. By allowing the use of chemicals like paraquat, officials are declaring that any resulting illness or injury is a consequence of the user's own actions. After all, the label dictates proper safety measures to prevent physical harm. However, even with the use of suitable equipment, many cases of pesticide poisoning are reported each year as a consequence of differing reactions to exposure. The truth is that evidence points to the fact that the harmful effects of pesticides are by no means uniform across different people or varying timelines. Linda Nash, author of Inescapable Ecologies: a History of Environment, Disease, and Knowledge, illustrates this point when she explains that, "The absorption of pesticides by a given individual varied with work rate, work style, personal habits, and the type of clothing worn."[6] So the reactions of each individual, the way in which he or she suffers, cannot be held to a standard definition. However, the action of the EPA to report an allowable concentration of any particular chemical implies just that type of thinking; suffering is delineated by a specific set of official boundaries. In the relation to "biopower," Petrayna states that, "Given the array of scientific and medical uncertainties, old measures of suffering lose their meaning and validity."[7] Workers who develop symptoms of Parkinson's disease after two years of spraying pesticides are dismissed because their suffering does not fall into the concretely-defined category outlined by the system.

The use of pesticides like paraquat, shown in several studies to be linked to Parkinson's disease, illustrates Foucault's concept of "biopower," in that the system is demonstrating control over the physical lives of citizens. Such control can be seen in the hierarchies formed through the sacrifice of workers' health as well as the rigid boundaries placed on "accepted" forms of suffering. Though much progress has been made in the regulation of pesticide use over the years, there are clearly still flaws in the system that need to be addressed. Parkinson's disease is a highly debilitating condition that is known to lead to continued and irreversible degeneration of the nervous system throughout life. While those involved in the system of agriculture in the U.S. admittedly must consider the economic consequences of any change in procedure, they must also acknowledge the value of a healthy life.

"...it would seem that the Dept. of Agriculture would have no choice but to take pesticides with paraquat...off the market."

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Suggested Reading List

1 *Polio: An American Story,* by David M. Oshinsky

2 *The Ghost Map: The Story of London's Most Terrifying Epidemic--and How It Changed Science, Cities, and the Modern World* ,by Steven Johnson

3 *Partner to the Poor: A Paul Farmer Reader* , by Paul Farmer

4 *Strength in What Remains*, by Tracy Kidder

5 *The Impact of Inequality: How to Make Sick Societies Healthier*, by Richard Wilkinson

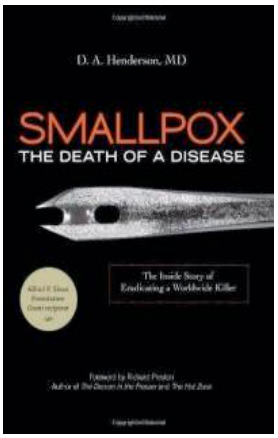
6 *Why Zebras Don't Get Ulcers,* by Robert Sapolsky

7 *A Primate's Memoir: A Neuroscientist's Unconventional Life Among the Baboons* , by Robert Sapolsky

8 *The First Human: The Race to Discover Our Earliest Ancestors* , by Ann Gibbons

Smallpox-the Death of a Disease: The Inside Story of Eradicating a World-wide Killer

Book by D.A. Henderson; Reviewed by Lauren-Elizabeth Palmer



It has been said that a single incidence of smallpox anywhere in the world would constitute an epidemic. Smallpox was eradicated in India, the last strong hold of the disease, in 1974. In D.A. Henderson's telling work *Smallpox- the Death of a Disease: The Inside Story of Eradicating a Worldwide Killer,* the author tells the story of the 115,000 volunteers, public health professionals and healthcare workers who bravely ventured in to the many remote villages and communities of India in a successful and concerted effort to squash this deadly disease. Even more engaging, however, is the account of events leading up to this effort which Henderson recounts. Henderson's background as a physician and public health professional coupled with his history as Director of the Center for Disease Control's Epidemic Intelligence Service and subsequently as the Director of The Eradication, the World Health Organization's initiative to end smallpox, lend great credence to this work.

Smallpox is a viral disease which presents as a rash and eventually fluid-filled blisters on the skin roughly two weeks after a person has come into contact with the virus. It is fatal in an estimated 50% of those who contract the disease, with fatality rates being higher in children and the immuno-compromised. Smallpox is highly contagious and quickly spread amongst families. As early as the 10th century, smallpox was combated by the process of variolation. Variolation involved the extraction of pus from the postules of an affected individual and the direct injection of said pus beneath the skin of a healthy individual. Much like modern vaccinations, this process was intended to expose the healthy individual in such a way that he or she might create antibodies to the virus without becoming ill. Unlike modern vaccinations which primarily use inactive strains of a virus, this process utilized a live strain of the virus and thus frequently worked not as a

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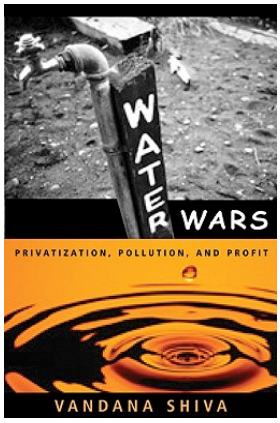
vaccine, but as an exposure point to the virus after which the healthy individual became ill.

Henderson recounts how the much safer, cowpox vaccine, was discovered in 1796. it was after this discovery that vaccinations became mandatory in many states and in the U.S. army. During this same time period, smallpox made its way out of Europe and Asia and into the Americas. Many Europeans had antibodies to smallpox, having contracted it and survived the disease earlier in life. By the time the cowpox vaccine was discovered, however, the Native American population had already suffered greatly from this deadly virus. Because the virus was foreign to the Americas, no Native Americans had antibodies to the disease nor did they have any knowledge of the disease progression ad treatment. Thus, by the time that the thirteen colonies rose up against England, much of the Native American population in what is now the United States had been completely decimated.

Henderson's account of the only official, successful eradication of a disease in history is a must-read for anyone interested in the world of contagious disease, of preventative medicine and of epidemics.

Water Wars: Privatization, Pollution, and Profit

Book by Vandana Shiva ; Reviewed by Lauren-Elizabeth Palmer



Most Americans are acutely aware of the problems caused by the ownership, privatization, commercialization and shortage of oil. Oil has become a deciding factor in politics, war and global poverty. It seems, however, that oil may soon lose its status as most fought over natural resource and be replaced by none other than water, basic H_20. It may seem hard to imagine a world in which something so seemingly plentiful and available as water becomes a commodity in the developed world.

In Vandana Shiva's *Water Wars: Privatization, Pollution and Profit*, the reader is exposed to just such a world and then made to realize that this world is neither fictional nor futuristic, but our very own.

Vandana Shiva is a leading physicists and environmental leader. She has written profusely on environmental issues and, in 1993, was awarded the alternative Nobel Prize (the Right Livelihood Award). Vandana writes that "[t]he water crisis is the most pervasive, most severe, and most invisible dimension of the ecological devastation of the earth".[1] The book greatly benefits from the fact that Shiva is first a scientist and thus her book is brilliantly researched and explained. Shiva gives basic and easily understood explanations for the global water shortage: deforestation reduces the capacity for water storage in tree canopies and forest floors, irrigation systems for agriculture use water at an unsustainable rate, cash crops which can draw in a higher profit, but are laso more water-dependent have replaced the locally bred, more suitable crops and the mining of the earth's surface is destroying underground caverns.

Shiva describes this global problem as indicative of branching value systems. The problematic value system is one which treats water as a private good which can be sold, bough, transferred and owned in a market. Shiva investigates the ways in which privatization has affected many different populations. She begins with anecdotal evidence of her travels throughout her home country of India before delving into the complex ways in which the country of Bolivia has been adversely affected. In the 1990s, water in the country of Bolivia was privatized and the cost of a monthly water bill rose to roughly 20% of the average individual's monthly income. Great public outrage and protests led to a reversal of the decision to privatize the nation's water supply. Bolivia benefited in a way many remote communities have not in that Bolivians had the ability to effectively organize and dissent in a way many populations are not able or allowed to effectively do.

Shiva neautifully and clearly describes different people of the world view water. Some view it as a the natural resource which it surely is, as belonging to the people. Others see it as a market good which must be quickly possessed for the most profit. She describes how villagers in India have successfully returned to traditional ways of managing communcal water sources. She concludes by investigating the nature of the Ganghes River, traditionally one of the holiest sites in India. The sacred, religious or even mythical status of water in people all over the world. She suggests that this view of water, as sacred, has led to successful communities for generations.

Shiva delves into the ways in which ethnic wars across the world are truly water wars, even suggesting that much conflict regarding the West Bank rests in part on scarcity of water resources. Shiva describes the ways in which global food scarcity and water waster, thus global water scarcity, are inextricably linked problems. For anyone interested in the roots of water scarcity, this surprisingly short book is an excellent primer on this overwhelming topic.

Reviewed Book Information

Smallpox- the Death of a Disease, D.A. Henderson, Prometheus Books,

Water Wars: Privatization, Pollution, and Profit, Vandana Shiva, South End Press.

ORIGINAL ARTICLE

The Efficacy of Retail Genomic Testing: A Case Study of 23andMe

Eric Lee

Propelled by the success of the Human Genome Project (HGP) in 2000, there has been a tremendous surge in computational genomic research. Through advanced genomic exploratory mechanisms, a working template of the human genome, with knowledge of spatial gene locations and single nucleotide polymorphisms that correlate to disease states, was established by the HGP. This new and promising front of knowledge concerning the human genome has spurred the commercialization and mass consumer-directed marketing of genetic testing for disease risk predictions. However, as discussed in this critical review of 23andMe, a leading personal genomics company, the collision of personal genomics, nascent interpretation technology, and unregulated retail marketing has raised many concerns in its societal implications and use. Variability issues arise in the interpretation of genomic data, due to omission of the impact of environmental and behavior factors; the lack of standardized testing and disease risk parameters; and the dearth of genetic experts capable of interpreting and utilizing information obtained from these direct-to-consumer genetic testing firms on retail level.

Honored with *Time Magazine's* 2008 Invention of the Year award for "…making personal genomics accessible and affordable," 23andMe, a privately held personal genomics and biotechnology company based in Mountain View, California, has quickly gained the attention of the press, consumers, and scientific community since its birth in April of 2006. With claims to provide consumers an accurate measure of their susceptibility to or existence of specific diseases, traits, and conditions, 23andMe charges $399 for a personal family tree, $429 for a "health" scan, and $499 for both, in its attempt to pioneer retail genomics. By using kits that were ordered online, consumers simply collect saliva at home and send these DNA samples back to the company for analysis and a report of the results in 6-8 weeks.[1]

Though 23andMe has exploded in the media spotlight, with features in the *New York Times* and on Oprah, as well as securing a recent $5.9 million dollar investment from Google, the startup company's history has been marred with warnings, regulation conflicts, and close scrutiny by governmental agencies with regards to its marketing and ethical practice. In 2008, 23andMe received a warning letter from New York State's Department of Health requiring a permit for genetic testing, as well as a physician's authorization for all cases. That same year, California's Department of Public Health issued a cease-and-desist letter to 23andMe barring them from operation until certified by the state and federal government and only after all tests were ordered by physicians. [2] In July of 2010, the Government Accountability Office (GAO) published an investigation of four genetic testing companies, including 23andMe, that concluded the quality of testing was "…scientifically misleading and meaningless". [3] To these claims, 23andMe co-founder Linda Avey states that the company does not perform "diagnostic," but rather "educational" genetic testing. [4] This defense was enough for the State of New York to grant them a practicing license, but leaves the lingering question of whether one's medical history and disease predilections can ever be purely educational if 23andMe recommends consulting a physician for follow-up after receiving test results.

23andMe contracts out their genomic work to CLIA-certified laboratories that utilize Illumina technology wherein single nucleotide polymorphisms (SNPs) are scanned by first replicating the DNA provided from cheek cells in the saliva sample. SNPs, which are defined as variations in a single base position that occur in greater than 1% frequency of the population, can be synonymous and cause no variation to wild type phenotypes, or these SNPs can be nonsynonymous, and result in an altered polypeptide sequence. Because the human genome is 99.9% similar between individuals, the 10 million commonly known SNPs are a major contributor to variation—averaging out gene base pair lengths estimates that there are 50 SNPs per gene. [5] The underlying importance of mapping out the common SNPs lies in correlations that can be drawn between specific changes in the DNA sequence and the susceptibility of disease and/or response to drugs: this frames the fundamental viability of pharmacogenomics. In order for Illumina to analyze SNP variations, DNA chips containing millions of probes are generated, and complementary DNA from the samples' cells base pair and are localized through fluorescent markers. By way of Chip-Sequencing, over 550,000 SNPs are determined by 23andMe.

However, the accuracy and efficacy of 23andMe and other direct-to-consumer genetic testing companies is brought into sharp focus and debate as only a small fraction of the 10 million commonly known SNPs are analyzed by these companies for personal genomic testing. For example, 23andMe only analyzes 550,000 SNPs out of 10 million for disease risk markers, and as the number of SNPs analyses increase, so does the price tag on tests. Another huge issue in terms of accuracy in disease risk prediction is how these specific fractions of SNPs are chosen, as it is not standardized across leading personal

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genomics companies and can lead to contradictory risk profiles with the same sample of DNA. These contradictions can be attributed to the fact that the companies analyzed different genetic "markers" in assessing the donors' risk for disease. As described in a recent article published in the science journal Nature, researchers determine which markers occur more frequently in patients with a specific disease by conducting "genome-wide association studies, which survey hundreds of thousands or millions of markers across control and disease populations". [3] Direct-to-consumer companies like 23andMe use these publicly available studies to decide which markers to include in their analyses, but none of the companies use the exact same markers in its tests for the same diseases. The GAO stated that 23andMe, as well as the three other leading genomic testing companies investigated, misled consumers by providing test results that were both medically unproven and confounding. For example, one of the results vaguely indicated that a DNA donor was at "significant risk of developing the age-related conditions associated with elevated levels of DNA damage." Another stated that a donor had "faulty methylation patterns" that may lead to "an above-average risk for developing cardiac aging, brain aging, and cancer". [3] In all of the companies interviewed post-investigation, there was a consensus that there is a need for standardization, but differing philosophies and attitudes regarding genomic information prevent such a merge.

In its 550,000 SNP analysis, 23andMe also fails to emphasize that the sequence itself is not the determining factor, but rather its expression; and thus as important outside considerations such as family medical history and environmental factors are not taken into account, there is much room for inaccuracies in disease risk predictions even if standardized genetic marker parameters were developed across private companies. With the still limited scientific knowledge currently available concerning the human genome and its intricate workings, it is almost impossible to predict an individual's real risk for developing such a wide range of diseases and traits as 23andMe claims—over 100—when such important outside factors are omitted by these genomic testing companies. Beyond those concerns, the screening done by 23andMe also does not cater to everyone. The data that 23andMe depends on to pick their SNP markers of interest are mined from clinical studies involving mainly Caucasian research populations and so cannot accurately predict comprehensive risk profiles for any other racial group. Finally, by only screening for SNPs rather than genes, Harvard Medical School's Mark Daley warns, "…you get a potentially dangerously misleading answer." A genomic profile based solely on SNPs cannot be an accurate representation of the entire genomic sequence or include all the most significant markers for disease risk. For example, 23andMe can analyze SNP variants that may slightly elevate breast cancer risk, but because they do not look at whole genes they cannot analyze the presence of distinct genes such as BRCA1 and BRCA2 that vastly increase breast cancer risk. [2]

The above issues involving the accuracy of predictive sequencing analysis directly translate into ethical concerns on the consumer level regarding the utility of the gathered data. As clients of direct-to-consumer genomic testing companies such as 23andMe are directly told that they may have an increased probability of getting certain diseases, unnecessary lifestyle changes and misplaced anxiety may result without warrant. Many experts remain concerned that the medical predictions contained in these results mislead consumers, which has spurred further debate that only physicians should have access to genomic profiles from private sequencing companies. In response, Esther Dyson, a director of 23andMe bluntly claimed, "People can understand statistics about baseball…and I think they ought to understand statistics about genetics". [4] On the other hand, Arthur Beaudet of Baylor College of Medicine stated, "The interpretations of findings that might warrant medical intervention require a level of expertise that is currently beyond the capacity of even most physicians". [6]

In addition to concerns regarding the release of genomic information to consumers and possible misinterpretation, the information itself has become controversial. Due to the sensitive implications of genetic results, the security of patient confidentiality must be approached with extreme care. The ethical management of medical records must be stringently regulated in order to prevent the leakage of private information. Access abuse, which could lead to the unauthorized disclosure of personal information to private or government groups without the permission of the patients, could have dire implications upon the storage of private data. If medical service agencies or insurance companies gained access to private genomic information, unjust screening and compartmentalization of patients into "high and low risk" categories could unfold.

«the [study of the] human genome has spurred the commercialization... of genetic testing for disease risk predictions»

Given the scientific evidence currently available, there are many limitations that personal genomics companies such as 23andMe face in terms of SNP sequencing number and genomic marker standardization for at-risk disease predictions. Equally confounding is the truly variable nature of genetic interpretation as impacted by family medical history, and environmental and behavioral factors. These accuracy issues are compounded by a dearth of expert genetic analysts who are able utilize this information on a retail scale if delivered to a mass consumer market where such testing is easily accessible and affordable. Representatives from multiple personal genomic companies admit that most doctors are not adequately prepared to use direct-to-consumer genetic test information to treat patients. In addition, there is currently no data or other evidence to suggest that consumers have taken steps to improve their health as a result of taking

to-consumer genetic tests. As one expert noted, "even if such information is found to be an especially effective motivator of behavioral change, we're in trouble...because for everyone you find who is at increased disease risk, you'll find another who is at decreased risk. So if this information is actually powerful in motivating behavior then it will also motivate undesirable behaviors in those found to be at low risk". [3]

It is only through the advancement of genomic sequencing techniques, clarification of utility, and stringent monitoring of medical database records that private sequencing companies will be able to navigate through the ethical minefield of determining their societal application. While the importance of genetics in individual medical care shows promise for the future, the usefulness of these direct-to-consumer tests is much debated, and begs the question of whether current genomic interpretation technology is appropriate for retail use in our society today, especially in the delicate arena of personal disease risk prediction.

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On Popularity of 'Body Worlds'

By Emily Clark

The 'Body Worlds' exhibits, which have been on display since 1995, are now the most widely viewed exhibition in the world. Anthropologist Jane Desmond has recently been tackling the question of why. Beyond mere toleration, the exhibit has accrued extraordinary amounts of enthusiasm alongside some controversies. How has this been accomplished? Why do people enjoy it so much? Desmond explains that the way the display is put together grounds the bodies in a context of legitimacy and science - in an effort to inspire wonder rather than discomfort in the visitor. They aren't seen to be people at all. Because the process of 'plastination' removes all identifying features from the person (hair, skin, body fat), they are seen as specimens rather than individuals. No cause of death is ever discernible either. The background, walls covered in images of historical anatomy labs, quotes from philosophers and Renaissance prints, soothes the viewer by saying that to learn from the dead is an honorable and acceptable practice. Plaques thank the people who donated their bodies and ensure that they were given voluntarily. The exhibit was clearly composed in a way that would minimize visitors' unease, and it has apparently been a truly effective method.

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"Anthropologist: 'Body Worlds' visitors confront bodies but not death." Science Daily. Web. http://www.sciencedaily.com/releases/2011/02/110207103613.htm. Feb 7 2011.

Portrait of an Ostracized Autism Theorist

By Emily Clark

A timely piece addresses the life behind that scientist who, with one research project, initiated a cascade of controversy about whether there was a vaccine-autism link. While the medical establishment has repeatedly discredited Andrew Wakefield's scientific integrity, revoked his medical license and retracted the original 1998 article from the Lancet, he continues to hold a curious position of power. Journalist Susan Dominus visits Wakefield in his adopted state of Texas and witnesses the way he holds sway over families impacted by autism. It is an interesting transformation that she describes from a man who once was a respected physician and researcher to one who is seen in the media as a fraudulent, slippery and unethical appropriator of science for profit, yet who sees himself as a martyr. The image she paints is one of a man devoted to his theories like a preacher is devoted to his beliefs, and who dismisses scientific scrutiny in favor of faith. Wakefield is widely blamed for the current decline in vaccine rates and for scaring parents away from immunizations without adequate evidence. It is easy to see how he's been able to hold this position in the eyes of someone who has seen autism develop in a child. He presents an absolute certainty and trust in the idea that "parents know best". This is something they often don't feel like they get from visits to doctors. As one mother professed, "I think that validation is all that parents want - just that someone is taking the symptoms that we report and looking at them to see what we can do about it." The incidence of autism in children is creeping up nationwide, and without a definitive treatment or any evidence about what parents can do to protect their children, the fact that Wakefield is able to defend his theories just enough to convince parents that he is onto something has huge implications.

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Dominus, Susan. "The Crash and Burn of an Autism Guru" New York Times. Web. http://www.nytimes.com/2011/04/24/magazine/mag-24Autism-t.html?pagewanted=1&_r=1&ref=globalhome. Apr 20 2011. me level of healthcare to its enrollees as private insurance.

ORIGINAL ARTICLE

Genetically Engineered Babies: An Ethical Debate

Sarah E. Gardner

As genetic research has become more and more commonplace, the potential for individually selecting specific genes for future offspring has been explored. The possibility of the common use of this technology gives rise to many benefits and doubts about topics ranging from the technology itself to the religious implications. The technology could potentially eradicate genetic disorders such as cystic fibrosis, but it could also cause high levels of mutations in the genome that might be irreversible. Allowing the use of this technology would also produce economical concerns and debates between quality of life and stigmatization of differences. Overall, the pros and cons of the technology need to be carefully weighed before genetically engineering human children becomes widespread.

Controversy aside, the technology is being heavily researched. Conceptually, in order to produce a genetically engineered human child, more commonly known as a designer baby, the DNA in the germ cells of the parents must be manipulated to produce a desired genetic makeup. The resulting child then will have the presence or absence of whichever gene was selected for or against in order to ensure certain characteristics of the child, such as gender or absence of a disease1. The desired gene can either be introduced into or removed from an embryo's genome in vitro and then gestated in the mother's womb1. The technology first proved to be successful in ANDi, a rhesus monkey with an inserted gene from a jellyfish that made him glow.[3] The technology used is called human genetic germline modification (HGGM), in which genes in human germ cells are removed or replaced6. If the procedure is successful, the offspring will then have specifically chosen characteristics that will be inherited by the subsequent generation. More commonly at present, pre-implantation genetic diagnosis (PGD) is used to screen embryos for a particular characteristic and the DNA is not manipulated. Rather, many embryos are tested for traits in vitro and then a specific embryo is chosen for implantation. [10] PGD requires many embryos in order to perform the screens, and HGGM could completely replace PGD as a more effective technology for genetic manipulation.

The first major benefit of modification of the embryonic genome is that certain genetic diseases could be made obsolete by eliminating the disease-carrying gene. [6] For example, cystic fibrosis is caused by an identified single gene, which could be removed and replaced with a healthy version of the gene, which would then be inherited by any offspring, eradicating the disease entirely6. The process may also be successful in selecting for gender to help avoid certain sex-linked diseases such as hemophilia4. However, the child will no longer be the direct genetic combination of its parents leading to potential legal and social difficulties, such as a child feeling as though he is not a member of his own family. Therefore, genetic modification may heritably eradicate some diseases, but may also lead to problems for the offspring.

In addition to the controversy associated with heritability, the idea of disease curability also gives rise to great benefits as well as some potential disadvantages. First of all, using germ-line technology over other technologies such as PGD allows for the curability of a disorder that would otherwise be expressed in any offspring. For example, select individuals who suffer from Huntington's disease have two irregular genes. Therefore, all offspring will receive at least one copy of the faulty gene, ensuring symptoms of the disorder. [11] HGGD could guarantee that any offspring only had healthy versions of the gene, and consequently would not have symptoms of Huntington's disease. Curing a disease could also greatly increase quality of life for offspring by allowing them to function regularly in society and to live full and productive lives. However, eliminating certain diseases could also have detrimental effects. For example, if an individual has one copy of the sickle cell anemia gene and one copy of the healthy gene making him heterozygous, he is protected against malaria. Eliminating the sickle cell gene completely would then actually raise morbidity levels resulting from malaria by eliminating the heterozygous population5. The greater implication is that a gene now thought to be only harmful could also be protective, and eliminating that gene could increase levels of other diseases. However, issues such as disease heritability and curability take a backseat to the issues with the technology, itself.

The most controversial issue has to do with the advantages and safety problems with the technology. Promotion of HGGM may make somatic cell technology completely replaceable with genetic changes being heritable rather than singly generational6. However, there are multiple safety concerns keeping the technology from being used in humans, at all. As the technology currently stands, it is extremely difficult to insert the gene into the genome at all, and if inserted, often the gene is not expressed. For example, when ANDi was being engineered, only three embryos of the 20 used actually glowed. [3] Lack of gene expression may occur because it is difficult to directly insert the gene where it is intended to go, and random insertion often occurs1. Since many different copies of the gene are required to even contemplate success, sometimes multiple copies of the gene are inserted where there should only be one copy, or the place in which the gene has been inserted interferes with expression of other genes necessary for the animal to survive, giving rise to over expression,

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under expression, or expression of genes in new places5. For example, when a new growth-hormone gene was added to pigs, the gene was successfully expressed and the pigs grew faster, but they also showed other unintended effects such as arthritis and gastric ulcers. [7]

There are other safety concerns, including high levels of mutagenicity found in manipulated chromosomes9. In addition, even if a gene is inserted in the correct place, most embryos die giving rise to spontaneous miscarriages or premature death. The two other fetuses that also glowed along with ANDi were both spontaneously aborted.[3] Finally, since all results will be heritable, all offspring will have the same problems as the parent generation, meaning without further technology, the process is virtually irreversible. Without fixing some of these problems, the technology cannot be used in humans.

If safety improves and HGGM assists in curing disease, the next step would be to allow parents to customize their own offspring. Parents would be able to select for a trait that would make the child more convenient to take care of in their family. For example two deaf parents who wanted to ensure they would have a deaf child to share in their language and cultural identity could select for a deaf gene8. However, some people believe that it is unfair to intentionally impair a child and deny them regular opportunities afforded other children8. In the bigger picture, some people liken choosing genes to eugenics and genetic "improvement," eliminating certain differences and traits and picking others.[1] Already, in certain cultures having a male child is much more valuable and steps are taken to reduce the likelihood that the child will be female4. Choosing specific traits for a child could stigmatize differences for those who were not genetically engineered and create a society intolerant of certain characteristics. There would be a fine line as to when this technology should be used and for what reasons.

«the pros and cons of the technology need to be carefully weighed before genetically engineering human children becomes widespread»

Some of the reasons for the use or nonuse of the technology would come from a religious standpoint. If a child is engineered to not have a disease before implantation, fewer individuals will have to make the ethically difficult decision to have an abortion6. HGGM also eliminates the necessity to use PGD and sacrifice multiple embryos to find one with a specific genetic makeup. However, for those who do believe in a god, they argue that the process of conception is a natural occurrence responsive only to divine intervention. Therefore, individuals who try to choose their child's traits are "playing God".[9] In addition, as the technology currently stands, genetic modification more likely than not will harm the fetus in some way, such as the aforementioned miscarriages of the rhesus monkeys.[3] Religious factions play a large role in decision making in the United States, and their concerns could not be ignored.

Another key determinant of when HGGM would be used has to do with money and cost. On one hand, it is much cheaper to remove a faulty gene than to care for a chronic or debilitating illness for years on end. However, as is true with most medical advances, the technology will only be available to wealthy people in wealthy countries for quite some time, indicating a global health injustice9. The concept is most certainly not a new one. For example, people living with HIV in low and middle-income countries such as South Africa, Cambodia, and Romania are much less likely to have access to antiretroviral medications (ARVs) because of cost than people living in countries like the United States. However, since 2001, many measures have been taken to lower drug prices leading to higher percentages of individuals able to take ARVs2. So, as with many medical technologies, with time and further research, the cost and accessibility of HGGM should increase. The technological and economical issues may be resolved in the near future, but some of the other ethical controversies may be much more difficult to solve.

The technology for customizing offspring via selecting for certain genes has been used successfully in animals. Although quite a few parts of the technology need to be made more reliable such as where the gene is inserted, the next step will be for its use in humans first to help eliminate certain disorders and then commercially to pick and choose particular desirable traits. The implications are vast and give rise to a multitude of questions about genetics, quality of life, religion, differences and cost. The day will come when final decisions need to be made about the ethics of engineering human offspring heritably and creating designer children.

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POLICY REPORT

Drug Dumping: The Hidden Costs of Corporate Pharmaceutical Donations

Emily Clark

The hesitancy with which we approach a critique of international aid is understandable. It seems that with too much scrutiny, and without constant encouragement and prodding from the Western world, the flow of cash, goods and services to needy places in the world might just dry up. This, however, is a sentiment that must be checked if we are to make sure that those in need tangibly feel the benevolence of the developed world. If indeed we are serious about global health equity, then we will realize the necessity of holding foreign aid to account in all of its manifestations. After nearly every major humanitarian emergency, the press catches hold of instances in which drug donations coming from Western countries have done more harm than good overall. From the African food crisis in the 1980's to Haiti's 2010 earthquake, it has been repeatedly clarified that in a disaster situation giving away things is not always better than giving nothing at all. Drug donations are a critical problem, and when not done in a highly regulated fashion, giving away medicines can produce more problems than we started with.

Let's examine a case study of the crisis that occurred in the former Yugoslavia in the mid-1990's. When civil war broke out between Bosnian Serbs and Croats in 1993, the UN declared several "safe areas" which were then cut off from all assistance by the Bosnian president Radovan Karadzic.[1] In the subsequent years, from 1992-1996, international aid centered on the region as NATO air strikes targeted the Bosnian Serb army.[1] In 1997, a ground study was conducted to determine the effects of over 30,000 tons of donated pharmaceuticals.2 What these researchers discovered was that nearly two-thirds of those materials could not be used, and not only were they not helpful in the aftermath of the crisis but something had to be done with the 17,000 metric tons of waste. Among the non-useful drugs, hazardous waste specialists found weight-loss drugs from the UK, toxic chemicals from the former East Germany, and expired medicines whose labels had been deliberately covered up.[3] After resources were deployed to figure out which of these drugs were useful, the rest had to be destroyed. Since pharmaceutical products constitute hazardous materials, certain classes require special incinerators and because war-ravaged Bosnia did not have the appropriate facilities, the WHO had to consider building facilities from scratch. In the end, the cost of safely dealing with these unusable drug donations was an incredible $34 million US dollars.[2]

What exactly constitutes "drug dumping"? According to the authors of the previously discussed study, there are several reasons why donated pharmaceuticals are potentially not useful or unusable. The donations come from private individuals, corporations, non-governmental organizations or from foreign governments, and they could be unhelpful if they arrive in poor quantity or quality, or are for other reasons inappropriate.3 This could include being useless, for example when weight-loss agents arrived in Bosnia, and clearly were not what was needed in this situation. It has also been well documented that the majority of drugs produced in the developed world, which often have to do with chronic disease and impotence, do not fit the epidemiological profile of most disaster situations.[2] WHO publishes a list of roughly 300 essential medicines that reflect global needs, and anything not on this list is generally not useful in the context of a humanitarian crisis.4 The donated drugs are also frequently unusable, which means they are a useful kind of medicine but the actual supplies cannot be used safely. Most commonly, this means that the drugs are expired.[3] The FDA stipulates that expired drugs cannot be sold in the US, therefore when surplus stocks exist there is an incentive to donate them abroad rather than to deal with the costs of disposal. Bosnia received packages of supplies left over from WWII armies, and a batch of plaster tape from 1961.[3] Drugs may also not be usable if they are not labeled and sorted properly.[3] If they are labeled in an unknown language or with a trade name that isn't an international standard, or if they don't arrive sorted properly in correctly labeled boxes, it often isn't possible to use them. In Bosnia many donations came in the form of unsorted free samples, of which 90% were unusable. Finally, certain classes of drugs are easily damaged in the transport process and if they are stored improperly. Insulin, for example is a commonly donated drug even though there is relatively little need for diabetes treatment in crisis situations compared to how often it is donated, and it needs to be refrigerated or is ineffective.[3]

It has already been shown that improper drug donations can cause an unnecessary burden on an already strained infrastructure during humanitarian crises. The costs of sorting through donations and disposing of waste are substantial. Yet there are also other serious consequences to consider. One of the gravest concerns is that use of improperly donated drugs will result in health problems for those that use them. The most well known example of this phenomenon is when in Lithuania, women were temporarily blinded by using a de-worming medication which was actually meant for veterinary use, but was donated for humans.[3] In 1994 in Zaire, a company chartered a plane to deliver cases of a soft drink meant for athletes, claiming that they would help address malaria. Yet if given to children, this product could have been extremely dangerous.[5] Related to this is the concern

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that individuals may want to donate partially used bottles of medication, which opens up the dangers of a drug being handled by multiple parties between its distribution and donation.[7]

A second concern is that drug donations will undermine national production of pharmaceuticals. With drugs being given away at sub-market prices, any national plants will not be able to sustain themselves. Eritrea is a good example of this because they were actually able to build capacity for the specific drugs needed in their country during the crisis. Domestic plants were used during the war for independence and became the foundation for the nation to supply the majority of its need for IV fluids and tablets after the war.5 East Timor has focused on government procurement of drugs to ensure an adequate and affordable supply without undermining the market by accepting international donations.5 Some argue that drugs in situations of need should always be provided through government procurement.[6] Import taxes from the receiving country often require the domestic Ministry of Health or another receiving entity to spend money on the donations, which may or may not end up being usable.[3] The lack of means of accountability from private voluntary organizations who act as the intermediary, accepting corporate donations and distributing them abroad, means that the donor has no further responsibility after handing the medical supplies over to the private organization, whether or not the drugs actually make it to their destination. In addition, this practice can result in problems by changing the pattern of prescription by health care providers in the receiving country if, for example, they come to rely on trade name drugs from Western countries rather than generics.[8]

Finally, the relative cost to the public of relying on corporate donation rather than on selling medicines at tiered prices internationally, because of the impact of taxes that subsidize charitable donations, is significant.3 Current US tax law is problematic for this reason. Corporations can claim donations of "in kind" charitable gifts against tax in the form of an enhanced deduction.[3] This means that they can claim the value of donated goods at either twice their base cost or at their base cost plus half of their "fair market value", whichever is lesser. This is a strong incentive for companies to donate drugs that they would otherwise not be allowed to sell domestically. The double standard of drug quality for sale in the US, which is strictly regulated by the FDA, compared to the lack of regulations about what drugs can be donated abroad, allows companies to get rid of drugs without bearing the costs of their disposal. We have already seen that in the case of Bosnia and Herzegovina, the cost of safe disposal can be monumental.2 Such a double standard distorts the impact of drugs as an environmentally hazardous waste, and represents an institutionalized inequality between populations.

This long list of issues that result from current drug donation practices makes it abundantly clear that a new set of policies is needed. Under the present system, the dual loyalty of pharmaceutical companies to their shareholders and to the general good of society is not well balanced. 9 Combined with the desire people have to donate material things rather than cash, drugs continue to be donated abroad in a relatively unregulated manner. This practice has not escaped international attention though. The World Health Organization has issued two sets of guidelines, one about drug donation and one about the safe disposal of drugs, which should lead countries toward better drug donation policy.[10, 11] The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, which entered into force in 1992, makes it illegal to engage in dumping practices of materials that are dangerous to environmental and public health.[12] The WHO guidelines, which were drafted in 1996 and revised in 1999, establish four principles upon which drug donation should be based. The first is of "maximum benefit to the recipient", which should take into account the needs of individual patients as well as the receiving community and nation. The second principle, "respect for wishes and authority of the recipient", means that drugs should not be donated unless they are requested and match the epidemiological need of the crisis. Thirdly, "no double standards quality" means that expired or spoiled medications are not fit for anyone to be given. Finally, "effective communication between donor and recipient" is emphasized, and means that there should be an opportunity for the receiving country to indicate their wishes.

It is obvious that there needs to be a revision of drug donation policy, both on the part of individual donor entities and donor governments. There has been evidence that simply being aware of the WHO guidelines does not necessarily lead to appropriate practices.[13] Therefore the most effective remedy would probably be to change the regulations about corporate donations in developed country governments. For example in the United States, it would be possible to make compliance with the guidelines a prerequisite for companies to benefit from enhanced tax deductions.[3] There should not be a double standard between the quality of drugs meant for domestic markets versus in crisis situations; it is unjust if we allow medicines that don't meet FDA standards for American consumers to be sent abroad. Other suggestions to address this problem encourage what should be donated more often. It is much more beneficial to donate medicines that are on the WHO essential medicines list as well as pre-packaged emergency drug kits that are put together based on established epidemiological needs, and less room for these donations to become a burden to the receiving community.[6] Finally, cash donations are almost always more useful than in-kind gifts simply because they can be tailored to the specific situation. By following these recommendations and guidelines, medical assistance in the wake of humanitarian emergencies can be made into a much more valuable contribution.

References for this editorial can be found at

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