



Seton Hall University School of Law

Seton Hall Health Law Outlook

Seton Hall Health Law Outlook

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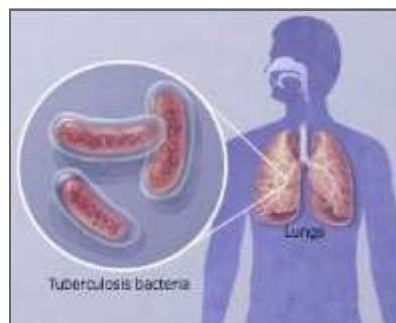
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Multi Drug-Resistant TB and Extensive Drug-Resistant TB: Regulating the Growing Crisis

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The Bacterium

On August 30, 2012, *The Lancet* published a troubling study detailing the increasing prevalence of drug resistant strains of *Mycobacterium tuberculosis* (“*M. tuberculosis*”), which is the bacterium that causes tuberculosis (“TB”). *M. tuberculosis*, much like other bacteria, can mutate in response to the drugs used to eradicate them; thereby, producing more resistant strains.



To be classified as Multi Drug-Resistant Tuberculosis (“MDR-TB”) the bacterium must be resistant to at least rifampicin and isoniazid; in contrast, Extensive Drug-Resistant Tuberculosis (“XDR-TB”), essentially a more resilient form of MDR-TB, requires the strain to be resistant to the aforementioned drugs as well as any one of the fluoroquinolone antibiotics and at least one second-line injectable antibiotic.¹ The study was conducted from January 1, 2005 to December 31, 2008 involving subjects from Estonia, Latvia, Peru, Philippines,

Russia, South Africa, South Korea, and Thailand with the purpose of examining the bacterium’s resistance to second-line drugs.² MDR-TB was confirmed in 1278 (83.0%) of the 1540 baseline isolates collected, and 1199 (93.8%) of those 1278 had a history of TB.³ Furthermore, there was a high frequency of resistance to second-line drugs in MDR-TB at 43.7% and the 6.7% risk of XDR-TB surpassed previous data provided by the World Health Organization (“WHO”), which showed a risk of only 5.4%.⁴ However, the prevalence of XDR-TB in the study ranged drastically from 0.8% to 15.2% indicating an increasing concern, especially in areas with high frequencies of XDR-TB.⁵

Regulating Disease

Fortunately, the WHO has taken precautions to prevent the spread of disease by adopting the *International Health Regulations* (“IHR”) on May 25, 2005, which went into effect on June 15, 2007.⁶ The purpose of the IHR is to “prevent, protect against, control and provide a public health response to the international spread of disease.”⁷ They do not address particular diseases in order to maintain their adaptability and applicability in the face of continued disease evolution.⁸ The IHR consists of sixty six articles, which form the basis of the regulations, as well as nine annexes and two appendices that supple-

ment and further explain the within provisions.⁹ Of these sixty six articles, eight are specifically applicable to the current issue of MDR-TB and XDR-TB.

Article 5 Surveillance and *Article 6 Notification* regard the Member States’ obligation to detect and report any events which may constitute a public health emergency as well as to “develop, strengthen and maintain” the capacity to do so.¹⁰ *Article 12 Determination of a public health emergency of international concern* details the guidelines used by the General-Director of the WHO when determining an international public health emergency, and *Article 13 Public health response* requires the Member States to “develop, strengthen and maintain... the capacity to respond promptly and effectively” to such international emergencies.¹¹

These articles are supplemented by Annex 1, which details the core capacity requirements for surveillance and response, and Annex 2, which assists Member States in determining whether an event may constitute an international public health emergency that should be reported to the WHO.¹² *Article 17 Criteria for recommendations* lists the criteria the WHO will consider when issuing, modifying or terminating any health recommendations, while Article 18 provides potential recommendations.¹³ General obligations are also set forth in Article 19 regarding point of entry, which is also supplemented by Annex 1 and

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concerns both persons and cargo.¹⁴

Through these articles, the WHO establishes the baseline requirements its Member States must follow in order to comply with the goals of the IHR. However, Article 43 permits Member States to implement their own health measures as long as they achieve an equal or greater level of health protection than WHO recommendations or are consistent with the IHR.¹⁵ The United States is one such member state that has established its own control laws and policies regarding TB.¹⁶ While the IHR are essential to the control and prevention of disease in general, the WHO has initiated programs specifically tailored to address TB.

The most recent manifestation of the WHO's efforts to curb TB is *The Stop TB Strategy* ("The Strategy"), which was implemented in 2006. This new stratagem to combat and ultimately eliminate TB relies upon the preexisting Directly Observed Treatment, Short-course ("DOTS") strategy and expands its scope to confront additional challenges in TB control.¹⁷ This program was implemented due to deficient progress towards the goal of halving the prevalence and mortality of TB by 2015 resulting from emerging obstacles – i.e. MDR-TB and HIV.¹⁸ The Strategy is based on six components: (1) Pursue high-quality

DOTS expansion and enhancement, (2) Address TB/HIV, MDR-TB and other challenges, (3) Contribute to health system strengthening, (4) Engage all care providers, (5) Empower people with TB, and communities, and (6) Enable and promote research.¹⁹

DOTS expansion and enhancement is the "cornerstone" and foundation of the Strategy that concerns political commitment with increased and sustained financing, case detection through quality-assured bacteriology, standardized treatment with supervision and patient support, an effective drug supply and management system, and a monitoring and evaluation system and impact measurement.²⁰ The second component requires implementing collaborative TB/HIV activities, the prevention and control of MDR-TB, and addressing high-risk groups such as prisoners and refugees.²¹ This component is the most significant, next to the DOTS expansion and enhancement, because it confronts the primary impediments to controlling and eliminating the disease. HIV fuels the TB epidemic by increasing the rate of recurrent TB, promoting the progression of latent and recent infections to active disease, and causing worse treatment outcomes and higher mortality.²² Therefore, the Strategy urges collaborative activities to address joint infection and reducing the burden of TB in HIV patients and vice versa.²³ Furthermore, MDR-TB is recognized as a

global threat to TB control due to inadequate treatment, rise in drug resistance caused by misuse of second-line drugs, and the lack of new drugs to treat MDR-TB.²⁴ The Strategy requires management of MDR-TB through detection, utilizing adequate treatment methods, a supply of reliable drugs, and assessments determining the capacity of TB control programs to manage MDR-TB.²⁵

Finally, it is essential to determine and address the needs of groups with higher risks of contracting and spreading the disease, such as prisoners, refugees, displaced peoples, migratory workers, the orphaned and homeless, and those with impaired immune systems.²⁶ It is equally important to pay close attention to special situations such as unexpected population movements due to war, political unrest, and natural disasters.²⁷ Even with this new and improved strategy that recognizes the importance of detecting and managing MDR-TB, the WHO still found it necessary to pass a resolution further addressing this issue.

At the Sixty-second World Health Assembly, which took place on May 22, 2009, a resolution was passed specifically addressing the prevention and control of MDR-TB and XDR-TB.²⁸ This resolution, formally known as WHA62.15, not only places

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‘Multi-Drug Resistant’

responsibilities upon all Member States of the WHO, but also the Director-General. WHA62.15 strongly urges the Member States to: (1) attain universal access to diagnosis and treatment of MDR-TB and XDR-TB, (2) enhance quality and coverage of DOTS in order to reach a detection rate of 70% and successful treatment rate of 85% to prevent secondary MDR-TB, (3) use all financing mechanisms to fill funding gaps acknowledged in the Strategy, and (4) increase investment by countries and partners in the research and development of new diagnostics, medicines, and vaccines to prevent and control TB, MDR-TB, and XDR-TB.²⁹ Furthermore, it requests the Director-General to: (1) provide assistance to Member States to develop and implement response plans for prevention and control of TB, MDR-TB, and XDR-TB, (2) provide assistance to Member States to develop and implement strategies to engage all health-care providers in training for and increasing prevention and control of TB, MDR-TB, XDR-TB and TB/HIV co-infection, (3) advise and support Member States to bring national drug regulatory standards up to par with international standards, (4) provide support to Member States for upgrading laboratory networks and facilitate evaluations of new and more efficient diagnostic technology,

(5) help expand access to quality assured first and second line drugs, (6) explore and promote incentive schemes for research and development, (7) work with countries to develop indicators and support monitoring and evaluation of the implementation of the measures in the resolution, and (8) report through the Execu-

IT IS CLEAR THAT THE WHO'S ACTIONS IN PREVENTING THE SPREAD AND CONTROL OF TB HAVE THE POTENTIAL TO PAVE THE ROAD TO A WORLD FREE OF TB. HOWEVER, BECAUSE THERE IS NOT ENOUGH EVIDENCE SUFFICIENTLY DETAILING THE DISTRIBUTION OF MDR-TB....THE ABILITY TO IMPLEMENT THE WHO'S PROVISIONS IS GREATLY COMPROMISED.

tive Board to future assemblies on overall progress.³⁰ Like the IHR, WHA62.15 is a legislative attempt to control and prevent the spread of disease, but addresses a specific disease. Additionally, it places a greater burden upon the Director-General to assist Member States, which certainly benefits poorer and less developed countries. The IHR, the Strategy, and WHA62.15 are the WHO's primary weapons in confronting the issue of TB as a whole, including MDR-TB and XDR-TB, but the ultimate question is whether or not these are adequate in the face of recent findings.

Application Today

Dr. Sven Hoffner of the Swedish Institute for Communicable Disease Control finds the prevalence of MDR-TB and XDR-TB a great cause for concern. Taking the aforementioned study as well as other resources at his disposal into account, Dr. Hoffner finds that most recommendations for MDR-TB control were developed for a prevalence of 5%, but today's prevalence may be as much as ten times higher in certain locales.³¹ He also alleges that despite all the research and studies done regarding MDR-TB there is still a need for “more solid epidemiological information” in order to understand the development and transmission of the disease.³² Dr. Hoffner is hopeful that the study published in *The Lancet* will contribute to the identification of tools necessary to control MDR-TB, but ultimately feels that there is insufficient information revealing the true distribution and magnitude of XDR-TB.³³ These contentions are further supported by facts presented by the WHO which found that an estimated 37% of TB cases in the world go undetected and untreated.³⁴

It is clear that the WHO's actions in preventing the spread and control of TB have the potential to pave the road to a world

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free of TB. However, because there is not enough evidence sufficiently detailing the distribution of MDR-TB and its prevalence varies greatly from place to place, the ability to implement the WHO's provisions is greatly compromised. Additionally, given the turbulent times the world now faces, people are fleeing their home countries in exceptionally large numbers. Relocation of this sort can lead to the transmission of diseases because of the breakdown of social support and thus requires a careful eye, as outlined in the Strategy.³⁵

One such situation is the migration of Africans to the Sicilian island of Lampedusa due to the current political unrest in many North African countries. Unfortunately, in May 2012, an inspection performed by the WHO in conjunction with Italian authorities, including the Minister of Health Renato Balduzzi, found the health facilities and services on the island inadequate, due to, among other things, lack of access to water and sanitation facilities, fire damage from a riot in August 2011, and lack of housing facilities.³⁶ Given the want of adequate care and inherently high risk of TB spreading in displaced populations, this situation is certainly precarious and may lead to a substantial outbreak of TB and disease in general. However, the WHO and the Italian government

now recognize these issues and have the opportunity to remedy them through the guidance of the IHR and TB prevention measures.³⁷ Although there is still much to be discovered about the true threat MDR-TB and XDR-TB pose and their prevalence, due to the WHO's actions in addressing TB and disease control in general, the world stands a fighting chance in controlling and eventually eradicating TB, especially as more data becomes available.

**CAN
YOU IMAGINE
A WORLD
WITHOUT TB?
WE CAN.**

From School to the ‘Real World’: Transition Rights for Students with Special Needs

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Transitional service plans are required by law to assist special needs students in integrating into the community after graduating from high school.

High school. College. Law school. Career. The path to becoming a lawyer requires these essential transitions throughout life: from school to the real world. Though career planning can be complicated and overwhelming for all students, a heightened complexity exists for students with disabilities. These students are required by law to transition from high school prepared for whichever future path they choose—whether it be attending post-secondary schools or joining the workforce. This responsibility for preparation falls largely on the shoulders of the student’s school district.¹ The Individuals with Disabilities Education Act (IDEA)² requires that such transitional services be mapped out within the student’s Individualized Education Plan (IEP) when the child is of high school age. Although Congress has explicitly determined that a plan for transition services must be present in a child’s IEP, courts interpreting the law vary on the legal accountability to

which a school is held responsible for linking graduating special needs students to meaningful and useful post-school³ opportunities. These transition services must be more detailed and individualized in order to accomplish the goal of integration into society.

Under the IDEA, “transition services” are “a coordinated set of activities” designed to be results-oriented and focused on improving a child’s academic and functional achievement in order to facilitate a successful movement from school to post-school activities including, but not limited to, post-secondary education, vocation education, integrated employment and independent living. Sufficient and successful transition services are based on the child’s personal needs, strengths, and interests and must provide recommendations for: 1) instruction, 2) related services, 3) community experiences, 4) development of post-school employment and other adult living objectives, and 5) when appropriate, the acquisition of daily life skills and functional vocational evaluation.⁴

The IDEA’s statutory goals shifted in 1990 from simply providing educational access and opportunities for students with disabilities to actually improving the quality of the education ultimately provided by requiring planned transition services.⁵ Transition planning is recommended

to begin at the age of 14, or sooner, if the student’s IEP team, comprised of parents, educational faculty, school district staff, etc., feel that an earlier start is more appropriate. By age 16, the student’s IEP must include a detailed listing of the specific transition services needed, the agency responsible for providing the service(s), and needed or known linkages to community agencies with or for whom the student may work or associate with post-high school.⁶ Just how far a school legally must go in order to connect high school students with disabilities to beneficial future opportunities is still unclear.



Applicable case law demonstrates that the requirements for acceptable transition plans are unclear and open to interpretation by the states.

Interpretation of a school’s efforts to connect students with post-education special needs agencies in satisfaction of IDEA requirements vary across

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jurisdictions. In some situations, courts have held that simply informing the student and his or her parents of the existence of post-high school community agencies was enough to satisfy the school's obligation.⁷ However, other courts have held that Congress intended for schools to go beyond just making students and their parents aware of community agencies. These courts articulate that Congress' intent was for schools to actually establish relationships with the outside organizations and even include the agencies in an appropriate student's IEP planning process.⁸ The importance of schools collaborating with post-education special needs agencies is immeasurable for a student's future because these organizations will help to make the rest of the lives of these children more purposeful and complete. Thus, "the establishment of these community connections should be viewed as an ongoing process, not a one time venture."⁹ There will always be students with special needs filtering through the public school system. The most efficient practice would be to stay in touch with these agencies so that each new student who is entitled to the protection of the IDEA does not have to start from square one.

A student's assertion of his or her own future goals is a significant factor in the court's view in determining whether a school has met the transition services requirement under the IDEA. For example, if a student suggests he or she

is interested in attending a community college, it is up to the school to reorganize the student's IEP, via a meeting of the IEP team, to include what preparations the student must make in order to be accepted into community college, be familiar with and utilize the special needs services that can and will be provided to him there and to succeed while there.¹⁰

A student's ability, or inability, to live independently after graduating from high school is another serious factor the court considers when determining whether the student had a proper transition services plan implemented. A student who is provided with meaningful vocational internships and socializing activities within the school system, and who displays independence in the school setting, still may be found to have had an inadequate transition services plan. For example, if a student is not educated on the "basics" of independent-living outside of high school, such as normal self-hygiene and navigating various transportation routes to get from his or her home to an out-of-school agency, the school will be deemed to have failed the student in this aspect of the transitions services requirement.¹¹

New York is making efforts to create better transition plans in light of 2011 research that reported poor post-high school activity for students with special needs.

In New York City, The ARISE Coalition (ARISE) is an organization comprised of parents, educators, and advocates working to systemically change New York City's public schools for the benefit of all students. ARISE is concerned with students' preparedness for life after high school. In February 2011, ARISE compiled a status brief focused on the need to improve the educational process for students with disabilities transitioning to adulthood. The brief revealed a 2009 statistic reported by the New York City Department of Education that less than seventeen percent of students with disabilities in New York State who graduate high school are college and/or career ready.¹² In response to this statistic, ARISE conducted its own research by reviewing over two hundred fifty New York City student IEPs. The major issue with most students' IEPs was the overuse of stock phrases within the transitions services portion of the form. It was common for IEPs that were reviewed to state, for example, "Johnny will integrate into the community with supports as needed."

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From School to ‘Real World’

This statement is completely unbeneficial to the student in question since it defines neither how he will integrate, nor what support he requires to prepare to integrate.¹³ The high prevalence of unhelpful generic statements such as these illustrates how the use of boilerplate language in IEPs that merely expresses integration is problematic, and affirms that a student’s IEP should be personalized and created with an individual student’s strengths, needs and goals in mind.

No two students are exactly alike and thus, no two students should have identical transition service plans. Transition plans must be detailed and individualized, and such vague language does not create an actionable process, in writing, which can be followed by the student and the IEP team throughout the child’s time in school. With such limited phrases being inserted into IEPs, no goals for the student are created. Therefore, at the time of graduation, no progress can be measured. Perhaps even more troubling, the student may be no better off when exiting school than when he or she had entered.

In order to alleviate the state’s shortcomings with regards to its students with disabili-

ties, the New York State Education Department (NYSED) has created Regional Special Education Technical Assistance Support Centers, one of which is located in New York City. These centers are staffed with professionals specializing in transition services, special education, bilingual services, positive behavior interventions, etc.¹⁴ Additionally, the NYSED has updated the state’s IEP form to emphasize

THOUGH CAREER PLANNING CAN BE COMPLICATED AND OVERWHELMING FOR ALL STUDENTS, A HEIGHTENED COMPLEXITY EXISTS FOR STUDENTS WITH DISABILITIES. THESE STUDENTS ARE REQUIRED BY LAW TO TRANSITION FROM HIGH SCHOOL PREPARED FOR WHICHEVER FUTURE PATH THEY CHOOSE—WHETHER IT BE ATTENDING POST-SECONDARY SCHOOLS OR JOINING THE WORKFORCE.

post-secondary school goals and the means necessary to obtain those goals. The NYSED has also created streamlined electronic IEPs with the incorporation of a new Special Education Student Information System (SESIS). The SESIS online program is designed to preclude IEP teams from glossing over the details of the transition services process by not allowing those facilitating the meeting to proceed to the next subject area without detailing the student’s planned transition procedure. ARISE reported that be-

cause the program is still in its infancy, it may not be possible to measure its success for some time.¹⁵ However, one could assume that such a program would nudge IEP teams to err on the side of including more actionable goals for the student than not. This program should lead to more accountability for the planners, for example preventing or lessening the use of stock phrases about general integration and creating for the student a path to a better life post-graduation.

ARISE’s status brief urges IEP teams to be thoughtful, collaborative, and understand that “legal requirements are not just red tape; they provide a framework for the type of planning that needs to happen for successful transitions from school to adulthood.”¹⁶ The organization notes that although NYSED does not require a student’s diploma goals to be identified at all during the planning of transition services, it would be in the best interest of special needs students to have their diploma goals outlined within their IEP. Emphasizing diploma curriculum helps ensure that the high school provides the student with whatever required coursework might be necessary for future educational or vocational programs.¹⁷ Finally, ARISE highlights the importance of successfully linking students with the appropriate outside agencies who can and

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will help support them in their post-secondary endeavors.¹⁸ The organization recommends that schools maintain a database of community services geared toward serving and working with those living with disabilities.

reers by providing a more useful curriculum. This curriculum must be designed with the student's individual needs, strengths, and interests in mind, while they are still within the protection of the public school system.

Conclusion: Students with disabilities who possess detailed transition service plans within their IEPs will be more prepared to handle life after school.

Although the IDEA's standards for transition services for students with disabilities seem clear, interpretation of what is and isn't enough varies by jurisdiction. As New York City's ARISE Coalition urges, it is in the best interest of special needs students for schools to interpret the requirements provided by the IDEA as the bare minimum. In order for students with disabilities to truly benefit from the educational opportunities the IDEA seeks to provide, they must have an appropriate place to go after they are phased-out of the school system by either accepting their diplomas and/or reaching a certain age determined by the district. Students with disabilities who contribute and have access to proper, detailed transition service processes within their IEPs will be more prepared to handle life after school. Well-developed transition plans give students the ability to succeed in higher education, vocational education and post-high school ca-



Government Tokophobia: Unjustly Denying Pregnant Women Access to Research

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Tokophobia, or the fear of pregnancy, is a psychological disorder predominately affecting pregnant women.¹ The disorder involves a lack of confidence in the mother and/or a concern of harm to the fetus.² As described in the following paragraphs, the disorder is not limited to pregnant women and—in selection of research candidates—the government has promulgated a set of regulations that reflects its own form of tokophobia.³ In order to increase equality, autonomy and safety for pregnant women, the government should shed its tokophobia and rewrite regulations to allow greater access to research for pregnant women.

Research is defined as “a systematic investigation designed to develop or contribute to generalizable knowledge.”⁴ The justification for allowing research on human subjects, particularly those who are at risk of harm, is the corollary benefit in the form of “generalizable knowledge” obtained from research results.⁵ For example, clinical trials for drug approval may involve a risk of toxicity to healthy individuals; however, the studies are used to enhance safety profiles of the drug.⁶ The information gathered from re-

search provides guidance to a prescribing physician to determine the right dosage and patient to receive the drug.⁷ If no such study is performed and the drug is approved with latent toxicities to an untested group of individuals, future patients in that group are at a much greater risk of harm.⁸



Under the current regulations, “generalizable knowledge” is not an acceptable ground for conducting research on pregnant subjects.⁹ Instead, research involving pregnant subjects at risk of harm is only permissible if there is a *direct benefit* to the mother or fetus.¹⁰ Accordingly, participation in clinical trials involving pharmaceuticals or therapeutic devices is severely limited for pregnant women because clinical trials generally involve risk of harm without direct benefit to the specific research subject.¹¹ The Food and Drug Administration (FDA), which regulates clinical trials in the U.S., even goes so far as to state that non-pregnant women of child-bearing age “must be counseled about the re-

liable use of contraception or abstinence from intercourse while participating in the clinical trial.”¹²

Nevertheless, the same drug that is too risky to test during research—where subjects are carefully selected, monitored, required to give informed consent and provided information on the risks of the intervention—will subsequently become available by prescription without sufficient knowledge or warning as to its teratogenicity (toxicity to the fetus).¹³ Accordingly, instead of reducing the risk of harm to pregnant women, the current regulatory regime just delays risk until the drug is actually approved, when more people are vulnerable and fewer are paying attention.¹⁴

The Belmont Report, which articulates the basic ethical principles for human subjects in research, provides that injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.¹⁵ The Department of Human Health and Services (HHS), the government agency in the United States that regulates human research, has, in contravention of the Belmont Report, promulgated guidelines that unjustly deny pregnant women access to the benefits of research.¹⁶

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HHS states that in the selection of research subjects, review boards “should be particularly cognizant of the special problems of research involving *vulnerable* populations, such as children, prisoners, *pregnant women*, mentally disabled persons, or economically or educationally disadvantaged persons.”¹⁷ Aside from pregnant women, each of the groups cited in the list of “vulnerable populations” have diminished autonomy as a result of physical confinement, age, mental capacity, or desperation.¹⁸ Pregnant women do not have diminished autonomy nor do they lack decision-making capacity.¹⁹ Thus, they do not logically belong to a “vulnerable population.” Such a designation is arbitrary, paternalistic and demeaning.

In reality, HHS and the underlying regulations are less concerned with pregnant women and more with the vulnerability of fetuses; specifically, that pregnant women cannot be trusted to make decisions for their fetus. A woman has the right to an abortion,²⁰ which clearly puts the fetus at extreme risk of harm, yet she is denied a choice to enter into research over concerns of harm to that same fetus.²¹ By simply comparing “risks” to the fetus, research is clearly on much stronger footing than abortion.

Pregnant women are permitted to engage in a number of other activities that are proven to be very dangerous to the develop-

ment of the fetus and, unlike the investigatory nature of research, hold out very little corresponding benefit to the fetus (and arguably even the mother). Some of those activities include: smoking, drinking alcohol, eating sushi and even participating in the Olympics.²² By permitting these activities, we as society trust the woman to make the best decision for herself and the fetus. Thus, it is unclear why in the case of research, women are denied individual autonomy and the ability to make their own fully informed decisions. The only logical basis is that research provides no corollary benefit worth protecting.



Research holds tremendous benefit in the form of knowledge and the potential reduction of risk to generations of future mothers. Without extensive research, patients would be naïve to the potential harm a particular drug may cause. An alarming example of the risk of naivety is the drug Thalidomide, which was approved for prescription to a select group of people needing a sedative or tranquilizer.²³ Thalidomide was never licensed for general use, nor was it approved for administration to pregnant women.²⁴ Nonetheless, physicians touted Thalidomide as a “wonder drug” and prescribed it off label to pregnant mothers for alleviation of morning sickness.²⁵ The drug was ultimately found to be a severe

teratogen and became responsible for as many as 20,000 horrific birth defects.²⁶ Had the teratogenic effects of Thalidomide been thoroughly evaluated prior to approval, it likely would have had many fewer victims.

While facially protective, current provisions limiting access to research actually increase the risk of harm to the fetus. Denying pregnant women the right to choose to enter research is inequitable, paternalistic and irresponsible. The ultimate decision as to whether the benefit outweighs the risk should at least partially lie with the mother and not entirely with the government.

According to the court in *Planned Parenthood v. Casey*, “[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives.”²⁷ HHS and the legislature should consider rewriting regulations to remove pregnant women from the list of “vulnerable populations” and include “generalizable knowledge” as a justification for research to eradicate this inequality. In doing so, the government can resolve its tokophobia and put research in line with existing federal law and community standards, which already recognize that women should be able to decide what is in their own best interest and that of the fetus.

Criminalizing Prenatal Substance Abuse: Hurting Women and Their Unborn Children

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Introduction

Criminalizing drug use during pregnancy is an attack on women's bodily autonomy framed as a protection of unborn children. This framework reduces women to, "being little more than incubators to unborn children."¹ This dehumanizing stance has a negative effect on the status of women in society and violates women's constitutional rights. Additionally, statutes and prosecutions targeted toward prenatal substance abuse do not accomplish the intended goal of promoting fetal health. As a result of this punitive legal system, women, unborn children, and their families suffer. This article will argue that a public health framework, in contrast to a punitive legal system, is a better and more functional approach for addressing problems associated with prenatal substance abuse.

A punitive legal approach endangers a woman's bodily autonomy. Bodily autonomy is the power of a woman to make choices about her own body, and specifically in the context of prenatal substance abuse, about her pregnancy and treatment.² When the legal system takes a punitive approach

towards women using drugs during pregnancy, it subordinates women and takes away their bodily autonomy.³ This is not to say that a woman's bodily autonomy is the only concern regarding prenatal drug use. *Roe v. Wade* established the states' interest in protecting the potential life of a fetus; however, neither the woman's right to privacy during pregnancy nor the states' interest in potential life is absolute.⁴

Policies criminalizing drug use during pregnancy pit fetal rights against women's rights and ultimately conclude that fetal rights trump the rights of women.⁵ Women using drugs during pregnancy have been charged with crimes ranging from assault with a deadly weapon to child endangerment and often receive stricter sentences than drug users who are not pregnant.⁶ This leads to the conclusion that pregnancy is a dominant factor in prosecutions, and it becomes clear that this punitive approach serves as another way for the state to reduce a woman's bodily autonomy.⁷ As discussed below, the punitive framework for drug-addicted pregnant women may actually hurt the fetus it is supposed to protect because it can result in fewer women seeking pre-natal care or drug treatment as well as children being separated from their mothers.⁸ In contrast, a public health approach

aims to balance the interests of women's autonomy and the states' interest in potential life resulting in policies that are more functional and just for women and their families.⁹

What does the Constitution say about bodily autonomy and targeting certain groups of pregnant women for prosecution?

The Supreme Court established in a line of case law, and affirmed in *Roe v. Wade*, that the Constitution provides a general right to privacy.¹⁰ Further, *Roe v. Wade* established the right to privacy in the context of terminating pregnancy; so it follows that this fundamental right to privacy must also apply to a woman's choices during pregnancy.¹¹ Within that right to privacy is the fundamental right to procreate, first addressed by the Supreme Court in *Skinner v. Oklahoma*, invalidating the state's forced sterilization of certain "habitual" criminals.¹² The right to procreate was expanded upon in *Griswold v. Connecticut*.¹³ As one scholar noted that while *Griswold*, "... specifically discussed only protecting the marital relationship, its holding in fact creates a right to privacy concerning intimate matters such as decisions about procreation."¹⁴

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When statutes criminalizing drug use during pregnancy infringe upon the privacy and procreation rights of women, they create a basis for an Equal Protection claim.¹⁵ The Equal Protection Clause of the Fourteenth Amendment was first applied to give equal protection of the law to racial minorities but has since been extended to apply to members of suspect classes, including women.¹⁶ In order to analyze an Equal Protection claim for state laws dealing with prenatal drug use, the level of appropriate scrutiny to be applied to the law needs to be determined. The Supreme Court has most recently applied a heightened form of intermediate scrutiny to gender based discrimination meaning a state must demonstrate an “exceedingly persuasive justification”¹⁷ of a government purpose for a law facially discriminating on the basis of gender.¹⁸ Laws targeting pregnant women are facially discriminatory because they only apply to females; so, the government would have to provide an exceedingly persuasive justification for an important government interest.¹⁹ One potential counter argument for the government to respond with would be that it is difficult and impractical to prosecute men for fetal harm caused by drug use; however, that is not sufficient to justify an important government interest.²⁰

Prosecutions targeting pregnant drug users are usually

based in a child abuse or endangerment statute and not an actual drug abuse charge, and “pregnant women receive harsher sentences than drug-addicted men or women who are not pregnant.”²¹ While statutes addressing prenatal substance abuse target women, there are no statutes or cases targeting fathers of unborn children who have used drugs that potentially harm their sperm.²² Consequently, even though the right to privacy applies equally to men and women, it is being applied differently in the context of drug use and procreation simply because women naturally carry the fetus that took a man and a woman to create.²³ Thus, women are treated more harshly when they are pregnant while men are not similarly impacted when they use drugs and procreate giving rise to an Equal Protection Clause claim on the basis of gender discrimination.²⁴

Additionally, an Equal Protection claim could be established where it is demonstrated that state law disproportionately impacts African American women and there was some discriminatory purpose behind the state law.²⁵ All too often, the common factor in prosecutions against pregnant women for drug use and hospital drug testing on pregnant women is that the women chosen for testing are African American.²⁶ This is true despite that fact that evidence shows drug use by pregnant women is similar across racial

lines, but, “black women are more than ten times more likely than white women to be reported for using drugs while pregnant.”²⁷ This disparate impact strongly implies that African American women are being specifically targeted; therefore, it suggests at least some evidence of a discriminatory purpose behind these laws.

Prenatal substance abuse laws can also be attacked as a Constitutional violation of the Due Process Clause. An important tenet of the Due Process Clause is fair notice of the scope of what is forbidden by the language of the laws.²⁸ This not only protects the accused from the court creating illegality retroactively, but also emphasizes the importance of the legislative intent.²⁹ When women are charged under various child abuse and endangerment statutes, they are not given fair notice because almost none of the statutes used to charge women using drugs during pregnancy include harm against a fetus; thus, such charges tend to equate a fetus with a minor child.³⁰ For example, in *State of New Mexico v. Martinez*, the defendant was charged under a felony child abuse statute after admitting to using cocaine during her pregnancy.³¹ Because the child abuse statute in question did not include a fetus in the statutory meaning of “human being,” the

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court concluded that convicting the defendant under the statute, “would violate Martinez’s constitutional due process rights, as she did not have prior warning and fair notice that her conduct was criminal under the statute.”³²

While the state has an established interest in the potential life of a fetus, a fetus is not legally equivalent to a child and therefore is not afforded the same rights and protections.³³ When women are prosecuted under various child abuse and endangerment statutes as a result of using drugs while pregnant, the state is effectively giving personhood status to the woman’s fetus, setting a dangerous precedent for policing women’s every action and choice during pregnancy such as the kinds of food she eats while pregnant, and her particular birth plan.³⁴ This disturbing possibility is already starting to become a reality in South Carolina following *Whitner v. State of South Carolina*³⁵ which upheld Whitner’s child abuse conviction received for using crack cocaine during her pregnancy, despite the fact that her child was born healthy.³⁶ This is especially alarming considering that in at least one major South Carolina hospital, African American pregnant women are much more likely to be tested for drug use than Caucasian pregnant women.³⁷ This opens the door for

state-sanctioned racial profiling and gender discrimination.

How a public health approach promotes fetal and maternal health while protecting women’s Constitutional rights.

It is clear that the punitive approach to prenatal substance abuse is constitutionally problematic for women; however, there are still concerns about how to best address the problems resulting from drug use during pregnancy. It is acknowledged that drug use during pregnancy can have detrimental effects on the unborn child. Nevertheless, how these women are dealt with afterwards is still of vital concern and importance. A public health approach rather than a punitive approach is more functional for women and their unborn children. A public health approach can be defined as one, “that identifies the population-based factors that may influence health, rather than focusing on an individual’s personal behavior.”³⁸ A useful framework for comparing the two approaches is thinking about the rationales for a punitive approach and the responses provided by supporters of a public health approach.³⁹

The first rationale given under the current punitive system is that prosecution of prenatal substance abuse will deter pregnant women from using drugs

because of the consequences of prosecution.⁴⁰ However, it appears that levels of prenatal substance abuse are not decreasing and may be in fact increasing.⁴¹ Moreover, it is also shown that prosecutions actually have the opposite effect, causing women to forego prenatal care altogether, resulting in an even riskier situation for women and their unborn children.⁴² This is further supported by many organizations including the American Academy of Pediatrics and the March of Dimes who agree that a punitive approach has the effect of deterring women from seeking medical treatment during pregnancy, depriving themselves and their unborn children of vital prenatal care.⁴³

The next rationale for a punitive system is based on retribution and the idea that pregnant drug users deserve legal punishment because their actions are wrong regardless of how the punishment affects their lives or the lives of their unborn children.⁴⁴ However, this rationale ignores the disease aspect of drug addiction as well as the social and economic disparities that often correlate with illegal drug use.⁴⁵ Furthermore, the retribution rationale should be analyzed with suspicion because it invokes Equal Protection and Due Process concerns.⁴⁶ Additionally, the idea of retribution makes less policy sense considering the limited number of drug treatment options

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for pregnant women, and evidence that many drug treatment centers turn away pregnant women in a time when they need treatment the most.⁴⁷

The final rationale used to justify the punitive system to drug use during pregnancy is that it promotes fetal and maternal health by facilitating medical intervention.⁴⁸ Unfortunately, the opposite appears to be true. When women are incarcerated during pregnancy because of drug use, they are sometimes forced to give birth shackled or in unsanitary prison facilities, resulting in dehumanizing and potentially dangerous situations.⁴⁹

Public Health Approach as an Alternative

A public health approach can provide functional solutions to the challenges faced by pregnant drug users while avoiding the constitutional and policy concerns raised by the punitive approach. Some of the best public health solutions focus on the importance of prevention and treatment, specifically educating women about the dangers of drug use during pregnancy and providing feasible treatment options to pregnant women struggling with addiction.⁵⁰ In order to encourage pregnant drug users to seek vital prenatal care and addiction treatment, programs that can provide healthcare without fear of punishment need to be

established and funded.⁵¹

A major barrier for many women seeking drug treatment is the lack of healthcare coverage and an inability to pay for a treatment program.⁵² It follows that access to universal healthcare coverage including drug treatment programs and prenatal care would alleviate this barrier for many women.⁵³ One specific example of a public health approach includes California's policy of addressing drug use during pregnancy that places the issue in the realm of child protective services rather than criminal law.⁵⁴ Combining access to affordable treatment and handling by child protective agencies is effective because it removes the threat of criminal prosecution while giving a greater opportunity for maternal and fetal health.⁵⁵

It is also important for treatment approaches to take into account the fact that many women who need treatment also have other children for whom they are responsible. Consequently, treatment programs should be welcoming to families and cognizant of the importance of keeping them together.⁵⁶ This promotes the ultimate goal of a healthy woman giving birth to a healthy child.

Conclusion

Accepting the status quo punitive approach to avoid difficult reform devalues the high

stakes of promoting healthy women and children. Protecting an unborn child from the negative effects of drugs use does not have to compromise the mother's bodily autonomy and Constitutional rights. Fetal and maternal rights should be protected together in the interest of a healthy family. The best way to do this is to establish a public health system that focuses on preventing and treating prenatal substance abuse.



Everyone Wants a Piece of Me: The Evolution of Biospecimen Research and the Regulatory World's Attempt to Keep Up

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A biospecimen is a sample taken from the human body that can come in many forms, including tissue, blood, and urine, and contains a vast amount of cellular material.¹ Biobanks are the repositories that house these specimens for safe keeping.² They usually involve cryogenic capabilities for preservation and are maintained by the organization conducting the research.³ In 2009, Time Magazine named Biobanks as one of the “10 Ideas Changing the World Right Now”.⁴ Needless to say, biospecimen research has been on the rise, and an investigation into whether the regulatory world has been able to keep up with this progress is essential.

The National Cancer Institute (NCI) is at the forefront of the biobanking movement due to the potential information that can be harvested from specimens that is also relevant to the field of oncology.⁵ It is one of the keys to the movement towards personalized medicine. Biospecimen analysis can and has led to better diagnostic, prognostic, and staging techniques and outcomes in cancer medicine by allowing for the evaluation of disease suscepti-

bility.⁶ Time magazine raised concerns surrounding the collection and storage of biospecimens, including maintaining the privacy of the individuals whose genetic material is stored for future use and the appropriate informed consent procedures for obtaining these specimens. These issues are especially pertinent with regards to modern cancer research.

BIOSPECIMEN RESEARCH IS EVOLVING AT A PACE FAR FASTER THAN THE REGULATIONS THAT GOVERN IT. IT IS QUITE CLEAR THAT CLARIFICATION IS NEEDED, ESPECIALLY CONSIDERING THAT MUCH OF WHAT APPEARS ESSENTIAL TO PATIENT PROTECTION IS SIMPLY A RECOMMENDATION AT THIS POINT.

The Intersection of HIPAA and Biospecimen Research

The Health Insurance Portability and Accountability Act (HIPAA) governs not only an individual's right to privacy of their individually identifiable health information, but also their right to access their protected health information (PHI).⁷ PHI is defined as:

“any information, whether oral or recorded in any form or medium” that “is created or received by a health care provider, health plan, public health authori-

ty, employer, life insurer, school or university, or health care clearinghouse” and “related to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.”⁸

Biobanking poses interesting challenges to compliance under HIPAA. One is whether a patient can ensure the confidentiality of their PHI when a chunk of tissue can include vast amounts of an individual's genetic information and HIPAA is not clear as to whether this type of information is covered. An individual's entitlement to know what information is collected from their biospecimen is further debatable.

Biospecimens are not directly covered by the HIPAA privacy rule. However, these specimens are often accompanied by identifiable PHI and may therefore be indirectly covered.⁹ The Department of Health and Human Services (HHS) established The Secretary's Committee on Human Research Protections (SACHRP) in 2001 to advise the Secretary of HHS on issues surrounding the protection of human research subjects.¹⁰ These recommendations can then

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be used by local practitioners using informed consent and research practices related to biospecimens. Their most recent release in July of 2011 was specifically targeted to researchers and institutional review boards (IRBs) involved in biospecimen research and provides some clarification on the privacy concerns by addressing any relevant HIPAA issues that arise under several commonly encountered clinical scenarios.¹¹ The guidance issued by SACHRP is **not** promulgated regulations, and it is unclear exactly how many institutions are aware of and follow their recommendations. One such recommendation includes the use of an honest-broker, which involves placing a barrier between clinical and research activities by removing any HIPAA-designated PHI and preventing reidentification.¹² An honest-broker can take the form of a person or system that replaces PHI with a code and then releases only the coded information to the research team.¹³ The recommendation states that this honest-broker procedure may be used “if appropriate” but does not define what an appropriate circumstance would be.¹⁴ Nevertheless, it would seem that this would be the best way to protect a patient’s identity throughout the biospecimen collection process because it includes measures to prevent reidentification by anything or anyone other than the honest-broker.¹⁵ Another benefit of this system comes from the fact that an honest-broker is

the only link between research identifiers and clinical identifiers and therefore reduces the opportunity for conflicts of interest to arise between the research and clinical teams.¹⁶

Another recommendation involves the use of Certificates of Confidentiality. These certificates are issued by the National Institutes of Health (NIH) to protect PHI and other information collected during a research study from being forcibly disclosed by investigators during any sort of legal proceeding.¹⁷ Again, the recommendations fail to explicitly state where such a certificate is appropriate and simply state that they “may not be appropriate for all biospecimen resources.”¹⁸ These certificates are promising in that they have the potential to encourage individuals to participate in biospecimen research. As such, they could become a mandatory part of biobanking so that participants are assured of confidentiality.

Additionally, if the hospital or institution performing the biospecimen collection is a HIPAA covered entity, the disclosure of any PHI would require a HIPAA authorization from the patient.¹⁹ Any subsequent disclosures of material containing PHI to various entities would require a new HIPAA authorization by the patient if that entity was not covered in the original authoriza-

tion.²⁰ This establishes a tracking mechanism of interested parties that desire access to a particular individual’s biospecimen and places the research participant in control of who has access to their information. A conflict arises when attempting to comply with both the HIPAA Privacy Rule that governs research authorizations and the Federal Common Rule for Protection of Human Research Subjects, which governs the informed consent process. According to the Privacy Rule, a research authorization must “pertain only to a specific research study, not to nonspecific research or to future, unspecified projects.”²¹ The Privacy Rule considers the creation and maintenance of a biorepository as a “specific research activity [and] the subsequent use or disclosure by a covered entity of information from the database for a specific research study will require separate authorization.”²² On the other hand, the Common Rule allows for future research to be consented to as long as the informed consent document sufficiently details the future research.²³ Although it would appear from a legal perspective that the appropriate approach in dealing with seemingly conflicting rules is to observe and comply with the stricter one, it is unclear how a research team on a local level decides to comply with two

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rules that govern their biospecimen research. An informed consent document usually goes hand-in-hand with its corresponding research authorization, which may cause further confusion for the local practitioner.

HIPAA regulations and NCI recommendations encourage the stripping of PHI from biospecimens and the prevention of reidentification, so how then might federal regulations comply with a patient’s right to access any health related information derived from these specimens? Unfortunately it is not clear whether information derived from biospecimens would be covered under HIPAA, but it would appear that genetic results would qualify as information that is “related to the past, present, or future physical or mental health or condition of an individual...”²⁴ Most human subjects research in the United States is governed by the Common Rule.²⁵ The Common Rule necessitates several basic requirements related to the informed consent process, such as that the consent form must include any additional costs that a research participant may incur from participation in the research and any reasonably foreseeable risks to the research participant.²⁶ None of the rule’s requirements includes an obligation to return any data, including genetic information, to a study participant.²⁷ These same in-

formed consent regulations include that the following should be provided to a research participant: “A statement that significant new findings developed during the course of the research



which may relate to the subject’s willingness to continue participation will be provided to the subject.”²⁸ Because results from genetic analyses could affect a participant’s willingness to continue in a research study, the significance of the generated information should undergo careful consideration when drafting an informed consent.²⁹

Stepping away from the regulatory aspects and considering the ethical aspects of an individual’s right to information unfortunately and surprisingly does not provide clarification. The National Bioethics Advisory

Board (NBAC) closely examined the ethical issues surrounding research with biological materials, but made no reference to a participant’s absolute right to access data from their participation in a research study.³⁰ The NBAC did recommend that the disclosure of research results be an exceptional event that occurs only when the results could have an impact on the subject’s health and ameliorative measures are available to cope with the clinical implications of these results.³¹ This guidance is based on what the clinician and researcher deems an appropriate circumstance for disclosure, rather than addressing what the patient may deem a disclosure event. Additionally, the NBAC ceased to exist in 2001 and no similar government groups or committees have been established to address the bioethics of biobanking.³²

A Truly Informed Consent

In 2008, the Arizona Court of Appeals reversed a summary judgment dismissal of a claim by the Havasupai Native Americans against Arizona State University for unconsented misuse of their blood specimens.³³ The Havasupai had initially consented to research involving diabetes, a disease that was plaguing the tribe, but later learned that data derived from their blood samples had been used in various publications unrelated to their

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initial purpose, such as schizophrenia, inbreeding, and population migration.³⁴ Particularly upsetting was the report on population migration that directly contradicted the tribe's own belief of their origin.³⁵ A large settlement in favor of the Havasupai was reached. In a New York Times article on the case, Dr. David Karp, a University of Texas Southwestern Medical Center internist who studies informed consent for genetic research, asked, "The question is, how far do you have to go? Do you have to create some massive database of people's wishes for their DNA specimens?"³⁶ One might think so and current regulations contemplate the progress towards a truly informed process of consent in the field of biospecimen research.

A patient's tissue has the potential to outlast the patient. Techniques for biospecimen preservation have improved as the prevalence of biobanking has increased. Thus, future and secondary uses of biospecimens have increased as well. The NCI Best Practices guidance document on informed consent recommends that a tiered structure of informed consent be instituted when biospecimens are involved so that patients can consent to only particular uses and not others.³⁷ For example, if this tiered consent structure had been used in the case of the Havasupai tribe, the participants would have been presented

with a consent form that would have included the potential uses for their tissue. They would have perhaps consented to the use of their biospecimens in diabetes research but not to any sort of research involving evolutionary or migratory patterns. This concept of future consent is complicated by conflicting federal guidelines. The Common Rule allows for future unspecified research, while HIPAA, as mentioned earlier, requires that every entity have authorization to conduct research.³⁸ It is not yet clear how these differences are being reconciled in the clinical and research settings.

The NCI has taken on the task of attempting to provide clarification to local IRBs and biospecimen researchers. In 2011, the NCI's Group Banking Committee drafted an Informed Consent Template which gives a patient the power to decide whether their biospecimens may be stored and used for future research.³⁹ Notably, the informed consent was also written in very simple language, with a preferred eighth grade reading level, which addresses any concerns that a patient may not fully understand what they are consenting to.⁴⁰

Future Considerations

Increasingly common within the field of oncology is the practice of collecting a biospecimen upon entry to a clinical trial.

The ethics of this mandatory biospecimen collection, that is when eligibility for a trial is dependent upon undergoing a biopsy, is currently being investigated. Clinical biopsies are common in oncology and are needed for diagnostic purposes. In contrast, research biopsies are biopsies performed for research purposes only and have no established direct benefit to the patient.⁴¹ Within the research biopsies group, there are two common categories: 1) research biopsies used for correlative studies that are often exploratory and rarely predefined; and 2) research biopsies used for studying an integral biomarker and the results will be used to guide patient care throughout the study and oftentimes to determine eligibility for study entry.⁴² There are always safety risks with invasive procedures, but at least there is direct benefit to the patient that balances out this risk when clinical biopsies are used for diagnostic purposes. The concern over research biopsies is that you are exposing a patient to a safety risk when there is no established direct benefit to the patient.⁴³ Given the lack of direct benefit, a patient should be given a very explicit option to consent to a research biopsy. But what if this biopsy is an entry criterion for a clinical trial? Some researchers

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have suggested that conditioning study participation in this way may be a form of coercion.⁴⁴ Clinical trials are often entered into because they are the last resort for a patient. The level of choice for someone during a Phase I clinical trial, for example, is often severely limited. If a patient does not want to undergo this biopsy, they should not be barred from perhaps the last therapy option available to them.

A survey of cancer patients showed that approximately one third of clinical trial participants would be hesitant to participate in a study involving mandatory research biopsies but a larger percentage (50%) said it would have no impact.⁴⁵ Very little has been written on this topic and it is still unclear how local IRBs are reviewing studies that include mandatory research biopsies. A higher level of scrutiny is appropriate for such studies, especially regarding the safety concerns. For example, a skin biopsy may not necessarily increase the safety concerns but a much more invasive liver biopsy should affect the safety profile of a study and therefore may not be as readily approved by an IRB.

Biospecimen research is evolving at a pace far faster than the regulations that govern it. It is quite clear that clarification is needed, especially considering that much of what appears es-

sential to patient protection is simply a recommendation at this point. Moreover, the regulations that do exist often conflict with one another, as evidenced by the disconnect between the HIPAA Privacy Rule and the Common Rule governing clinical trials research. The case involving the Havasupai tribe is promising in that it demonstrates the attention the courts are willing to focus on potential abuses of biorepository banking and damaging resulting consequences of research with insufficient regulation and oversight in this area.

Complications of Globalization: FDA Cracks Down on Fraud in the Pharmaceutical Industry

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On February 14, 2012, the United States Food and Drug Administration (FDA) announced that 19 US medical practices had purchased counterfeit Avastin, a commonly used cancer drug, from a foreign supplier named Quality Specialty Products.¹ Also this year, two separate instances have been reported concerning the purchase of counterfeit Vicodin, a pain relief medication, via the Internet. Abbott Laboratories subsequently issued a consumer alert to help prevent the sale of the counterfeit drug through rogue websites.² In a third instance, in September, China State Food and Drug Administration and the US FDA initiated a joint campaign, which resulted in the shutdown of 18 Chinese-language web sites in America selling counterfeit drugs, in violation of US laws.³

These incidents are only a sampling of what the FDA's Office of Criminal Investigations (OCI)⁴ tackles. OCI is charged with the responsibility to keep consumers safe and to ensure the public's health, a broad delegation that encompasses a wide array of duties. In so doing, the FDA must balance all the interests at stake—the need for safe, legitimate medication and health care services, while at the same time such medi-

cation and services must be affordable and readily available for everyone in the nation. In light of the need for a balance and as the examples above show, the FDA faces a dilemma since the demand for drugs is high and there has been a rise in both fraudulent, unlicensed drug manufacturers and sellers, and counterfeit drugs on the market. These issues are in part the results of the rise in globalization, which largely affects the nature of the pharmaceutical industry.

Black Market Rings and Globalization

Black market pharmacy rings continue to threaten the nation's public health. While many ring members have been arrested for violating the Federal Food, Drug, and Cosmetic Act (FDCA),⁵ a myriad of problems persist, and for a variety of reasons. For one, many undocumented immigrants purchase and seek treatment from these FDCA violators who offer reduced services and/or medication, out of fear that their status will be discovered and they will be deported if they seek treatment at legitimate, state-licensed clinics.⁶ Second, some criminals falsely claim to have medical backgrounds, and sell prescription drugs or counterfeit drugs, perhaps even administering injections.⁷ Furthermore, some sell prescription drugs that have

been approved in a foreign country but have not passed FDA inspection in the United States.⁸

The issues are numerous and the degree of harm grave. Drug standards and regulations vary from country to country, and the FDA is responsible only for those marketed and sold in the US. The FDA accomplishes this task by imposing stringent standards for drug approval and manufacturing. Additionally, US pharmacists and wholesalers must be licensed or authorized in the states where they operate. This type of process has been referred to as a closed distribution system.⁹ Clearly, this system is disrupted when counterfeit drugs enter the market and when individuals hold themselves out as being licensed when they are not.

Globalization has contributed to the rise and persistence of counterfeit drugs, as the pharmaceutical industry's complex manufacturing, operations, and supply sourcing is increasingly being shifted overseas.¹⁰ These are particularly challenging times, due in large part to tremendous breakthroughs in science and technology.¹¹ Such worldwide explosion of knowledge and capabilities affects many fields of research, innovation, and industry.¹² Currently, almost forty percent of

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American drugs are imported. Moreover, nearly 80 percent of the active ingredients in the drugs on the American market come from overseas sources.¹³ It has been acknowledged that,

“in addition to the growth in volume of imports, there has been a dramatic increase in the variety and complexity of imported products. As the variety and complexity of imported products has increased, the supply chain involving a web of numerous repackaging facilities and distributors has correspondingly become more intricate and mysterious. Like any chain, the drug supply chain is only as strong as its weakest link, and the proliferation of additional handlers, suppliers and middlemen creates new entry points through which contaminated, adulterated and counterfeit products can infiltrate the drug supply.”¹⁴

With the rise of globalization and the increasing complexity of the drug market, it has become easier for the very kind of criminal behavior described earlier to increase and persist.

The FDA Criminal Unit and Special Agents

The special agents of the FDA are the team of criminal

investigators within OCI who protect the public health from “theft, counterfeiting, fraud, tampering, and false advertising as spelled out in [the federal laws].”¹⁵ The special agents are equipped with specialized knowledge and training to investigate violations throughout the nation. OCI investigates about 1,200 criminal cases each year that result in arrests of about 300 criminal suspects; over \$11 billion in fines and restitution were made from 1993 through November 2010 due to OCI’s efforts.¹⁶

Of course and as with any other agency, OCI’s resources are limited and not every suspected case can be investigated. Because of this, the FDA continues to develop risk models¹⁷ and management tools to identify drugs and their ingredients that are the most at risk of economically motivated adulteration. The FDA allocates a majority of its resources and efforts to monitor those identified.¹⁸ Commissioner of Food and Drugs Margaret Hamburg explained, “We combine risk-based approaches with sound scientific evidence to protect the public from adulterated drugs and take a number of factors into account in determining whether a particular drug ingredient may be at risk for adulteration.”¹⁹ The FDA also acknowledge that, to a large extent, their “success or failure in this effort will depend on the relationships we establish and maintain with our foreign partners.”²⁰

Thus, to mitigate the effects of globalization the FDA engages in joint efforts with other countries.²¹ Additionally, the FDA launches national campaigns to warn consumers of the various risks they run, such as when purchasing from online pharmacies, or how to keep an eye out for counterfeit drugs.²²

Challenges to prosecuting FDCA violators: Illegal Internet Pharmacies

Under the FDCA,²³ each importer and each imported drug must comply with the extensive verification process laid out in the Act. However, there are several challenges to ensuring and prosecuting those who are in violation. The Internet poses a huge problem in prosecuting FDCA violators. Because drugs can be legitimately sold via online pharmacies, there has been a rise in many scam websites purporting to be licensed when they are, in reality, sham websites. Illegal online pharmacies prey on prescription drug abusers and the most vulnerable members of society who must rely on a daily medicine regimen.²⁴ These individuals make up a large portion of their consumers.²⁵ The National Association of Boards of Pharmacy (NABP) created the Verified Internet Pharmacy Practice Sites (VIPPS) accreditation program in 1999 in order to help consumers find safe sources for purchasing medicine online, and

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to avoid purchasing medicine through fake online pharmacies.²⁶

For example, federal search warrants were filed and investigations entered this past summer for the illegal importation of low-cost foreign drugs²⁷ sold by a Minnesota pharmaceutical wholesaler called U.S.



Drugs, who is suspected of operating as a shipping hub for an online pharmacy based in Winnipeg with connections to entities in Barbados.²⁸ The NABP reports that there are more than 9,000 “rogue sites” on the Internet, which are out of compliance with U.S. pharmacy laws and standards. Undercover buys have been taking place in order for these illegitimate sales to be uncovered.²⁹ This issue is multi-faceted, and in order for it to be adequately addressed, there is a necessity for advocacy and for information to be actively relayed to all those involved and “victimized”.

Current FDA Legislative Action

In July of this year, President Obama signed and approved the Food and Drug Administration Safety and Innovation Act (FDASIA), also known as the FDA Reform Act of 2012, under which several amendments to the

FDCA were made. These amendments aim to address various issues such as the nation’s current drug shortage and to implement policies to improve and accelerate access to treatments and drugs.³⁰ The Act also enhances penalties for counterfeiting drugs, and Section 717 directs the Attorney General to “give increased priority to effects to investigate and prosecute offenses under the law that involve counterfeit drugs.”³¹ The FDASIA adds to the Extraterritorial Jurisdiction provision of 21 USC §331 that, “over any violation of this Act relating to any article regulated under the Act is such article was intended for import into the US...”³² Such an extraterritorial federal jurisdiction provision enables United States law enforcement to hold accountable those who violate our safety law.³³ The legislature, for the first time in history, provides FDA with information about importers and enables the FDA to control imported pharmaceuticals and devices. It also allows FDA to detain or to destroy counterfeit or adulterated drugs, prohibit the entry of imported drugs that have been delayed or been denied inspection by the FDA, and will encourage parity in the inspections of domestic and foreign drug establishments.³⁴

Despite these efforts by the federal government to address the issues regarding counterfeit drugs and illegal internet sales,

one major recent criticism is that Congress hasn’t gotten around to passing certain legislation needed in order for “FDA’s plan to level the playing field by visiting foreign plants at least as often as it does U.S. facilities [to] get off the grounds [as soon] as planned.”³⁵ Surely, the ability for the FDA to inspect foreign plants plays a role in its ability to ensure that there is no criminal activity within the US pharmaceutical industry. This is also reflective of the role of globalization and its effects on the pharmaceutical industry, mentioned earlier. “With an explosion in global API [active pharmaceutical ingredient] and pharmaceutical manufacturing, the FDA has been hard-pressed to keep up with inspections.”³⁶ Lawmakers have been discussing legislation which would grant the FDA ability to better regulate and inspect foreign plants and drugs processed therein, but such provisions were ultimately left out of the legislation that did pass—thus the issue will have to wait until after the November 6 elections.³⁷ This is a pressing issue, since the agency currently lacks resources to conduct reviews and inspect facilities. Therefore, millions of dosages of drugs come in from overseas without any inspection. A majority of pharmaceutical

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ingredients are made in foreign factories, but the standards in these other countries fall below those mandated by the U.S.³⁸

Another major criticism discussed during the Congressional hearings on the FDASIA prior to its passage relates back to the globalized structure of the pharmaceutical supply chain.³⁹ So much of the pharmaceutical supply chain relies on interstate commerce, and so federal government must ensure that properly licensed entities are involved in the pharmaceutical supply chain. One speaker pointed to the fact that “the way prescription drugs are moved from the manufacturer to the consumer has changed over the past several years,”⁴⁰ and “we cannot realistically expect to have a thorough and comprehensive national supply chain track-and-trace system without providing for a clear and accurate definition of third party logistics providers.”⁴¹ Our federal laws must reflect this new reality.

The rise in and effects of globalization has been a common thread throughout this article, and I have hinted at but have not explicitly mentioned how transparency may effectively alleviate some of its negative consequences. However, it should be clear how the transparency is fundamental. Only if the consumers are aware of safety risks and scams, will they be

able to make smart and responsible choices. Further, while there is no factual evidence, it can be speculated that perhaps the enhanced criminal penalties will deter potential violators from acting illegally, finding that the risk of prosecution outweighs the benefits from engaging in counterfeit drug distribution. Improving transparency of FDA regulation was also one major goal of Congress when passing the FDASIA;

GLOBALIZATION HAS CONTRIBUTED TO THE RISE AND PERSISTENCE OF COUNTERFEIT DRUGS, AS THE PHARMACEUTICAL INDUSTRY’S COMPLEX MANUFACTURING, OPERATIONS, AND SUPPLY SOURCING IS INCREASINGLY BEING SHIFTED OVERSEAS.

it was stated during a Congressional hearing on this legislation that the bill includes significant accountability and reform measures designed to hold the FDA responsible for its performance, and the committee overseeing the FDA can ensure that the FDA is adequately performing.⁴² “A significant improvement was made to the FDA’s ability to police an ever-growing global drug supply chain to improve patient safety, and these provisions will give the FDA critical tools it needs to keep our medicine safer.”⁴³

Though it is ultimately among the FDA’s responsibilities to ensure the public health and

consumer safety, the effects of globalization such as the rise in sale of fraudulent drugs brings rise to the need for all involved to step up efforts against illegal drug sales,⁴⁴ including consumers themselves. The FDA will continue its public education campaigns, using several different approaches including the FDA web site, radio and print public service announcements, brochures, newspaper articles, and outreach by public affairs specialists,⁴⁵ in order to reach the maximum amount of consumers and increase consumer awareness of risks.

Medical Malpractice Apology Law: “Don’t Tell Me What Happened, Tell Me That You’re Sorry”

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Last month, Massachusetts passed a new law allowing for medical malpractice apology reform with a “Disclosure, Apology, and Offer” approach, hoping to change the way lawsuits evolve between the legal and medical communities.¹ The basic premise of medical malpractice apology laws is that patients are less likely to sue for extreme monetary damages, or at the very least, more willing to come to a meaningful settlement conference if their emotional damages have been addressed by those parties responsible for the suffering.² While over half of the states have already enacted various forms of apology laws, this new effort by Massachusetts is the most extensive and ambitious of its kind making patient safety a top priority.

The Massachusetts Disclosure, Apology, and Offer approach is far-reaching in its goals and the medical and legal communities are currently working through a series of pilot programs to find out which measures work most effectively.³ The goal of the law is to create a proactive system that allows doctors to be frank and open with patients instead of being told by insurance companies that the medical staff is not allowed to contact the patients. Under the law, doc-

tors are allowed to admit responsibility for patient injuries and offer apologetic statements that cannot be used as an automatic admission of guilt in a court of law. In the end, the goal is not to avoid medical payments to suffering patients, but to make the process less adversarial, rendering the court a last resort for conflict resolution.⁴ Massachusetts legislators hope to tackle complex issues surrounding patient relationships, the measures needed to encourage doctor disclosure, the tort system, and how costs may be reduced overall.⁵ With enactment of the Patient Protection and Affordable Care Act and its goals of cost containment in the national medical system, the conversation now turns to how unnecessary costs can be avoided.⁶ In turn, states are looking to reduce costs in every possible arena, including litigation. Apology laws and similar legislative efforts are a creative way to bridge patient needs with those of the medical community in a mutually beneficial arrangement while at the same time, navigating the wake of adverse medical experiences.

Apology laws work to open the lines of communication that a functional doctor-patient relationship requires. The Massachusetts law in particular creates a six month “cooling off” period between patients and medical professionals. This period allows

both sides to come to a better understanding of what should have happened during the medical treatment, what did happen, whether positive or negative results, and how to proceed after the fact.⁷ If a patient is angry about a hospital stay or the results after a surgery, these concerns need to be addressed by the responsible medical professional and in a timely fashion. During this cooling off period, the parties are required to come to the negotiation table to exchange information about the episode and doctors are allowed the opportunity to safely offer empathetic apologies without the threat of admissibility in court.⁸ Legislators are hopeful this can aid the state in moving toward a more efficient process of handling medical malpractice cases.

There are several possible advantages to implementing apology laws such as those being reviewed and instituted by the Massachusetts legislature. Instead of being stalled in courthouse discovery and trial schedules, cases can more rapidly move toward meaningful negotiation because both parties have committed to the mutual goal of resolving the conflict, rather than continuing the lawsuit for purposes of anger or revenge.⁹ Advanced apology laws create a

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healthy mix of streamlined dispute resolution for both monetary and emotional suffering. In this type of negotiation setting, extra medical payments could be offered by the physician to mitigate damages and patient relationships could be more effectively mended after these adverse medical experiences.¹⁰ In moving toward this process, we have to get away from a place where the legal relationship with the medical community dances on the edge of mistrust because of rising medical costs and quality of care issues.

Disputes are not static, rather some scholars argue that arguments and disagreements are a social construct requiring two actors, reacting to and advancing the situation.¹¹ For two parties to constructively work through a disagreement and reach a point of negotiation, both must “perceive, interpret, and understand the context of the negotiation, the other parties, and themselves.”¹² Patients who feel wronged by their doctors are less likely to retain feelings of anger and mistrust if a meaningful agreement is reached, ideally one where a patient’s emotional anger and financial injury have both been redressed. Research has shown that participants who made a favorable evaluation of an apology, that is, believed the apology and its information were adequate, were more likely to agree to settle a case than they

were to reject an offer.¹³ In order to get to an ideal point, apologies cannot be simplistic statements of sympathy or dry explanations of the facts.¹⁴ It takes more than a simple conversation to repair the relationship between a doctor and a patient who feels something has gone wrong. We have to craft medical malpractice apology law to encourage the *right* kind of apologies. Massachusetts takes one step closer to this ideal in its creation use of the Disclosure, Apology, and Offer law.

When patients feel that something has gone wrong, or that a doctor has not treated them the way they wanted, quick and effective action is needed. While it is unfair to say that every bad result in medicine equates to a particular doctor at fault, most patients still aspire for open communication and assistance in problem resolution.¹⁵ Honesty hits at an important part of the medical malpractice process if patients feel that facts were distorted or that the doctors were not being forthcoming. Doctors have so long feared the unpredictability of the medical malpractice industry and the consequences of their patient interactions in a court of law that the culture of practicing protectionist medicine has developed without the opportunity for us to stop, reflect, and correct it.¹⁶ An apology works to chip away at the raw anger the patient feels about what has happened. Furthermore, mere expressions of sympathy do

not achieve the same results as a full acceptance of responsibility and an expression of willingness to work together to rectify the situation.¹⁷ In offering up full and complete apologies rather than statements of sympathy which only get halfway to understanding, doctors bring themselves down to the laymen’s level where they can reach the level of humans who share the same goals. In the end, we can hope to avert “unwarranted malpractice claims filed in anger instead of true wrongdoing.”¹⁸ In the end, the medical malpractice apology laws are efforts to give angry patients by giving them a sense of closure, as well as reduce the amount of extra punitive damages.

A harsh example of apologies gone wrong, outrage was recently re-sparked in the case of Thalidomide manufacturer Grünenthal when they issued an apology on August 31, 2012 expressing remorse for the negligent sale of the dangerous drug in the 1950s.¹⁹ The drug, used by pregnant women to relieve morning sickness, caused thousands of babies to be born with shortened or missing limbs. The drug was pulled from the market in 1961, but no formal apology had ever issued from the company.²⁰ The recently offered apology came so long after the initial injuries, many decades after thousands of families were ignored in their suffering, that Grünenthal’s CEO Harald Stock had to preface his

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statement with an apology for not apologizing.²¹ As a result, the goodwill effect that an apologizer hopes the apology will have is misplaced because the victims instead become focused on the neglect they previously faced.²² While it would have been inappropriate for the company to never offer a statement of remorse for the mistakes it made, one must question the severe delay of this particular Thalidomide apology. Effective apologies provide remediation to the victims, opening up a line of communication that assures the public that nothing as horrific will happen in the future.²³ If Grünenthal had apologized earlier, perhaps its victims would have been quicker to forgive and move on with closure in their lives. Instead, the tragedy leaves one with even worse tainted memories.



As an analogy for the city dweller, the effect of proper apologies and the laws that allow for them explain why commuters were so pleased last November when the NYC subway finally changed their “This train is late” message.²⁴ Previously, when someone was delayed to work or school, the tinny, mechanical voice overhead acknowledged that the train was moving slow, but also added in a reminder to, “Please be patient.”

Now we commute in a world where the NYC subway not only recognizes the inconvenience caused but also adds in a remorseful “We apologize for the delay.”²⁵ People want to be told that the wrongdoers are sorry and that they are doing everything possible to fix it. The sting of conflict comes most painfully when an apology feels insufficient, insincere, or is offered far too late to do any reparations. People do not want the MTA telling them to be patient. Similarly, we do not want our doctors to tell us that something went wrong; there will be an innate sense that something went wrong when a medical bill has extended far beyond the expected cost, or an anticipated recovery time period is botched by further complication. Instead, we want doctors to stop, accept responsibility for whatever part they may have played in the error, and then express remorse and empathy for what is happening. Perhaps this is what our nation’s doctors want as well - to be able to relate to patients as real people without the constant threat of lawsuit always lurking behind them.

In the end, the new law in Massachusetts and other efforts across the country take great steps toward opening up the conversation between aggrieved patients and doctors nervous about the legal consequences of honesty. The cloud of litigation looms over all parties, but if the legal community

is able to work with both doctor and patient, perhaps everyone will be able to be more honest with themselves about what needs to be achieved. Patients have a need to feel like people after they have adverse medical experiences and they want their doctors to treat them like peers, perhaps paying necessary bills incurred out of the controversy. Doctors have a need for the leeway to make healthcare decisions without fear that a lawsuit will necessarily result and if something adverse occurs, doctors need to be able to apologize on a basic human level without it being an automatic admission of fault. Eventually, everybody’s needs come down to emotional human interaction. This is what separates the bad apologies from the good apologies, and this is where we need medical malpractice laws to head.

Gaps in Affordability: A Vision of Medical Bankruptcy through Health Care Reform

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Introduction

On March 23, 2010, President Barack Obama signed into law the Patient Protection and Affordable Care Act (hereinafter “PPACA”).¹ Congress intended the PPACA to reduce the cost of health care to the consumer and to make health insurance affordable to all Americans.² Prior to the PPACA, fifty million individuals under age sixty five were uninsured.³ Most of these uninsured were part of a family with at least one full-time worker.⁴ Often the reason for being uninsured laid not with availability, but with affordability.

This Article purports to conduct a simple analysis of the actual affordability of health care under the Patient Protection and Affordable Health Care Act. There is an unfortunate gap between the income level where many of the new cost reducing measures end and higher income levels where households do not feel the cost as sharply. Those in this gap who experience significant medical costs beyond their premiums risk medical bankruptcy due to extensive and expensive out-of-pocket costs.

What makes health care affordable

Any determination of what constitutes affordable health care will, at least to some extent, be arbitrary because individual households must determine what level of coverage they believe best suits their needs. For example, the PPACA health plans in insurance exchanges fall under several categories, each of which carries its own premium price based on actuarial statistics.⁵ Additionally, households have a variety of health needs with varying costs. Combining these two realities results in a spectrum of actual household expenditure on health.

There are, however, potential objective metrics of affordable care. The cost sharing subsidies and premium tax credits available to those between 300% and 400% of the federal poverty level set the maximum percentage of household income that a health policy will cost at 9.5%.⁶ Ostensibly, this means that the federal government believes that a policy costing more than 9.5% of one's income becomes unaffordable. However, ten percent may be a better number to use as a baseline. It is slightly higher than the 9.5% and much evidence supports ten percent of household income as the line above which health care becomes unaffordable.⁷ The same research indicates that to fully understand and determine the af-

fordability of health insurance and health care one must take a holistic approach and take into account all other necessary expenses.

One of the main approaches to defining affordability⁸ considers other (non-health related) necessary budgetary requirements on families.⁹ Necessary budgetary requirements include childcare, food, housing, taxes and transportation.¹⁰ Karen Davenport proposes two approaches to affordability.¹¹ The first considers household budgets, measuring the dollar amount each household spends on necessities and then treating health care expenditures as an extra expense.¹² This approach considers any remaining money after the purchase of necessities in the household budget to be available for the purchase of health care.¹³ Her second approach considers the share of income Americans can actually spend on health care, measuring premiums and out-of-pocket expenses as a share of income.¹⁴ Ms. Davenport postulates that health insurance is unaffordable if over ten percent of income must be spent.¹⁵ Her approach is very similar to the method employed here: a determination of affordability using both objective and subjective metrics.

The type of healthcare plan analyzed in order to deter-

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mine the affordability of the PPACA will be one obtained on an insurance exchange created through the Act.¹⁶ The analysis will be narrowed by concentrating on households in extremely expensive medical situations. These families tend to be most at risk and are the people the law should work hardest to protect. In the most severe cases, the end result of serious medical costs can be bankruptcy.¹⁷ Since 2000, an estimated five million families have filed for bankruptcy in the aftermath of serious medical problems.¹⁸ The families filing for bankruptcy do not necessarily belong to lower income brackets but indeed fall under an array of income levels.¹⁹ This problem should be one that the PPACA helps to alleviate (if not eliminate) by allowing families, at any income level, the ability to deal with serious medical problems affordably.²⁰

Does the Affordable Health Care Act actually make health care affordable?

The first step in the analysis will be to find, generally, at what income level health care costs for the most expensive consumers become unaffordable. In order to hone in on the specific case where this may occur, it is helpful to illustrate several scenarios generally and go in depth regarding the scenario of interest. Health insurance premiums are calculated in 2014 dollars and assuming an average insurance price

market.²¹ Premium calculations are consistent with estimates of premiums under the PPACA prepared by the Congressional Budget Office.²² However, it is important to note that all values are estimates and subject to change.

Affordable care begins with an analysis at the bottom level of household income, those making less than 133% of the poverty level. So long as the individual's income does not exceed 133% of the federal poverty level that individual may be covered through Medicaid.²³ The details of Medicaid exceed the scope of this article. However, coverage through Medicaid may be acquired for very low, if not effectively zero cost.²⁴ The efficacy of Medicaid lies beyond the focus of this article, and therefore it may be assumed that households whose income falls below 133% of the federal poverty level may obtain affordable health coverage.

The next scenario involves a single forty-year-old adult making 134% of the federal poverty level. Such an individual would have \$15,417 dollars in annual income.²⁵ This person's unsubsidized health insurance premium costs \$4,500 dollars.²⁶ However, the maximum percent of income the person must pay if eligible for a subsidy is 3.06%.²⁷ Therefore, the insured would only actually pay \$472 dollars in premium, receiving a \$4,028 dollar tax cred-

it.²⁸ Additionally, the maximum out of pocket (hereinafter "OOP") costs will be \$2,083 dollars (which is equivalent to two-thirds of maximum OOP cost for any health insurance consumer).²⁹ In the worst-case scenario, assuming the most catastrophic medical costs, this person will have to pay \$2,555 dollars in the year for medical expenses. Although the premium only costs this individual 3.06% of his annual income, should this person require a lot of health care, and incur the maximum cost, his or her health care costs balloon to 16.6% of annual income.³⁰ Such cost at high levels of medical expense demonstrates the risk of medical bankruptcy, especially if these costs are maintained for several years.³¹

For a family of four making 134% of the federal poverty level, household income increases to \$31,389 dollars.³² In this situation the pattern previously demonstrated continues. The premium price, through the PPACA's subsidy provisions, may be completely reasonable at 3.06% of annual income.³³ However, should the family experience serious medical issues and be forced to pay the maximum amount of costs under the PPACA rubric this family's health care costs balloon to 16.3% of annual income.³⁴

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A single 40-year-old adult when making 250% of the federal poverty level has an annual income of \$28,763 dollars.³⁵ Confronted with the most expensive possible medical year, the total medical costs of this individual equal \$5,440 dollars under PPACA.³⁶ In such a situation, 18.9% of the individual’s income must be spent on health care. This increase can be largely contributed to the lesser OOP cost protection.³⁷

Like in the previous scenarios illustrating costs at 134% of the federal poverty level, the family of four’s relative health cost, when making 250% of the federal poverty level, comes to similar values as the single adult at 250% of the federal poverty level. Assuming the worst medical financial situation, this family’s health expenses cap at \$10,964.³⁸ Should the family incur these maximum costs, health care will constitute 18.7% of their annual income.³⁹

A single 40-year-old adult making 403% over the federal poverty level makes \$46,466 dollars of income.⁴⁰ In the worst-case scenario, the individual will be responsible for \$10,750 dollars.⁴¹ Therefore, should this person require the most expensive health care needs it will cost 23.1% of annual income.⁴²

A family of four making

403% of the federal poverty level makes \$94,402 dollars of income.⁴³ Should this family incur the most expensive medical circumstances, this family will pay \$24,630 dollars.⁴⁴ Should the family be required to pay this maximum amount due to expensive medical care, twenty six percent of their annual income will go towards medical expenses.⁴⁵

Medical costs will, of course, be most expensive at incomes just over the end of PPACA subsidization.⁴⁶ As income increases, the percentage of income spent on health care decreases. At some point health costs revert back to subsidized levels. For a family of four making 515% over the federal poverty level, their income reaches \$120,638 dollars.⁴⁷ Their health insurance premium will be \$12,130 dollars, and they are not eligible for any subsidies and so will pay the full amount.⁴⁸ This premium price constitutes 10.05% of the family’s income. The maximum OOP costs the family will be responsible for is \$12,500.⁴⁹ Assuming the family must cover the maximum amount, they will incur \$24,630 of medical expenses, which constitutes 20.4% of their annual income.

A. The Gap in Affordability

These scenarios illustrate two of the gaps in affordable health coverage. For a single adult, the PPACA seems to cover

all incomes (assuming the insured remains healthy). The single adult making just over where the PPACA subsidies stop kicking in only has their premium costs increase by a marginal 0.21%.⁵⁰ The first gap in affordable coverage lies under middle class families with income levels between approximately \$94,400 and \$120,600 dollars. When families breach the barrier of federal subsidies, the baseline percent income spent on health coverage jumps to over 12.85%.⁵¹ However, once a family’s income increases to around 515% of the federal poverty level the premium only costs 10.05%. As discussed above, ten percent appears to be a reasonable cost for a health insurance premium.⁵² So it would seem then that, objectively, the PPACA does not cover a significant amount of households within the middle class of income level and therefore leaves this group to pay an unreasonably high premium price in relation to their income.⁵³ The law, despite trying to treat everybody equally⁵⁴, continues in practice to maintain, albeit unintentionally, a certain discrimination in terms of affordability.

Another dichotomy also presents a troubling and serious problem, illustrating the second gap in affordable health coverage. The difference between a premium costing ten or thirteen percent of a household’s income, while not achieving the PPACA goal of affordable health coverage for all,

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likely does not pose too serious a financial risk.⁵⁵ However, the evidence presented suggests that the PPACA envisions a system of affordable care for the healthy, while condoning medical bankruptcy for the seriously and chronically ill. The family making 134% of the poverty level must only pay 3.06% of their annual income on the insurance premium.⁵⁶ However, confronted with an extremely expensive medical situation, even with the most protection in place, the PPACA forces the insured to contribute 16.3% of their annual income to health expenses.⁵⁷ This portends the second gap where the healthy may obtain affordable health insurance while the chronically sick must still endure extremely high costs. For a family of four making 134% of the poverty level, this means that they must pay \$5,127 dollars from their income of \$31,389 dollars, leaving \$26,262 dollars of income for the year.

Out of this remaining \$26,262 dollars the average family then must spend in necessities about \$27,950 dollars (in food, housing, apparel, transportation, and education).⁵⁸ Although this is a rough estimate, large health costs clearly result in at least no savings without taking into account any amenities. At worst, a family with the maximum health costs allowed by the PPACA actually incurs debt every year by simply purchasing the necessities of life.

B. The PPACA continues to allow medical bankruptcy

When the PPACA ceases to provide price protections, the situation becomes much more dire for the insured on the wrong side of the line. For a family of four making 403% of the federal poverty level facing the most expensive health coverage costs allowable by the PPACA, twenty-six percent or \$24,630 dollars will be spent.⁵⁹ From an after tax income of about \$91,218 dollars, this leaves \$66,588.⁶⁰ Out of this remaining money, other necessities must be paid.⁶¹ Data exists regarding nearly all consumer expenditures. However, the expenditures that “count” in this analysis must be “necessary.”⁶² Necessary expenditures include childcare, food, housing, taxes, transportation, and certain miscellaneous expenses (calculated as 10% of other costs).⁶³ These expenses total \$42,557 dollars.⁶⁴ Combined with health care costs of \$24,630 dollars, this family of four will pay \$67,187 dollars to simply survive. The family will retain \$24,031 dollars, or 25.5%, of their annual income to be used for “non-essentials.”⁶⁵ Of the \$67,187 dollars of necessary expenses, 35.8% derive from health care and 18.6% from OOP costs.⁶⁶ All of these costs must be taken into account because they are necessities. Housing and food must be considered in any discussion of affordability. These necessities are not itemized by the family,

and so neither should they be itemized in any discussion of the goals of a law directed towards making life essentials affordable.

This one scenario illustrates clearly where the PPACA fails to deliver: to those most at risk and most vulnerable. A significant portion of families filing for bankruptcy do so because of medical reasons.⁶⁷ This is the class that the PPACA purports to protect the most. Instead, the PPACA envisions a system of health insurance that assumes good health, and leaves those with the most serious health problems out to dry. Much federal legislation has been designed to provide a social safety net.⁶⁸ The PPACA, however, is designed less as a safety net and more as simple insurance regulation to prevent price gouging.⁶⁹ However, if, as Title I of PPACA claims, the Act envisions “affordable health care for all Americans” then medical bankruptcy should cease to exist following the implementation of all PPACA provisions.⁷⁰ As demonstrated above, unfortunately families outside the structure of price modifications shall continue to suffer.⁷¹

Thus, there is the gaping hole in the PPACA. A typical family of four making an average income must pay a quarter of their income towards health care

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should one member get severely ill.⁷² When taking other necessary expenses into account, as the literature suggests must be done to truly measure affordability, the family retains merely one quarter of their annual income. To pose a purely economic argument, with such little disposable income their contribution to consumption in areas other than health care diminishes greatly and therefore harms all other sectors of the economy.⁷³ Even if this family remains perfectly healthy (and so must only pay a premium for the health insurance) their premium exceeds virtually all determinations of affordability.⁷⁴

The true problem with the gap in affordability, especially with the nature of the gap being predominately an extreme exposure to out of pocket costs, lies with medical bankruptcy as discussed above. A study conducted and published in the American Journal of Medicine analyzed the effect that the Massachusetts health care reform laws, enacted between 2006 and 2007, had on medical bankruptcy in the state.⁷⁵ The study was performed in order to shed light on how national health reform, in the form of the PPACA, would affect nationwide medical bankruptcy. The analogy is possible because the PPACA closely resembles the Massachusetts reforms and in many ways the Massachusetts reforms were a

precursor to the PPACA.⁷⁶ The study concluded that, while the number of uninsured decreased, the Massachusetts health reform laws did not decrease the amount of medical bankruptcies.⁷⁷ The study further concluded that the Massachusetts reforms left many of the insured with inadequate financial protection.⁷⁸

THE PATIENT PROTECTION AND AFFORDABLE CARE ACT SUPPOSEDLY PROVIDES AFFORDABLE HEALTH CARE TO ALL AMERICANS. FOR MUCH OF THE CITIZENRY OF THE UNITED STATES, THE SYSTEM CREATED BY THE PPACA WILL LIKELY HELP ALLEVIATE SOME OF THE BURDENS OF ACQUIRING HEALTH INSURANCE...UNFORTUNATELY, THERE ARE SIGNIFICANT HOLES IN THE RELATIVELY NEW LAW.

This risk of medical bankruptcy may affect even those individuals and families able to scrape by while incurring heavy medical costs. By investing so much income into health care, the family loses its capability of absorbing any shock to either their expenditures or their income. If suddenly one of the two working heads of the household loses their job, the ability to sustain high medical costs may, with little warning, put that family on the path to medical bankruptcy. In the same vein, a sudden sharp expenditure, such as the need to purchase a new car due to an accident, may also put a

family with no anti-shock capability over the edge. In either case the PPACA places families in a situation with no anti-shock ability and thus one bad life event away from possible medical bankruptcy.

Combining the gap in the PPACA's cost sharing provisions and the study above, the PPACA's potential failure to protect those most vulnerable to financial disaster due to medical costs jumps out. Medical bankruptcy will still be a very real possibility for those in the gap, such as the family of four making 403% of the poverty level described above. Couple these currently existing gaps in affordability with the rate of medical cost inflation and the PPACA allows, albeit unintentionally, families that endure high medical costs to experience the kind of economic pressure that the PPACA should be eliminating.

Conclusion

The Patient Protection and Affordable Care Act supposedly provides affordable health care to all Americans. For much of the citizenry of the United States, the system created by the PPACA will likely help alleviate some of the burdens of acquiring health insurance and provide those left out of the traditional employer-provided health insurance model with access to health insurance at a reasonable price and thus allow them to receive health care affordably.

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Unfortunately, there are significant holes in the relatively new law. Generally, the Patient Protection and Affordable Health Care Act places a significantly larger burden on families making between 400% and 500% of the federal poverty level (squarely middle class income levels). Far more serious, however, remains the narrow case of a family of modest income who unfortunately experience serious medical costs resulting in the maximum amount of health care expenses the PPACA allows the consumer to bare. Here, the PPACA fails to alleviate one of the largest causes of bankruptcy in the United States.

This article is not a total condemnation. Rather, the PPACA simply contains some holes that (much like the infamous Medicare doughnut hole) leave a few vulnerable people out to dry. If the goal of the PPACA and the Federal Government is to ensure all citizens equal and affordable health care coverage, then this problem must be addressed and fixed.



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2 The IDEA defines the term “child with a disability” as “a child with mental retardation, hearing impairments, visual impairments (including blindness), serious emotional disturbance, orthopedic impairments, autism, traumatic brain injury, other health impairments, or specific learning disabilities and who, by reason thereof, needs special education and related services. See 20 U.S.C. § 1400(3)(A)(i-ii).

3 The IDEA protects children with disabilities who fall within the ages of three and twenty-one. Once a child reaches the age of twenty-one, The IDEA no longer applies. See 20 U.S.C. § 1412(a)(1)(A)

4 The IDEA defines the term “transition services” as “a coordinated set of activities for a child with a disability that is designed to be within a results-oriented process, that is focused on improving the academic and functional achievement of the child with a disability to facilitate the child’s movement from school to post-school activities, including post-secondary education, vocational education, integrated employment (including supported employment), continuing and adult education, adult services, independent living, or community participation; is based on the individual child’s needs, taking into account the child’s strengths, preferences, and interests; and includes instruction, related services, community experiences, the development of employment and other post-school adult living objectives, and, when appropriate, acquisition of daily living skills and functional vocational evaluation. See 20 U.S.C. § 1400(34)(A-C).

5 Jonathan M. Ray, J.D., *Components of Legally Sound, High Quality Transition Services Planning Under IDEA*, 170 Ed. Law Rep. 1, Dec. 5, 2002, at 1.

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10 Kevin T., *et al v. Elmhurst Cmty Sch. Dist. No. 205*, No. 01C0005, 2002 WL 433061, at *10 (N.D. Ill. Mar. 20, 2002).

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12 ARISE Coalition, *supra* note 1 at 2 and see <http://schools.nyc.gov/Accountability/data/GraduationDropoutReports/default.htm>.

13 *Id.* at 5.

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4 45 CFR § 46.102(d).

5 D. L. Moore, *An IRB Member’s Perspective on Access to Innovative Therapy*, 57 ALB. L. REV. 559, 579 (1994).

6 *Id.* at 562.

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10 *Id.* (If it is only directly beneficial to the fetus, than the father must consent as well—a separate issue I will not address here).

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19 *Id.*

20 *Planned Parenthood v. Casey*, 505 U.S. 833, 870 (U.S. 1992).

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Criminalizing Prenatal Substance Abuse: Hurting Women and Their Unborn Children

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Women, the Rights of the Fetus and the Rights of the State: A Critical Analysis of the Criminal Prosecution of Drug Addicted Pregnant Women, 16 *ST. JOHN'S J. LEGAL COMMENT.* 267, 280 (2002).

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6 *Id.* at 298-299.

7 *Id.* at 299-300.

8 *Id.* at 302-303; see also Mohapatra, *supra* note 2, at 265 (discussing how criminal sanctions function as a deterrence to prenatal care).

9 See generally Mohapatra, *supra* note 2 at 259-270 (describing prenatal substance abuse issues through a public health lens).

10 *Roe v. Wade*, *supra* note 4, at 726; see also Reitman, *Supra* note 3 at 276 (discussing *Roe v. Wade* establishing a fundamental right to privacy).

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13 *Griswold v. Connecticut*, 381 U.S. 479, 485, (1965).

14 Horn, *supra* note 1, at 645.

15 Ehrlich, *supra* note 12, at 405.

16 Ehrlich, *supra* note 12 at 397; see also *Reed v. Reed*, 404 U.S. 71, 76 (1971) (first applying the Equal Protection Clause to laws discrimination on the basis of gender).

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- 30 The maximum this individual would be forced to pay in medical expenses was \$2,555. This constitutes 16.6% of their annual income of \$15,417 dollars.
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- 33 Subsidy Calculator, *supra* note 26; 26 U.S.C. §36B; 42 U.S.C. §18071. The unsubsidized health insurance premium cost for a family of four making 134% of the FPL is \$12,130. However, the maximum percent of income the family has to pay for the premium if eligible for a subsidy is 3.06%. Therefore, the family will actually be required to pay only \$960 dollars as premium payment and receive a \$11,170 tax credit. Such a family's maximum OOP costs will be limited to \$4,167 dollars. Combining premium with OOP costs means that if this family experienced the most severe medical expenses, the cost caps out at \$5,127.
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- 36 Subsidy Calculator, *supra* note 26; 26 U.S.C. §36B; 42 U.S.C. §18071. This adult's premium costs \$4,500 dollars. However, the maximum percent of income the person must pay for the premium if eligible for a subsidy is 8.05%. Therefore, this individual would be eligible for a \$2,185 dollar tax credit, leaving \$2,315 dollars to be covered by the insured in premium cost. Such an individual's maximum OOP costs amount to \$3,125 dollars.
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- 39 *Id.*
- 40 Subsidy Calculator, *supra* note 26.
- 41 Subsidy Calculator, *supra* note 26; 26 U.S.C. §36B; 42 U.S.C. §18071; At this level of income, the insured loses the PPACA's financial help and all eligibility for subsidies limiting premium and OOP costs. This individual's unsubsidized health insurance premium costs \$4,500 dollars. Without any PPACA intervention, the full amount must be paid. At this cost, the premium equals 9.71% of the individual's income. The maximum OOP costs for this person may not exceed \$6,250 dollars.
- 42 *Id.*
- 43 Subsidy Calculator, *supra* note 26.
- 44 Subsidy Calculator, *supra* note 26; 26 U.S.C. §36B; 42 U.S.C. §18071; This family's unsubsidized health insurance premium costs \$12,130 dollars. This premium equals 12.85% of the family's income. Their maximum OOP costs are \$12,500 dollars.
- 45 *Id.*

WORKS CITED

- 46 42 U.S.C. §36B. This will be at 400% of the federal poverty level.
- 47 Subsidy Calculator, *supra* note 26.
- 48 Subsidy Calculator, *supra* note 26; 26 U.S.C. §36B.
- 49 42 U.S.C. §18071.
- 50 *See supra* notes 41-43.
- 51 *See supra* notes 44-46.
- 52 *See supra* note 8.
- 53 2009 census data, table A-1, available at <http://www.census.gov/hhes/www/income/income.html>. 23.4% of households lie within \$75,000 and \$149,999 dollars of income.
- 54 42 U.S.C. 300gg; 42 U.S.C. §18012. Regards the PPACA treating insured equally and removing discriminatory practices in insurance policies).
- 55 Warren, *supra* note 18. Serious financial problems due to medical issues are rarely derived from premium payments.
- 56 Subsidy calculator, *supra* note 26.
- 57 *See supra* notes 26-28. A family of four making 134% of the federal poverty level must contribute 16.3% of annual income in the situation where they must pay the premium as well the maximum OOP limit of \$4,167 dollars.
- 58 Bureau of Labor Statistics, Consumer expenditure survey, 2010, available at <http://www.bls.gov/cex/tables.htm>.
- 59 *See supra* notes 41-43.
- 60 *Id.*
- 61 *See supra* Part II (regarding determining affordable health care should be done by including all necessary expenses in conjunction with health care costs and then compare to annual income).
- 62 Davenport *supra* note 8; Gruber *supra* note 9
- 63 Gruber *supra* note 9, citing *Family Economic self-sufficiency standard*, THE CENTER FOR WOMEN'S WELFARE, available at <http://www.selfsufficiencystandard.org/standard.html#whatis>. In order to further simplify and narrow the analysis, I ignored miscellaneous expenses and will simply include expenses for food, housing, clothing, transportation and education. *See* Part II.
- 64 Consumer expenditure survey, *supra* note 59.
- 65 \$24,031 dollars calculated from a before tax income of \$91,218 dollars subjected from the expenses of \$67.187 dollars.
- 66 *See* notes 44-46.
- 67 Warren, *supra* note 18 ("about half of all families filing for bankruptcy do so in the aftermath of a serious medical problem) (citing Himmelstein, *Illness and injury as Contributors to Bankruptcy*, *Health Aff. Web Exclusive* W5-66 exhibit 1, 2005; Igor Livshits, James MacGee, and Michele Tertilt, *Consumer Bankruptcy: A fresh start*, THE AMER. ECON. REV., Vol. 97 No. 1, Mar., 2007 (67.5% of bankruptcy filers claimed the main cause of their bankruptcy to be job loss, 22.1% cited family issues such as divorce, and 19.3% blamed medical expenses). However, they reference Warren's study finding that forty-six percent of the filers report either a medical reason or substantial medical debt. Domowitz and Robert L. Sartain, *Determinants of the Consumer Bankruptcy Decision*, JOURNAL OF FINANCE, Vol. 54, No. 1, Feb. 1999 (concluding that medical debt accounts for roughly thirty percent of filings).
- 68 42 U.S.C. Ch. 7 (Medicare and Social Security).
- 69 42 U.S.C. 300gg; 42 U.S.C. §18012.
- 70 42 U.S.C. §18071.
- 71 26 U.S.C. §36B; 42 U.S.C. §18071.
- 72 *Supra* note 46.
- 73 Jordi Gali, Javier Valles, J. David Lopez-Salido, *Understanding the Effects of Government Spending on Consumption*, JOURNAL OF THE EUROPEAN ECONOMIC ASSOCIATION, Mar., 2007.
- 74 *See supra* note 8, 9.
- 75 David Himmelstein, Deborah Thorne, Steffie Woolhandler, *Medical Bankruptcy in Massachusetts: Has Health Reform Made a Difference*, AM. J. MED., 124, 224 (2011) .
- 76 *Id.*
- 77 *Id.* at 227-28.
- 78 *Id.* at 228.

Student Contributors



Phillip DeFede is a first-year student at Seton Hall University of Law. Phillip graduated from The College of New Jersey in 2011 with a B.A. in History and a minor in Italian. His upbringing in a family full of medical professionals has given him an intense interest in the field of medicine as well as the policies and legislation that regulate pharmaceuticals, disease control and prevention, and medical research. He plans to focus on the international health regulations and policies governing these fields due to his extensive travel experiences.



Kristine Kodytek is a second-year law student at Seton Hall University School of Law. She graduated from The University of Tampa in 2010 with a degree in Advertising and Public Relations and a fondness for public service. She plans to pursue a legal career centered around public interest and policy as they pertain to children and adults with special needs.



Joel Silver is a fourth-year evening student at Seton Hall University School of Law. He is also a Patent Agent registered to practice before the United States Patent and Trademark Office (USPTO). He currently works at Pfizer Inc., where he drafts and prosecutes patents for the Animal Health division. Prior to working as a Patent Agent, Joel worked as a medical chemist at Chiron Corp (now Novartis) and is an inventor on several patents. Joel has a B.S. in Biochemistry and Molecular Biology from the University of California, Santa Cruz.



Sara Smith is a second-year student concentrating in Health Law and is interested in healthcare access as a social justice issue, especially in the context of reproductive rights. Sara graduated from Wake Forest University in 2009 with a B.A. in Sociology and Women's and Gender Studies. After college, she spent two years as an AmeriCorps member in Oakland, CA teaching an after-school program to fourth and fifth grade girls and working on various food justice and community service projects.

Student Contributors



Isabel Heine is a second-year student at Seton Hall University School of Law pursuing the Health Law concentration. She graduated from New York University with a major in Biology and pursued her interests in healthcare immediately thereafter at Memorial Sloan-Kettering Cancer Center where she worked in the field of clinical oncology research. Her main focus was on immunotherapy trials related to metastatic melanoma. Her legal experience consists of interning at the Community Health Law Project - a non-profit, legal-aid group that provides direct legal services to disabled New Jersey residents and other needy populations.



Clarissa Gomez is a second-year law student at Seton Hall University School of Law and is pursuing the Health Law concentration. She is an article writer for the SHU health blog, healthreformwatch.com. Over the summer she worked with Essex Newark Legal Services, the Health law unit and SSI unit; there, she dealt primarily with Medicare/Medicaid issues. Clarissa is currently working on an article for the SHU Legislative Journal regarding the interaction of immigration policy and health policy, as these are among the areas of her research interests.



Courtney Lyons is a third-year student at Seton Hall School of Law where she also serves on the executive board of the Health Law Forum. After working on both sides of medical malpractice cases in different jobs, her interest was sparked; however, she is still open to other health law career avenues after graduation. Courtney is also an avid half-marathoner and lover of underwater sea creatures.



Marco Ferreira is a third-year student at Seton Hall University School of Law pursuing the Health Law Concentration. He graduated from Rutgers University with a B.A. in Sociology. While attending Rutgers he interned at a pharmaceutical corporation which inspired him to pursue a career as an in house council for a pharmaceutical company. He currently works at the New Jersey Office of the Attorney General in the Consumer Affairs Counseling Group where he works with, among others, the Pharmacy and Nursing Boards.



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