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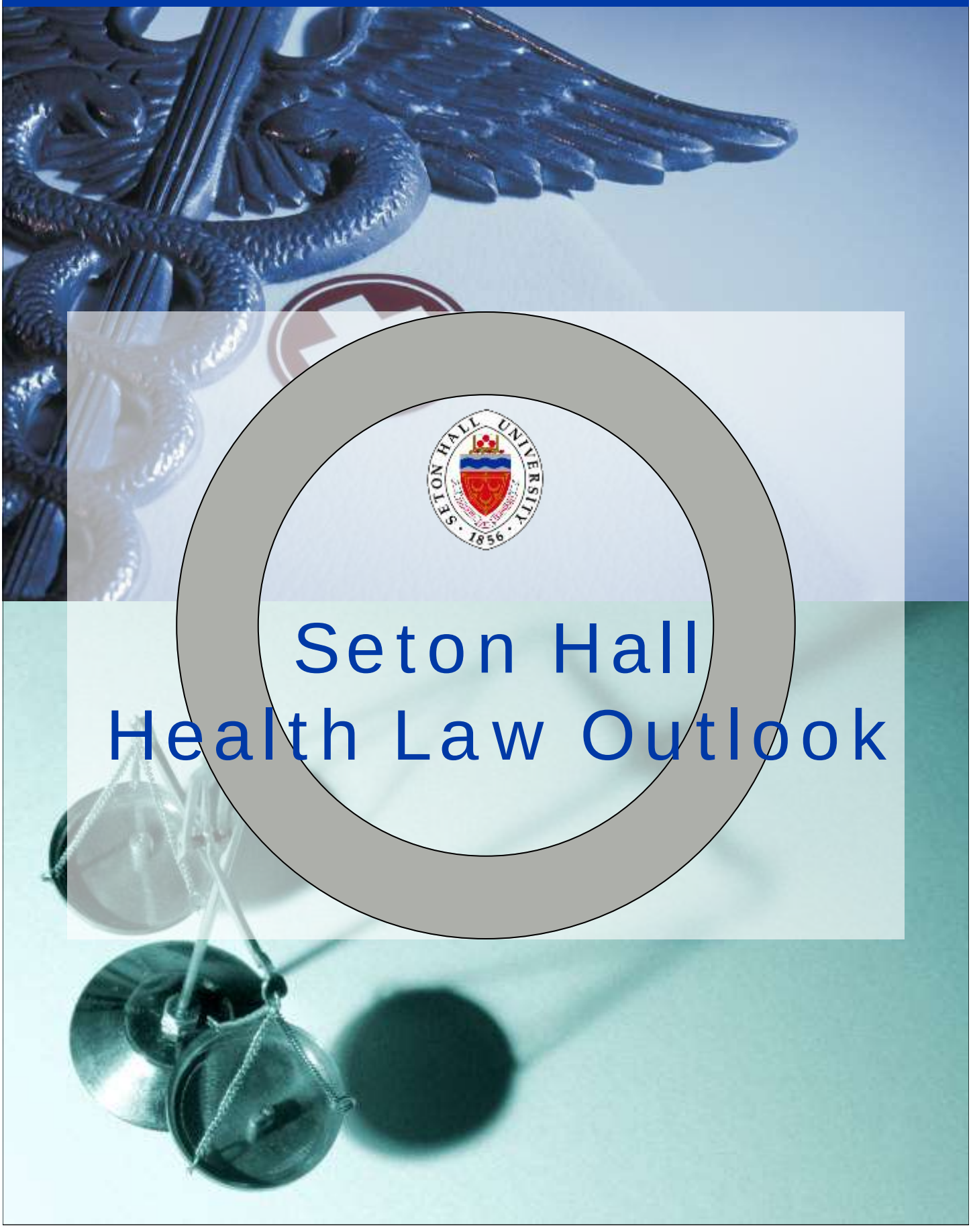

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Side Effects May Vary: The Aftermath of the *United States v. Caronia* Decision on Off-Label Drug Promotion

Christina Le
Christina.Le1@student.shu.edu

Introduction

On November 4, 2013, health care giant Johnson & Johnson agreed to pay more than $2.2 billion to resolve criminal and civil allegations of off-label marketing of three of its prescription drugs: Risperdal, Invega, and Natrecor.[1] The civil settlement with federal and several state governments totaled $1.72 billion.[2] Further, criminal fines and forfeitures reached $485 million. This settlement was the second largest health care fraud settlement in United States history.[3] Less than four months later, Endo Health Solutions, Inc., and its subsidiary, Endo Pharmaceuticals, Inc., agreed to pay $192.7 million to resolve criminal and civil claims for the off-label promotion of the drug, Lidoderm.[4] In a statement about the settlement, Zane D. Memeger, United States Attorney for the Eastern District of Pennsylvania, said, "pharmaceutical companies have a legal obligation to promote their drugs for only FDA-approved uses."[5] But what about the companies' constitutional right to free speech? The United States Court of Appeals for the Second Circuit has been the only circuit to hold that truthful, non-leading off-label promotion[6] is protected under the First Amendment in *United States v. Caronia.*[7] Nevertheless, as evidenced by the recent Johnson & Johnson and Endo Health Solutions settlements, the free speech defense introduced in *Caronia* does not seem to be too promising for pharmaceutical companies faced with allegations of off-label promotion.

United States v. Caronia

When the United States Court of Appeals for the Second Circuit decided *Caronia* in December 2012, the case was hailed as a "landmark" decision.[8] It created a circuit split between the Second Circuit and every other federal circuit because the Second Circuit was the only one to hold that off-label promotion was protected free speech under the First Amendment. Until this decision, no court had held that off-label promotion by pharmaceutical and medical device manufacturers and their representatives was protected under the Free Speech Clause of the First Amendment. This defense was not available when the Food and Drug Administration ("FDA") prosecuted off-label promotion for violating the misbranding provisions of the Food, Drug and Cosmetic Act ("FDCA").

The defendant in *Caronia* was convicted of conspiring to introduce a misbranded drug, Xyrem, into interstate commerce in violation of the FDCA. On appeal, the defendant ultimately prevailed on the grounds that the off-label promotion of the drug was lawful and protected under the First Amendment. In a 2-1 decision, the Second Circuit held that prohibiting the lawful off-label marketing of a drug unconstitutionally restricted free speech. Further, it held that the misbranding provision does not prohibit off-label promotion. The Second Circuit was the first Federal Court of Appeals that interpreted the FDCA's misbranding provision to not expressly prohibit off-label promotion.

The Food and Drug Administration's Views on Off-Label Promotion

Before entering interstate commerce, new drugs are subject to approval from the FDA to be marketed for specific uses.[9] Once the FDA approves a drug, physicians are free to prescribe it for approved and unapproved, or "off-label uses."[10] Under the FDCA, introducing any adulterated or misbranded drug into interstate commerce is prohibited.[11] A drug is considered misbranded if its label does not have adequate directions for use.[12] "Adequate directions for use" is defined as directions under which laypersons "may use the drug safely and for the purposes for which it is intended."[13] "Off-label use" refers to the use of a drug, or other product, in a way that is not indicated on its FDA-approved label.[14] This term is applied when a drug is used to treat a disease not indicat-

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ed on the FDA-approved label. In addition, "off-label use" is also applied when prescribing the drug for the indicated disease for a different dosage or for a different patient population than indicated on the FDA-approved label.[15]

The FDA has acknowledged that under certain circumstances, off-label use may be appropriate, such as when it is used as medically-necessary standard of care.[16] The FDA has expressed reluctance to interfere with the practice of medicine or create barriers to physicians exercising their best judgment when considering treatment options for patients.[17] The FDCA expressly states that none of the provisions of the Act "shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health-care-practitioner-patient relationship."[18]

The prohibition against off-label promotion is mainly directed at pharmaceutical and medical device manufacturers and their agents.[19] A free speech violation may exist when these manufacturers and their agents are prohibited under the Act, but physicians, and other entities, such as medical journals, are allowed to promote the off-label use of drugs. The intent of physicians to promote a certain drug for an off-label use is presumably driven by the best interests of the patient, whereas such promotion by a pharmaceutical company and its employees is driven by profit, not safety. By promoting off-label uses, dosage, and patient populations, drug companies are able to expand its market to a broader range of consumers and increase profits. Following the 2012 decision in *Caronia*, the Federal Government argues that off-label use is only *evidence* of misbranding.[20] The government's argument is that promoting an off-label use is evidence that the speaker is asserting an intended use.[21] Because it is off-label, the labeling of the drug does not bear adequate directions of this off-label use.[22]

"Until this decision, no court has held that off-label promotion … was protected under the Free Speech Clause of the First Amendment."

Impact of *Caronia*: The Use of the Free Speech Defense

Since the *Caronia* decision in December 2012, at least one medical device manufacturer has asserted that off-label marketing is constitutionally-protected speech and is not a violation of the FDCA. This defense, however, has not been universally successful. Some courts adopted the *Caronia* decision,[23] while others found it was unpersuasive.[24] The *Caronia* decision demonstrates an expansion in commercial speech rights in the context of pharmaceutical and medical device marketing. Nevertheless, the case law following the decision suggests that the decision will not significantly impact off-label promotion. Recently, Medtronic, Inc. ("Medtronic"), a medical technology company, has faced numerous lawsuits involving its InFuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device ("InFuse Device). As a defense in these cases, the company has utilized the Second Circuit's holding that off-label promotion does not violate the FDCA. The FDA approved the InFuse Device after its rigorous premarket approval ("PMA") process.[25] The plaintiffs in the InFuse Device lawsuits against Medtronic contended that it was the off-label promotion by Medtronic representatives to physicians that induced the physicians to perform the spinal surgeries using off-label methods.[26] Specifically, the plaintiffs alleged that the representatives encouraged the surgeons to implant only one component in the three-part InFuse Device system and to use a posterior approach during surgery, rather than the FDA-approved anterior approach.[27] The plaintiffs claimed that the off-label promotion of the device was executed without fully disclosing all the adverse effects and risks of the off-label uses.[28] The plaintiffs further asserted

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that these two off-label approaches caused them to suffer from resultant injuries.[29] These injuries ranged from severe bone growth, pain, numbness, and difficulties with certain motor function.[30]

Several United States District Courts[31] and a Minnesota state court have followed the Second Circuit's decision in these InFuse Device actions. These courts have held that off-label promotion is not unlawful under the misbranding provision of the FDCA and subsequently rejected the off-label promotion and use claims asserted by the plaintiffs. The courts recognized that the FDCA does not prohibit all promotion of off-label uses.[32] The United States District Courts and the Minnesota state court identify *Buckman Company v. Plaintiffs' Legal Committee* as binding authority.[33] The Supreme Court held that physicians are able to prescribe drugs and devices for off-label uses.[34] Moreover, the Court recognized the importance of not interfering with the practice of medicine and allowing doctors to prescribe drugs and devices for uses that have not been approved by the FDA.[35]

In the above referenced Medtronic cases, the plaintiffs failed to establish a link between off-label promotion and their respective injuries. The plaintiffs could not state the specific statements made by Medtronic Inc., or its agents, which induced the physicians to use the device and perform the surgery in an off-label way. Since the plaintiffs could not identify specific instances of off-label promotion to the physicians, these courts adhered to the Supreme Court's presumption in *Buckman* that physicians have the discretion to use drugs and medical devices in off-label ways as long as they are an appropriate course of treatment.[36]

Although the adoption of the *Caronia* holding in the Fourth and Fifth Circuit, as well as in a Minnesota state court, would appear to be evidence of the persuasiveness of the holding in *Caronia*, this is not the opinion held by all courts. The Ninth Circuit decisions in a number of InFuse Device cases[37] and a decision in a Maryland state[38] court reveal that the Second Circuit's decision in *Caronia* is not binding on jurisdictions outside that circuit, and off-label promotion can still be illegal under the provisions of the FDCA. These courts rejected the holding under *Caronia* and held that off-label promotion violated the FDCA outright.

"[The government] did not believe that the *Caronia* decision will impact the FDA's ability to enforce the FDCA's drug misbranding provisions."

Based on the district and state courts' differing interpretations on whether the misbranding provision of the Act prohibits off-label promotion, it is unlikely that the *Caronia* decision will affect government litigation tactics or enforcement efforts. Numerous pharmaceutical manufacturers have pled guilty to charges of violating the FDCA by promoting off-label uses and have settled with the government.[39] Following the Johnson & Johnson settlement, Attorney General Eric Holder stated that the settlement "demonstrates the Justice department's firm commitment to preventing and combating all forms of health care fraud."[40] The government has adamantly prosecuted manufacturers and their representatives for off-label promotion in the past.[41] Between 2003 and 2007, the FDA issued 42 regulatory notices and demanded that drug manufacturers cease circulating information about off-label uses.[42] During this period, the Department of Justice settled eleven criminal and civil cases involving off-label promotion.[43]

The government decided not to bring the Second Circuit's decision to the Supreme Court for further review. It did not believe that the *Caronia* decision will impact the FDA's ability to enforce the FDCA's drug misbranding provisions.[44] The likely reasons for the government's unwillingness to appeal the decision to the Supreme Court are two-fold. First, the Second Circuit's decision in *Caronia* did not question the validity of the misbranding provisions of the FDCA or find a conflict between these provisions and the First Amendment. Sec-

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ondly, the Second Circuit did not strike down the FDCA's drug approval framework. Since the *Caronia* decision is only binding on courts with the Second Circuit, the government may not want to risk a broadly applicable decision by the Supreme Court—especially since the Supreme Court's decision in *Sorrell* seems to be protective of pharmaceutical speech.

Conclusion

Over a year has passed since *Caronia*. What was once hailed as a landmark decision, and what appeared to be an expansion in pharmaceutical speech, has had little persuasive effect on the prosecution of off-label drug promotion by pharmaceutical companies. The government has remained steadfast in its commitment to prosecute for violations under the misbranding provision of the FDCA and in targeting companies that promote drugs for uses that have not been approved by the FDA. Since *Caronia,* numerous pharmaceutical companies have settled with the government for allegations of misbranding through off-label promotion, including three settlements in the Second Circuit itself.[45] Because settlements with pharmaceutical companies for off-label marketing have been so successful, there is little reason for the Department of Justice to abandon its tactic of aggressive prosecution.[46] Not only will the government continue to prosecute off-label promotion and regard it as a per se violation of the misbranding provision, but pharmaceutical manufacturers are also not optimistic that the Second Circuit decision will be a useful defense. Instead, pharmaceutical companies appear to prefer to settle and plead guilty.

Furthermore, the government has an alternate avenue to prosecute off-label marketing. It could allege that off-label promotion violates the False Claims Act ("FCA"). Under this alternative claim, the government would allege that a pharmaceutical company promoted the sale and use of drugs for uses that are not FDA-approved and not covered by the federal health care programs; thus, the promotion of off-label uses would result in the submission of false claims. Regardless of whether the government prosecutes off-label promotion under the Food, Drug and Cosmetic Act or under the False Claims Act, it is evident that a free speech defense is weak at best. The "side effect," or predicted results, of the *Caronia* decision have not been as desirable as anticipated.

Big Soda: The Key to Curbing Obesity in America?

Alice Anderson
Alice.Anderson@student.shu.edu

Introduction

It is no secret that Americans are struggling with their health. The United States consistently ranks among the top ten obese countries in the world.[1] This epidemic has become extremely problematic for Americans: it is not just expensive but it is killing people. As the serious detrimental consequences to America's health mount, state and local governments are attempting to fight the problem head on by implementing a number of policies that encourage Americans to curb their appetite and make smarter choices when it comes to their health. Sugar sweetened beverages, particularly soda, have become a large target for these public health initiatives.[2] Famously introduced by former New York City mayor Michael Bloomberg, probably the most restrictive health initiative called for a 16-oz cap on soda at restaurants, movie theatres, and sports venues.[3] More frequently, state and local governments are attempting to impose a one to two penny-per-ounce tax on soda.[4] As a consequence soda manufacturers, often referred to as "Big Soda," are painted in a negative light.[5] A clear comparison can be made between this campaign and the events surrounding the tobacco litigation of the 1990s.[6] But, with the complex interaction of genes, lifestyle, culture, and socio-economic status contributing to obesity, are narrow restrictive measures like a soda tax the key to improving America's health?

At a Glance: Obesity in America

The co-morbidity of obesity and chronic diseases makes the current obesity epidemic a very serious, not to mention expensive, problem for the United States.[7] Being overweight or obese drastically increases a person's risk for a number of serious and chronic health problems, including coronary heart disease, Type 2 diabetes, certain types of cancer, and stroke.[8] According to the World Health Organization, chronic diseases are the leading cause of mortality in the world, making up 60% of all deaths.[9] In addition to the health risks, the estimated medical cost of obesity in America is $147 billion per year.[10] This cost is primarily attributed to the cost of treating the chronic diseases that are closely connected to obesity, including the provision of prescription drugs. As obesity rates rise, so will the cost of dealing with the negative effects of America's weight gain.

The Soda Tax

Lawmakers can point their fingers in many directions as to whom to blame for the high obesity rates in the United States.[11] Soda has been a relatively easy scapegoat for officials to focus upon. This is due not only to the general popularity and prevalence of these products, but also to the high sugar content of sodas and other sugar sweetened beverages and their almost complete lack of nutritional value. The typical amount of sugar in any given soda vastly surpasses the recommended daily intake, a main reason why sodas have been a large target of public health campaigns.[12] The World Health Organization's newest proposal recommends that the average person should consume no more than 25 grams of sugar a day (which amounts to about 6 teaspoons).[13] A 12 ounce can of Coke has 39 grams of sugar (a little over 9 teaspoons of sugar).[14]

The soda tax is a relatively new development in the national effort to decrease obesity among American adults and children.[15] The tax is intended to reduce soda consumption, thus reducing daily sugar and caloric intake, which in theory would reduce average Body Mass Index (BMI).[16] This past year alone there were 26 bills proposed across the United States relating to taxes on sugar-sweetened beverages, including San Francisco, Chicago, California and Hawaii, though none of these have been passed.[17]

These taxes have been met with strong criticism. When research was released showing the negative effects of smoking, a similar situation emerged.[18] In one respect, it is hard not to compare the obesity epidemic to tobacco. The obesity epidemic, like the harmful side effects of smoking,

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came as a shock to everyone.[19] It took a number of years to establish the taxes and policies we have now for tobacco.[20] Analogously, many people today do not see how soft drinks are harmful to them, and, even if they do, they are not willing to give them up. Consumers often do not look at the nutrition labels or if they do, they are unable to decipher them. Consequently, many are not aware of the actual nutritional content of soda. In addition, many consumers who are aware that soda contains high levels of sugar or high fructose corn syrup still continue to drink soda regardless of its lack of nutritional content.[21] This lack of knowledge coupled with a lack of concern makes it difficult to convince consumers that soda may be harmful to their health, just as with tobacco.[22] Soda is also marketed in much the same way tobacco was, targeting children and young adults who will grow up to be the main consumer base of these products.

The parallels between tobacco regulation and the new push to start regulating the eating habits of Americans are incredibly similar. This comparison signals that a tax on soft drinks could be just as effective as the tax on cigarettes has been, especially on consumption by children and young adults.[23] Since tobacco taxes have been in effect, studies have shown that the tax has been effective in reducing consumption, especially in young adults.[24] The theory is that if the tax on tobacco has been so successful, it should similarly work to lower rates of consumption for soda, a less addictive product.

The Benefits and Detriments of Soda Taxes

Taxing soda seems to be a decent remedy to a small part of a larger problem. The only genuine concern of taxes like the soda taxes is that they are, in theory, im-

posing lifestyle choices onto consumers by the government. Provided that the tax does not become an arbitrary exercise of government power for the sole purpose of raising money at the expense of consumers or the businesses that manufacture and produce soda, a soda tax is a decently justifiable policy to consider. These penny-per-ounce soda taxes will not be a substantial economic burden to any one group over another because they are relatively small.[25] It is unclear whether soda taxes will do much to reduce actual consumption, but it will generate considerable revenue that could be used to mitigate the already high costs of healthcare or for programs that help educate the public about healthy lifestyles.[26] While there is a strong link between soda consumption and weight gain, it is hardly the only culprit. Soda is not the magic solution that will solve the obesity epidemic in America, but it is a worthy starting point.

Probably the largest concern these soda taxes raise is the underlying use of governmental power, and if public health is something that a government has the legitimate right to regulate. Many Americans resent the government imposing their beliefs about what a healthy lifestyle looks like, as shown by the overwhelming backlash former mayor Bloomberg received with his 16-oz soda cap which was ruled unconstitutional (a ruling that is currently being appealed).[27] The New York Supreme Court Appellate Division held in *New York Statewide Coal. of Hispanic Chambers of Commerce v. New York City Dep't of Health & Mental Hygiene* that the Board of Health did not have the power to enact such a ban. The court looked to the legislature as the source of power to enact such a regulation.[28] While many of the soda taxes are proposed by state legislatures, not many have been passed, indicating that Americans seem to be resistant towards government regulation of health measures.[29] These concerns are valid; imposing such a tax does incentivize behavior; however, there is a big difference between policies that restrict behavior among consumers and policies that incentivize behavior.

Opponents of the tax also

"Big Soda"

argue that the tax will not only restrict consumer freedom but will negatively impact low-income populations; however, these concerns are misguided. The opposition is concerned that the tax is potentially harmful primarily to low income households and also to non-obese consumers. Opponents believe that soda taxes are regressive, meaning they negatively impact lower income households. These groups believe that the product's increased cost as a result of the tax will be passed along to the consumers and not the producers.[30] Low-income households already spend a large portion of their monthly expenses on food and beverage costs and typically buy soda because it is cheaper than the alternative choices such as juice or milk.[31] This means that the soda tax is an unnecessary burden on a population that spends a considerable portion of their income on food and drink. Minority populations also disproportionately purchase soda compared to other groups.[32] Beyond individuals with low-income and minorities, there is also concern that the tax is unfair to non-obese or overweight consumers. By charging everyone the same regardless of the consumer's weight, the tax does not discriminate against overweight consumers and non-overweight consumers. Thus, the benefits for overweight and obese customers would be at the expense of non-overweight customers. Because the purpose of soda taxes are to reduce obesity and mitigate the related health concerns associated with obesity, opponents argue that asking non-obese people to finance this cost with a soda tax is unfair.[33]

The concern of individual freedom may be outweighed in this case by the overall concern of society's health. Both the government and Americans themselves are already feeling the impact of the obesity epidemic: obesity costs Americans a staggering $147 billion a year.[34] This is not an arbitrary exercise of the government's power; it is an attempt to ensure that Americans are healthy and not unnecessarily wasting their money. Similar to tobacco, the negative health impact on a large scale necessarily gives the government the ability to intervene, to an extent, a precedent which has been set by tobacco itself.[35] So long as the taxes are reasonable and merely incentivize rather than restrict, they are within the government's interest to impose and can hardly be considered an undue restriction on the freedom of consumers.

"...the government and Americans are feeling the impact of the obesity epidemic: obesity costs Americans a staggering $147 billion a year."

Concerns over the impact on low income or non-obese persons are misguided. A penny-per-ounce tax is so small an increase in price that it will hardly make an impact (this, however, may raise the question of why have the tax at all).[36] However, if a penny-per-ounce tax did indeed make sodas expensive enough to become too costly for lower-income consumers to afford, there are cheaper and healthier alternatives available to them. Economists believe that, in raising the price of items like soda that have no nutritional value, consumers will turn to healthier alternatives like milk which would be less expensive than soda after the tax increase.[37] This makes the tax an incentive rather than a restriction and illustrates the main concept behind the idea of the soda taxes in general. Rather than impose a ban which may be seen as an over use of government power (as discussed above), the government can raise the price of non-nutritional foods compared to nutritional foods which might incentivize consumers to make healthier choices. In the end, the added cost onto sodas would pale in comparison to the $147 billion obesity already costs Americans every year.[38]

Additionally, the revenue generated by the soda tax can mitigate any unfair implications of the tax by taking the money gained by the tax and putting it back into low-income communities. The Yale Rudd Center for Food Policy and Obesity has developed a revenue calculator which calculates the estimated revenue a penny-per-ounce soda tax would generate for each state or major U.S. city.[39] For instance,

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New York City alone would generate an estimated $345 million in 2014 from a soda tax. If these funds were returned to low-income areas, the revenue may mitigate any disparities for low-income households. For example, the recent California bill imposing a penny-per-ounce tax on soda proposes to put all revenue raised by the tax into the "Children's Health Promotion Fund," a program that promotes children making healthy choices in diet and exercise.[40] The amount of money these bills would raise is enough to take notice. The revenue could go a long way to fund future programs or even mitigate some of the costs obesity has imposed on the healthcare system. For instance, the money could help decrease the annual cost of healthcare due to chronic diseases caused by obesity, be put into research, or be used to fund programs to educate low-income families on cost efficient ways to have a healthy diet. The potential benefit of such revenue is one of the main reasons soda taxes are popular among the state legislatures.[41]

Conclusion

America's obesity epidemic will not go away anytime soon. Soda taxes are but a small part in a sea of regulations and measures that the government has proposed to help with the effects of American obesity. Soda taxes may not be the best solution, but they do offer access to money that can be used to fund more successful measures. Penny-per-ounce soda taxes are not likely to be very successful at curbing America's soda addiction. The taxes are a small increase in price that is unlikely to stop most from buying soda. If the government truly wanted to discourage behavior, they would have to drastically increase the price of soda, much like it has done with the price of cigarettes.[42] As research continues to show the negative effects of the obesity rates in America, citizens will be more likely to accept measures such as a soda tax. For now, however, the policy is met with resentment and resistance by the general public and is not likely to be successful in changing the public's attitude towards soda. If the federal and state legislatures can find better ways to incentivize "healthy" behavior rather than regulate unhealthy behavior, they will be more successful in promoting health improvement measures. A popular place to start is with children. One new measure that the Obama administration has recently unveiled is a plan to ban all junk food advertisements in schools, including soda.[43] Ultimately, some regulation is necessary. Public health measures will inherently include some sort of imposed restriction on an individual's behavior, but the numbers show that American obesity has become too big to ignore and it is time for the government to get serious about getting healthy.

Emergency Medicaid: Healthcare Reform and Undocumented Immigrants

Alexandra Pearsall
Alexandra.Pearsall @student.shu.edu

Introduction

A major issue surrounding the Patient Protection and Affordable Care Act (PPACA), often referred to as "Obamacare," concerns the nearly 12 million undocumented immigrants currently living in the United States and their ineligibility to apply for federal health care.[1] Although federal law does not allow undocumented immigrants to apply for health care because of their illegal resident status, undocumented immigrants still have access to emergency medical care under federal law.[2] When it comes time to pay for the emergency medical care given to undocumented immigrants, providers often turn to Medicaid, specifically what is colloquially known as "emergency Medicaid" because Medicaid reimburses hospitals when patients are unable to pay for their emergency room bills. Funding for Medicaid is provided by United States citizen taxpayers, and it is estimated that 1.3 billion dollars of taxpayer money goes towards "emergency Medicaid."[3] Because of the heated debate over illegal immigration in the United States and the heavy burden on taxpayers to support these illegal immigrants, the issue of extending federal health care to undocumented immigrants is highly controversial. This article considers why it would be beneficial to American citizens to allow illegal immigrants to have the right to apply for health care.

The Difference Between Medicaid and "Emergency Medicaid"

Medicaid provides health coverage to "more than 50 million children, families, pregnant women, the elderly, and people with disabilities."[4] It is available in every state and it pays for a "full set of services for children, including preventive care, immunizations, screening and treatment of health conditions, doctor and hospital visits, and vision and dental care."[5] Additionally, these services are often provided at no cost to families.[6] However, undocumented immigrants are not eligible for federally funded public health insurance programs such as Medicaid.[7] Therefore, when undocumented immigrants are not eligible under these circumstances to apply for Medicaid, they must resort to "emergency Medicaid" in order to seek professional medical treatment.

The existence of "emergency Medicaid" does benefit society as a whole, in that its purpose is to prevent the spread of communicable diseases and to ensure general health.[8] In this context, "emergency" means "sudden-onset conditions that threaten life or could cause serious impairment."[9] This is highly beneficial to every American citizen because immigrants travel from all different parts of the world and, in order to ensure public health from the various strains of illnesses and diseases, undocumented immigrants must be able to access medical services. When an illegal immigrant is struck with these "emergency" conditions, they have the federal right to obtain medical services from hospitals, which in turn protects American citizens from these very conditions.[10] Diane Rowland, executive vice president for the nonpartisan Kaiser Family Foundation writes that "from the perspective of our health-care system, when people show up and they're sick, the health-care system is obligated to take care of them."[11] It seems just and fair to provide these types of services to non-citizens, whether they have entered illegally or not. However, a much debated issue comes from how medical providers are affording to provide this medical care to undocumented immigrants.

After medical assistance, hospitals may try to bill the undocumented immigrant patient first.[12] However, if the patient cannot pay for any reason, the hospital will turn to "emergency Medicaid" to recoup their costs.[13] In 2011, the federal government paid out 1.3 billion dollars under "emergency Medicaid".[14] Additionally, states paid "hundreds of millions of dollars" to repay hospitals for these services.[15] Sandhya Somashekhar wrote in the Washington Post, that a "large percentage" of the financial burden imposed on hospitals

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is labor and delivery costs because the majority of patients that use "emergency Medicaid" are pregnant women.[16] These costs likely will only increase as immigrants continue to enter the United States illegally. Therefore, there is a strong need for health care reformation. Allowing undocumented immigrants to apply for federal health care would alleviate the burden on taxpayers who fund "emergency Medicaid."

Why Illegal Immigrants Cannot Apply For Federal Health Care

The legal authorization to limit federal health care services to illegal immigrants comes from The Code of Federal Regulations of the United States. 42 C.F.R. § 440.255 limits services available to illegal immigrants to certain circumstances and conditions.[17] § 440.255(c) addresses aliens who are not lawfully admitted for permanent residency in the United States.[18] The pertinent part states that an illegal alien must receive the services necessary to treat this condition:

> The alien has, after sudden on set, a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: (i) Placing the patient's health in serious jeopardy; (ii) Serious impairment to bodily functions; or (iii) Serious dysfunction of any bodily organ or part…[19]

This provision protects the safety of American citizens because if an undocumented immigrant is permitted to acquire medical care to prevent such symptoms that could be indicative of communicable diseases, then undocumented immigrants will not pose as a threat to American health safety.

Therefore, though undocumented immigrants are not allowed access to federal Medicaid, the fact that they have access to "emergency Medicaid" shows that undocumented immigrants still can obtain the vital medical care that they require.

Additionally, the Supreme Court in the 1976 case *Mathews v. Diaz* ruled that limits are placed on the ability of illegal immigrants to obtain medical benefits and services.[20] At the time, "in order to qualify for Medicaid benefits, a noncitizen had to be lawfully admitted to the United States and continuously reside therein for the five years preceding application for benefits."[21] In *Diaz,* the Court found that Congress is not required to provide every benefit it provides to citizens to all aliens, nor must it extend identical benefits to every distinct class of alien.[22] Patrick J. Glen, in his article titled "Health Care and the Illegal Immigrant" reasons that "The Constitution does not require identical treatment for every individual in the United States, citizen or alien, or identical treatment across different classes of aliens."[23] The *Diaz* ruling remains good law and can be cited as precedent that health care does not need to be extended to illegal immigrants.

Finally, in 1986, Congress enacted the Emergency Medical Treatment and Active Labor Act (EMTALA), which was meant to provide patients with access to emergency medical care and "to prevent hospitals from 'dumping' unstable patients that could not afford to pay for their care."[24] Even though EMTALA refers specifically to hospitals with an Emergency Department, the federal government has applied the law requirements to "all facilities that participate in the Medicare program and offer emergency services."[25] Therefore, over time the concept that undocumented immigrants cannot apply for federally funded public health insurance programs has been solidified, while simultaneously the ability for undocumented immigrants to obtain emergency care has been legally recognized in hospitals around the country.[26]

"Emergency Medicaid"

PPACA And "Emergency Medicaid"

Somashekhar writes that the issue of taxpayers subsidizing health care for undocumented immigrants will likely expand under Obamacare.[27] Somashekhar defines undocumented immigrant "emergency Medicaid" issues as: "reimbursement offered to hospitals to provide emergency and maternity care to people who, based on their income and other factors, would be eligible for regular Medicaid if only they weren't a) in the country illegally, or b) in the country legally but not lawful long enough to join Medicaid (five years)."[28] Additionally, Phil Galewitz, in his article "How Undocumented Immigrants Sometimes Receive Medicaid Treatment" writes:

> A little-known part of the state-federal health insurance program for the poor pays about $2 billion a year for emergency treatment for a group of patients who, according to hospitals, mostly comprise illegal immigrants. Most of it goes to reimburse hospitals for Delivering babies for women who show up in their emergency rooms, according to interviews with hospital officials and studies.[29]

Galewitz writes that this funding accounts for less than one percent of the cost of Medicaid and the percentage "underscores the political and practical challenges of refusing to cover an entire class of people."[30]

Galewitz uses Florida as an illustration of the impact of illegal immigrants in the health system.[31] Galewitz cites Joanna Aquilina, the chief financial officer of Bethesda Healthcare System in Boynton Beach, Florida, who says: "We can't turn them away."[32] Aquilina sees many illegal immigrants because of the hospital's proximity to farms that harvest sugarcane and other seasonal crops.[33] Galewitz writes:

> Nearly one-third of Bethesda Hospital East's 2,900 births each year are paid for by Emergency Medicaid, the category that covers mainly illegal immigrants. The category includes a small proportion of homeless people and legal immigrants who've been in the country less than five years. Hospitals can't ask patients whether they're illegal immigrants, but instead determine that after checking whether they have Social Security numbers, birth certificates or other documents.[34]

Additionally, "one study of Medicaid spending from 2001 to 2004 in North Carolina estimated that 99 percent of emergency Medicaid recipients were illegal immigrants."[35] This demonstrates a real issue exists with the distribution of emergency Medicaid in the United States for illegal immigrants, which places a high financial burden on American taxpayers.

Why The United States Should Extend Health Care to Illegal Immigrants

Health care for illegal immigrants has become a hotly debated topic, as the United States has been unable to curtail the influx of illegal immigrants from several countries around the world. PPACA is part of the U.S. Department of Health & Human Services (HHS). Observing the aims of the current health reform, the website for HHS makes it clear that only Americans are covered. HHS states: "The mission of the Department of Health and Human Services is to help provide the building blocks that Americans need to live healthy, successful lives."[36] Further, the website writes: "The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves."[37] This issue, however, goes well beyond an isolated argument for allowing undocumented immigrants the right to health care.

Some pundits argue that access to health care is a basic human right, analogous to education and employment.[38] Michael J. McKeefery in his article, "A Call to Move Forward: Pushing Past the Unworkable Standard That Governs Undocumented Immigrants' Access to Health Care Un-

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der Medicaid" writes that one perspective is to realize that undocumented immigrants are human beings and "it is their moral right to have access to services that are essential to sustaining life."[39] Further, some undocumented immigrants are children who have had no choice but to follow their parents.[40] Therefore, it would seem unfair to deny these basic human rights to innocent children. Finally, scholars contend that undocumented immigrants are found to pay more in taxes than they collect in benefits; many undocumented immigrants stay in the United States for a "substantial period of time" and thus contribute much to their communities by paying taxes.[41] Therefore, undocumented immigrants serve as a valuable asset to the economy.

The other side of the argument is that undocumented immigrants should not be entitled to apply for Medicare because the cost considerations justify excluding undocumented immigrants from coverage.[42] McKeefery writes that "tax-supported services, like federal health care plans, cannot sustain the increase in demand that would result if undocumented immigrants were included in public health care programs."[43] Other substantial arguments are that immigrants who reside illegally in the United States should not be allowed to receive the benefits of health care coverage because undocumented immigrants do not usually pay taxes to support federal programs.[44] Finally, McKeefery argues that by denying coverage to undocumented immigrants, it would "likely create a disincentive for individuals to enter the United States illegally."[45] Thus, there is a strong argument for continuing to bar undocumented immigrants ability to apply for Medicare and to further restrict undocumented immigrants access to "emergency Medicare."

"[O]ne study of Medicaid spending from 2001 to 2004 in North Carolina estimated that 99 percent of emergency Medicaid recipients were illegal immigrants."

Considering both sides of the debate, it is hard to deny what the United Nations, of which the United States is a charter member, considers to be fundamental and basic human rights. Article 25 of The Universal Declaration of Human Rights protects the right to adequate medical care:

> Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.[46]

The purpose of the United Nations is to "achieve its goals and coordinate efforts for a safer world for this and future generations." In addition, the UN has provided an Article that specifically addresses the need to provide all humans with adequate medical care. Since the Untied States is a charter member of the UN, how does the United States have any right to deny this emergency medical care to undocumented immigrants on American soil?[47]

Conclusion

There are certainly many powerful and compelling arguments on both sides of the debate. However, from a humanitarian perspective, it seems that the only fair and reasonable solution to this issue is to extend the ability to apply for Medicare to undocumented immigrants because it would eliminate the issue of American taxpayers needing to pay for immigrant medical care and also allow undocumented immigrants to take the necessary steps in order to cover themselves when future medical ailments arise, thus protecting national health and economy. Therefore, eligibility for all federal health care programs ought to extend to undocumented immigrants.

President Obama's Notable Advance toward Battling Health Care Fraud

Anna Vaysberg
Anna.Vaysberg@student.shu.edu

Health care fraud is a white-collar crime that involves the filing of dishonest health care claims in order to make a profit. This fraud occurs in many ways and the list encompasses individuals obtaining subsidized or fully-covered prescription pills that are medically unnecessary and then selling them on the black market for a profit; billing by practitioners for care that they never rendered; filing duplicate claims for the same service rendered as well as countless others.[1] In fact, the ways to defraud are continuously increasing while detection has become increasingly more difficult.[2] Health care fraud costs the country an estimated $80 billion dollars a year and that figure has been growing exponentially. Due to this fact, health care fraud has been attracting political attention and was most recently placed to the legislative forefront by President Obama. The graph shows the increase of health care fraud prosecutions in the last 20 years. As is readily apparent, Obama's administration has been the most efficient and proactive with regards to combating health care fraud. President Obama's efforts to ramp up the fraud and abuse investigations resulted in $4.1 billion recovered in 2011.[3] The increasing number of prosecutions shows that the steps the President has taken including expanding the Health Care Fraud Prevention and Enforcement Action Team (HEAT), increasing the punishment for those accused, and lessening the standard required for prosecution of health care fraud cases, which have all proven to be effective in tackling fraud within our health care system.

President Obama has specifically addressed the issue of fraud in relation to Medicare insurance. Medicare and Medicaid programs comprise the largest single purchaser of health care in the world, and account for over twenty percent of all U.S. federal government spending.[4] Thus, much of the fraud that occurs is targeted at Medicaid and Medicare insurance providers. HEAT is at the forefront of investigating and prosecuting for such crimes. Since the creation of HEAT in 2009, the Medicare Fraud Strike Force, (a branch of HEAT) has expanded from 2 to 9 locations and more than 320 defendants were charged with allegedly billing more than one billion dollars in false claims. The locations now span the entire country with offices in the following states: Louisiana, New York, Illinois, Texas, Michigan, California and Florida.[5]

"[Health care fraud] violations can now occur whether or not the individual has actual knowledge or specific intent to commit a violation."

The Patient Protection and Affordable Care Act of 2010 (PPACA) has revised preceding provisions dealing with health care fraud. One goal of the revision was to disincentivize this type of fraudulent behavior by increasing the level of punishment. Specifically, there has been a two-level increase in the offense level for any defendant convicted of a federal health care offense relating to a government health care program which involves a loss of up to $1 million; a three-level increase in the offense level for any defendant convicted of a federal health care offense relating to a government health care program which involves a loss of up to $7 million and a four-level increase in the offense level for any defendant convicted of a federal health care offense relating to a government health care program which involves a loss of up to $20 million.[6] So what would have previously been punished on a scale of a misdemeanor has the possibility of being punished as a felony. Increasing the risk associated with committing such a crime is thought to be proportionate with a reduction of such crimes.

President Obama, through the PPACA, has also lessened the standard of criminal culpability required for the prosecution of health care fraud cases.[7] Specifically, there has been a diminished requirement in terms of the *mens rea*—the subjective intent—

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required for prosecution of health care fraud cases. Prior to the passage of the PPACA, a conviction for health care fraud under 18 U.S.C. § 1347, required the government to prove that the defendant: (1) knowingly and willfully executed, or attempted to execute, a scheme or artifice; to (2) defraud a health care benefit program or to obtain by false or fraudulent pretenses any money or property under the custody or control of a health care benefit program; (3) in connection with the delivery of or payment for health care benefits, items, or services.[8] The passage of PPACA has relaxed the *scienter*–guilty knowledge— requirement by inserting subsection (b), which states: "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."[9] This wording encompasses a broader range of violations by not requiring intent to commit. Simply put, prior to PPACA the government had to prove that an individual knowingly and willfully executed, or attempted to execute, a fraudulent scheme or artifice. PPACA has lowered the bar for the prosecution by relaxing that standard. Violations can now occur whether or not the individual has actual knowledge or specific intent to commit a violation. If fraud occurred, the person will be held accountable.

As can be seen from the aforementioned examples, President Obama has stepped right into the forefront of America's battle with health care fraud. Over the past few years, we have seen a 75% increase in the number of individuals whom we have charged with criminal health care fraud due to actions by HEAT and the prosecution of more than 1,400 defendants who collectively falsely billed the Medicare program more than $4.8 billion.[10]

In conclusion, the number of agencies dealing with health care fraud has increased and there has been more severe punishment for those convicted of health care fraud. In addition, the standard of culpability needed for the prosecution of health care fraud cases has been reduced. These changes have been successful initiatives in battling health care fraud.

Data Mining & Electronic Health Records: HITECH Act's "Meaningful Use" and "Secondary Use" of Health Data

Donna Hanrahan
Donna.Hanrahan@student.shu.edu

Healthcare providers are establishing electronic health record (EHR) systems at an astonishing rate, due in part to the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act was created as a part of the American Recovery and Reinvestment Act of 2009.[1] The $27 billion dollar piece of legislation offers eligible providers incentives for expanding the use of healthcare information technology (HIT).[2] This includes promoting the "meaningful use" of EHRs. The "meaningful use" standard was designed to use HIT to improve quality of care and health outcomes for patients, as well as to lower costs by eliminating repeat medical tests and reducing preventable medical errors that pervade the health-care system today. This legislation has been extremely effective in persuading healthcare providers to use EHRs. In fact, the incentives outlined in the HITECH Act are estimated to increase EHR adoption rates to 90% of all physicians by 2019.[3] Despite healthcare technology's vast potential to improve patient health in the medical arena, a host of complex legal, technical, and ethical issues surrounding the use of HIT as incentivized in the HITECH Act still exist, specifically privacy, confidentiality, autonomy, and the preservation of the physician-patient relationship. By reevaluating, clarifying, and enforcing HIPAA guidelines as they pertain to secondary use of EHRs, researchers can access large valuable data sets without compromising patients' rights to privacy and autonomy. However, EHRs cannot be considered a cure-all for patient health. We must acknowledge the potential detrimental effect it may have on the physician-patient relationship. It is important to provide patients with the right to dictate which information they choose to share and allow them to opt out of the platform to protect patient autonomy while optimizing the research potential of electronic health data.

"[T]he secondary use of health data for research has great potential to improve health outcomes, reduce medical errors, predict health trends, and demonstrate the comparative value of drugs and other treatments."

The HITECH Act and "Meaningful Use"

The HITECH Act offers hospitals and eligible healthcare professionals incentives for expanding the use of healthcare information technology, including the "meaningful use" of EHRs.[4] Incentive payments are made available through the Medicaid and Medicare programs. The Centers for Medicare & Medicaid Services (CMS) judges whether a healthcare provider has satisfied the meaningful use core objectives through the use certified health technologies.

The Department of Health and Human Services (HHS) defines "meaningful use" as using certified EHR technology to: (1) improve quality, safety, efficiency, and reduce health disparities; (2) engage patients and families; improve care coordination, and population and public health; and (3) maintain privacy and security of patient health information.[5] This "meaningful use" framework incentivizes improvements to clinical care and quality by encouraging healthcare professionals to take advantage of instantaneous and patient-specific information.

There are three stages of "meaningful use." The first stage is the use of HIT for basic data collection, including demographic and medication history. The second stage is the use of EHR data to improve clinical processes including patient controlled data, clinical decision support, health information exchange, and quality measurement and research. The third stage is the use of EHR data to improve health outcomes, quality, safety, efficiency, and population health at the national level.[6] Hospitals and providers eligible for the EHR Incentive Program do not need to attest to meaningful use in their first year of participation. Rather, healthcare entities must simply implement an EHR to receive an incentive pay-

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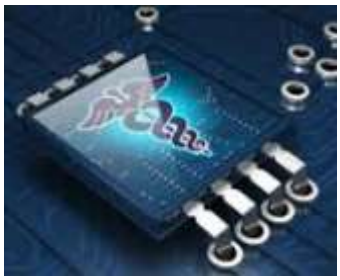
ment from their State.

The HITECH incentive payments are quite substantial. To receive payments, eligible professionals and hospitals must meet at least 5 of the "meaningful use" criteria defined, consisting of 15 core data points and 10 menu options.[7] The criteria require the entry of patient demographic and insurance information, e-prescribing, and the use of drug interaction software to ensure patient safety. [8] Eligible professionals and hospitals that meet the criteria can be rewarded up to $44,000 in Medicare and $63,750 in Medicaid payments over 5 years. After 2015, all physicians who fail to meaningfully use EHRs will be subject to reductions in Medicare and Medicaid reimbursement.[9]

Health Information Exchanges

The HITECH Act is a step towards the eventual goal of a national, interoperable, private, and secure electronic system to allow information to be shared among all the sites where patients receive care.[10] While still in its infancy, Health Information Exchanges (HIEs) are being established at the community, state, and national level to facilitate the electronic exchange between systems. The State Health Information Exchange Cooperative Agreement and the Nationwide Health Information Network (NHIN) received $600 million in federal funding to create a platform for health information exchange across the United States.[11] At the state level, governments are creating statewide health information networks (HINs). At the national level, the Office of the National Coordinator (ONC), which oversees deployment of the HITECH Act, is executing plans to create an NHIN. Provider organizations participating in NHIN include Kaiser Permanente, the Cleveland Clinic, and the Veterans Administration.



These networks can lead to the development of data repositories filled with rich sets of health data for millions of individuals. Such data repositories can provide researchers with information necessary to improve quality of care and make significant discoveries in medicine that they may not otherwise have access to. Despite their great potential, progress in developing HIEs and repositories has been gradual. Many hospitals and clinics are hesitant to implement the systems because they do not have the finances or infrastructure necessary to do so.[12] Moreover, there are also significant concerns over patient privacy and autonomy.

Secondary Use of Health Data

Until recently, collecting data for "secondary use" was an arduous task. "Secondary use" in healthcare is defined as the use of information collected from health records, electronic or manual, outside of direct patient care delivery. This includes data collection for the purpose of "research, quality and safety measurement, public health, payment, provider certification or accreditation, marketing, and other business applications." [13] Such use of healthcare data in biomedical research has the potential to drastically improve the quality and affordability of healthcare services in the United States. EHRs contain structured information about patients, which is extremely valuable in research because now information can be retrieved in a much quicker and more efficient fashion than more traditional methods of record keeping. Researchers can develop algorithms to search through EHRs, including free-text clinician notes, to find data valuable to a specific study.[14]

By providing researchers with rich ready-made large data sets, the secondary use of health data for research has great potential to improve health outcomes, reduce medical errors, predict health trends, and demonstrate the comparative value of drugs and other treatments.[15] Other benefits include the increased ability to analyze the efficacy of treatment options and identify evidence-based best practices. Furthermore, predictive modeling techniques may be applied to electronic health data to identify medical conditions before the onset

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of symptoms and promote earlier interventions. While experimental studies, such as randomized controlled clinical trials, are likely to continue to be the gold standard of clinical research compared to observational studies, they are more expensive and time consuming. As such, electronic health data serves as a rich resource for the conduction of valuable observational studies which can be performed quickly and inexpensively.

Nevertheless, the unprecedented surge in the amount of healthcare data, as well as the relative ease with which that data can be aggregated and exchanged between providers and researchers, raises ethical questions about its use in research, particularly concerning patient privacy and autonomy. The Health Insurance Portability and Accountability Act (HIPAA) requires protected health information (PHI) to be de-identified or authorized by the patient for release in order to be used in research. However, de-identified data would omit significant clinical, demographic, and time-related data that would render the data sets much less useful for many research purposes. While de-identified data leads to incomplete data sets, it seems like a small price to pay for protecting the privacy of patients, especially those with stigmatized conditions.

Accordingly, researchers are forced to walk a fine line between ensuring patient privacy and maximizing the descriptive power of their data sets. Before the research value of secondary use can be fully realized, ethical considerations surrounding the mining of electronic health data must be explored, namely infringements on an individual's privacy, confidentiality, and autonomy. It is necessary to establish a national framework of policies for the secondary use electronic health data to allow stakeholders to harness valuable information to improve the United States' healthcare systems while maintaining patient autonomy and privacy protections.[16]

Data Quality Concerns

The mass amount of recent electronic health data makes it possible to assess the overall burden of disease and evaluate the impact of interventions on a national scale. Despite its promise, research through electronic health data mining and "secondary use" is not without flaws. Data quality concerns are inherent in data that is being used for any purpose other than what it was originally intended, especially considering the fragmented nature of the healthcare industry and the numerous platforms on which data is being collected.[17] First, there are hundreds of different EHR systems, each with a distinct representation of data that makes it difficult to aggregate.[18] Second, even within the same EHR system, information incompleteness, inaccuracy, and inconsistency are common challenges.[19] Different healthcare professionals tend to use the same system differently.[20] Third, clinicians tend to prefer using free text compared to structured data entry because it is more easily adapted to their individual practice styles and work flows, although it may make it more difficult to compile and analyze.[21] Fourth, incomplete and duplicate records threaten the quality of research using data mined from EHRs.

Some critics may argue that EHRs make it more possible for clinicians to falsify charts and reports, which would lead to both data quality and trust issues with patients. However, the falsification of records would not only violate the moral imperative against lying, but also infringe on the fiduciary relationship between the physician and patient. Furthermore, there are methods to protect against such acts, including audits, fraud charges, and reclamation of funds under the False Claims Act and the Deficit Reduction Act.[22] These measures are valid disincentives to data falsification when it comes to patient records.

Lastly, while the incentives and mandates of HITECH and "meaningful use" have led to an enormous amount of data being stored and generated by the U.S. healthcare system, there is an extreme lack of interoperability. The electronic data exists in different formats on hundreds of different systems. Aggregating this sizeable amount of data for research purposes will prove difficult, if not

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impossible, without a national regulatory framework to reduce inter-system variation and improve data quality. The federal government must determine national data standards or guidelines and clinicians to decrease data variation between systems.[23] By implementing legislation to address these issues, the federal government can alleviate many ethical concerns while allowing the United States healthcare system to benefit from more effective and larger scale use of secondary data.

HIPAA and Privacy Concerns

With improved access to data comes increased risk of wrongful disclosure of patient health information. Human error, hacking, IT glitches, and theft or loss of hardware that contains such information are just a few possible risks. HITECH challenges certain notions of privacy and security found in HIPAA yet enhances others. HIPAA prohibits the disclosure of protected health information (PHI) without the consent of the patient except for the purposes of treatment, payment, or healthcare operations. Under HIPAA, "business associates" of covered entities with access to PHI are not directly regulated.[24] Rather, they are obliged to comply with HIPAA pursuant to mandatory written agreements within the covered entities for which they work. The HITECH Act, on the other hand, provides for regulation of business associates and stipulates that HIPAA's privacy and security rules directly apply to them.

When it comes to security breaches involving PHI, HITECH mandates public notification when unsecure, unencrypted PHI is disclosed or used for an unauthorized purpose, similar to many state and federal financial data breach laws. The HITECH Act also requires that patients be notified of both internal and external breach of their data security. If a breach affects over 500 patients, HHS must also be notified and the name of the breaching institution will be posted on the HHS web site. There are also certain circumstances where local media will need to be notified to inform the public of breaches than effect many people within a given area.[25]

"Data quality concerns are inherent in data that is being used for any purpose other than what it was originally intended…"

While HITECH is a federal law, HHS and state officials are granted with the authority to enforce the law. Subtitle D of the HITECH Act addresses the privacy and security concerns of EHRs by strengthening both the civil and criminal enforcement of the HIPAA rules.[26] Section 13410(d) of the HITECH Act revised the Social Security Act by establishing significant penalties for violations of security policy of the HITECH Act.[27] If an institution or individual is unaware of a violation despite due diligence, the minimum penalty is $100 per violation, with a cap of $25,000 for violations of an identical requirement within the same year.[28] If the security violation is due to "willful neglect," the minimum penalty is $10,000 per violation, with a cap of $250,000.[29] The maximum penalty is $50,000 per violation, with a cap of $1.5 million.[30] These are clear examples of the HITECH's acts attempts to deter data breaches and mitigate security concerns.

The healthcare industry continues to tread carefully when it comes to pursuing "meaningful use" of HIT while protecting patient privacy under HIPAA regulations. Some argue, however, that the current HIPAA regulations do not accommodate the powerful research opportunities that may become possible as HIT and HIEs become more commonplace. The public health benefits of secondary use merit careful consideration of how such data can be optimized while protecting patient autonomy.

Autonomy, Informed Consent, and Syndromic Surveillance

Several ethical considerations must be addressed before a national framework is implemented to address issues of autonomy and informed consent. Patient autonomy is threatened when an individual's PHI is shared without that person's knowledge or consent. When data mining electronic health data, it is unlikely that pa-

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tients are told that their data is being accessed. It is even less likely that they are contacted for their consent.

This is concerning, as champions of patient autonomy argue informed consent is necessary for the secondary use of health data. Patients often believe they have a right to know who is viewing their medical information, why it is being accessed, and how it is being used. Additionally, those who champion patient autonomy believe that patients have a right to take an active part in decisions about the access, content, and ownership of EHR data. It would appear to be a violation of autonomy to aggregate and generate new information about a patient's health without their knowledge or permission. Patients provide information to healthcare professionals in confidence with the specific goal of advancing their own personal health outcomes. If the principle of autonomy is intrinsically linked to advancing an individual's own personal health outcomes, then any form of secondary use (by definition as the use of PHI outside of direct patient care delivery) appears to be a violation of the principle of "respect for persons." A critical question here is whether or not you can turn a patient into a research subject without their knowledge or consent.

To overcome these issues of autonomy, patients should be able to access their EMRs with relative ease. Moreover, patients should maintain the right to have a degree of control over the records' content. While it seems unreasonable to allow patients to modify or delete any of the content entered by healthcare professionals per se, it seems judicious to allow autonomous patients to review, annotate, or challenge their own electronic medical record. Furthermore, federal regulations must be reassessed to determine what is considered valid informed consent for research using electronic health data specifically. Some HIEs are attempting to develop new consent processes to overcome HIPAA compliance issues. Some are calling for a blanket "opt-in" or "opt-out" policy, while others suggest the independent ability to exclude certain types of sensitive data in one's own health record.[31] Ideally, to maintain the highest level of patient autonomy, the patient would have full say as to what specific information may be shared and with whom it may be shared.

Certain public health situations, though, necessitate the use of electronic health data without informed consent. This is particularly true during public health emergencies. Syndromic surveillance systems seek to use existing health data in real time to provide immediate analysis for early detection of disease outbreaks, and to monitor disease trends.[32] In the interest of population health, the HITECH framework allows for syndromic surveillance to notify public health officials of reportable conditions.[33]

It is also necessary to note the point of "electronic exceptionalism." There is a longstanding history of manual disease surveillance. However, it seems more ethically unsettling when this process is done with high technology tools that can quickly aggregate and share data in unprecedented ways. While critics may look at syndromic surveillance through EHR data as exceptional because of its electronic nature, its use may not be so different than traditional methods after all. There has been mandatory reporting of certain conditions to public health officials at the local and national level for decades before EHRs existed, including the reporting of drug-resistant tuberculosis, certain cancers, and HIV. EHRs will make reporting of these conditions and others deemed necessary to protect public health easier, and may actually do a better job at protected patient health data by encrypting and preventing unauthorized access through password protection.

Meaningful for Whom?

It is clear that the "meaningful use" of EHRs is on the rise, but is important to question for whom is it meaningful, and how meaningful is it? Let us consider one of the primary goals of "meaningful use," which is to provide patients with electronic resources to increase participation in their own care. Patients are provided with an electronic copy of their health information within three business days if requested,

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including diagnostic test results, medication lists, allergies, discharge summaries, and procedures.[34] Accordingly, providers often offer patients access to their online personal health record (PHR). PHRs are largely secure as they are encrypted and password-protected. However, it is important to note that patients need more than just Internet access and a very basic understanding of health information to fully benefit from PHRs.[35] Not only must patients be able to read and interpret lab results; they must be willing and capable to act on the information he or she receives. This point has been largely neglected in discussions surrounding the HITECH Act. For those without access to the Internet, those with very limited health literacy, and those unable to act on that information for financial or other reasons, EHRs have limited to no direct benefit. It is important to acknowledge these limitations and ethical concerns under the HITECH Act. In response, one must consider community outreach and education programs that focus on Internet and health literacy, rather than merely advertising new electronic and personal health record capabilities.[36] Many fear that patients will misunderstand or misinterpret information if they read it without a medical professional to interpret it. It is possible that the HITECH Act granted healthcare providers a new ethical obligation to work with patients to ensure they understand these tools and how to use them.

Furthermore, healthcare professionals run the risk of relying solely on PHRs to communicate important health information to their patients. This stands to cause great harm to the doctor-patient relationship. Electronic tools must not replace the face-to-face communication between the healthcare provider and patient that is essential to maintaining trust and achieving improved health outcomes.

"[F]ederal regulations must be reassessed to determine what is considered valid informed consent for research using electronic health data…"

It has been well established that the government has the police power authority to regulate for the safety and welfare for the population. However, it is important to consider from a bioethical perspective where the line ends between public health surveillance and an intrusion on one's own individual liberty and autonomy. On the other hand, it could be argued that it would be a "tragedy of the commons" if individuals independently acted according to each one's self-interest and refused to be surveilled. To take a communitarian perspective, aggregation of public health data is an essential resource to public health officials and necessary for the welfare and beneficence of the population as a whole.

Beneficence of Electronic Data in Medical Research

Despite the ethical concerns addressed above, the use of electronic health data is critical to ensuring patient health, improving our healthcare system, and making new scientific discoveries in this technological age. Critics may question whether EHRs are truly meaningful or whether it is an "excessive bureaucratic requirement to spend public dollars on doctors' computer systems."[37] The answer to this question can be discussed through the principle of justice. One can argue that it is ethical to expend public funds for EHR systems that provides for the greater good and benefits for the public as a whole. Data that is well-structured and easily retrievable benefit clinicians, patients, and the greater population. These benefits include safer prescribing, prevention of medication errors, epidemiological tracking to protect population health, and public medical error reporting. Furthermore, there is a clear demand to switch from outdated, burdensome, and inefficient clinical charting traditions to electronic format.

EHR adoption aims to reduce cost, which is a primary goal of health reform in the United States.[38] The increase in information available to clinicians can help prevent redundant or unnecessary tests and imaging. Furthermore, EHRs can provide point-of-care clinical decision support (CDS) as doctors prescribe tests,

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medications, and imaging requests, which can also help reduce costs. EHRs can also enable users to measure desired outcomes and report this data more quickly and easily, saving both time and money. With regard to the costs associated with EHRs, studies demonstrate strong returns on financial investment that may be achieved following EHR implementation.[39] Other financial benefits include increased revenues due to improved care coordination, averted costs of paperwork, chart pulls, and billing errors, and fee-for-service savings including the rate of new procedures and charge capture.[40]

In addition, the secondary use of health record information is anticipated to become one of the healthcare industry's greatest assets and the key to greater quality and cost savings over the next five years.[41] A recent report by the McKinsey Global Institute, estimates the potential annual value to the healthcare industry at over 300 billion dollars.[42] These savings in cost benefit both the patient and provider.

There are also several patient-centered benefits that result from the "meaningful use" EHR data. Perhaps one of the most promising results of EHR data mining is the use of predictive modeling techniques to identify medical conditions and promote interventions before the onset of symptoms. Furthermore, retrospective analysis of the health data mined from EHRs could expedite scientific discovery in medicine by providing valuable information for research. In addition, physicians' access to data and analysis could demonstrate the efficacy of different treatment options across large populations, which could help treat and prevent chronic conditions. Lastly, such data can be used to identify evidence-based best practices, identify potential patients for clinical trials, and monitor patient compliance and drug safety. These measures show beneficence towards the patient by providing better more individualized care.

"It is possible to reconcile the use of electronic health data for research while maintaining respect for patient's autonomy."

Conclusion

EHRs can facilitate the efficient delivery of healthcare in a cost-effective, safe, and patient-centered way. The safety and privacy of patients and potential research participants is of utmost concern and can be maintained while capitalizing on technological advances to improve the United States healthcare system. It is possible to reconcile the use of electronic health data for research while maintaining respect for patient's autonomy. Accomplishing this will require collaboration among ethicists, researchers, clinicians, informatics specialists, and policy makers.[43] By reevaluating, clarifying, and enforcing HIPAA guidelines as they pertain specifically to secondary use, the federal government could point the healthcare field in a direction that both protects of patients' privacy and autonomy while empowering researchers with valuable data sets. Permitting the establishment HIEs and data repositories of EHR data for research purposes has great potential for identifying evidence-based best practices, monitoring patient compliance and drug safety, and showing the efficacy of different treatment options across large populations. However, we must provide patients with the right to dictate which information they choose to share and allow them to opt out of the platform to protect patient autonomy while optimizing the research potential of electronic health data. Moreover, EHRs cannot be considered a cure-all for patient health and we must acknowledge the effect it may have on the physician-patient relationship.

The HITECH Act's initiatives take us a step closer to President Obama's stated goal of "an EHR for every American by 2014."[44] The integration of HIT into our healthcare system is more than just a technological upgrade; it represents a fundamental change in our approach to healthcare practice. EHRs will continue to evolve as a critical component in the medical field, and can be ethically integrated to deliver the highest quality healthcare to Americans in the 21st century.

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President Obama's Notable Advance toward Battling Health Care Fraud

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Student Contributors

Alice Anderson is a first year law student pursuing the health law concentration. Alice graduated summa cum laude from St. Edwards University in Austin, Texas in 2012, earning her B.A. in History with a minor is Psychology. During undergrad, Alice built a background in public policy which she hopes to continue to build while at Seton Hall Law. Alice spent a year doing research for the National Consumer Law Center in Boston working on energy policy. She also worked at an immigration law firm in Washington D.C. After graduating from St. Edwards, Alice worked as the office manager of a small firm in Austin which represented local governments as well as individuals with their legal needs. Since starting at Seton Hall Law, Alice was elected Treasurer of the Health Law Forum and will be working with the Community Health Law Project in Trenton, New Jersey during the summer. Outside of school, Alice plays on a social soccer team in Hoboken.

Donna Hanrahan earned a M.S. in Bioethics at Columbia University and a B.A. in Political Science at SUNY Geneseo. Donna is involved in qualitative research at Columbia University Medical Center and works as the lead research strategist designing clinical trials at CheckedUp, a medical technology startup in New York. She is passionate about exploring the role of emerging technologies in healthcare to create better, more cost-efficient health outcomes. She was a Health Policy and Ethics Fellow at Healthcare Innovation and Technology Lab and recently spent time at Yale University's Interdisciplinary Center for Bioethics Summer Institute researching the intersections of the online social networks and epidemiology. Donna has written two articles for the Health Law Outlook in her first year and will serve as the Vice President of the Health Law Forum next year.

Christina Le is a second year law student at Seton Hall University School of Law. She graduated from Rutgers, The State University of New Jersey, with a B.S. in public health in 2011. After graduation, she worked at an orthopedic sales company and became interested in medical device litigation. She is currently an intern for the New Jersey Office of the Attorney General, Government and Healthcare Fraud section. Christina is a member of the Seton Hall Legislative Journal and will serve as a Senior Editor of the Health Law Outlook next year.

Student Contributors

Alexandra Pearsall is a first year law student pursuing the health law concentration at Seton Hall University School of Law. She recently earned her B.A. in English and Spanish from James Madison University. While at James Madison, she volunteered at a local elementary school where she gained a first-hand perspective as to the sensitive issues involving the children of undocumented immigrants attending the American public school system. Her direct contact with the community sparked her interest in the prevailing arguments for and against illegal immigration in the United States.

After graduating from James Madison, she volunteered at Children's Specialized Hospital, where she has been able to interact with staff caregivers and families of admitted patients. Many of those families involve non documented immigrants with children who require their services. She is passionate about combining her interest in health care with the current issue of illegal immigration in the United States. She is excited to continue writing for the Seton Hall Health Law Outlook and will serve as the Secretary for the Seton Hall Health Law Forum next year.

Anna Vaysberg is a second year law student at Seton Hall Law School. She has an interest in health law, family law and bankruptcy. She is involved with many different organizations in school including the Health Law Outlook, the Center for Policy and Research and the Women's Law Forum. Last summer Anna interned for the Honorable Judge Stephen Bernstein, in the family law part of the chancery division. Currently Anna is working at a bankruptcy law firm.

Her undergraduate studies took place at Rutgers University, where she was a Management major in the Business School. She was a member of Gamma Phi Beta sorority and participated in activities such as Camp Fire USA, Robert Wood Johnson's "Adopt-A-Child" program, Rutgers University's Dance Marathon, Crescent Classic, and the New Brunswick Campus Clean Up. Her hobbies include playing tennis, traveling and reading. Anna will serve as a Senior Editor of the Health Law Outlook next year.

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