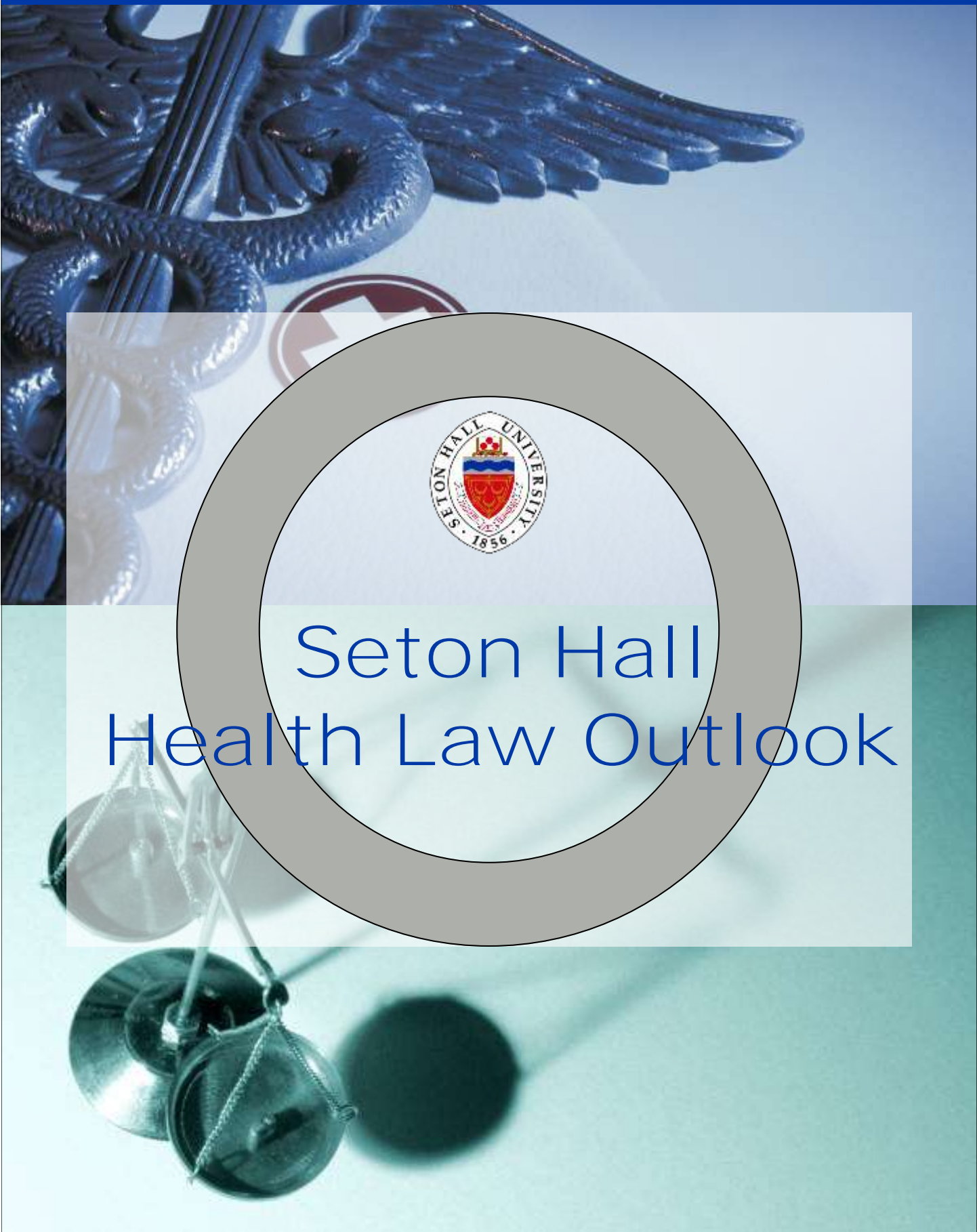




# Seton Hall Health Law Outlook



# **Seton Hall Health Law Outlook**

VOLUME SEVEN  
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## Changing the Landscape of New York Hospitals

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### Introduction

Hospital mergers and other forms of transactions, such as joint ventures and affiliations, have been occurring more frequently in recent years.<sup>1</sup> A report issued by the accounting firm, Dixon Hughes Goodman, noted the predominant reasons for hospitals to undergo these structural changes are: (1) to achieve economies of scale; (2) to benefit from a partner's unique clinical or managerial strength; and (3) to expand geographically to better provide for patient and community needs.<sup>2</sup> An economy of scale is the theory by which long-run average total costs decrease as output increases.<sup>3</sup> When hospitals merge or undergo other forms of transactions, the result is increased efficiency, which ultimately reduces average costs.<sup>4</sup> Often, a smaller hospital or a hospital that is not as nationally recognized will strategically merge with a larger hospital to attain the benefits of the larger hospital's managerial or clinical strengths.<sup>5</sup>

Recently, hospitals in New York City have undergone significant organizational changes. Mount Sinai Medical Center has merged with Continuum Health Partners ("CHP").<sup>6</sup> Mount Sinai Medical Center is a 1,171 bed hospital nationally ranked by the U.S. News and World Report and

internationally recognized for several specialties including: Cardiology & Heart Surgery, Diabetes & Endocrinology, Ear, Nose & Throat, Gastroenterology & GI Surgery, Geriatrics, Nephrology, Neurology & Neurosurgery, and Rehabilitation.<sup>7</sup> While CHP's hospitals are renowned and recognized in various clinical areas, these hospitals will now have a stronger force in the New York area under the Mount Sinai Health System umbrella.<sup>8</sup> Another signif-



icant organizational change is the expansion of Manhattan's Memorial Sloan-Kettering Cancer Center (MSKCC) to Connecticut.<sup>9</sup> These changes will likely have positive impacts on quality of care and improved access for patients of these hospitals. Further, the proposed closure of Brooklyn's Long Island College Hospital (LICH) has been postponed, allowing consideration of alternatives to closure, as closure would have a negative impact on area residents that rely on its services for primary care.<sup>10</sup> Accordingly, the changing landscape of New York City hospitals will have implications on patient care.

### Mount Sinai and Continuum Health Partners: The Love Triangle

Once upon a time, in the late 1990s, Mount Sinai Medical Center and NYU Langone Medical Center wooed one another and eventually merged; the merger proved to be a failure three years later.<sup>11</sup> Ken Davis, the CEO of Mount Sinai, explained that:

[T]here was no more perilous time than the period from 2001 through the end of 2003 when the merger with NYU was unraveling. By 2001, both Boards of Trustees had acknowledged that the merger was not working, auguring a period of extreme operational and financial chaos for Mount Sinai. Bond ratings plunged, faculty left, key management sought other positions, consultants were engaged, morale fell, and, most important, patients sought other institutions for their care.<sup>12</sup>

A New York Times report explained the union, "on its face, ...was a strong merger of esteemed institutions" but yet "the union fell victim to many forces, notably turf wars, as forces on each side resisted yielding autonomy."<sup>13</sup>

In June 2012, NYU and CHP, consisting of Beth Israel Medical Center, St. Luke's Hospital, Roosevelt Hospital, and The New York Eye and Ear Infirmary, were in the preliminary phases of

## Continued...

a merger.<sup>14</sup> This deal, however, never occurred.<sup>15</sup> NYU became aware that Mount Sinai approached the Board of CHP to discuss a possible merger and issued the following statement: “Given the good faith in which we have worked with CHP over the past eight months, we have determined that it is in the best interests of NYU Langone Medical Center to suspend all further discussions with CHP.” Because of the history of these institutions, this situation embodies a complicated love triangle. However, Mount Sinai and CHP, together known as Mount Sinai Health System, do not have the fairytale ending quite yet.<sup>17</sup>

Moody’s Investors Service (“Moody’s”), which offers credit ratings and research for debt instruments and securities, released a “negative” rating on October 1 for Mount Sinai’s \$392 million of outstanding rated bonds. Moody’s has concerns because CHP “bring[s] additional debt, operating leases, pension obligations, thin liquidity and historically weaker financial performance.”<sup>19</sup> Moody’s further explains that this could cause a “material deterioration” of Sinai’s financial stability and performance.<sup>20</sup>

Despite the negative outlook by Moody’s, the enhanced coordination of care between the hospitals will likely result in an overall transactional success.<sup>21</sup> In 2012, Mount Sinai created an

Accountable Care Organization (ACO) called Mount Sinai Care, LLC.<sup>22</sup> ACOs are groups of health providers that offer coordinated, high quality care to Medicare patients.<sup>23</sup> The idea behind coordinated care is that health providers will have the necessary information and resources to provide quality care to patients.<sup>24</sup> The intended goal of ACOs is to provide patients, par-

**“[T]he changing landscape of New York City hospitals will have implications on patient care.”**

ticularly those with chronic illnesses, with quality health care and the prevention of medical errors.<sup>25</sup> With the merger, the Mount Sinai Health System will have an increased number of primary care physicians which will likely result in superior coordinated care.<sup>26</sup>

### **Brooklyn Blues**

Brooklyn, where nearly one in five individuals lives in poverty, has one of the highest rates of chronic health conditions in New York City.<sup>27</sup> Furthermore, the access to primary care in Brooklyn remains scarce as many patients utilize the Brooklyn hospitals as their chief resource for care.<sup>28</sup> The problem, however, is that a majority of Brooklyn hospitals are operating

at a loss and are in dire financial distress.<sup>29</sup> The hospitals’ overall financial decline can be attributed to Medicaid funding cuts and the fact that patients with commercial insurance are seeking hospital care outside of Brooklyn.<sup>30</sup> Plans to open new clinics to accommodate the need for primary care services have been halted due to the absence of funding.<sup>31</sup>

There are two Brooklyn hospitals in particular danger of being closed.<sup>32</sup> Interfaith Medical Center, in Bedford-Stuyvesant, has suffered financially due to its high population of Medicaid patients.<sup>33</sup> The State Department of Health has considered the possibility of transforming Interfaith into a “medical village” to address the community’s needs by offering a vast array of clinical services.<sup>34</sup> Long Island College Hospital (LICH), purchased in 2011 by SUNY Downstate Medical Center, is also in financial distress and nearly closed in the summer of 2013.<sup>35</sup> The chairman of SUNY stated that LICH is operating at a loss of \$40 million each year, which is quickly draining SUNY’s resources.<sup>36</sup> The Brooklyn Supreme Court recently ruled, however, that the state did not provide clear methods for the Department of Health’s approval process for hospital shutdowns.<sup>37</sup> Until the state provides clear methods for hospital closures, other potential

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closures will be stalled.<sup>38</sup> If these Brooklyn hospitals shutdown, following clear approval processes, overcrowding and increased wait times in emergency rooms are likely to result.<sup>39</sup>

### **Memorial Sloan-Kettering: Beyond the Big Apple**

As one of the nation’s leading cancer centers, Memorial Sloan-Kettering Cancer Center (MSKCC) plans to expand into Connecticut.<sup>40</sup> MSKCC formed an alliance with Hartford HealthCare in order to better serve a larger community with high-quality cancer care.<sup>41</sup> As a result of this alliance, clinical trials for cancer treatment will be onsite at Hartford Hospital, thereby eliminating the need for sick patients to travel to Manhattan.<sup>42</sup> The motivation behind the alliance comes from the need to address issues that the Institute of Medicine explained could be problematic.<sup>43</sup> The Institute of Medicine reported that by 2030, 2.3 million new cancer diagnoses per year are anticipated because of the aging population.<sup>44</sup> The concern is that there will not be enough oncologists to treat these patients with effective care.<sup>45</sup> The alliance does not require the expenditure of resources for building new facilities, so MSKCC and Hartford hope to deliver state-of-the-art cancer care to local communities in a cost-effective manner.<sup>46</sup>

### **Conclusion**

Assuming the merger between Mount Sinai and CHP proves successful, this will have a positive impact on patients in New York. An integrated health care system will offer patients coordinated care, which will improve quality. While it is problematic that Brooklyn residents are utilizing LICH and other Brooklyn area hospitals’ emergency rooms for primary care and other non-urgent services, the closure of the hospitals will likely not be an effective solution. Funding is needed to open more primary care centers which will increase efficiency for patients in the emergency room. This funding would also enable the hospitals to remain open and available to patients for services unique to the hospital setting. Lastly, MSKCC’s alliance with Hartford will benefit those patients who currently lack seamless access to cancer care in their community. The patients will be able to receive care in the comfort of their community without having to travel to Manhattan while sick. This alliance will be a model for other specialty centers to expand their expertise to those communities lacking the resources.

# The Internet, Privacy, and Public Health: How Social Media and “Big Data” are Changing the Landscape of Public Health Surveillance and Research

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## Introduction

Communications technology use is growing at a near exponential rate on a global scale.<sup>1</sup> A recent United Nations study shows that more people have access to cell phones than toilets, as 6 billion of the world’s 7 billion people (85%) have access to mobile phones, while only 4.5 billion (64%) have access to working toilets.<sup>2</sup>

Throughout the past fifteen years, communications and information technology have become essential components of public health surveillance and research.<sup>3</sup> This technology allows for cheaper and more accessible forms of disease surveillance and epidemiological research, particularly through the mining of online social network data. Social media has potential to change the nature, speed, and scope of public health surveillance and research by offering a real-time stream of user-generated updates from millions of people around the world.

Data mining is a field of computer science involving methods such as computational epidemiology, artificial intelligence, statistics, algorithm development, database systems management, and data processing to identify patterns in large sets of data.<sup>4</sup> Data mining from informal internet

sources may lead to the discovery of new information about disease patterns, both communicable and chronic, as well as health risk behaviors. Moreover, developing risk prediction models from data aggregated from informal sources, such as social media, has great potential to supplement formal data sources in predicting disease spread. Earlier intervention and control measures based on this information may mean the difference between containment and epidemic. In recent years, systems using informal data mined from



social media sources have been credited with reducing the time it takes to detect an emerging outbreak, preventing governments from suppressing outbreak information, facilitating public health responses, and contributing to the generalizable knowledge about health risk behaviors in a quick and cost-efficient manner.<sup>5</sup>

Despite the inherent public nature of social media, there are many ethical implications inherent in the systematic acquisition of personal information, especially that pertaining to health. Concerns

surrounding social network data analysis include issues of privacy, data quality, public panic, autonomy, access, and informed consent. While online social network data analysis holds great promise in the field of public health, it is essential that this valuable data be systematically harnessed in compliance with the law and ethical principles, keeping in mind salient privacy concerns, to yield population-level health benefits.

## Social Media In Tracking Infectious Diseases

Infectious diseases account for more than 13 million deaths each year.<sup>6</sup> It is estimated that 45% of those within developing countries have infectious diseases, making infectious diseases one of the leading causes of mortality for children and young adults.<sup>7</sup> The threat of infectious disease is accelerating with the high mobility of populations due to airline travel and increasing resistance to antimicrobial medicines due to mutations.<sup>8</sup> Given the severity of the infectious diseases as a public health threat, culling social media information for epidemiological surveillance during outbreaks is generally accepted as ethically permissible.

Data mining social media sources to track the early stages of an infectious disease outbreak has great potential in developing countries. Although developing

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countries often lack strong public health infrastructure, they have burgeoning mobile communication infrastructures.<sup>9</sup> Aggregating and analyzing social media’s informal data in near real-time allows public health officials to gain early insight into an evolving epidemic in order to help plan a response weeks sooner than formal routes.<sup>10</sup> A two-week jump on an infectious disease may mean the difference between life and death; between containment and an epidemic. The quicker a potential disease can be located, the quicker public health authorities can establish control measures ranging from vaccinations and antibiotics to clean water.

### **Case Study: Twitter and the 2010 Cholera Outbreak in Haiti**

Dr. Rumi Chanura and her team of researchers from Harvard University conducted one of the pioneer studies that demonstrated the value of social media data in monitoring an infectious disease outbreak. The study demonstrated the value of monitoring social media during an outbreak. The study analyzed information from social media sources, primarily Twitter, during the first 100 days of the cholera outbreak in Haiti in 2010. In October 2010, ten months after Haiti experienced a devastating earthquake, hospitals in the Artibonite River basin saw a swell of patients with severe diarrhea,

vomiting, and dehydration.<sup>11</sup> By December 31, 2010, more than 170,000 people were afflicted with cholera and 3,600 lost their lives to the disease.<sup>12</sup> According to the World Health Organization, “the devastating cholera epidemic provides stark reminder of the challenges that arise in the absence of the infrastructure and institutions that most of us take for granted.”<sup>13</sup>

Dr. Chanura collected 188,819 tweets and 4,697 online reports that contained the word *cholera* during the first 100 days of the cholera outbreak.<sup>14</sup> The team analyzed the relationship between frequency of mentions and the occurrence of a secondary cholera outbreak, and evaluated them through risk prediction models.<sup>15</sup> They found a very close correlation between the aggregated social network data and the formal Haitian Ministry of Health data.<sup>16</sup> The study demonstrated that informal data has been surprisingly accurate when it comes to disease tracking. The undeniably strong correlations between formal data and informal data collected from social media sources demonstrated that informal sources can produce reliable decision-making data during disease outbreaks in near real-time.

While Haiti lacks water and sanitation infrastructure for the prevention of cholera, they do have a strong mobile communication infrastructure. This communi-

cation infrastructure allowed for the sick, their families, their communities, and healthcare providers to share information about conditions on the ground, allowing cholera cases to be reported that may have otherwise gone untracked since many patients never reported to clinics.<sup>17</sup> This also allowed for speedier intervention with oral rehydration tablets and antibiotics in the afflicted areas.<sup>18</sup>

### **Hypothetical: Role of Social Media in HIV/AIDS Tracking, Contact Tracing, and Partner Notification**

Having discussed the role of social media data in a contagious disease case in the developing world, let us now turn to a potential role of social media data that is much more ethically contentious: the use of social media data in HIV/AIDS tracking.

The principle of confidentiality between physician and patient dates back to before the Oath of Hippocrates.<sup>19</sup> Nevertheless, the scope of confidentiality is subject to limitations, especially in cases where public welfare is endangered. Affirmative disclosure obligations have expanded throughout the years, and every state in the U.S. has some type of mandatory reporting of certain communicable diseases in place. In addition to mandatory reporting, public health officials can exercise police power authority to



## Continued...

mandate contact tracing. Contact tracing is the process by which individuals who may have come into contact with an infected person are identified and later notified of potential exposure by a public health official without directly naming the infected individual. For the purposes of HIV/AIDS, this is generally limited to sexual partners or individuals involved in sharing intravenous needles. Despite its controversial nature because of privacy concerns, and potential deterrence of testing, it remains standard practice in nearly all states.

These concerns have inspired various legislative efforts. For example, the Mayersohn-Vearella Bill, developed in New York during the early 1990's to prevent the mother-child transmission of HIV, mandated a three-step process to contain the spread of HIV through surveillance measures: (1) Doctors must report the names of HIV-infected patients to the state Health Department; (2) Public health officials are to contact those individuals for the names of partners whom they might have exposed; (3) Public health officials will contact the partners and be informed of exposure, but not specifically by whom.<sup>20</sup> Additionally, the Ryan White Care Act, in effect today, provides grants to states to implement partner notification programs for individuals with HIV.<sup>21</sup>

It is not unprecedented for

nontraditional methods to be used as a means of contact tracing as a last resort. Consider the example of Nushawn Williams in 1997. Williams, a 20-year old male, was allegedly responsible for a "cluster" of HIV infections through sexual activity in Chautauqua County and New York City despite knowledge of his HIV-positive status. Because of his self-declared intention of non-compliance, New York state and

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local health officials declared him a "clear and imminent danger to the public health" and released his identity to the news media, an untraditional outlet to inform the public about an alleged public health threat.

Now let us consider the following hypothetical involving an adult HIV-positive male who is unwilling to cooperate with public health officials. He refuses to disclose his contacts in 2012. He also refuses to inform future sexual partners of his HIV status, will not use condoms during sexual activity, and continues to use popular social networking websites to seek out sexual partners. Due to his re-

fusal to assist in the identification of those exposed, and future non-compliance, the Department of Health and Human Services believes that social media could be of considerable use for the purpose of contact tracing to identify and notify individuals who may have been exposed. Taking into consideration the privacy implications of the proposed expansion of surveillance activities, would it be appropriate to incorporate social media into surveillance for the purpose of contact tracing?

There are two key conflicting principles in this hypothetical: (1) The privacy "right to be let alone" by the individual, and (2) The public health interest as a "right to know" of potential exposure. In other words, the state's fundamental authority to protect the population's safety and welfare is at odds with the individual's legally protected rights to autonomy, privacy, liberty, and property.

Under the Millian harm principle, intervention and regulation on individual behavior is justified to prevent harm and risk to others.<sup>22</sup> To intrude on individual liberties, the state must first demonstrate a rational and legitimate interest in intervention.<sup>23</sup> Accordingly, one must assess the nature, duration, probability, and severity of risk at hand. In the case of HIV, there is a potentially high duration and magnitude of harm if exposed, so there is a clear

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rational interest for intervention. It can be argued that there is a duty for public health officials to warn exposed individuals. The population’s reliance on the protection from the state implies an ethical obligation for the government to exercise its authority to ensure health and safety.<sup>24</sup>

Generally, public health policy strives towards the least restrictive means of intervention to be exercised, so as to not unduly compromise the rights and liberties of an individual.<sup>25</sup> Accordingly, the use of online social network data without consent should be seen as permissible only as a last resort, rather than standard practice. While it is often argued that individual liberty must be subordinated to protect the common public health good, it is important to weigh the incidental costs of implementing policies, such as decreased levels of public trust and deterrence of HIV testing. Consequently, the proposed policy of using online social network data in contact tracing may translate to reduced rates of public cooperation, which may make a community more vulnerable to public health harms.

### Privacy Concerns

Privacy is an inherently complicated topic in the field of public health. Balancing the protection of an individual’s personal health information with the need

to protect public health is no easy task. Advancements in information and communication technologies only further distort the boundaries between what is public and what is private. Users of online social networks often share identifiable information about themselves, including their full names, birthdates, e-mail addresses, GPS coordinates, job titles, and the names of their employers.<sup>27</sup> By providing researchers with rich, ready-made data sets, social media

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is incentivizing researchers to develop innovative methods to search the Internet for health-related information. The mining and mapping of social networks, including names, dates, and places, has become a common practice, from market research to biomedical studies.<sup>28</sup> It is important then to consider what obligations researchers and public health officials have in determining and meeting their online subjects’ expectations of privacy.

An individual’s constitutional right to privacy hinges on “whether that individual had a personal and objectively reasonable expectation of privacy.”<sup>29</sup> Similarly, the Code of Federal Regula-

tions governing human subject research defines private information as individually identifiable information about behavior “that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.”<sup>30</sup>

While mining publicly available data from open sources is within the letter of the law, it raises a number of ethical issues. Some might argue that it seems unreasonable to some that a public posting on a public site can hold an expectation of privacy. However, privacy can conceptually be considered to be an individual’s right to determine what information one would like to share with others and the ability to control when others can access that information. While the practice of data mining is growing, many social media users are unaware of how public their data is.<sup>31</sup> Privacy settings on some social media sites, such as Facebook, are complicated. Many individuals post information to be shared with an intended audience of friends, family, and peers, without the intent of being turned into research subjects by having this information collected, analyzed, and published without notification or consent.

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The federal definition of human subject research is the “systematic investigation involving living individuals about whom a researcher obtains data through intervention or interaction with the individual or identifiable private information.”<sup>32</sup> It follows that such research activities would require institutional review board (IRB) approval. However, it remains unclear whether subjects in internet research involving data mining of health information qualify as a human subject research under this definition.

Researchers must take into consideration the level of sensitivity of the information detected, such as stigmatized health conditions. Recent studies have shown that the Internet is used more often by patients with “stigmatized conditions,” such as mental disorders or sexually transmitted diseases, to get health information and communicate with healthcare professionals than by patients with “non-stigmatized conditions.” The misuse of such data collected from the Internet by researchers can have maleficent consequences, such as stigma, discrimination, and discomfort of the subject.

Accordingly, researchers and bioethicists are left to grapple with the issue of determining when it is permissible to turn unsuspecting individuals into research subjects without notification or consent.

### **Autonomy and Informed Consent**

Voluntary informed consent of study participants is a cornerstone of modern biomedical research ethics. Many ethical issues arise when it comes to respecting the autonomy of human subjects in Internet-based research. Respecting the autonomy of subjects necessitates that prospective subjects are given adequate information to make an informed decision before agreeing to participate in a study. This is done properly through a formal informed consent process, which includes: (1) providing subjects with the information to decide whether to take part in a study (i.e. risks and benefits, compensation, duration of study, etc.) and (2) documenting that the information was provided and that the subject willingly volunteered to take part in the study.<sup>33</sup> The principle question here then is whether or not it is necessary to provide informed consent to an individual before his informal data via social media platforms is mined for public health surveillance and research.

While it is generally accepted that data mining for public health surveillance in emergency circumstances and communicable diseases is permissible, it would be wise to develop an opt-out system on social media platforms for non-emergency research purposes.

While this would surely lead to more incomplete data sets, it can be considered a small price to pay for protecting the privacy of patients, especially those with stigmatized conditions. Further, there are statistical methods designed to deal with missing data so that the incomplete data sets would not render the research impossible.<sup>34</sup>

### **Conclusion**

Historically, advancements in bioethics standards have been reactionary to human subject abuses. It is vital to resist this reactionary approach to a lack of research oversight, but rather take a proactive stance to develop acceptable standard procedures for using big data sets culled from online social network websites before foreseeable abuses occur. One need only consider the recent public outrage surrounding the National Security Agency (NSA) leaks on the federal government’s PRISM surveillance program, which included online social network data, to gauge the high salience of these concerns.

Achieving a just balance between maintaining individual liberties and ensuring the health and safety of the population is an enduring problem for authorities, particularly those in the field of public health. Champions of autonomy may view social media data mining as an unwarranted

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and potentially maleficent violation of one’s autonomy and personal liberties. On the other hand, utilitarian thinkers may consider it a beneficent measure to ensure the health and welfare of the community. Accordingly, efforts should be taken to counter ethical concerns while reaping the benefits of our ability to analyze the massive amount of online data available through social media for the purposes of public health.

Privacy concerns notwithstanding, the potential societal benefit of digital epidemiology remains clear. The utilization of social media has the capacity to transform disease surveillance and change how healthcare workers respond to public health emergencies. As public health threats become increasingly complex, trade-offs must be made to ensure that the collective benefits of population health warrant infringement on individual rights, while balancing competing ethical, health, economic, and legal concerns. Public health researchers must work together with policy makers, medical professionals, and bioethicists to develop unambiguous ethical guidelines to answer the challenges stemming from today’s technological advances and changing communications structure.

## Ending Philosophical Exemptions for Mandatory Vaccinations

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Mandatory vaccination, as a matter of public policy, is overwhelmingly accepted within the United States as a prerequisite for children seeking a public education. Vaccination continues to be upheld by the Supreme Court's decision in *Jacobson v. Commonwealth of Massachusetts*,<sup>1</sup> and is considered established law. Unfortunately, exemptions to mandatory vaccination remain in effect in 48 states, based upon religious—and in some cases, philosophical—objections. While medical exemptions serve a legitimate interest, other opinion-based exemptions threaten the policy on which mandatory vaccinations are based. States that allow such exemptions should cease the practice. Furthermore, parents should pursue the possibility of tort liability against other parents who subject children to harmful diseases with their decision not to immunize their own children.

The *Jacobson* court recognized that the majority of the medical community, the citizens of the State, and the Massachusetts legislature all accepted that vaccines provide a necessary benefit. Since the state had a duty to protect its citizens' welfare, it was within its rights to pass a law compelling them to be immunized, even if immunization was unattractive to a few:

. . . In every well-

ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.<sup>2</sup>



While no municipalities are currently under the threat of smallpox, they should still consider diseases like pertussis, polio, and measles—diseases that stand to threaten communities—as “great dangers.”<sup>3</sup> *Jacobson* ruled that Massachusetts could compel its citizens to receive smallpox vaccinations, and that such compulsion was constitutionally justified under the police power afforded the states.<sup>4</sup> In so ruling, the Supreme Court stated:

We are not prepared to hold that a minority, residing or remaining in any city or town where smallpox is prevalent, and enjoying the general protection afforded by an organized local government, may thus defy the will of its constituted author-

ities, acting in good faith for all, under the legislative sanction of the state.<sup>5</sup>

The Court was not prepared to let the whims of a minority refute laws that were designed for the protection of the people in good faith. The Court recognized that the mandatory smallpox vaccinations were for the benefit of the entire community, including those who may oppose them. Had the immunizations been designed to oppress the opposing minority, the Court may have decided differently.

What the Supreme Court did *not* do in *Jacobson* was prevent states from enacting statutes exempting certain individuals from vaccination. Forty-eight states have enacted statutes exempting individuals from vaccination for religious reasons. In addition, nineteen states have statutes which also exempt individuals from vaccination for “philosophical” reasons. While philosophical reasons vary by state, the most common exemptions allow a very broad array of reasons that can be deemed “philosophical.” As a result, a parent in most of these states can simply choose a “philosophical exemption” without stating any actual reason.<sup>6</sup> Obviously no child should be compelled to receive vaccinations if she or she is predisposed to health risks as a result. It is recklessly irresponsible, however, for states to allow exemptions for any reason aside

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from health risks, when those exemptions create a public health danger and subject all unvaccinated children to easily preventable diseases.

It is well established that a parent may not forego lifesaving medical treatment while substituting prayer or other religious means of treatment.<sup>7</sup> Courts have time and again recognized the fact that religion is no substitute for proper medical care, and that even a fervent belief in the power of prayer to heal does not excuse the parents and caretakers of children from their proper duty of care. Parents and guardians are required to submit to the expertise of medical professionals when a child is in imminent danger. It follows that, since we do not allow parents to substitute prayer for medicine, we should likewise not allow parents to substitute their religious beliefs for the proven vaccines that would prevent their child’s death.

In a series of cases leading directly back to the *Jacobson* holding, courts have established that there is no constitutional guarantee of religious exemption, and the Supreme Court, through their refusal to hear cases challenging compulsory vaccination, seems to believe the matter settled with *Jacobson*. The most current cases in vaccination address, and dismiss, free exercise claims when it comes to mandatory immunizations for children entering public school.<sup>8</sup> With no constitutional

hurdle, then, religious and philosophical exemptions rely solely on the discretion of the states, only two of which have refused to allow them.

The matter then becomes one of state policy. Unfortunately, states presently have little reason to compel vaccination against religious or philosophical arguments when the will of its voters does not reflect a desire for such compulsion. No state wants to enact a

**“As a matter of public policy, concerned citizens must take every available step to vaccinate all children and protect our communities.”**

statute that defies most citizens’ expectations of free speech and free exercise without a particularly persuasive argument. Almost certainly, religious and anti-vaccination groups will oppose such a statute. It is a politically risky endeavor, which politicians would be loath to pursue without a strong public push in that direction. So how do concerned parents achieve such a push?

First, there must be strong public outcry *for* mandatory vaccination without exemption for any reason other than real health concerns. While respecting the First Amendment rights of those who strongly push an anti-vaccination agenda, parents can bring reason and truth to the public, slowly eroding the influence

of celebrities and discredited doctors. The anti-vaccination movement relies a great deal upon the disproven theories of Dr. Andrew Wakefield, a discredited physician whose faulty research created the erroneous belief that vaccines cause autism. Wakefield fabricated any connection between autism and vaccines, though many in the movement still point to his research as the “smoking gun,” proving such a connection.<sup>9</sup> Introducing scientific support and peer-reviewed research, concerned citizens can win over all but the most obstinate conspiracy theorists. After all, our public policy should promote better overall health for the general population; a policy that those who believe the anti-vaccination rhetoric are actually trying to follow. However for individuals who refuse to acknowledge the science, the only alternative may be litigation.

Efforts at viable tort liability claims against non-vaccinating parents are speculative at best, but there are some possibilities. Dorit Rubinstein Reiss points out several theories that may be pursued in a cause of action.<sup>10</sup> While acknowledging that a level of autonomy should be protected, she says, “autonomy should be accompanied by responsibility. If you choose to reject expert opinion and believe you know more than the majority of doctors, scientists, and health officials, you should not roll the costs of that choice onto others.”<sup>11</sup> While tort

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liability is never grounded in non-feasance, Reiss argues that the intentional choice of parents not to vaccinate contrary to the prevailing public policy can be construed as an act:

The decision not to vaccinate is not typically a passive one. Parents who consciously choose not to vaccinate their children often claim that they've done extensive research and actively defend their decision against pressure from doctors and others. This is not a stand-and-watch situation: it's more of an active choice.<sup>12</sup>

Of course, parents attempting such a lawsuit would have to show that, more likely than not, the non-vaccinating parents caused the harm. True to the litigious spirit of the United States, this approach aims not at the religious or philosophical inclinations of its citizens, but rather at the pocketbooks of negligent parents. At the same time, it promotes the public policy behind *Jacobson*, a policy aimed at minimizing threats from disease to public welfare. Whether a judge would hear such a case has yet to be seen, but, if more children get sick from preventable diseases, the opportunity may be close.<sup>13</sup>

This approach is attractive. Legislators get off the hook, at least until individuals who get sued for liability advocate for legislation that protects them. But then the legislators have the much

easier—and less politically charged—decision of regulating the issue or leaving the matter to the courts. It is less controversial for a politician to say she will not try to pass legislation limiting liability against arguably negligent parents than for her to pursue statutes limiting religious liberty. After all, her constituents can all point to religious liberties and free speech principles they hold dear; not many of them will admit to sympathies for negligent parents. In the end, we can nudge parents into vaccination by holding them responsible for a breach of duty, rather than using the coercive power of the state. Unfortunately, this strategy means that some children will actually have to suffer to create the necessary cause of action, whereas state power could enforce vaccinations without the casualties. Furthermore, the litigation approach relies heavily on an untried theory of liability, establishing grounding on what would normally be construed as non-feasance. As attractive as it may look to lawyers, this approach could be impracticable.

The possibility that states will enact legislation to end religious and philosophical exemptions to vaccinations seems remote, though it would be the simplest and arguably least expensive solution, both financially and in human cost.<sup>14</sup> While there is no constitutional barrier to such legislation, public opinion would almost certainly foreclose on it. The

practical answer is to hit anti-vaccination activists where it hurts—their wallets. As a matter of public policy, concerned citizens must take every available step to vaccinate all children and protect our communities. It makes practical and economic sense to legislate religious and philosophical exemptions away, but failing that, parents suffering because of those exemptions should seek relief through litigation.

## The Affordable Care Act's Impact on Individuals with Disabilities

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Insurance premiums have risen in the last 13 years at a much greater pace than the rate of inflation.<sup>1</sup> Individual premiums have increased on average from \$2,196 per year to \$5,615 per year.<sup>2</sup> Family premiums have increased from \$5,791 per year to \$15,745 per year.<sup>3</sup> The top 10 percent of the population (averaging costs in excess of \$9,570 per year) account for 65 percent of all costs spent on healthcare.<sup>4</sup> Individuals with chronic illness and disabilities are likely overrepresented in this group, since healthcare costs related to disabilities accounted for 26.7 percent of all adult healthcare expenditures and have totaled \$397.8 billion in recent years.<sup>5</sup> If a health insurer sells only to people with disabilities, they will instantly lose money. As a result, health insurers care who they insure and employers care who they employ (because of concerns of raising healthcare costs for the company), which can incentivize disability discrimination.

Individuals with chronic illnesses and disabilities have been traditionally discriminated against in their access to healthcare because of the higher cost they pose to insurers. The Americans with Disabilities Act of 1990 was a big advancement for people with disabilities; however, 23 years after its passage, people with disabilities are still

having trouble accessing healthcare. For example, individuals with disabilities have faced challenges in accessing habilitative care, which helps a patient attain a skill that was never learned due to a disabling condition.<sup>6</sup> As a result, this care may be required for long periods of time and could cost more than rehabilitative care, which helps a person regain a skill that was lost due to a disabling condition.<sup>7</sup>

**“Individuals with chronic illnesses and disabilities have been traditionally discriminated against in their access to healthcare because of the higher cost they pose to insurers.”**

The Affordable Care Act's ("ACA") inclusion of habilitative services as one of the 10 required essential health benefits that insurance carriers must include in their health plans is a meaningful advancement for disabled individuals.<sup>8</sup> However, the lack of a national standard for essential health benefits leaves open the possibility for states to choose a plan that will not cover habilitative services.<sup>9</sup> Moreover, without a definition of habilitative care, the services that the ACA intends to include within its scope remain unclear.

This article will explore the Affordable Care Act with a specific focus on essential health

benefits. Since the Affordable Care Act does not denote the authority charged with regulating insurers, companies still distinguish between covering rehabilitative care but not habilitative care, even though they usually involve the same skills, instructors and facilities. The Department of Health and Human Services ("HHS") should issue a regulation, which defines habilitative care to prevent disabled individuals from being denied coverage because of semantics. A regulation should also provide insight regarding who will actually be empowered to regulate insurers to protect individuals with disabilities from discriminatory access to essential health benefits. In addition, a regulation should ban risk selection by design to prevent insurers from designing their plan, in a way that is unfriendly to people with higher cost conditions (such as designing plans with mediocre or poor oncologists or oncology facilities to avoid insuring people with cancer).

HHS also needs to properly define medical necessity in order to clarify what services essential health benefits will cover. Until then, insurers will use their own definitions to exclude habilitative services, which will adversely affect individuals with disabilities. The Affordable Care Act was a step in the right direction for the disability community, but there is still work to be done to ensure people with disabilities



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are not unfairly discriminated against in obtaining access to healthcare.

### Limits of the Americans with Disabilities Act

The Americans with Disabilities Act of 1990 (“ADA”) defines a disability as “a physical or mental impairment that substantially limits one or more major life activities of such individual.”<sup>10</sup> Major life activities include eating, sleeping, walking, learning, reading, concentrating, thinking, communicating and working.<sup>11</sup> The ADA “prohibits discrimination on the basis of disability in employment, state and local government, public accommodations, commercial facilities, transportation, and telecommunications.”<sup>12</sup> The ADA is limited to protecting against discrimination “in access to care itself or access to places in which insurance is sold.”<sup>13</sup> As a result, “the regulation of insurance design and risk avoidance stems from the fundamentally voluntary nature of health insurance.”<sup>14</sup> Even though most state insurance regulations prohibit exclusions based on disability, insurers still use risk-shielding devices, which allows for “adverse selection and moral hazard.”<sup>15</sup> Both Section 504 of the Rehabilitation Act and the ADA prohibit “insurers from refusing to sell products to, or barring enrollment of, individuals with disabilities.”<sup>16</sup> However, neither law pro-

hibits insurers from designing their plans in a way that can discriminate against individuals with disabilities.<sup>17</sup> As a result, insurers are able to design their plans in a way that limits the coverage and prevents people with disabilities from purchasing a particular plan.<sup>18</sup>

**“Insurers are able to design their plans in a way that limits the coverage and prevents people with disabilities from purchasing a particular plan.”**

Insurers often put large “restrictions upon groups or individuals who are suffering from certain disabling diseases.”<sup>19</sup> Insurers will frequently prevent individuals from being reimbursed for particular conditions.<sup>20</sup> Insurers in a self-insured plan will sometimes cap reimbursement for a particular condition.<sup>21</sup> Once this cap is reached, the insurer will no longer pay for that condition.<sup>22</sup> Insurers may also deny coverage for assistive medical equipment, such as wheelchairs, hearing aids or prostheses.<sup>23</sup>

The Mental Health Parity Act of 1996 was the most significant law before the Affordable Care Act that “addressed discrimination in the content and administration of state-regulated health insurance and employer-sponsored health benefit plans.”<sup>24</sup> However, the law only reached mental illness and addiction disor-

der conditions.<sup>25</sup> Discrimination based on other disabilities was still not addressed before the Affordable Care Act.

### Affordable Care Act

The Affordable Care Act requires health insurance plans, which are sold to small businesses and individuals, include a minimum of services in at least 10 categories, called essential health benefits.<sup>26</sup> Health plans need to include at least: “ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventative and wellness services and chronic disease management; and pediatric services, including oral and vision care.”<sup>27</sup>

However, instead of establishing a national standard for the essential health benefits, HHS leaves each state to choose a plan to serve as the benchmark plan in their state.<sup>28</sup> “Whatever benefit that plan covers in the ten categories will be deemed the essential benefits for plans in the state.”<sup>29</sup> The extent of coverage will vary depending on type of coverage a person has and the premium they pay.<sup>30</sup> However, there are exceptions for insurance policies sold to young adults.<sup>31</sup> Congress drafted this part of the law broadly, to

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give the Secretary of Health and Human Services more discretion to promulgate standards.<sup>32</sup>

Each state will need to set its own definition of essential benefits by choosing a benchmark plan for 2014 and 2015.<sup>33</sup> “According to HHS, most of the potential benchmark plans that it has identified cover similar services in nearly all of the ten required categories.”<sup>34</sup> However, “the categories least likely to be covered in potential benchmark plans are pediatric oral services; pediatric vision services; and ‘habilitative’ services to assist people with disabilities to learn new skills and functions, such as helping autistic children improve language skills.”<sup>35</sup> Yet, “if a state chooses a benchmark plan that does not cover services in a required category, the state must supplement the essential benefits package by adopting benefits from any other possible benchmark plan.”<sup>36</sup>

By 2014, all Medicaid plans must cover these 10 benefits and all insurance plans must cover the benefits if they would like to be offered in exchanges.<sup>37</sup> “The extent of coverage of habilitative services and devices should at least be in parity with rehabilitation coverage.”<sup>38</sup> Regardless of the diagnosis, “the coverage and medical necessity determinations for rehabilitative and habilitative services and devices should be based on clinical judgments of the effectiveness of the therapy, ser-

vice or device to address the deficit.”<sup>39</sup> Experts in the habilitative and rehabilitative fields should make any limitations in benefits.<sup>40</sup>

Prohibiting coverage limits connected to recovery or restoration will no longer be allowed under the Affordable Care Act.<sup>41</sup> Insurers will not be able to use words that exclude disabled individuals from coverage. For example, insurers cannot claim that a person was normal before treat-



ment so that a treatment is just restoring the individual to “normalcy.”<sup>42</sup> In addition, “[s]peech therapy or surgery on a cleft palate for a child whose disability precludes speech is not restorative; it is instead a medical intervention that enables speech initially.”<sup>43</sup> Furthermore, physical therapy for an adult with multiple sclerosis is designed not to restore normal functioning but rather to maintain functioning and prevent further deterioration.<sup>44</sup>

Services should also be consistent both inside and outside of the educational setting. Many students with disabilities receive services under the Individuals

with Disabilities Education Act (IDEA). If a student receives habilitation services at school, then private insurance should not deny the student the same essential health benefit once the student leaves the educational setting at the end of school day.<sup>45</sup> The continuity of services outside of school is essential to ensure children with disabilities do not suffer any gaps in service that could adversely affect the productive services provided in the school setting. Going forward, “with full and robust implementation of the essential benefits statute, one can at least hope that the nation will come to understand the enormous value of an approach to coverage that moves away from penalizing persons with disabilities.”<sup>46</sup>

### **Ambiguity About What Constitutes Habilitative Care and Rehabilitative Care**

Habilitation services are “provided in order for a person to *attain*, maintain or prevent deterioration of a skill or function never learned or acquired due to a disabling condition.”<sup>47</sup> These services include those that “help a person keep, *learn*, or improve skills and functioning for daily living.”<sup>48</sup> One example is therapy for a child who is not talking or walking at the expected age.<sup>49</sup> There are also other services available “for people with disabilities in a variety of inpatient and/or outpatient settings.”<sup>50</sup>

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Rehabilitation services and devices are “provided to help a person *regain*, maintain, or prevent deterioration of a skill that has been acquired but then lost or impaired due to illness, injury, or disabling condition.”<sup>51</sup> These services include those “that help a person keep, *get back* or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt or disabled.”<sup>52</sup> Habilitative care and rehabilitative care have caused much confusion before and after the Affordable Care Act. The lack of a definition of habilitative care in the Affordable Care Act has added to the confusion.

### *Clarifying the Confusion*

Habilitation services are “appropriate for individuals with many types of developmental, cognitive, and mental conditions.”<sup>53</sup> In the absence of these services, individuals will be prevented from acquiring certain skills and functions over the course of their lives, particularly in childhood.<sup>54</sup> On the other hand, rehabilitation services and devices include physical therapy, occupational therapy, speech-language pathology and audiology services.<sup>55</sup> Other therapies include those “that improve function and support independent living within the community.”<sup>56</sup> In addition, durable medical equipment, prosthetic limbs, orthopedic braces, and augmentative communication devices also count as re-

habilitation services.<sup>57</sup> Rehabilitation services can also include psychiatric services.<sup>58</sup>

The Medicaid program defines habilitation as “services designed to assist individuals in acquiring, retaining, and improving the self-help, socialization and adaptive skills necessary to reside successfully in home and community based settings.”<sup>59</sup> Habilitation services are provided to individuals who would need care in a hospital or a nursing facility.<sup>60</sup> In ad-

**“The same care can be considered habilitative care in one situation but rehabilitative care in another...[T]he same skills are being taught but the difference lies in the source of the injury.”**

dition, habilitation services are provided in facilities that treat individuals with mental retardation, cerebral palsy, epilepsy, and autism.<sup>61</sup> However, with habilitation services and devices, these individuals are able to live in home and community based settings.<sup>62</sup> “For children, Medicaid provides for comprehensive coverage of habilitative services under its Early and Periodic Screening, Diagnosis and Treatment (EPSDT) mandate.”<sup>63</sup> It is important to keep in mind that habilitative care will *help* a patient but will not actually *cure* a patient’s ailment.<sup>64</sup> In contrast, rehabilitative care seeks to allow a patient to *regain* skills, which were lost

due to an illness, injury or disabling condition. Thus, habilitative care and rehabilitative care are distinct concepts, each with different purposes in terms of acquiring or re-acquiring certain skills.

While habilitative care and rehabilitative care are distinct concepts, the same care can be considered habilitative care in one situation but rehabilitative care in another. For example, a speech-language pathologist providing speech therapy to a three-year-old with autism who has never spoken would be considered habilitation.<sup>65</sup> However, providing speech therapy to a three-year-old to regain speech after a traumatic brain injury would be considered rehabilitation.<sup>66</sup> Another example of habilitation is a physical therapist who provides a “strength training program for an individual with a congenital spine condition to prevent osteoporosis and decline in function as they age.”<sup>67</sup> However, a strengthening program for individuals who recently acquired a spinal cord injury would be considered rehabilitation.<sup>68</sup> The key is that the same skills are being taught but the difference lies in the source of the injury.<sup>69</sup>

An additional example of habilitation is an occupational therapist teaching children with developmental disabilities the “fine motor coordination required to groom and dress themselves.”<sup>70</sup> In contrast, teaching children with developmental disabilities the

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“fine motor skills required to re-learn how to groom and dress themselves would be rehabilitation.”<sup>71</sup> Once again it is the same skills but the difference lies in the source of the injury.<sup>72</sup> One final example of habilitation is a “therapist or orthotist fitting hand orthoses for a child or an adult with a congenital condition to correct hand deformities.”<sup>73</sup> In contrast, “fitting orthoses for a child or adult who has had hand surgery for a torn tendon repair would be rehabilitation.”<sup>74</sup>

Thus, often the same skills are being taught in rehabilitative and habilitative services.<sup>75</sup> It is usually the same instructors teaching in the same type of facilities.<sup>76</sup> In addition, similar function deficits and similar outcomes can arise from both types of services.<sup>77</sup> Despite the difference in their purpose (acquiring or re-acquiring a skill), there are actually many similarities between habilitative care and rehabilitative care.

### **Insurers Continue to Differentiate Between Habilitative Care and Rehabilitative Care**

Since the care usually involves the same skills, instructors and facilities, under the Affordable Care Act there should not be a distinction about whether an insurance carrier pays for rehabilitation services but not habilitation services.<sup>78</sup> Furthermore, both habilitation and rehabilitation ser-

vices and devices are “highly cost-effective and decrease downstream costs to the health care system for unnecessary disability and dependency.”<sup>79</sup> This is further evidence that insurance companies should equally pay for habilitation and rehabilitation services.<sup>80</sup> However, the Affordable Care Act has not answered how insurers will be regulated regarding their provision of essential

**“Habilitative and rehabilitative care usually involves the same skills, instructors and facilities, so insurance carriers should not be allowed to pay for rehabilitation services but not habilitation services.”**

health benefits (including habilitative and rehabilitative care).

“It is inappropriate to deny coverage to a person who...has never gained the capacity to speak at age-appropriate levels, or has a hearing loss, simply because they never possessed the ability to speak and hear, and did not lose these functions through an accident or injury.”<sup>81</sup> An essential health benefits regulation that does not properly cover habilitation services would go against the spirit of the Affordable Care Act.<sup>82</sup>

“The ACA’s overarching goal is to eliminate discrimination in private insurance based on health status, to eliminate pre-existing condition exclusions, and

to design a benefit package that, among other things, meets the needs of children and adults with disabilities.”<sup>83</sup> However, discrimination in healthcare will continue if habilitative care and rehabilitative care are treated differently.<sup>84</sup> “The inclusion in the ACA of the category of rehabilitative and habilitative services was a major milestone for the disability community.”<sup>85</sup> Congress recognized the importance of these benefits “to improve the health and functioning of the American people.”<sup>86</sup> Yet, it is now up to the states to make sure they choose habilitative and rehabilitative care as one of their 10 essential health benefits.<sup>87</sup>

People with disabilities will now have more healthcare options in the private market.<sup>88</sup> People who depend on the state to provide a minimum amount of specialty care to maintain function can now get similar support in the private sphere.<sup>89</sup> Access to care in the private market will allow disabled individuals to free up scarce Medicaid dollars.<sup>90</sup> These funds can then be used for the more expansive habilitative care, which is needed by the people with the most severe disabilities.<sup>91</sup> “The considerations required of the Secretary [of HHS] could not be clearer: even if employer benefit plans today typically discriminate against the sick, this type of discrimination should cease given the risk-spreading design of the statute and its purpose of assuring reasonable coverage for covered

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persons.”<sup>92</sup> Thus, habilitative and rehabilitative care usually involves the same skills, instructors and facilities, so insurance carriers should not be allowed to pay for rehabilitation services but not habilitation services.

### Conclusion

The Affordable Care Act’s establishment of 10 required essential health benefits was an important step forward for the disability community to prevent discrimination.<sup>93</sup> Habilitative care and rehabilitative care are two benefits that are included in the required essential health benefits. However, the lack of a national standard for essential benefits still leaves open the possibility that states can choose a plan that will not cover habilitative services, which forces the state to supplement the essential benefits package by adopting benefits from another plan.<sup>94</sup> If this is not done properly, disabled individuals who require habilitative services could be adversely affected by not having access to covered habilitative care.<sup>95</sup>

There should not be a distinction about whether an insurance carrier pays for rehabilitation services but not habilitation services, because the care typically involves comparable facilities, instructors and skills. HHS should issue a regulation defining habilitative care, to prevent disabled individuals from being denied coverage because of semantics. This would allow people with disabilities to have access to much-needed services like speech

therapy. A regulation should also provide insight regarding who will actually be empowered to regulate insurers to make sure they are not discriminating against individuals with disabilities in their provision of essential health benefits.

A regulation should also ban risk selection by design to prevent insurers from designing their plan, in a way that is unfriendly to people with higher cost conditions (such as designing plans with mediocre or poor oncologists or oncology facilities to avoid insuring people with cancer). Finally, medical necessity should be properly defined in order to clarify what services will be covered as essential health benefits. Until then, insurers will use their own definitions to exclude habilitative services, which will adversely affect individuals with disabilities.<sup>96</sup> While the Affordable Care Act was a step in the right direction for the disability community, there is still more work to be done to ensure people with disabilities are not unfairly discriminated against in obtaining access to health insurance.

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Nina Schuman is a second year law student pursuing the health law concentration. Nina earned her B.A. in Economics with a concentration in pre-medicine from Emory University in 2008. While at Emory, she interned at the Centers for Disease Control and Prevention (CDC), which sparked her interest in public health. She decided not to pursue medical school but instead earned a Master's Degree in Public Health (MPH) from Boston University, with a focus on Health Policy and Management. She interned at the Massachusetts Department of Public Health and the Massachusetts Association of Health Plans while earning her MPH.

After graduating from BU, she worked at Mount Sinai Hospital for two years in the Department of Surgery as a Quality Improvement Analyst and later promoted as Project Manager. She became interested in the legal side of health care after working with the Risk Management Department in the hospital. She writes for Seton Hall's blog, The Health Reform Watch, and currently serves as the secretary for the Health Law Forum. Outside of school and work, Nina enjoys playing tennis.



Donna Hanrahan is a J.D. Candidate at Seton Hall University School of Law. She recently earned her M.S. in Bioethics from Columbia University where her research focused primarily on emerging health technologies. Donna's background is in public policy and she earned her B.A. in Political Science from the State University of New York at Geneseo. She currently works as the lead research strategist at a medical technology startup, where she designs study protocol and analyzes data to determine the clinical efficacy of a mobile health technology. Donna is also involved in qualitative research at Columbia University Medical Center exploring the influence of national governments and Ministries of Health on U.S.-sponsored HIV/AIDS clinical trials abroad. Other current research of hers examines the ethical issues surrounding the secondary use of electronic health data, the challenges new healthcare technologies pose to the HIPAA privacy and security rules and the meaningful use requirements of the HITECH Act, and regulatory challenges surrounding direct-to-consumer marketing of health-related products.

Donna recently worked as a Health Policy and Ethics Fellow at HITLAB, a healthcare innovation firm, and spent time at Yale University's Interdisciplinary Center for Bioethics Summer Institute researching the intersections of the online social networks and epidemiology. She is passionate about the ethical application of healthcare technology in creating better, more cost-effective health outcomes. She is a member of the American Society for Bioethics and the Humanities, Bioethics International Young Professionals, and the International Neuroethics Society.

## Student Contributors



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A.J. earned a Bachelor of Science in liberal studies from Oregon State University, where he focused on critical thinking and analysis. Before pursuing law, A.J. lived in St. Louis, Missouri, where he had a career in event production: designing digital lighting programs, managing a crew of hosts/DJs, and hosting many weddings and other events, eventually earning several St. Louis awards for excellence. A.J. is an avid fan of science fiction, fantasy, and horror, and enjoys many kinds of music.



Brandon Lee Wolff is the Editor-in-Chief of the Seton Hall Health Law Outlook and Executive Board member of the Seton Hall Health Law Forum. Brandon received a Certificate in Healthcare Compliance and will graduate from Seton Hall Law in 2014 with a Concentration in Health Law. Brandon currently works as a Law Clerk at Summit Health Management where he drafts policies related to HIPAA, clinical research, record retention, advance directives, patients rights, peer review and ambulatory surgery centers. Brandon previously worked as a Law Clerk at Summit Medical Group, McCarter & English and the North Jersey Media Group. He also worked as a Summer Associate at LeClairRyan in both the Newark and New York offices.

Outside of health law, Brandon is an Articles Editor of the Seton Hall Legislative Journal and a member of the school's Appellate Advocacy Moot Court Board and Mock Trial Board. Brandon has completed internships with three federal judges, the New Jersey Supreme Court and the United States Attorney's Office. He has participated in the school's Impact Litigation Clinic (where he submitted a brief to the Second Circuit Court of Appeals), the Civil Rights & Constitutional Litigation Clinic, and the Southern District of New York's Representation in Mediation Practicum.

Before law school, Brandon was a National McCabe Scholar at Swarthmore College where he received the Deans' Award for Sustained Contributions to the Swarthmore Community. In high school, Brandon started the anti-violence organization SAVE R US (Students Against Violence Everywhere Are Us) and was recognized as the Prudential Spirit of Community Awards Pennsylvania State Honoree.

After graduating from Seton Hall Law, Brandon will clerk for The Honorable Garry Rothstadt in the New Jersey Superior Court, Appellate Division before returning to work in LeClairRyan's New York office.



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