



Seton Hall University School of Law

Seton Hall Health Law Outlook

Seton Hall Health Law Outlook

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Inside this issue:

The Losing Battle: Veterans' Backlogged Mental Health Issues Need Reinforcements Daniel Gilbert	5
Surrogacy and Silence: Why State Legislatures Should Attempt to Regulate Gestational Surrogacy Agreements Melissa Cartine	8
The Social Responsibility of Federally Funded Health Care for Undocumented Immigrants Anthony Liberatore	13
Pharmaceuticals, Crime, and the Constitution: Promoting Off-Label Drug Use and the First Amendment Phillip DeFede	19
Physician Assistants in the Era of Health Reform Nina Schuman	23
Reproductive Ramifications: The U.S. Refusal to Ratify the Convention on the Elimination of All Forms of Discrimination against Women and the Damaging Collateral Consequences on the Right to Choose Elijah Bresley	26
Playing Doctor: How the FDA's Regulation of Access to Experimental Drugs Limits Patient Autonomy Benjamin Smith	30



Health Law Outlook

Inside this issue:

Anti-Aging Cosmetics: The Thin Line Between Advertising Puffery and FDA Enforcement Suzan Sanal	37
The Future of Genetic Testing and the Legal and Ethical Implications of ENCODE Melody Hsiou	40
Are You In Or Out? A Possible Solution to the United States' Organ Donation Crisis Robert Granzen	45
Works Cited	49
Student Contributors	64

The Losing Battle: Veterans' Backlogged Mental Health Issues Need Reinforcements

Daniel Gilbert

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President Barack Obama used the recent "State of the Union" address to definitively end the war in Afghanistan. Approximately 34,000 American servicemen and women will come home by the end of this year with the remaining 32,000 soldiers home by 2014's end.¹ But at what cost? Our servicemen and women constantly place themselves in harm's way, sacrificing their lives and their limbs to ensure American victories. It goes without saying that these honorable men and women deserve our support. Yet the support they need extends beyond a hug and a handshake; a job and a paycheck; and a home. These heroes also need accessible mental health services as the incidence of mental health problems among returning soldiers continues to rise.

One report by the Congressional Research Service, specifically a statistical analysis of the Iraq and Afghanistan wars produced by members and committees of Congress, estimated there are currently 50,450 wounded soldiers as a result of these conflicts.² Yet, some believe this figure is, at best, a very conservative estimate. Former Congressman Bob Filner estimates that over one million veterans have sought help from the United States Department of Veterans Affairs ("VA").³ Secretary

of Veterans Affairs Eric Shinseki further states that the most recent data indicates "roughly 67%" of the approximately 1.4 million veterans returning from the recent conflicts rely on aid, compensation, or support from the VA.⁴ One unpublished study provided by the VA, entitled "VA Benefits Activity: Veterans Deployed To The Global War On Terror," stated that through May 2012, there were 1,634,569 veterans from post-9/11 conflicts, of which 46% have filed disability claims.⁵

Further, the unseen illnesses and mental health condi-

THE 2013 CONGRESSIONAL RESEARCH SERVICE SURVEY REPORTS THAT 103,792 DEPLOYED SERVICE MEMBERS WERE DIAGNOSED WITH PTSD AS OF DECEMBER 7, 2012.

tions like Post Traumatic Stress Disorder (PTSD), Traumatic Brain Injury (TBI), and depression have also gone unreported. One VA-commissioned study, conducted by RAND Health of The RAND Corporation and the Altarum Institute, found veterans with schizophrenia, bipolar disorder, PTSD, major depressive disorder, and substance use disorder "[comprised] a large and growing number of veterans with severe and complex general medical, mental, and substance-use disor-

ders and accounts for a disproportionately large proportion of utilization and costs for the VA".⁶ Another study suggests that 834,467 veterans have sought VA healthcare since being discharged. Of these veterans, 444,551 (53%) have been diagnosed with "mental disorders" – though the study notes that this number might encompass an individual veteran multiple times due to multiple diagnoses.⁷ Whether out of pride or inability to access resources, many veterans are reluctant to seek help. This issue must be addressed as our veterans with mental disorders cannot continue to be left without proper services.

The VA claims on its web site that up to 20 of every 100 Veterans of the Iraq and Afghanistan wars suffer from PTSD. These numbers parallel those of America's most recent wars: 10 of every 100 Gulf War Veterans and approximately 30 of every 100 Vietnam Veterans.⁸ These figures are unacceptable and further illustrate the need for better access to mental health services for our veterans. The 2013 Congressional Research Service survey reports that 103,792 deployed service members were diagnosed with PTSD as of December 7, 2012.⁹ These numbers are skewed for a few reasons. First, a service member might have developed PTSD *before* deployment. Distinguishing when a service member first demonstrated PTSD symptoms is often a difficult task. Second, the Army Office of the Surgeon General qualifies that a diagnosis of PTSD is validated when an individual has

‘The Losing Battle’

accumulated “at least two outpatient visits or one or more hospitalizations at which PTSD was diagnosed. The threshold of two or more outpatient visits is used in the Defense Medical Surveillance System to increase the likelihood that the individual has, or had, PTSD.”¹⁰ If a veteran visits a VA to get a consultation but does not have a subsequent follow up visit, a PTSD diagnosis is not considered valid by the Army Office of the Surgeon General. This lack of diagnosis may be due to a lack of adequate resources, funding and able medical professionals.

These figures tell a deeper tale – one not anticipated by civilians, the Department of Defense (“DoD”), or the VA. Perhaps the departments failed to identify the potential problems that an increase in wounded service members would cause, or perhaps they did not want to share the information with the rest of the country. Either way, progress and reform is necessary. Finally, improvement is on the horizon.

During a joint hearing before the House Armed Services Committee and the House Veterans’ Affairs Committee, Defense Secretary Leon Panetta and Secretary of Veterans Affairs Eric Shinseki discussed the major problems facing today’s veterans, and the support system entrusted to treat them. Among the problems addressed was the proliferation of PTSD. The VA and DoD

are jointly combating these problems together, primarily with the development of the Integrated Disability Evaluation System (“IDES”).

The IDES, which has been in use for the past two years, is advertised as “a seamless and transparent Disability Evaluation Sys-



tem”.¹¹ *The Wounded, Ill and Injured Compensation & Benefits Handbook*, administered by the DoD, states that the IDES is now used at more than 139 VA facilities across the country, ultimately allowing “military members to file a VA disability claim when they are referred to the Disability Evaluation System.”¹² According to Secretary Panetta, the IDES has increased the effectiveness of the joint disability system, ensuring that service members are cared for quicker and more efficiently. Specifically, the time it takes to transition from military discharge to receipt of VA disability compensation has decreased by 70%, from 243 to 63 days. Additionally, the overall time to receive disability compensation is reduced by 26%, from 540 (conducted separately by

DoD and VA) to 396 days jointly.¹³

These numbers are great, considering where the programs started. However, the the issue of access to these services is still prevalent because the number of claims entered and benefits sought is not expected to decrease. In fact, last May 2012, the VA reported 904,000 claims.¹⁴ This current year’s end is expected to yield more than 1.25 million claims. The backlogged claims, lasting longer than 125 days to be reviewed, were, for May 2012, numbering at more than 65%, or 550,000 of the 904,000 total claims. This number is indicative of a larger problem the VA and DoD cannot remedy quickly enough: Neither the VA or the DoD have the manpower or resources to adequately support our wounded heroes.

The VA and DoD need to make changes. The status quo is inadequate. We call these brave Americans into combat only to fall short on our end of the bargain. Perhaps the VA and DoD should use private health care companies, such as United HealthCare, Blue Cross Blue Shield, and Aetna. These companies have the financial resources and qualified doctors within their networks to care for the rising incidence of mental health problems. United HealthCare, for example, has 712,622 physicians and health care professionals, 80,000 dentists and 5,594 hospitals within its network.¹⁵ Aetna has over 1 million health care pro-

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fessionals, approximately 600,000 doctors and specialists, and 5,400 hospitals in network.¹⁶ Medical treatment for veterans would be readily available, and become more efficient. Veterans would not have to drive several hours away to see a medical doctor at a VA. A doctor within one of these health care companies' networks would be available to treat a veteran. The greater availability would help alleviate the number of backlogged claims.

The use of private health insurance companies is only one suggestion worth exploring by the VA and DoD. We must deal

UP TO 20 OF EVERY 100 VETERANS OF THE IRAQ AND AFGHANISTAN WARS SUFFERS FROM PTSD.

with this challenge now. Service for many veterans does not stop after an honorable discharge or a military victory. For many, the

battle continues long after they exchange their military gear for civilian clothes. The transition back into society is hard enough. We need to do what we can and take better care of our veterans. They have sacrificed life and limb. The time is now for us to do our part.

12 Steps of PTSD

Randy J. Hartman, Ph.D

Acute Anxiety	Panic/anxiety episodes
Depression	Self-esteem in a downward spiral
Resentment	Distrusting others
Anger	Fight or flight developing
Fear	PTSD is now forming
Anxiety	Mixed episodes occur
Self-Worth Dissipating	Feeling worthless
Shame	Filled with shame; who else knows?
Guilt	Feeling guilty; how responsible am I?
Confusion	Trying to remember; can I trust my memory?
Pain	Emotional, spiritual & physical pain
Activating Event(s)	Any event that causes distress

Surrogacy and Silence: Why State Legislatures Should Attempt to Regulate Gestational Surrogacy Agreements

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In 2011, television personalities and married couple, Giuliana and Bill Rancic, revealed their struggle to have a child on their television show “Giuliana and Bill.”¹ The couple had struggled for several years to get pregnant through *in vitro* fertilization (IVF), which is one method of assisted reproductive technology (ART).² In 2011, Giuliana was diagnosed with breast cancer and although treatment was successful for her cancer, she would not be able to conceive naturally for a number of years due to the cancer.³ As the couple desperately wanted to be parents, they opted for another form of ART, surrogacy.⁴ Genetically, Giuliana is the mother of the resulting child.⁵ Her eggs were combined with her husband’s sperm to form an embryo that was implanted into the surrogate.⁶ This type of surrogacy is called gestational surrogacy.⁷

The surrogacy process



was successful for Giuliana and Bill as they now have a healthy, thriving baby boy.⁸ While the couple’s story appears inspiring, the process can be riddled with legal complexity due to a lack of statutory regulation. In the United States, a majority of state legislatures have remained silent as to the legality of surrogacy contracts and as to the question of parental rights when such contracts are signed. The failure of state legislatures to regulate in this area leaves parties without guidance and can ultimately harm well-meaning parents and innocent children.¹⁰

Several state courts have developed tests to determine parental rights when surrogacy contracts have been entered into because the state legislatures are silent on the issue. New Jersey state courts have banned surrogacy contracts as a matter of public policy.¹¹ California has consistently used an intent-based test, which considers the intending parents that initiated the surrogacy process, to be the legal parents of the resulting child.¹² Alternatively, Ohio departed from an intent-based test and adopted a genetic-based test, which considers the genetic link between the parent and the child to be the dispositive factor in deciphering parental rights.¹³ A few states have attempted to regulate surrogacy contracts, either by banning them or taking a selective approach in re-

gards to what types of surrogacy contracts the state will render enforceable.¹⁴

While the lack of regulation of surrogacy contracts does not pose a problem in unremarkable cases, such legislative silence can have devastating results for some families. If the surrogacy process goes awry, the parties that entered in to a surrogacy agreement could spend years litigating over whom the child’s legal parents are. As evidenced by the various tests state courts have adopted, there is not much uniformity from state to state regarding surrogacy. The unpredictability of what a particular state court might decide makes surrogacy a precarious method of ART for those in states where no statutory guidance or case law is provided.¹⁵ To address this problem, state legislatures should regulate gestational surrogacy contracts as this method has seen expansive growth over the last decade and the utilization of this method is only predicted to increase with time.

Assisted Reproductive Technology: Surrogacy

Generally, those seeking to start a family unit have three options: natural conception, adoption, and surrogacy. Since natural conception may not be an option for many seeking to start a family, they must revert to the latter two options. If an individual or family opts for gestational surrogacy and utilizes its own gametes, it has a

Continued...

genetic link with the child, making it the closet option to natural conception. Thus, it is easy to fathom why so many families place their faith in the surrogacy process despite its potential legal pitfalls due to lack of statutory regulation.

The term surrogacy usually refers to one of two methods: gestational and traditional. The Rancic couple opted for the former method, which usually creates a genetic link between the child and at least one intending parent contracting to have a surrogate carry their child. As described previously, a woman's egg is removed and combined with her partner's sperm before being implanted into a third person, the surrogate.¹⁶ If only one or no intending parent can supply gametes, then third party donors could be used to supply the needed gametes.¹⁷ This would also be considered gestational surrogacy.¹⁸ In both such arrangements, the surrogate has no genetic link to the child since her gametes were not used.¹⁹ Those that choose to can instead utilize the surrogate's eggs.²⁰ This is called traditional surrogacy and creates a genetic link between the child and the surrogate.²¹

According to the Society of Assisted Reproductive Technology (SART), gestational surrogacy is the method more frequently used today.²² However, the Council for Responsible Genetics claims that accurate statistics are not available to deduce

how many more people have utilized this method rather than traditional surrogacy.²³ Instead, the Council for Responsible Genetics found that studies that looked at IVF success rates demonstrate that the rate of gestational surrogacy has increased dramatically and will continue to do so over time.²⁴ The data from IVF success rates itself can be used to determine that gestational surrogacy arrangements have increased because in the gestational surrogacy process, the embryo of the intending parents is then implanted via IVF into the surrogate's uterus.²⁵ The CDC requires ART clinics, which perform IVF, to report the success rates of IVF cycles and to report when the patient is a gestational surrogate.²⁶



The Council for Responsible Genetics is hesitant to conclude that gestational surrogacy is more prevalent than traditional surrogacy because the metric used to determine success rates of IVF is the IVF cycle.²⁷ The measurement does not consider the individual, so there is no way to know how many women actually serve as surrogates.²⁸ As previously highlighted, the Council for Responsible Genetics did conclude

that the rate utilization of gestational surrogacy has increased dramatically, doubling from 2004 to 2008.²⁹ It was also comfortable in predicting that the rapid growth of gestational surrogacy was not likely to slow in the future.³⁰

Seminal Case Law

There are a few states that attempt to deal with the legal issues that arise in surrogacy via the court system and case law, and then, some states that provide legislative guidance in regards to surrogacy.³¹ Specifically, there are two seminal surrogacy cases that are cited extensively: *In re Baby M* and *Johnson v. Calvert*.

The traditional method of surrogacy was used by the Stern family in *In re Baby M*.³² In this case, the Sterns entered into a surrogacy agreement whereby Mr. Stern's sperm was implanted into the surrogate.³³ The Stern family opted to use the surrogate's eggs due to Mrs. Stern's fertility issues, although no court or legal commentary has expounded upon what those fertility issues were.³⁴ Up until the child was born, the process had been successful for the Sterns.³⁵ Then, the surrogate, Mary Beth Whitehead, decided that she wanted to keep the child and the Sterns sued for parental rights.³⁶ The New Jersey Supreme Court was left to decide who the child's parents were as the state legislature provided no statutory guidance on the mat-

'Surrogacy and Silence'

ter.³⁷ The court invalidated the surrogacy contract between the Sterns and the surrogate based on public policy implications that it felt stemmed from such agreements.³⁸ The court reasoned that surrogacy agreements exploited lower income individuals, who would be inclined to use their bodies for money.³⁹ Ultimately, the court used the best interests of the child analysis to determine placement of the child.⁴⁰ It reasoned that placing the child with the Sterns was the best outcome for the child.⁴¹ The court did find the surrogate to be the child's legal mother, and thus, Mrs. Stern could not adopt Melissa until she became an adult.⁴²

While protection from exploitation of lower income individuals was a guiding public policy concern for the New Jersey Supreme Court in *Baby M*, this is not the only theory that has been offered in response to the legal issues surrounding surrogacy. There is also the feminist approach, which advocates for the enforceability of surrogacy contracts, under the view that a woman should have autonomy of her body and its reproductive capabilities.⁴³

A California court appeared to adopt a more feminist approach, considering the freedom to contract in its analysis of a surrogacy agreement in *Johnson v. Calvert*.⁴⁴ In this case, the Calverts, seeking to start a family, used the gestational method of surrogacy. The court used an intent-based analysis.⁴⁶ It reasoned that but-for the Calverts, who had the intent to bring the

child into the world, the child would not exist and, therefore, they were the child's legal parents.⁴⁷

This case is clearly factually different than *In Re Baby M*, where the Sterns used the traditional method of surrogacy.⁴⁵ The facts in *Johnson v. Calvert* probably made it more palatable for the court to find the Calverts to be the child's legal parents as they had a genetic link. But the court was unequivocal in regards to the parties' freedom to contract when it stated, "[T]he parties voluntarily agreed to participate in in vitro fertilization and related medical procedures before the child was conceived; at the time when Anna [the surrogate] entered into the contract, therefore, she was not vulnerable to financial inducements to part with her own expected offspring."⁴⁸ This part of the court's analysis was less paternalistic than the approach the New Jersey Supreme took in *Baby M*, and thus, exemplified another policy that could shape a court's decision in a surrogacy case.

Another case that is illustrative of how a court may decide when presented with a surrogacy agreement gone awry is *Belsito v. Clark*. In this case, the Clarks sought to start a family via the gestational surrogacy method.⁴⁹ The court did not use the intent-based test of *Johnson v. Calvert* but instead looked to the genetic link of the parents to the child.⁵⁰ The Ohio court limited the legal

parents in a surrogacy agreement to those with a genetic link to the child.⁵¹ Although the court's decision made surrogacy contracts more predictable at the outset, it is important to note that it also expanded the amount of individuals that could not be deemed to be the legal parents of a child resulting from gestational surrogacy arrangements.

Current Statutory Regulation

A few states and the federal district of Washington, D.C. have banned surrogacy agreements.⁵² In Washington, D.C. all surrogacy contracts are unenforceable and the entrance into such agreements may result in prison confinement, fines, or potentially both.⁵³ New York has also banned all surrogacy agreements.⁵⁴ In the state of New York, the heaviest penalties are for those who act as intermediaries, which could be anyone who tries to facilitate a surrogacy contract.⁵⁵ Michigan also bans surrogacy agreements; its statutory scheme closely resembles New York's approach.⁵⁶ Finally, Nebraska and Indiana have also statutorily banned surrogacy contracts.⁵⁷

While statutory regulation of surrogacy is the exception rather than the norm in the United States, a few states have attempted to provide guidance to those seeking to start a family via surrogacy. Florida allows for gestational agreements but requires that the intending parents must be mar-

Continued...

ried.⁵⁸ Several other states such as Virginia, Texas, and Nevada have similar statutory frameworks to Florida regarding gestational agreements.⁵⁹ Finally, Illinois has some of the most comprehensive legislation regarding gestational surrogacy agreements.⁶⁰

Illinois enacted its Gestational Surrogacy Act (GSA) to standardize various aspects of a gestational surrogacy agreement.⁶¹ Under the GSA, intending parents will be deemed the legal parents of the child result-

REGULATION IN THE FORM OF ELIGIBILITY REQUIREMENTS MAY HAVE PREVENTED A HEART-BREAKING CASE OF A GESTATIONAL ARRANGEMENT GONE AWRY.

ing from a gestational surrogacy arrangement when certain requirements have been met.⁶² First, those seeking to start a family through this method of surrogacy must be doing so out of medical necessity.⁶³ The GSA also requires that at least one intending parent supply reproductive cells to be implanted in the surrogate.⁶⁴ There has been some criticism of Illinois's approach, which provides guidance for only intending parents who can supply gametes.⁶⁵ It is understandable that some individuals feel this is unfair, as the in-

tending parents who use only donor gametes are not protected by Illinois's GSA.

Another feature of the GSA is Illinois's attempt to protect the surrogate via certain eligibility requirements:

A gestational surrogate shall be deemed to have satisfied the requirements of this Act if she has met the following requirements at the time the gestational surrogacy contract is executed:

- (1) she is at least 21 years of age;
- (2) she has given birth to at least one child;
- (3) she has completed a medical evaluation;
- (4) she has completed a mental health evaluation⁶⁶

A surrogate must be, at a minimum, 21 years of age. The statute also requires that the surrogate have previously bore a child and mandates mental and physical health evaluations.⁶⁷ These regulations aim to ensure that the woman choosing to become a gestational surrogate is mentally fit to be one.⁶⁸

Regulation in the form of eligibility requirements may have prevented a heart-breaking case of a gestational arrangement gone awry. Crystal Kelley, a 29-year old woman, agreed to be the gestational surrogate for a Connecticut couple.⁶⁹ Everything was going according to plan until about half way through the pregnancy.⁷⁰

In February 2012, an ultra-

sound revealed that the baby that Ms. Kelley was carrying had severe deformities including a brain cyst, heart abnormality, and cleft palate.⁷¹ The baby would require numerous surgeries and constant medical treatment.⁷² This medical treatment would be immensely expensive.⁷³ Furthermore, the surrogacy agreement that Ms. Kelley and the couple entered into had a specific clause, which stated that Ms. Kelley was to abort the baby in the event of a "severe fetus abnormality."⁷⁴

The Connecticut couple desperately wanted Ms. Kelley to have an abortion.⁷⁵ They even offered her an extra \$10,000 dollars to abort the baby.⁷⁶ Ms. Kelley presented a counter-offer of \$15,000 dollars but the couple would not pay it.⁷⁷ Ultimately, Ms. Kelley claimed she would not have an abortion for religious reasons.⁷⁸

While Connecticut has case law that may be instructive to parties entering into surrogacy arrangements, the legislature has not produced anything comprehensive regarding such arrangements.⁷⁹ Mandating eligibility requirements, such as a mental health evaluation of the surrogate, may have revealed Ms. Kelley's anti-abortion beliefs. Such information may have made the Connecticut couple reconsider entering into an agreement with a woman whose religious beliefs were in opposition to

‘Surrogacy and Silence’

the abortion provision in the surrogacy contract.

The legal process between Ms. Kelley and the Connecticut couple became increasingly more painful and complex for the parties as each day passed.⁸⁰ Under Connecticut case law, the intending parents privy to the surrogacy agreement are the lawful parents of the child resulting from the arrangement.⁸¹ When it became clear that Ms. Kelley would not have an abortion, the couple decided that right after the baby's birth, they would give the baby to the state.⁸² Upon learning this, Ms. Kelley decided to flee to Michigan, where the state laws deemed her to be the legal mother of the baby.⁸³ She bore a baby girl who is now known as Baby S.⁸⁴ Ms. Kelley knew that financial factors would prevent her from keeping the baby.⁸⁵ She gave Baby S up for adoption to another couple.⁸⁶ Since being born, Baby S has undergone serious surgeries on her heart and her intestines, with more major surgeries to come in the future.⁸⁷

Conclusion

As discussed previously, SART has concluded that gestational surrogacy is the more prevalent type of surrogacy.⁸⁸ The Council of Responsible Genetics has concluded that the method of gestational surrogacy has seen rapid growth and has predicted that this trend is not likely to slow down.⁸⁹ Since the trend demon-

strates rapid growth in the utilization of gestational surrogacy, pragmatism would suggest that state legislatures should begin to thoroughly regulate this method of surrogacy. From a humanistic standpoint, those seeking to start a family utilizing surrogacy likely have infertility issues or an alternative family unit and have endured emotional hardships as a result. Comprehensive statutory regulation that aims to guide and protect both the intending parents and the gestational surrogate will prevent such families from experiencing more emotional hardships such as being dragged through years of litigation to assume parental rights over a child.

While the recommendation is that only gestational surrogacy be regulated by state legislatures, a ban on traditional surrogacy would have serious implications where both partners are infertile and cannot afford gestational surrogacy but wish to start a family. When such arrangements do not work out, the court system is best apt to deal with the challenges presented by such scenarios.



The Social Responsibility of Federally Funded Health Care for Undocumented Immigrants

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Introduction

In the winter of 2000 an undocumented Guatemalan migrant laborer named Luis Jimenez was struck by a Florida drunk driver and suffered traumatic brain damage, among other serious injuries, that would forever change his life.¹ Doctors at the Martin Memorial Medical Center, where Jimenez was taken after the accident, treated him until June 2000, when he was transferred to a nursing home.² In January 2001, Jimenez was readmitted to the hospital for emergency treatment.³ Because he was unable to pay for his medical care, which totaled more than \$1.5 million, a court granted an order allowing the Martin Memorial Medical Center to forcibly return Jimenez to his native Guatemala.⁴ The order was issued over the objections of Jimenez and his court appointed guardian.⁵

Today, Luis Jimenez, who is now 37, cannot walk and has the mental age of a young child.⁶ He is cared for by his elderly mother in Guatemala. In the summer of 2008 *New York Times* reporter Deborah Sontag visited Jimenez and found him largely confined to his bed suffering from routine seizures.⁷ He had not received medical care for over five years.⁸

Hospitals in the United States that receive federal Medicare funding are required to provide

emergency treatment regardless of ability to pay and immigration status.⁹ This is how Luis Jimenez was able to receive emergency medical care at the Martin Memorial Medical Center in Florida after his accident. However, once a patient is stabilized, the federal government ceases to pay for ongoing medical care in both hospitals and rehabilitation and nursing facilities.¹⁰ There is dispute over whether the requirement in the Emergency Medical Treatment and Labor Act ("EMTALA"), which requires hospitals to stabilize patients before releasing or transferring them, continues to apply after the patient has been admitted to the hospital.¹¹ What is clear, however, is that many private and even public hospitals have begun to forcibly and coercively deport undocumented immigrant patients to their native countries when they are unable to pay for provided medical care.¹² Luis Jimenez is just one example of countless individuals who have been adversely affected by this practice.¹³ Other patients are deemed stabilized and released from the hospital without the prospect of continuing medical care.

The emergency medical care mandated by EMTALA is the only federally funded public health care available to undocumented immigrants in the United States.¹⁴ Because federal funds

may not be used to provide non-emergency health care to undocumented immigrants, those who are in this country illegally are ineligible to receive federally funded public health insurance programs, including Medicaid, Medicare, and the Child Health Insurance Program (CHIP).¹⁵ Had Luis Jimenez had access to some form of sustained public health care after his accident, it is possible that he would not be largely confined to his bed suffering from routine seizures today. Luis Jimenez's case clearly demonstrates that EMTALA's provisions alone are insufficient to adequately care for the medical needs of the vulnerable undocumented immigrant population.¹⁶ As a nation that purports to respect the life and dignity of all people, we must do more to provide access to medical care for everyone within our borders, even those here unlawfully.

Providing Health Care to Undocumented Immigrants is Our Social Responsibility

We have a social responsibility to provide for the medical needs of all those within our borders. This includes undocumented, or illegal, immigrants. Regardless of where a person came from, how they arrived in the United States, how long they have been here, or what legal

‘The Social Responsibility’

status they hold, every person within the borders of the United States *should* have access to medical care. For vulnerable populations such as undocumented immigrants such access cannot exist without the ability to receive federally funded public health insurance benefits, for example, from Medicaid, Medicare, or CHIP.

It has long been undisputed that undocumented immigrants are highly susceptible to receiving uncompensated medical care.¹⁷ Poor living and harsh working conditions, as well as the lack of sufficient income to pay for health insurance or medical care, are paramount reasons why undocumented immigrants often rely on EMTALA as their only option to seek medical care in hospital emergency rooms.¹⁸ A lack of preventative and early intervention care has developed among this population as a result.¹⁹ Moreover, seriously ill and injured undocumented immigrants often must make the difficult choice of staying in the United States where they are unable to receive necessary medical treatment, or leaving their family behind and return to their native country in order to receive medical care. This, of course, is conditioned on them having not already been forcibly medically repatriated by the treating hospital here in the United States.²⁰ Access to health care and federally funded health insurance programs for the immigrant population at large, and in particular the undocumented immigrant population, is an im-

portant issue for everyone in the United States. Such access will limit the amount of uncompensated medical care provided, will increase the overall health of our population, and will foster our nation’s commitment to equality and fairness for every person within our borders.

The long-term health and societal benefits that stem from increased access to health care, including preventative and early intervention care, expound our social responsibility to provide

EVEN IF ILLEGAL IMMIGRANTS DO NOT HAVE ANY COGNIZABLE LEGAL RIGHT TO GOVERNMENT-PROVIDED HEALTH BENEFITS, THEY SHOULD NEVERTHELESS BE PROVIDED WITH THOSE BENEFITS. IT SIMPLY IS THE RIGHT THING TO DO.

federally funded health care to undocumented immigrants. First, the entire population benefits from providing the health care to an at-risk and vulnerable population. Undocumented immigrants “live, work, and attend school in communities throughout the country; laws and bureaucratic barriers that reduce their use of key preventative health services, such as immunizations and screenings for infectious disease, make for bad public health policy...” reports

Susan Okie, a volunteer physician at a primary care clinic in Maryland that cares for uninsured immigrants from Latin America and West Africa.²¹ In addition to increasing access to quality care and decreasing costs of quality care for everyone in the system, extending coverage to undocumented immigrants “would also have carry-over benefits in the realm of public health, as it would begin to act as a preventative regime rather than allowing the progression of illness to more advanced points.”²² For a population that has lower frequencies of doctor’s visits and lower utilization of health care services, access to health care and health care coverage can help prevent disease, including epidemic and contagious conditions, thereby safeguarding the overall public health.²³ Finally, lack of health care among this vulnerable population could potentially lead to drug-resistant or more virulent strains of disease that would pose a risk to everyone, not just undocumented immigrants.²⁴

Second, the wholesale denial of health care and federal health insurance access to a class of people is both discriminatory and dehumanizing. Access to health care is a human right that cannot be ignored. The 1948 Universal Declaration of Human Rights (UDHR) guarantees a right to life and to health.²⁵ Article 25 of the UDHR states that “[e]veryone has the right to a

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standard of living adequate for the health and well-being of himself and of his family, including...medical care and necessary social services.”²⁶ The United States, as a signatory to the UDHR, is legally bound by its provisions and must endeavor to protect the human rights, including guarantee of life and health, to all peoples within its borders. The ethical debate about providing health care to undocumented immigrants has been transformed into a political debate. However, we must not deprive a whole population of people access to health care merely because they entered the United States illegally.²⁷ It is simply untenable to deny any individual access to health care because they broke a law, particularly when we have an affirmative duty under the UDHR to guarantee all persons’ right to health.

Third, undocumented immigrants contribute to our society in very meaningful ways. In fact, it can be argued that the services they provide are invaluable. Illegal immigrants are our neighbors and co-workers, members of our church congregations, and, for many of us, good friends. They are hard workers, good parents, and productive members of our communities. They are no different than those who happened to be born here. However, many undocumented immigrants are willing to per-

form unglamorous jobs, such as washing dishes in a restaurant or working as a farm hand, which many Americans do not want.²⁸ While many argue that illegal immigration negatively impacts our economy, in fact “[i]llegal immigration...tend[s] to provide the U.S. economy with workers who are in scarce supply.”²⁹ According to Giovanni Peri, an economist at the University of California, Davis, undocumented workers do not compete with skilled laborers, but rather they comple-



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ment them.³⁰ Peri found that “[i]n states with more undocumented immigrants...skilled workers made more money and worked more hours; the economy’s productivity grew. From 1990 to 2007, undocumented workers increased legal workers’ pay in complementary jobs by up to 10 percent.”³¹ Providing undocumented immigrants with health care and coverage under federally

funded health care programs will not only benefit the undocumented immigrants, but will provide long-term societal and health benefits.

While the benefits to providing undocumented immigrants with access to health care coverage under federally funded health care programs are overwhelming, there are some arguments that challenge this view. For example, it has been argued that permitting undocumented immigrants to gain access to health care and, more particularly, federally funded health care programs, will impose additional burdens on an already overwhelmed U.S. health care system, including hospitals. It has also been argued that a burden would be placed on taxpayers and the federal budget to fund any expansion of benefits to undocumented immigrants. While these arguments have been advanced, securing the life and dignity of all peoples within our country mandates that we provide undocumented immigrants with access to health care, as well as coverage under federally funded health care programs. Securing the health and safety of every person within our borders is worth the minor additional burden that *could* be placed on our health care systems or our taxpayers (some of whom are undocumented workers).

'The Social Responsibility'

The Patient Protection and Affordable Care Act and the DREAM Act Fail to Provide Solutions

The Patient Protection and Affordable Care Act ("PPACA" or "ACA"),³² fails to provide undocumented immigrants access to federal funding for health care. The Act's individual mandate provision does not cover undocumented immigrants.³³ Moreover, government subsidies and other benefits associated with the reform are similarly unavailable.³⁴ The individual mandate requirement of the PPACA defines "applicable mandate" to exclude "an individual for any month if for the month the individual is not a citizen or national of the United States or an alien lawfully present in the United States."³⁵

In June 2012 President Obama announced that undocumented immigrants who came to the United States as children, attended school here or served in the U.S. Armed Forces, and met certain other requirements would be permitted to remain in the country without fear of deportation.³⁶ Instituted by executive action, the Deferred Action for Childhood Arrival (DACA) program, or the mini-Dream Act, permits young undocumented immigrants to obtain work authorization.³⁷ The DACA program does not, however, make young immigrants eligible for health insurance coverage under the PPACA.³⁸ Moreover, the Obama administration has de-

clared that young immigrants granted relief "shall not be eligible" for Medicaid or the Children's Health Insurance Program.³⁹

Despite widespread agreement among the American people that the United States must reform the largely expensive and dysfunctional health care and immigration systems, there is passionate disagreement about what reform measures are necessary. At the intersection of this collision are the more than 11 million undocumented immigrants currently



living in the United States. If access to health care and federally funded health programs for all undocumented immigrants is too much to ask for, those granted relief under the DACA program, commonly referred to as Dreamers, are exactly the type of subgroup that should be targeted. Young people who came to the United States at a very young age, often brought by their parents, are here to stay. They are socially and culturally engrained into our society and they are an important part of our future.

Despite the comprehensive exclusion of undocumented

immigrants from provisions of the recently upheld health care reform legislation and the DACA program, undocumented immigrants, particularly young immigrants, should be entitled to federally funded health care. Even if illegal immigrants do not have any cognizable legal right to government-provided health benefits, they should nevertheless be provided with those benefits. It simply is the right thing to do. An overwhelming body of evidence shows a direct correlation between lack of insurance, lack of health care, and poor health among Americans.⁴⁰ For example, "[t]he long-term uninsured face a 25 percent greater likelihood of premature death than do insured Americans, and uninsured Americans with breast or colorectal cancer are 30 to 50 percent more likely to die prematurely. An estimated 22,000 Americans die every year because they are uninsured."⁴¹ This evidence of the importance of health insurance is likely more troubling when considered in the context of undocumented immigrants, who generally have no access to health insurance.

San Francisco's *Healthy San Francisco* Program is a Workable Model

In July 2006 the San Francisco Board of Supervisors adopted the Health Care Security

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Ordinance, which created the Healthy San Francisco (“HSF”) program.⁴² While not health insurance, Healthy San Francisco provides access to affordable health care services for uninsured residents of the city regardless of immigration status.⁴³ HSF provides “access to basic and ongoing medical services, including primary and specialty care, inpatient care, diagnostic services, mental health services, and prescription drugs” at twenty-nine participating clinics and five local hospitals.⁴⁴

Enrollees in the HFS program pay quarterly participant fees based on income, while employers must spend a minimum amount per hour on health care for their employees.⁴⁵ Medium and large employers with over 50 workers are required to participate.⁴⁶ Small employers (i.e., businesses with less than 50 workers) and non-profit organizations are exempt.⁴⁷ Employers must contribute between \$1.17 and \$1.76 per hour per covered worker, who include all workers employed for at least 90 days and who work a minimum of ten hours per week.⁴⁸ Those employers subject to the HFS program “can satisfy these requirements in a number of ways, including by directly paying for health care services or purchasing health insurance on behalf of their employees, by funding health savings accounts, or by

contributing to the city option.”⁴⁹

Although highly controversial, the HFS program’s employer funding requirement was upheld by the Ninth Circuit Court of Appeals against challenges that it violated the Employee Re-



tirement and Income Security Act of 1974 (ERISA), which prohibits its state or local governments from regulating employee benefit plans, including health insurance plans.⁵⁰ The court found that employers could be legally forced to either provide health benefits to its workers or pay into the city fund for providing health benefits to the uninsured.⁵¹ The U.S. Supreme Court refused to grant certiorari, effectively ending legal challenges against the program.⁵²

William H. Dow, a senior economist for President George W. Bush’s Council of Economic Advisors and a professor of health economics at the University of California, Berkeley, reported in 2009 that “[t]oday, almost all residents in the city have affordable access to comprehensive health care delivery systems...”⁵³ Moreover, he revealed that “[a]s of December 2008, there was no indication that San Francisco’s

employment grew more slowly after the enactment of the employer-spending requirement than did employment in surrounding areas in San Mateo or Alameda counties. If anything, employment trends were slightly better in San Francisco.”⁵⁴ What is most telling about the HFS program’s potential is that it has “demonstrated that requiring a shared-responsibility model—in which employers pay to help achieve universal coverage—has not led to the substantial job losses many feared. The public option has also passed the market test, while not crowding out private options.”⁵⁵

The tens of thousands of uninsured San Franciscans that have enrolled in the HFS program certainly pales in comparison to the roughly 11 million undocumented immigrants living in the United States. This is to say that the Healthy San Francisco program is not a perfect solution for providing all undocumented immigrants with access to health care and health care coverage. The HFS program is not even a perfect solution for providing Dreamers with health care coverage. But, the HFS program represents a workable model. At the end of fiscal year 2011-2012, concluding its fifth year in operation, the HFS program had 46,822 participants and had provided access to care to over 116,000 uninsured adult residents.⁵⁶ The program’s office

'The Social Responsibility'

visit rate per year, at three visits, was the same as the national Medicaid average, while avoidable emergency department utilization was lower than California's Medical average.⁵⁷ HSF's readmission rate, moreover, was below the national average of 18%.⁵⁸ This is a model for access to affordable health care for uninsured undocumented immigrants that if implemented carefully could work at a national level. The Dreamers are the perfect group on whom to test the model's applicability and success. This is a model that should apply now to Dreamers, and if successful, eventually to all undocumented immigrants.

Conclusion

Providing undocumented immigrants with health care beyond the emergency care already provided under EMTALA is crucial. We have a social responsibility to provide for the medical needs of all those within our borders, including undocumented immigrants. Access to health care and federally funded health insurance programs for the immigrant population at large, and in particular the undocumented immigrant population, is important to the overall population of the United States, as such access will help limit the amount of uncompensated medical care provided, will increase the overall health of our population, and will foster our nation's commitment to equality and fairness for every person within

our borders. Enrolling Dreamers in a program modeled after Healthy San Francisco is a sensible and workable beginning, but we must strive to ensure that eventually all undocumented immigrants within the United States have unhindered access to quality health care. This can only occur if undocumented immigrants are granted access to the federally funded health care programs.



Pharmaceuticals, Crime, and the Constitution: Promoting Off-Label Drug Use and the First Amendment

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The Decision

When pharmaceutical companies and their representatives promote off-label uses for the drugs they produce, criminal charges for violating the Federal Food, Drug, and Cosmetic Act ("FDCA") will almost inevitably follow. In most, if not all, of these cases, conversations with physicians and others regarding off-label indications constituted promotion of an off-label use. It was therefore surprising when the Second Circuit vacated the conviction of a pharmaceutical sales representative who verbally conveyed to a physician off-label uses of the FDA-approved drug Xyrem in *United States v. Caronia* ("Caronia").¹ The defendant was originally found guilty of conspiring to introduce a misbranded drug into interstate commerce in violation of 21 U.S.C. §331(a).² His conviction was founded on the oral promotion of Xyrem to a physician in order to cause him to prescribe the drug for off-label indications.³ Following sentencing, the defendant argued on appeal that the conviction violated his First Amendment right to free speech.⁴

On appeal, the government argued that it did not prosecute defendant for his speech

per se, but rather used it as evidence to demonstrate that the promoted off-label uses of Xyrem were intended usages of the drug, which were not provided for in its instructions.⁵ The Circuit Court rejected the government's argument and held that the defendant was prosecuted for his promotion and marketing efforts and, thereby, his speech.⁶ The court then held that the prosecution was impermissible under applicable First Amendment doctrines, and that the government could not prosecute pharmaceutical manufacturers or their representatives for "speech promoting the lawful, off-label use of an FDA-approved drug."⁷ However, the court did not find the applicable FDCA provisions unconstitutional.

Although this case ultimately turned upon issues of constitutional law, it has clear and severe collateral impacts upon health and pharmaceutical law. To appreciate the significance of the ruling, an in-depth look into the FDCA and Food and Drug Administration ("FDA") regulations concerning off-label drug promotion is warranted.

Acts and Regulations

The government prosecuted the defendant under 21 U.S.C. §331(a) of the FDCA which prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, de-

vice, tobacco product, or cosmetic that is adulterated or misbranded."⁸ Pursuant to the FDCA, a drug is misbranded if it does not bear "adequate directions for use," meaning instructions under which a "layman" can use a drug safely and for its intended uses.⁹ At first glance, it would appear that oral off-label promotion of a drug would not violate this provision of the FDCA because it concerns misbranding; however, this issue ultimately depends upon the manifestation of the drug's intended uses.

Under FDA regulations, a drug's intended uses refer to the objective intent of those legally responsible for the labeling of drugs, such as pharmaceutical companies.¹⁰ This objective intent is determined by their expressions, such as oral statements by their representatives including off-label promotion.¹¹ Thus, off-label promotional statements may serve as evidence of a drug's intended use that has not yet been approved by the FDA.¹² This would effectively make the drug misbranded under 28 U.S.C. § 331(a) because the drug's labeling would not provide adequate instructions for the off-label intended use.¹³ Therefore, although the FDCA does not expressly prohibit off-label marketing, the government may prosecute pharmaceutical representatives who do so.¹⁴ The Sec-

‘Pharmaceuticals, Crime, and the Constitution’

ond Circuit in *Caronia* viewed this as the government construing the FDCA to “prohibit promotional speech as misbranding itself.”¹⁵

Those guilty of “misbranding” are subject to criminal prosecution and may face imprisonment for up to three years, a fine of \$10,000, or both.¹⁶ However, it is important to note that these provisions of the FDCA and the FDA regulations apply solely to those responsible for a drug’s labeling and its representatives. The FDCA does not inhibit a physician’s ability to prescribe drugs for uses, patient populations, or treatment regimens not approved by the FDA.¹⁷ In fact, it is often argued that such off-label uses may be the most appropriate form of drug therapy in certain situations



and, as the Supreme Court stated, are “an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.”¹⁸ Therefore, the FDCA and FDA do not consider off-label drug use in itself unlawful, but rather criminalize the promotion of non-indicated uses. The holding in *Caronia* effectively challenges this

long held “tradition” of prosecution for off-label promotion.

Aftermath and the Policy War

Although the decision in *Caronia* may be viewed as having a limited holding, its consequences are nothing short of extraordinary. The government has repeatedly and successfully prosecuted pharmaceutical companies and their representatives for misbranding through off-label promotion.¹⁹ Convicted companies face both civil and criminal liability for discussing or influencing physicians to prescribe their products for off-label indications, and have paid billions of dollars to date in civil and criminal penalties for doing so.²⁰ In the aftermath of *Caronia*, this trend should come to a halt, at least within the Second Circuit. As long as the companies and their representatives are truthfully promoting the off-label uses of drugs, they cannot be criminally liable for that conduct. However, widespread adoption of this interpretation is contingent upon a future Supreme Court ruling, should the issue ever reach the Supreme Court. Until then, Circuit Court judges who face similar issues as those presented in *Caronia* will have to look at it as persuasive authority and consider the underlying policy issues.

The *Caronia* decision has been on the front lines of the ongoing policy war concerning the issue of off-label promotion. The

court itself was split and the majority and dissenting opinions took into account the policy concerns on both sides of the issue. The majority justifies its position by citing the importance of free flowing medical information, efficiency, and the protection of freedom of speech. The dissent, on the other hand, values upholding precedent, safety, and ensuring the integrity of the FDA approval process above all else. Both sides have compelling policy arguments in support of their positions on this difficult question, which may eventually play a deciding role in resolving this issue once and for all.

The majority embraces the potential benefits that may result from its decision such as the free flow of medically relevant and potentially lifesaving information. The majority argues that prohibiting off-label promotion but permitting off-label use by physicians unreasonably interferes with both doctors’ and patients’ ability to receive treatment information.²¹

Furthermore, the restriction of off-label promotion may be a detriment to the public by inhibiting “informed and intelligent treatment decisions.”²² The majority strongly believes that “in the fields of medicine and public health, where information can save lives, it only furthers the public interest to ensure that decisions

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about the use of prescription drugs, including off-label usage, are intelligent and well-informed.”²³ Although the majority does acknowledge certain fora where off-label information is conveyed to the medical profession, such as scientific journals and continuing medical education programs, it still views the prosecution of off-label promotion as prohibiting free flowing information that can inform treatment decisions.²⁴

The majority views pharmaceutical companies and their representatives as being in an informed position readily capable of advising the public and health professionals about the benefits associated with the off-label uses of their products. In fact, the majority presented various alternatives to the current



FDA regime without resorting to First Amendment restrictions, such as the government counseling physicians and patients in distinguishing between misleading promotion and truthful statements.²⁵ The majority’s position reemphasizes the belief that, “[i]f the First Amendment means anything, it means that regulating

speech must be a last, not first, resort.”²⁶ It was this principle that the majority most wanted to further and that played the pivotal role in shaping its decision.

The dissent would rather uphold the status quo to ensure pharmaceutical companies comply with FDA regulations. The dissent holds fast to the precedent that the “First Amendment does not prohibit the evidentiary use of speech to establish the elements of a crime to prove motive or intent,” and views the defendant’s speech as just that.²⁷ Furthermore, the dissent argues that the majority’s approach departs from the Circuit’s precedent that promotion of a certain use demonstrates an intent that the drug be used for that purpose.²⁸ While courts are permitted to overrule their own precedent, the dissent clearly feels that doing so will result in harmful standards of industry compliance with FDA regulations and the FDCA.

A touchstone of the FDCA is the premarket approval process that all drugs must go through prior to being sold. Although the *Caronia* decision applies to drugs that have already gone through this process, it still bears severe consequences for the future of the approval scheme. The dissent argues that since drug companies can now promote FDA-approved drugs for off-label indications they no longer have any incentives to seek approval for those indications.²⁹ The prohibition of off-label promotion has

been instrumental in compelling drug developers to further participate in the approval process when expanding a drug’s industry recognized uses, which ensures as well as improves the drug’s safety and efficacy.³⁰ Essentially, by permitting off-label promotion for FDA-approved drugs, pharmaceutical companies do not need to seek approval for any subsequent uses. This would subject the public to a plethora of potentially dangerous uses that would not be subject to the FDA’s approval process.

To illustrate this point, the drug Xyrem in *Caronia* was approved by the FDA for different indications on two occasions. It was first approved in July 2002 for the treatment of narcolepsy patients experiencing cataplexy.³¹ It was then approved for an additional use in November 2005 to treat narcolepsy patients with excessive daytime sleepiness (“EDS”).³² Pursuant to the dissent’s theory, once approved in 2002, Xyrem’s manufacturer could promote its uses for narcolepsy patients with EDS without obtaining FDA approval and without fear of prosecution. Therefore, there would be no need for the manufacturer to obtain further approval leaving open the possibility for the promotion of a dangerous indication without limitations.

The dissent is also concerned that *Caronia* will undercut the legitimacy of the process for new drugs seeking FDA approv-

‘Pharmaceuticals, Crime, and the Constitution’

al. The FDCA requires a balancing of a drug’s benefits and risks when determining whether a drug should be approved.³³ Typically, the FDA Commissioner considers a drug safe when the therapeutic gain justifies the drug’s risk.³⁴ However, according to the dissent, if a manufacturer can distribute a drug “for any use so long as it is approved for one use” the balancing of risks and benefits becomes extremely difficult or impossible.³⁵ This is because a drug “viewed as safe for certain uses might be considered unsafe overall if the benefits and risks being weighed are not for a specific intended use but rather for any use at all.”³⁶ This means that a manufacturer of a new drug may front the safest intended use during the approval process and then promote any other uses afterwards without having to reapply and risk disapproval. Therefore, drugs that would fail the process because the total benefits do not outweigh the total risks would be approved and made available to the public.

The Road Ahead

It is important to remember that the holding in *Caronia* is limited to the Second Circuit and is at best persuasive authority in other jurisdictions. Furthermore, the court did not rule any provision of the FDCA or its accompanying regulations unconstitutional; it only held the manner in which the prosecution proceeded was unconstitutional. Moreover, the holding

only applies to truthful statements regarding lawful off-label use. Any promotion that is misleading or false is not protected under the First Amendment doctrines used in *Caronia*. It may therefore be tempting for compliance firms counseling clients within the Second Circuit to no longer warn against off-label promotion so long as it is truthful, non-misleading, and for lawful off-label indications. Although *Caronia* condones this type of promotion, with the FDCA and its regulations still in full force this may continue to be a risky course of action.

**THE FDCA REQUIRES A
BALANCING OF A DRUG’S
BENEFITS AND RISKS
WHEN DETERMINING
WHETHER A DRUG
SHOULD BE APPROVED.**

However, it is equally important to remember the various policy implications that result from this decision and the benefits and drawbacks that come with them. As the majority and dissent make evident, there are various reasons for permitting off-label promotion and an equal amount for prohibiting it. Unless other jurisdictions follow the precedent set out in *Caronia*, there will be a jurisdictional split on this issue until the Supreme Court has the final say in the matter. Unfortunately, the Department of Justice

will not appeal the decision to the Supreme Court presumably fearing that it might affirm the *Caronia* decision making it binding throughout the United States. Therefore, the resolution of this issue is currently in limbo and uncertain to say the least. It is likely that other jurisdictions will continue to follow their precedents and prosecute those who promote off-label indications. However, there is always a chance that *Caronia* may find its way into an appellate brief and persuade the circuit judges otherwise. All that is certain is that this will remain a heavily debated and contested issue due to the involvement of the interests of the public welfare, freedom of speech, the FDA, and an entire industry.

Physician Assistants in the Era of Health Reform

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As the United States health care system continues to evolve, especially with the passage and upholding of the Affordable Care Act, several shifts have occurred in the provision of care.¹ The Centers for Medicare and Medicaid (CMS) released a report describing the impact of the Affordable Care Act on health insurance coverage.² With Medicaid expansion and the mandates, health insurance will extend to an additional 34 million people in the United States by 2019.³ To address the rise in newly insured individuals' need for medical care, President Obama has called for an immediate expansion of primary care providers including: primary care physicians, nurses and physician assistants.⁴ Even though U.S. medical schools are expanding to account for this increased need for primary care doctors, the number of residency positions is not increasing.⁵ Therefore, these changes necessitate greater autonomy to other primary care providers, namely, physician assistants.⁶

A study recently published in the *Annals of Family Medicine* predicted the number of primary care physicians that will be needed through 2025 after the passage of the Affordable Care Act.⁷ Utilizing various sources of data—like the Medi-

cal Expenditure Panel Survey, demographic data from the US Census Bureau, and American Medical Association's Master File—to forecast use of primary care services, the study indicated that the total number of primary care office visits would increase from 462 million in 2008 to 565 million in 2025.⁸ The main factors contributing to this surge are population growth and aging.⁹ By 2025, there will be a need for roughly 52,000 additional primary care physicians in the United States.¹⁰ Insurance expansion accounts for 8,000 additional physicians while aging and population growth contributes 10,000 and 33,000 additional physicians, respectively.¹¹



Medicare has historically provided direct and indirect financial support to hospitals for residency programs for doctors.¹² Since 1983, Medicare has reduced its indirect funding to hospitals for residency programs numerous times, yet the number of residents has increased by nearly

25%.¹³ As a result of these funding cuts, some hospitals have shifted resources from primary-care training to specialty programs that generate greater revenue for the hospital, such as cardiothoracic surgery.¹⁴ This has caused a 20% reduction in the number of primary care physicians.¹⁵

With the simultaneous predicted increase in demand and reduction in supply of primary care physicians other forms of primary care providers will be crucial, namely, physician assistants ("PAs").¹⁶ The Bureau of Labor Statistics projects a 30% increase in employment of PAs from 2010 to 2020, which is rapid compared to the average growth for all other occupations.¹⁷ This demand is especially high in rural areas since more doctors are choosing to specialize and practice in urban areas.¹⁸

According to the American Academy of Physician Assistants (AAPA), a PA is "a medical professional who works as part of a team with a doctor."¹⁹ PAs undergo educational training similar to that of condensed medical school training.²⁰ Applicants for PA programs are required to have completed basic science requirements during their undergraduate studies.²¹ The majority of PA programs award a Master's degree after completion of 2,000 hours of clinical rotation in addition to medical science classes.²² PAs have an extensive

‘Physician Assistants’

range of responsibilities including: executing physical examinations and procedures, treating and diagnosing illnesses, ordering and interpreting laboratory tests, assisting in surgeries, providing education for patients, counseling, and making rounds in hospitals and nursing homes.²³ While PA practice is a “team model approach” in which physicians supervise PAs, supervising physicians are not required to be present and direct each phase of PA-provided care. However, there are states with some exceptions during the early stages of a PA’s career.²⁴

Furthermore, PAs are allowed to prescribe medication with the supervision of a physician.²⁵ With controlled medications, however, the ability of PAs to prescribe varies with state law.²⁶ Federal and state laws regulate controlled medications, or “scheduled drugs,” because of their potential for dependence and abuse.²⁷ For example, Kentucky and Florida do not authorize PAs to prescribe controlled substances.²⁸

Initially, state laws limited the number of PAs that were to be supervised by a single physician.²⁹ The ratio was generally 2:1 but most of these ratios have been modified.³⁰ As PA practice progressed and became more recognized, the need for specific ratio laws lessened because medical practice has embraced these providers as team members.³¹ In 1998, the American Medical Association

determined that the proper ratio of physician-to-physician extenders should be left to the discretion of supervising physicians at the practice level and consistent with state law, if applicable.³² The American College of Physicians alongside the AAPA also adopted the belief that ratio levels should be established at the practice level.³³ In 2012, Delaware increased the number of PAs that one physician could supervise from two to four; Illinois from two to five (with ratios abolished in hospitals, hospital affiliates, and ambulatory surgical centers); Iowa from two to five; and Virginia, from two to six.³⁴

Since Massachusetts passed its comprehensive health reform to provide universal health insurance coverage, the state continues to be progressive in the health sector. Governor Deval Patrick signed a bill on August 6, 2012 intended to improve the quality of health care and reduce costs through transparency, efficiency, and innovation.³⁵ With roughly \$200 billion in expected savings over a 15-year period, this legislation marks the next phase of health care reform.³⁶ Within this law, important changes have expanded the role of PAs.³⁷ Specifically, health plans must recognize PAs as a primary care provider.³⁸ The PAs will continue to work as a team with the doctors, but they will largely be independently responsible for their patients.³⁹ Because of the demand

for physician assistants, Tufts University School of Medicine and Boston University School of Medicine have launched physician assistant programs.⁴⁰

In contrast, a recent Wall Street Journal report indicated that PAs in Kentucky are struggling to expand their responsibilities.⁴¹ Currently, the law necessitates physician supervision for the first 18 months after certification.⁴² During this time, a supervising physician must be on site—phone interaction will not suffice.⁴³ This law greatly inhibits practices in rural areas where the amount of primary care physicians relative to patients is low.⁴⁴ A physician in rural Kentucky, Dr. Naren James, explained this struggle in the WSJ Report.⁴⁵ As a doctor covering two clinics that are 25 miles apart, it becomes problematic when the patient volume reaches levels of 25,000 annually and only two of his four PAs can treat without on-site supervision.⁴⁶ The two other PAs that work with him are less than 18 months on the job, so his on-site supervision is required.⁴⁷ The only other state with this type of strict requirements is Colorado, but supervision is only mandated for the first 1,000 hours after certification.⁴⁸

The delivery of primary care has indeed changed since the medical profession has accepted physician assistants as part of the overall medical team.

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As states provide greater autonomy to PAs, more efficient allocation of resources will be utilized. This greater autonomy will surely assist doctors with the overwhelming amount of new patients that will be covered under the Affordable Care Act.



Reproductive Ramifications: The U.S. Refusal to Ratify the Convention on the Elimination of All Forms of Discrimination against Women and the Damaging Collateral Consequences on the Right to Choose

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Among the scant handful of countries that have not ratified the Convention on the Elimination of All Forms of Discrimination against Women (the Convention) are Iran, Sudan, Somalia, and strangely enough the United States of America.¹ President Carter signed the Convention in 1980 and thirty years later the U.S. still has not ratified it. Among other obligations, Article 16(1) (e) of the Convention requires countries to provide women with the right to choose whether to have children.² This is interpreted to further include reproductive rights.³ A woman's right to choose an abortion has a contentious and complicated history in the U.S., with much of the debate focused on the Supreme Court's interpretation of the Constitution. This article takes the position that the U.S.'s reliance on Constitutional interpretation explains the failure to ratify the treaty, as well as the potential of the treaty to help protect women's reproductive rights in the U.S. Because the Convention is a stronger articulation of a woman's right to choose an abortion, ratification of the Convention would help

protect women's rights in a way that would supplement the Constitution's vague standard.

Before beginning a dis-



cussion about women's reproductive rights, the argument that this article makes needs to be justified constitutionally.⁴ If the Convention were signed by the President and ratified by two thirds of the Senate the treaty would have been ratified correctly under Article II of the constitution.⁵ This is a different power than that of Section Five of the Fourteenth Amendment. Article II has been interpreted by the courts to allow boarder range of legislation to Congress than the Fourteenth Amendment.⁶ The seminal case on this issue is *Missouri v. Holland*, 252 U.S. 416 (1920) where a treaty was judged to be part of the supreme law of the land and to preempt state law despite Tenth Amendment concerns

where no other constitutional provisions prevented federal action. Similarly, *Reid v. Covert*, 354 U.S. 1, 17-18 (1957) takes the position that the treaty power is unlimited except by the Constitution. Consequently, as long as the subject matter of the treaty is not in conflict with the Constitution, the treaty is valid law. Taken together these cases show that the federal government has a large amount of leeway to legislate through its treaty powers that it does not have through the Fourteenth Amendment. It is also of note that even when Congress enacts law even in an area where state legislation would otherwise be valid, the federal law (including treaties) preempts the state legislation.⁷

Unfortunately, the discussion about the exact effects of the treaty is not the most important debate because the Convention is not self-executing. This means that just because the Convention is ratified, and becomes part of the law of the land, it will not have any enforcement mechanisms or means of implementation. It will be a backdrop and standard to live up to more than a piece of legislation that is implemented and enforced in an day-to-day context. As this article discusses below, it will have an effect as a standard even if it does not supply a cause

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of action in and of itself. The Convention would ultimately be in a similar situation to that at issue in *Medellin v. Texas*, 552 U.S. 491 (2008) where the Supreme Court said that while a treaty was an international agreement under which the U.S. had obligations, without an enforcement provision, it was not binding on states and enforceable there. In the same way the Convention would be a standard to shape and develop U.S. laws without creating new causes of action.

Abortion and a woman's right to choose is a very political issue in the U.S. Many of the defining moments in the longstanding debate have been Supreme Court decisions setting out the constitutional standard.⁸ The two camps ("pro-life" and the "pro-choice") are especially divisive between political parties and religious groups. As a result, this issue features prominently in political campaigns and debates.⁹ In an article arguing for U.S. ratification of the Convention, Ann Elizabeth Mayer, an Associate Professor of Law at the University of Pennsylvania, discusses the effects of religious groups' efforts to counter women's rights in the U.S.¹⁰ Mayer also notes that Democrats are more in favor of ratification than Republicans.¹¹ This demonstrates the split in American politics on the issues and how the political parties differ over the treaty. Democrats are more like-

ly to be in favor of the right to choose an abortion as well as ratification of the Convention, while Republicans are less likely to be in favor of either.

Article 16(1)(e) of the Convention grants women "[t]he

THE IMPLEMENTATION OF AN INTERNATIONAL STANDARD [FOR WOMEN'S REPRODUCTIVE FREEDOM] WOULD ALLOW FOR THESE RIGHTS TO BE RECOGNIZED AND CONSIDERED MORE CAREFULLY IN THE FUTURE LEGISLATION

same rights to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights."¹² The article implies, but not explicitly grants the right to choose an abortion. In 1994, the Committee on the Elimination of Discrimination against Women (CEDAW) concluded that under Article 16(1)(e) women should have the right to decide whether to have children or not.¹³ It also states that while this decision can be made with consultation of a spouse or a partner, ultimately this is the woman's decision to make.¹⁴ Abortion is plainly a method that a woman could use to determine the number and spacing of her children.¹⁵ Consequently an abortion is a "means to enable them to exercise these

rights," and the interpretation of the right by CEDAW firmly encloses that option.

Harold Hongju Koh, a Legal Advisor to the Department of State, supports ratification of the Convention. However, he takes the position that the Convention does not create a right for women to choose an abortion.¹⁶ He defends his position by arguing that the Convention is neutral on abortion (just discussing family planning matters) and by pointing to several countries that are signatories to the treaty that have banned abortion.¹⁷ Regardless of other countries' positions, Koh's interpretation cuts against the apparent meaning of the treaty and CEDAW's interpretation. Abortion is a "means" of enabling women to choose the number and timing of their children. While it is true that abortion is not specifically named as a means that should be enforced, it is reasonably within the scope of the term. The plain and ordinary meaning of the words used in the Convention fairly describe this type of "means" to choose. Consequently, Koh's argument is helpful in trying to persuade Americans to support ratification of the Convention, but its conclusion is contrary to the Convention itself.

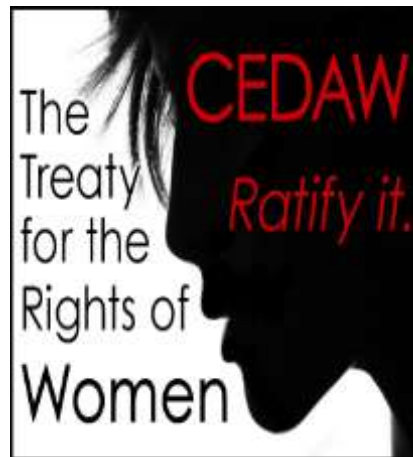
One of the reasons that the U.S. has not ratified the Convention is because there were people in Congress who believed that all of the rights enumerated in the Convention are previously

‘Reproductive Ramifications’

guaranteed by the Constitution.¹⁸ The fact that the Convention goes beyond the Constitution and guarantees more rights to women was a difficult issue for certain lawmakers during the ratification process.¹⁹ While it may be the case that there is significant overlap, the Convention provides a clearer standard and when it is added to the legal landscape, it can only support and uphold women’s rights. Constitutionally, finding and enforcing women’s rights begins by interpreting the Equal Protection Clause of the 14th Amendment (though *Roe v. Wade*, 410 U.S. 113 (1973) is an exception because it turned on an implied right to privacy).²⁰ This requires judicial interpretation every time that a new right is asserted. A list of enumerated rights would be clearer and more manageable because it would be a part of the framework of US laws and would help bolster the case for women’s reproductive rights. A problem arises however, because this decision is not made free from existing precedent. The U.S. has a long history of looking for guidance to the Constitution on many new issues that afflicts the country, such as issues of gun control, taxation, and the right to vote for women and African-Americans. Since abortion is such a complex and personal issue in the U.S. it makes sense

that the U.S. would not ratify a treaty that had the slightest possibility of adding weight to either side of this spirited and partisan debate.²¹

The reluctance of the U.S. to ratify the Convention despite the benefits that it offers to women’s rights demonstrates the importance of the Convention and its potential advantages as a



backdrop for the protection of reproductive rights for women. The set of standards would be more effective to protecting women’s rights because the rights would be enumerated, and they could better woven into the fabric of American society instead of being imposed arbitrarily from a vague standard in the Constitution. This is preferable to a system where no set of enumerated rights for women exist, and they can only be enforced after a case is made and proven in court. In the case of the right of women to choose abortions, the Convention is a preferable starting point

for these rights because it is a clearer standard, and does not rely on murky and potentially inconsistent interpretations of the Constitution.

The Convention would have a discernible and positive effect on reproductive rights in the U.S., but there are proponents of the Convention who argue that it will have only a limited effect if ratified. The best example of this mixed message is Koh. He encourages ratification and adoption of the Convention to provide protections that his ancestral family has in Korea but which are still unavailable in the U.S.²² Nevertheless, he simultaneously asserts that the Convention will not alter state or domestic laws in any significant way.²³ It seems odd to argue that the Convention is necessary because of the protections that it affords, but at the same time existing laws render it essentially irrelevant.

There are other backers of the Convention that ignore its potential effects in the U.S. A significant one is Melanne Verveer, the Ambassador-at-large for Global Women’s Issues. She advised the U.S. to ratify the Convention for American appearances abroad, but makes no mention of the treaty’s effects domestically.²⁴ Another organization in favor of ratification, GlobalSolutions.org, maintains that the Convention will not supersede domestic laws, that the

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Convention has no enforcement mechanism, and therefore is no threat to U.S. law.²⁵ The Convention's perceived futility hardly seem like grounds for encouraging ratification. Even though all support ratification of the Convention, these authors focus on the fact that the Convention will not change existing laws in order to increase its appeal.

Despite these assertions to the contrary, the Convention is important and should be ratified in the U.S. because it will have a positive effect on the facilitation of women's reproductive freedom. The U.S. does not have Constitutional mandates that explicitly ensure that women's rights are upheld or even that equality between the sexes is enforced.²⁶ The implementation of an international standard would allow for these rights to be recognized and considered more carefully in the future legislation. There must be some benefits that are worth obtaining as a result of ratification given the difficulties of compliance. In this case, there is more than just the global image boost that the U.S. would receive by joining most of the world as signatories. A clear standard of women's reproductive rights would be given a voice, and its application would improve the legalistic and partisan debate on abortion in the U.S. Because the Convention makes women's rights so much clearer than the Constitution, it is a preferable standard, especially

in regards to reproductive rights issues.

Unlike the U.S., the United Kingdom (the "UK") is an example of a country that does not face Constitutional issues regarding the legality of abortions. The UK does not have a written constitution that needs to be referred to in an attempt to ensure that new legislation conforms to an antiquated vision for the country. Parliament passed The Abortion Act of 1967,²⁷ which effectively legalized abortion before the country signed the Convention in 1981, and then ratified it in 1986.²⁸ (The UK has a reservation to Article 16, but it applies to (f), and not (e) which is at issue in this article.)²⁹ The fact that the UK was able to do this without excessive litigation illustrates the difference between the British and American approaches to the issue. It is of note that the majority of people in the UK support a woman's right to choose an abortion and think that the government should not interfere.³⁰ This shows that the UK has a majority of public support for the right to choose an abortion, in addition to having legislation in place and the Convention to help enforce that right.

Without the complex and dividing Constitutional issues that hampers change in the U.S., the UK was able to ratify a major treaty that promotes equality and helps to enforce women's reproductive rights. Like the UK, the U.S. had previously legalized abortion, but it was through litigation and not the legislature. In the U.S., both

the partisan nature of the debate and the powerful role of the courts have made ratification of the Convention almost impossible. This helps to demonstrate that the written and controversial Constitution of the U.S. is what is standing in the way of the ratification of a clearer and stronger standard for women's rights.

Abortion remains a major issue in the U.S. that has significant political and Constitutional consequences. Due to the clarity it would provide as to women's reproductive rights and the implied right to an abortion enumerated within, the U.S. should ratify the Convention on the Elimination of All Forms of Discrimination against Women. This is a pertinent example of an issue where the ratification of a human rights treaty would have a significant benefit to women's reproductive rights in the U.S.

Playing Doctor: How the FDA's Regulation of Access to Experimental Drugs Limits Patient Autonomy

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By the time more than 1,000 members of the AIDS Coalition to Unleash Power ("ACT UP") surrounded the FDA's headquarters on the morning of October 11, 1988, more than 62,000 Americans had already died of HIV/AIDS.¹ The epidemic, though only a few years old, was claiming thousands of lives a month and new diagnoses were increasing exponentially.² The members of ACT UP had gathered outside of the FDA's suburban Maryland headquarters to demand immediate agency action to stem the flood of AIDS-related illness and death.³



The conceptual thread connecting the demands made of the FDA that day was expanding access to experimental drug therapy and treatment for the seriously or terminally ill.⁴ Although the FDA had implemented a new avenue for access⁵ the year before the demonstration, those actually suffering from terminal illness had not experienced any significant relief.⁶ The demonstrators demanded that the FDA shorten the drug approval process for the seriously or terminally ill by allowing access to experimental drugs as early as the beginning of Phase 2 trials.⁷ Citing ethical concerns, ACT UP also called for the end of double-blind placebo trials, in which some subjects receive a placebo instead of a new treatment or study drug.⁸ While ACT UP's demands were not immediately met by the FDA⁹, their protests raised the profile of terminally-ill patients and the groups that advocate for them.¹⁰

The ACT UP demonstration, and the FDA's response to the HIV/AIDS crisis, illustrates a critical shortcoming in modern American healthcare. The desperation of the protestors, who were driven to forcibly occupy the headquarters of an entity created to protect them, was a result of the FDA's utter failure to adapt to the needs of terminally ill patients.¹¹ Today, a quarter of a century after the ACT UP demonstrations, individuals with serious or

terminal illnesses face similar challenges. Ironically, while ACT UP was protesting FDA inaction, today the primary obstacle to accessing experimental treatment is a recent FDA action.¹²

In the context of regulating access to experimental drugs, the FDA is tasked with assessing the safety and efficacy of proposed new drugs.¹³ The FDA has attempted to satisfy this mandate by creating a multi-phase clinical trial process, and strictly limiting access to the drug while it is being assessed.¹⁴ Patients who satisfy the rigorous statutory requirements for entry into a trial may access a drug in Phase 2 testing.¹⁵ However, those who are seriously or terminally ill typically cannot meet these requirements.¹⁶ For over 25 years, terminal patients had to wait until testing was completed, a process that averages 12 years.¹⁷ Since 1987, the FDA has made multiple attempts to expand access to experimental drugs for the seriously or terminally ill, with little success.¹⁸ The most recent incarnation of this parade of half-measures came in 2009, when the FDA promulgated a new set of regulations to replace the 1987 rules.¹⁹ The new rules attempted to expand access to those disqualified from clinical trials by allowing access when the patient's treating physician has determined that several treat-

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ment criteria have been met.²⁰ The fundamental flaw in the new regulations—specifically section 312.305—is that they require the FDA to do a “risk-benefit” analysis of the physician’s decision before releasing the drug.²¹

While the FDA’s recent attempt to expand access to experimental drug treatment for the seriously and terminally ill is laudable, it not only falls short of achieving its objective, it oversteps its statutory authority. The FDA is tasked with assessing the safety and efficacy of proposed drugs before they are released to the public, not with assessing the private, intimate discussions and decisions made between a patient and their physician.

Congressional Action and the FDA’s Response

In drafting the Food and Drug Amendment and Modernization Act of 1997 (FDAMA), Congress explicitly set out to establish a route of access for the individual patient excluded from the clinical trial process.²² Specifically, Section 360bbb states that individual patients seeking treatment outside clinical trials and “acting through a physician...may request from a manufacturer or distributor...an investigational drug or investigational device,” subject to certain conditions.²³ Functionally, §360bbb makes no mention of FDA supervision or input out-

side of determining whether the proposed new treatment has been shown to be at least minimally safe and effective.²⁴ Under the new framework, the decision to seek an experimental treatment is one for the patient and their physician alone, with the FDA merely deciding whether initial clinical trials have established some level of safety and efficacy.

THE ACT UP DEMONSTRATION, AND THE FDA’S RESPONSE TO THE HIV/AIDS CRISIS, ILLUSTRATES A CRITICAL SHORTCOMING IN MODERN AMERICAN HEALTHCARE.

In response to growing criticism over the discrepancy between the promise of expanded access under the §360bbb framework and the actual functioning of expanded access programs,²⁵ the FDA created new rules for its experimental drugs access scheme.²⁶ The final rules, promulgated in 2009, established three population categories eligible for expanded access: 1) individual patients (including emergency requests, formerly known as “compassionate” or “emergency use” requests), 2) intermediate-sized patient groups, and 3) general access (also known as a treatment protocol).²⁷ Further, the new regulations established a baseline criteria for expanded access, stating that the FDA must determine: 1) that “the patient or patients to

be treated have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;” 2) “[t]he potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated;” and 3) “[p]roviding the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.”²⁸ Under the 2009 rules, the FDA evaluates the operative criteria on a sliding scale, which in some cases could provide access to drugs based on as little as early Phase 1 safety data.²⁹

In promulgating the new rules, the FDA intended to clarify existing procedure, create new categories of expanded access, and “improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and who may benefit from such therapies.”³⁰ In an attempt to balance the agency’s mandate to foster research and development while also protecting potential consumers, the FDA sought to “appropriately authoriz[e] access to promising drugs while protect-

‘Playing Doctor’

ing patient safety and avoiding interference with the development of investigational drugs.”³¹ To further this effort at balancing the competing interests involved in the expanded access context, the FDA also promulgated new regulations to allow drug sponsors to recover the cost of expanded access to investigational drugs.³² Specifically, drug sponsors can recover the direct costs of making the investigational drug available, which are typically limited to the costs of manufacturing and shipping the drugs as well as monitoring the treatment protocol.³³ Finally, in yet another attempt to balance the interests of patients, physicians, and pharmaceutical manufacturers, the new rules required that doctors overseeing patients with access to investigational drugs outside of clinical trials report both positive and adverse outcomes to the FDA.³⁴ Beyond ensuring that each instance of expanded access does not interfere with a sponsor’s clinical testing of the proposed new drug, this measure seems to facilitate an expanded access program actually making a contribution to the FDA’s evaluation of a drug.

Taken together, Congress’ creation of a pathway to access—by passing §360bbb of the FDAMA—and the FDA’s subsequent promulgation of the 2009 rules are a significant development for terminally-ill patients. However, while these measures seem to offer an increased opportunity for patient autonomy and decision-

making, a single provision in the FDA’s new rules stands as both an unprecedented expansion of the agency’s authority as well as a significant obstacle to expanded access. Section 312.305 of the 2009 regulations, which authorizes the FDA to assess the “reasonableness” of a patient’s decision to take an experimental drug,³⁵ threatens to undermine the promise of expanded access created by §360bbb. Without corrective action, this single provision could prevent seriously or terminally ill patients from accessing the experimental treatments Congress intended to authorize in the FDAMA.

SINCE 1987, THE FDA HAS MADE MULTIPLE ATTEMPTS TO EXPAND ACCESS TO EXPERIMENTAL DRUGS FOR THE SERIOUSLY OR TERMINALLY ILL, WITH LITTLE SUCCESS.

What the FDA’s 2009 Regulations Got Right, What They Got Wrong, and What Can Be Done About It

Although the FDA purportedly promulgated its 2009 regulations in an effort to expand access to experimental drugs, they ultimately only served to reinforce the agency’s existing practice. Further, by interposing a distant, outside regulator³⁶ into a de-

cision-making process that should be both deeply personal and individualized,³⁷ the FDA’s regulations exceeded the agency’s statutory authority. In an attempt to both critique the agency’s action and offer potential solutions, it would be helpful to divide the analysis and look first to the statutory and practical problems created by the new rules, then offer potential solutions for an expanded access scheme that seeks to address the concerns of patients, the industry, and the FDA.

In promulgating the 2009 rules—specifically §312.305(a)(2), which delegates to the FDA the risk-benefit analysis determining whether a patient should receive an experimental drug³⁸—the FDA has exceeded the statutory mandate of the FDAMA.³⁹ In passing §360bbb of the FDAMA, Congress delegated a very limited power to the FDA, only intending it to play its traditional role of reviewing clinical data to inform physician prescription practices.⁴⁰ Section 360bbb does not at any point refer to individual patient risk-benefit analysis and only authorizes an inquiry into whether there is sufficient evidence of safety and efficacy.⁴¹ This clearly functions as a reinforcement of the spirit of the 1962 Amendments and in no way expands the FDA’s au-

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thority beyond that point. In §312.305(a)(2), however, the FDA has created a far more invasive role for itself by stating that the Secretary of Health and Human Services (HHS) has both the discretion and the authority—not to mention the scientific and medical expertise—to assess potential patient benefits and risks and ultimately decide what is “best” for that patient.⁴² Even assuming that an outside regulatory body could—without firsthand knowledge of a patient’s condition—actually have a better understanding of that patient’s immediate medical needs than their own doctor, Congress explicitly prohibited such agency action in the FDAMA.⁴³ Section 360bbb explicitly reserved the type of risk-benefit analysis at issue here for the physician and their patient.⁴⁴

In promulgating §312.305(a)(2), the FDA not only interposed itself into a situation it does not have the authority to encroach upon, it dramatically rewrote the fundamental role of the FDA.⁴⁵ The FDA—in one of its central operating manuals—defined its role in the clinical trial context as one of reviewing information submitted by drug sponsors, aggregating and interpreting this data, and offering this information as a foundation for prescribing physician treatment decisions.⁴⁶ Section 360bbb(b)(1) of the FDAMA seems to reinforce this conclusion by giving physicians the

authority to weigh and assess the relevant factors of an individual’s case in deciding treatment, while the FDA has the authority to ensure that there is a sufficient evidential foundation supporting the decision.⁴⁷ Simply ensuring that there is enough evidence to support a physician’s decision is a very different proposition than attempting to ensure that the physician has made the right decision.

This type of institutionalized second-guessing of clinical treatment decisions has never been a part of the FDA’s mandate, and Congress—in passing §360bbb and creating separate duties for physicians and the FDA⁴⁸—seems to have gone out of its way to reinforce this idea. Further, the Supreme Court has held that an agency, absent explicit authorization from Congress, should not assume “a responsibility that runs counter to its previously delegated powers and responsibilities.”⁴⁹ In promulgating §312.305(a)(2), the FDA has both violated the *Brown* doctrine by assuming a new role that runs counter to previous duties,⁵⁰ and overstepped the authority delegated by §360bbb of the FDAMA, which merely serves to reinforce the FDA’s previous practice of assessing safety and efficacy. As long as patients are making reasoned and informed decisions in consultation with their physician, the FDA should limit itself to assessing the adequacy and veracity of the data on safety and efficacy, and not on the substance

of the patient’s treatment decision.

Historically, the FDA has only been one of many obstacles to expanded access. Perhaps the principal limiting factor has been drug manufacturers’ unwillingness to shoulder the costs of participating in expanded access programs.⁵¹ Potentially increased liability due to adverse reactions and decreased participation in clinical trials make expanded access economically unattractive.⁵² In the past this had been compounded with FDA-mandated limitations on cost-recovery.⁵³ Although the FDA has amended the previous regulations to allow drug sponsors to recover the cost of expanded access,⁵⁴ this new cost recovery is limited to the direct costs of making the investigational drug available, which are usually limited to the costs of manufacturing and shipping the drug, as well as monitoring the treatment protocol.⁵⁵ Balancing the risks and costs of participation for pharmaceutical manufacturers is an essential aspect of a successful expanded access scheme.

The FDA’s recent decision to rule out recovery for the costs of research and development will presumably decrease industry incentive to participate in expanded access programs.⁵⁶ At the very least, allowing a drug sponsor to provide their product at or near market value would make participation in an expanded access program slightly more attractive. If the industry was al-

‘Playing Doctor’

lowed to recoup some of the cost of research and development—especially when a drug is still in the testing phase and not bringing in any revenue—not only would the incentive to participate increase, the incentive to introduce new treatments for less lucrative illnesses would also increase. Especially in the context of drugs targeted towards diseases that afflict a relatively small population-base, recovery at or near market value for expanded access would function as an incentive for developing new drugs for those illnesses. This does raise the specter of dubious sponsors proposing dubious drugs, but §360bbb’s safety provisions provide a solid framework for vetting treatments introduced under this new cost-recovery scheme. Increased cost-recovery also raises issues of payment and insurance-coverage; increased recovery for industry will mean increased cost for insurance providers. While this is a significant concern, it is one that many other industrialized nations have effectively addressed.⁵⁷ Even if a physician and patient have to negotiate or fight for insurance pre-certification and coverage for an experimental treatment, such inconveniences would be an improvement over the status quo. Without industry participation in developing experimental treatments, patients will not have the opportunity to request insurance coverage.

Similarly, in an attempt to

strike a balance between expanding access, providing incentives to industry, and maintaining its responsibility for monitoring the development of new drugs, the FDA’s new regulations require that physicians overseeing the use of investigational drugs outside of clinical trials report all outcomes, both positive and adverse.⁵⁸ This

IN PROMULGATING §312.305(A)(2), THE FDA NOT ONLY INTERPOSED ITSELF INTO A SITUATION IT DOES NOT HAVE THE AUTHORITY TO ENCROACH UPON, IT DRAMATICALLY REWROTE THE FUNDAMENTAL ROLE OF THE FDA.

is a clear example of the FDA’s 2009 regulations getting something right. The pharmaceutical industry has—since the beginning of expanded access—voiced a concern that allowing participation outside of trials will stifle the process. They argue that patients who can access a drug outside of clinical trials, thus avoiding potentially receiving a control group placebo, will do so. As access expands, trial participation will shrink. The FDA’s newest provision ensures that each instance of expanded access does not interfere with clinical testing, and actually provides drug sponsors with another source of data that could be reported to the FDA. In essence, the industry is receiving

a supplementary source of outcome data that the FDA will accept and include in its final NDA analysis. These two measures, allowing cost recovery at or near market value and mandated outcome reporting used to bolster existing clinical trial data, should alleviate some of the pharmaceutical industry’s economic concerns over an expanded access program.

With expanded access, especially access outside the controlled environment of clinical trials, an increase in tort claims arising from adverse reactions seems unavoidable. As more and more patients get access to drugs that have not fully completed “safety” and “effectiveness” testing, instances of negative outcomes will likely rise. Industry concern over increasing liability has not been addressed by the FDA in the past, and the 2009 regulations are no different. Although regulations prohibit asking a participant to waive any future tort or negligence claims,⁵⁹ there are effective tools for mitigating liability. An increased focus on the importance and practical effectiveness of informed consent would be productive here. While many patients will not want to risk the chance of adverse effects from experimental treatment, many will,⁶⁰ and it is difficult to justify respecting the preferences of one class of patients and not the other. Although there are

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concerns over decision-making capacity, studies have shown that patients in the late stages of an illness still make reasoned and informed decisions.⁶¹ Informed consent provides a framework in which these preference-based decisions can be made and respected while also providing the drug manufacturer with some level of liability protection.⁶² If the expanded access patient has made an informed and reasoned decision, based on initial clinical data from the sponsor and guidance from her physician, industry liability should be minimal. As long as the manufacturer follows the guidelines set out in the IND and NDA, responsibility for the patient's decision should rest with the patient. This raises a final concern created by the 2009 regulations.

Section 312.60 mandates an intricate informed consent protocol that, while satisfactorily addressing many of the industry concerns discussed above, makes the prescribing physician responsible for any patient decisions made under the influence of her medical judgment.⁶³ Failure to follow these strict rules may result in loss of investigator privileges⁶⁴ and, because these rules could ultimately inform standards of care, open the practitioner up to medical malpractice claims.⁶⁵ By requiring a prescribing physician to be as knowledgeable about the experimental drug and its attendant

usage protocols as its sponsor,⁶⁶ as well as potentially liable if the treatment is for any reason contraindicated for that patient, the FDA's 2009 regulations establish a significant burden of care for the physician. And while this new standard of care makes the secondary FDA analysis required by §312.305 both redundant and cumbersome,⁶⁷ it also presumably reduces physician participation rates.

A significant liability burden is placed on the prescribing physician when they must know as much about the drug as its sponsor, and the risk of increased negligence claims resulting from expanded access will most likely drive down physician participation. However, a slight rewording of §312.60 should alleviate the concerns of prescribing physicians. While the 2009 regulations shifted the informed consent burden from the sponsor to the physician, which is entirely appropriate in the expanded access context, they failed to elucidate a clear and coherent standard of care. Rather than let a court determine what the standard of care is by assessing the intent of the regulation's punitive measures,⁶⁸ the FDA should have created an explicit standard for a physician prescribing an experimental drug. In the medical malpractice context generally, most states use the "what would a reasonable physician in a similar situation have done" standard, which essentially looks to the common medical

practice appropriate for that scenario.⁶⁹ Similarly, a re-drafting of §312.60 which explicitly establishes a "common practice" protocol for the expanded access physician would alleviate concerns over increased liability. The FDA should re-draft the regulation—with input from physicians who regularly prescribe and administer experimental treatments—in such a way that any potential prescriber has no doubt as to what his or her obligations are. A clear and explicit standard of care for the prescription and administration of experimental treatments would not only protect the patients who might receive the drug, it would offer a substantial liability shield for the prescribing physician.

While the risk of adverse effects for patients and the economic burdens for manufacturers are very real and play a significant role here, arguably the greatest obstacle to expanded access created by the FDA's 2009 regulations is §312.305(a)(2). Whatever improvements the new rules engendered are negligible compared to the enormous setback §312.305(a)(2) constitutes. Its severe and unprecedented restriction on patient autonomy effectively eliminates choice in a scenario where choosing between treatments truly is a life or death proposition. Therefore, changing §312.305(a)(2) is essential to expanding access to experimental drugs.

Although the FDA has explicitly and repeatedly rejected

‘Playing Doctor’

calls for a re-wording of §312.305(a)(2),⁷⁰ this would seem to be the simplest and most direct route to rectifying the FDA’s overstep. Congress could amend the FDCA⁷¹ to directly address the issue, including language specifically separating the analysis done by physicians and the analysis done by the FDA. Congressional action of this sort would make §312.305(a)(2) immediately invalid and subject to litigation if the FDA does not alter it. Patients or

WITH EXPANDED ACCESS, ESPECIALLY ACCESS OUTSIDE THE CONTROLLED ENVIRONMENT OF CLINICAL TRIALS, AN INCREASE IN TORT CLAIMS ARISING FROM ADVERSE REACTIONS SEEMS UNAVOIDABLE.

stance would be remedial action by the FDA itself. In crafting the provisions outlining the physician’s responsibilities under the new framework, the FDA imported the exact language from the FDAMA.⁷³ It would be difficult to argue that simply importing the FDAMA’s language on the separate function of the FDA in this context would be untenable. In promulgating §312.305(a)(2), the FDA overstepped the authority granted it by Congress, and a simple re-wording of that subsection would radically alter the new regulations’ impact on the seriously and terminally ill. A revised subsection, echoing the mandate of §360bbb, would firmly place a deeply personal and life-altering decision in the hands of the individuals most qualified to make it—the patient and their physician.

patient’s rights groups could also challenge the regulation on the grounds that it exceeds the statutory delegation of authority provided by §360bbb of the FDAMA, therefore constituting an agency overreach of the type seen in *Brown*.⁷²

While litigation could force the FDA’s hand, and Congressional action could clarify misconceptions and cement the parallel but separate functions of physicians and the FDA, both of these options are expensive and time-consuming. The simplest, most efficient, and most direct form of change in this circum-

Anti-Aging Cosmetics: The Thin Line Between Advertising Puffery and FDA Enforcement

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"[B]oosts the activity of genes and stimulates the production of youth proteins"

-Génifique Youth Activating Concentrate

"Pro-Xylane™, a patented scientific innovation-- has been shown to improve the condition around the stem cells and stimulate cell regeneration to reconstruct skin to a denser quality."

-Absolue Precious Cells Advanced Regenerating and Reconstructing Cream SPF 15 Sunscreen

"[U]nique R.A.R.E. oligopeptide helps to re-bundle collagen."

-Rénergie Microlift Eye R.A.R.E.™ Intense Repositioning Eye Lifter

In September of 2012, Lancôme became the object of an uncommon and undesired form of attention for a cosmetics company. The Food and Drug Administration (FDA) issued a Warning Letter¹ against L'Oreal, Lancôme's parent company and the world's largest cosmetics maker,² citing the above claims gathered online from their expensive Génifique, Absolue, and Rénergie skincare lines (priced between \$60 to \$350 an item for amounts of up to 1.7oz).³ The agency, charged with promoting

public health through its regulation of food, drugs, and cosmetics, deemed these claims "intended to affect the structure or any function of the human body."⁴ This intent moved these cosmetics to the drug category under section 201(g)(1)(C) of the Food Drug and Cosmetics Act ("FDCA"). L'Oreal had two options: submit their cosmetics to the rigorous New Drug Approval ("NDA") process or discontinue making such claims.

Under the FDCA, cosmetics are only permitted to make

not only safety, but also efficacy.

For decades now, however, cosmetic companies have been walking a thin line with anti-aging products. Products purporting to physically turn back the hands of time without the intervention of surgery are very appealing to American consumers. In fact, in 2011 alone, the U.S. anti-aging market was assessed at \$2.9 billion.⁶ However, such claims of permanently reducing fine lines and wrinkles or tightening the skin, all consequences of aging, come across as suspiciously similar to drug structure/function claims. And with drug claims, there are concerns of effectiveness.

While cosmetic companies might not detail the biological mechanisms contained in their products that imply to promote a youthful appearance, they make efforts to create the impression that their products are backed-up by science and have been clinically tested to be effective. In fact, on their retail website, Lancôme stated that their "Absolue L'Extrait" anti-aging product, which contains "2 million Lancôme Rose native cells," had been clinically studied on 41 women.⁷ Brand names such as "Perricone MD" and "Dermadoctor" along with the growing use of the term "cosmeceutical," a term not formally recognized by the FDCA⁸, can lead consumers to believe that there is scientific evidence to



superficial claims of enhancing beauty or aesthetics. Treatment claims or claims with reference to affecting physiological structure or function of the body (i.e. structure/function claims) place products in the drug category, which mandates submitting products to an NDA that takes "on average 12 years and over \$350 million."⁵ An NDA would require a showing of

'Anti-Aging Cosmetics'

back-up anti-aging claims and permanent drug-like benefits derived from these products.

Courts, too, have struggled with anti-aging cosmetic claims. In *Sudden Change*, the Second Circuit Court of Appeals interpreted a face cream product's claims advertising to provide a "Face Lift Without Surgery."⁹ The trial court found that the product only created temporary change in appearance and the Second Circuit found a "vulnerable consumer" might reasonably believe that references to "face lift" and "surgery" would indeed "affect the structure of the body."¹⁰ It determined that the reasonable consumer may react with skepticism to such claims and find them to be "advertising puffery,"¹¹ but "the ignorant, the unthinking, and the credulous"¹² cannot be expected to understand that such unfamiliar claims might be an exaggeration. In order to best protect the consuming public, the court reasoned that cosmetic companies do not deserve immunity for "advertising puffery," thus, *Sudden Change* had to discontinue making their facelift claim.

Since *Sudden Change*, however, the FDA has opted to send regulatory Warning Letters instead of pursuing cosmetic companies in court.¹³ This has left the cosmetics industry to be basically self-regulated through competition. The FDA generally takes a hands-off approach, further, due to industry concerns about safe-

guarding trade secrets and patented and trademarked processes. The agency does not explicitly approve cosmetics as with drugs, since resources are limited, but instead operates as a reactionary to cosmetic company claims.

SINCE *SUDDEN CHANGE*, HOWEVER, FDA HAS OPTED TO SEND REGULATORY WARNING LETTERS INSTEAD OF PURSUING COSMETIC COMPANIES IN COURT.

It appears though that the FDA is beginning to rev-up their reactionary activities. In October of 2012, the FDA sent a Warning Letter to Avon because of claims made in regards to their Anew product line.¹⁴ The letter cited the claims such as "The at-home answer to wrinkle filling injections...Start rebuilding collagen in just 48 hours;" "[W]rinkles are a result of micro-injuries to the skin, so AVON studied how skin heals... ANEW's Activinol Technology helps reactivate skin's repair process to recreate fresh skin & help dramatically reverse visible wrinkles;" and "In just 3 days, see tighter, firmer, more lifted skin." As with Lancôme's products, the FDA concluded that these products "are not generally recognized among qualified experts as safe and effective for the above referenced uses."

Recipients of Warning

Letters are given 15 working days from receipt of the letters to correct the violations and failure to comply could result in enforcement action and potential seizure of the products. Legal teams are forced to scramble. In November 2012, the FDA published a "Close Out Letter" addressed to the Law Offices of Hyman, Phelps, & McNamara, P.C. and carbon copied the President of Lancôme. The letter stated that it appeared Lancôme had addressed the violations contained in the September Warning Letter, but emphasized, "This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act."¹⁵

Given the popularity of anti-aging products and their sweeping use of structure/function claims, additional Warning Letters are likely. The purpose of an FDA Warning Letter in terms of litigation remains unclear and the legal industry is beginning to take notice. Attorneys at Venable LLP point out in their analysis of the FDA's warning letter to Lancôme, "[F]ederal action has been shown to encourage consumer class action lawsuits."¹⁶ Attorneys at Shook Hardy & Bacon LLP note, "Plaintiffs will allege that consumers were defrauded into purchasing the product because of illegal marketing claims and trumpet those

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same FDA warning letters as proof that the marketing claims were deceptive under state consumer fraud statutes.”¹⁷

In fact, Warning Letters are already being used in litigation by plaintiff’s firms. Both Avon and L’Oreal and subsidiary Lancôme have been named defendants in multiple proposed class actions for defrauding consumers, of which the L’Oreal and Lancôme lawsuit is to be centralized in the District of New Jersey.¹⁸ Each of the complaints cite to the above Warning Letters issued against the companies. With the potential for growing class actions lawsuits resulting from FDA Warning Letters, as Shook Hardy & Bacon LLP write, cosmetic companies can no longer afford “to take a sit-back-and-wait approach.”

The Future of Genetic Testing and the Legal and Ethical Implications of ENCODE

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Advancements in genetics research are rapidly transforming the fields of personalized medicine and population research. These developments will introduce a wide range of difficult bioethical issues and raise many yet unaddressed legal concerns. On September 5, 2012, *Nature*, *Cell*, *Science*, *Genome Research*, and other scientific journals released a coordinated publication of thirty articles detailing the groundbreaking findings of The Encyclopedia of DNA Elements (ENCODE) consortium.¹ The ENCODE consortium represents new research that for the first time confirms that over eighty percent of our DNA, which was once thought of as “junk” with no function, actually plays a “critical role in controlling how cells, tissue, and organs behave.”² These portions of the genome, once disregarded as non-protein-coding DNA (ncDNA) are now being described as genetic “switches” that may lead to many discoveries about disease.³

Imagine a patient walking into his physician’s office, handing the physician a memory stick and saying: “Here, look at all 3.2 billion base pairs of my DNA and tell me exactly what caused my cancer, why it is progressing as it is, and how you are going to treat it.” According to Dr. George Sledge Jr., a past president of the

American Society of Clinical Oncology, this scenario could become a reality in as few as two to three years.⁴ Advancements in the field of genetic testing will change clinical practices and patient expectations, shift boundaries of medical malpractice law, expand the meaning of informed consent, and present new challenges in bioethics and privacy. In

THE ENCODE CONSORTIUM REPRESENTS NEW RESEARCH THAT FOR THE FIRST TIME CONFIRMS THAT OVER EIGHTY PERCENT OF OUR DNA, WHICH WAS ONCE THOUGHT OF AS JUNK WITH NO FUNCTION, ACTUALLY PLAYS A CRITICAL ROLE IN CONTROLLING HOW CELLS, TISSUE, AND ORGANS BEHAVE.

order to promote the advancement of personalized medicine, it will be important to increase genetics education and establish professional guidelines that recognize advancements made in whole genome sequencing while preserving patient confidentiality.

I. Encode: the New Frontier of Genetic Testing

Technological innovation has made genetic testing more accessible and an increasing num-

ber of individuals now have the opportunity to access and interpret their own genetic information.⁵ The price of sequencing an entire human genome is dropping rapidly and it may soon cost a consumer only \$1,000 for an entire genetic blueprint.⁶ This genetic blueprint can reveal predispositions to cancer, diabetes, and even psychiatric conditions.⁷ The cost of sequencing the entire genome, consisting of more than 20,000 genes and 6 billion DNA building blocks, will soon be less than that to perform individual tests for cancer or metabolic disease.⁸

Whole genome sequencing has already made promising developments in the field of targeted gene therapy.⁹ In 2009, the Memorial Sloan Kettering Cancer Center conducted a phase II trial of the kidney cancer drug Everolimus on patients with bladder cancer.¹⁰ Although the trial was unsuccessful overall, one patient (Patient X) responded remarkably well to the drug and went into complete remission.¹¹ The researchers then used array-based tools to perform a targeted search of the Patient X’s tumor DNA for mutations and variations.¹² When that did not produce significant results, they sequenced the tumor’s entire genome to detect potential biomarkers.¹³ This whole genome sequencing revealed that there were indeed two mutations

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unique to Patient X.¹⁴ Upon referencing previous studies, scientists discovered that one of these mutations had been shown to sensitize patients to the same protein that is targeted by Everolimus, likely deducing the source of Patient X's positive response.¹⁵ Scientists believe that experiments in this vein can continue to identify previously undetected subtypes of disease that can then be targeted and treated through personalized therapies.¹⁶

Whole genome sequencing is likely to be used increasingly as a discovery platform.¹⁷ Namely, the federal government spent \$288 million to support development of the Encyclopedia of DNA Elements (ENCODE), an international research collaboration that follows up on and supplements the Human Genome Project (HGP).¹⁸ The goal of the HGP, an international, collaborative research program jointly managed by the U.S. Department of Energy and the National Institutes of Health, was to map and sequence the genes of the human body.¹⁹ In 2003, the HGP was successfully completed.²⁰ ENCODE now aims to provide a deeper understanding of the "functional" elements of the genome and serve as a catalog of these segments.²¹

One of ENCODE's most ground-breaking discoveries is that certain non-protein coding regions serve much larger functions than previously thought.²²

So far, four million switches, also called transcription factors or "regulatory genes," have been discovered.²³ Study results found that regulatory genes are responsible for common diseases such as Crohn's disease and about 17 various types of cancer.²⁴ Gaining understanding of these networks of genetic switches may prove to provide new targets for drug therapy and greatly expand personalized medicine.²⁵ Namely, genome-based research will eventually allow scientists to develop highly effective diagnostic tests to better understand the health needs of people based on their unique genetic make-ups, and to design personalized treatments for diseases.²⁶

Laboratories and clinicians will benefit from collaborating to understand the relationships between sequence variations and health conditions within the context of ENCODE's findings. Clinical decisionmakers will be also need to take these findings into account in order to avoid inappropriate recommendations that may cause patient harm.²⁷ As data on current practices on genetics reporting and its impact on health outcomes continues to accumulate, it will be important to survey these practices and how they link to patient outcomes. These new discoveries will reshape the boundaries of medicine and should be taken into account when addressing legal and bioethical quandaries that will inevitably arise as whole genome se-

quencing becomes more prevalent.

II. The Changing Landscape of Liability

The possibility of linking DNA variations with health conditions will result in unprecedented ways to predict and treat diseases.²⁸ In a pilot study Mike Snyder, the head of the Center for Genomics and Personalized Medicine at Stanford University, decided to sequence his own genome in order to demonstrate the capabilities of personal genomics.²⁹ Snyder explained that he wanted to sequence his DNA to see if it would predict conditions that he might be at risk for, particularly those that were not evident from his family history.³⁰ The sequencing revealed that the seemingly healthy Snyder was at high risk for type 2 diabetes.³¹ Snyder stated that he believed that the early detection would allow him to manage the risk through diet and increased exercise, thereby mitigating an otherwise debilitating disease.³²

Although advancements in whole genome research will play a role in making medicine more preventative, personalized and effective, there are significant gaps in the U.S. system of genetic testing oversight that can lead to harms.³³ Further, customs in the genomics industry are not yet fully developed.³⁴ As genetic testing continues to grow exponentially, the number of qualified clinical

'Future of Genetic Testing'

geneticists and genetic counselors is unlikely to meet the demand, and an increasing amount of general physicians may be expected to offer, interpret and convey genetic tests results.³⁵ Thus, increased validation and acceptance of genetic testing in clinical practice could result in a challenging time for physicians.³⁶ Physicians will be at the forefront of genetics medicine and may be faced with changing forms of liability for medical malpractice, lack of informed consent, and the legal duty to warn.

III. Medical Malpractice: Standard of Care

As physicians incorporate genetic services into their practice, the framework for analyzing medical malpractice cases will change. Medical malpractice claims are based on negligence³⁷ and must include a duty owed by the physician to his patient, a breach of that duty, causation, and damages.³⁸ The physician-patient duty is unique in that it is upheld if the physician meets the required standard of care.³⁹ Generally, the standard of care is measured by the level of care demonstrated by other physicians in the same field in terms of skill, knowledge and care.⁴⁰

Genetics knowledge, skills, and abilities vary greatly across the discipline, making it difficult to make standard of care determinations. In a survey of six allied healthcare training programs, 78 percent of graduates reported that

they received marginal to no instruction on genetics knowledge and skills.⁴¹ However, even though they had minimal levels of genetics education, these professionals were still responsible for providing clinical services relevant to genetics, such as taking family genetic histories and counseling patients on the genetic basis for the disorders.⁴² As the personal genomics industry grows, it will be important for primary care providers to equip themselves with the necessary

AS PHYSICIANS INCORPORATE GENETIC SERVICES INTO THEIR PRACTICE, THE FRAMEWORK FOR ANALYZING MEDICAL MALPRACTICE CASES WILL CHANGE.

knowledge and skills to assess patients' situations. The wide range of genetics care providers, ranging from geneticists who have medical degrees to laboratory technicians, implies that some types of providers may be more qualified than others depending on the nature of the test and the complexity of the condition at issue.⁴³

Currently, the American Medical Association (AMA) predicts that only ten percent of physicians possess the requisite knowledge to use genetic testing.⁴⁴ Due to the low percentage of general physicians who offer genetic testing services, it may be

difficult to establish a standard of care that would give rise to liability for failure to administer genetic testing services.⁴⁵ However, as more genetic tests for common chronic disorders become incorporated into primary practice, even health care professionals who do not have specialized training in genetics may be held to the same standard of care as clinical geneticists. This may impose general practitioners with a heightened standard of care and resulting malpractice cases that they are not prepared to prevent.

This issue is compounded by the fact that patients may be more confident in their primary physicians' ability to convey genetic services than statistics should currently suggest.⁴⁶ The AMA reported in a survey that over 60 percent of respondents would choose their primary care doctor as their first consultant on genetic disorders.⁴⁷ In addition, about 80 percent reported feeling "very confident" or "somewhat confident" that their primary care provider could advise them or their family members about risk for developing inherited cancer, counsel them about available genetic tests, and interpret results from the test.⁴⁸ However, a separate study conducted by the National Cancer Institute concluded that only 40 percent of primary care physicians and 57 percent of tertiary care physicians felt that

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they were qualified to recommend genetic testing for cancer susceptibility to their patients.⁴⁹

Studies have shown that the level of genetics knowledge of the primary care provider greatly determines willingness to offer genetic testing and services.⁵⁰ Attitudes and acceptance of testing are also dependent on complex balancing tests of the benefits, risks, and costs of genetic testing.⁵¹ Notably, providers will be faced with the challenge of constantly maintaining knowledge of what tests are currently available, and how accurate and valid the tests are.⁵² The burden of attaining rapidly changing knowledge about genetics, including new findings that come from ENCODE, may prove to be a deterrent for providers who do not wish to incur liability for care related to genetic services.⁵³

Further, even if a physician purports not to offer genetics services, plaintiffs may still succeed in bringing a case under the current standard of care. If there is sufficient knowledge in the medical community that a certain set of gene mutations cause a particular disease to develop, and the physician does not follow up with a patient whose medical records show these gene mutations, which in turn lead to that patient's injuries, the physician could face liability under this standard.⁵⁴ The physician may argue that due to his limited background in

genetics related care, medical custom would not dictate him to follow up with his patient regarding the predicted disease.⁵⁵ However, if a reasonable person, given the prominence of the predictive test, would have conducted follow up care, medical custom may not prescribe the outcome.⁵⁶ This reasonable person objective standard has been applied by at least one court in a medical malpractice setting.⁵⁷ In *Helling v. Carey*, the court stated that although an early glaucoma detection technique using air puffs tests was not in routine use by ophthalmologists, the court could impose liability for breaching the standard of care.⁵⁸ The court stated that "irrespective of its disregard by the standards of the ophthalmology profession, it is the duty of the courts to say what is required to protect patients."⁵⁹ Under this same reasoning, the lifesaving potential of genetic testing and follow up care could lead courts to impose liability for physicians who fail to utilize available testing and care.

Physicians who do choose to offer genetic testing services will be exposed to even more forms of liability. For example, they could be held liable for an incorrect interpretation of test results and for recommending a suitable course of treatment or drug therapy. Further, physicians will have to consider the fact that simply revealing genetic information to patients could have unexpected effects on the patients' psyche.⁶⁰ To prevent these situa-

tions, it will be crucial for physicians to establish obtain informed consent with patients before engaging in genetics services.

IV. Recommendations: Increased Education and Uniform Standards

Newly emerging genetic discoveries and testing techniques such as whole genome sequencing are likely to be accompanied by an onslaught of litigation previously unseen by physicians and courts. Presently, the majority of physicians is not adequately trained and educated about advancements in genetic research and may be unaware of legal consequences. Currently, no state or federal laws exist to address whole genome sequence data comprehensively, while specific laws designed to protect genetic information in general typically address where the data is collected and by whom, but may or may not offer protection.⁶¹ In order to assist the medical community to adopt these valuable new resources, as well as to provide courts with a suggested standard of care, it will be important to incentivize increased genetics education and a set of uniform medical practice guidelines.

The development of practice guidelines and protocols for testing will help physicians by providing a reference for the changing standard of care and serve as strategies for patient management and clinical decision

‘Future of Genetic Testing’

making. In addition to helping physicians with decision making in patient care management, courts may benefit from having these practice guidelines in malpractice litigation as a reference to the current standard of care. This will help promote efficiency and uniformity and reduce wasteful litigation that may deter physicians from incorporating genetic counseling and testing into their practices. These guidelines may also be used for patient education and could possibly lower the risk of physician liability by resolving ambiguity as to the governing standard. Genetic malpractice actions may force physicians either to overuse genetic diagnostic testing to defend against genetic malpractice suits or to avoid genetic services altogether by making blanket referrals.⁶² Without such policies and guidelines physicians may fear litigation and may not be able to act responsibly, leaving courts with the burden of determining when a duty exists. With both the medical and legal communities better prepared for the obstacles that will accompany newly emerging genetic technologies, the genetic revolution can continue to make unprecedented breakthroughs in personalized care.

Are You In Or Out?

A Possible Solution to the United States' Organ Donation Crisis

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Currently, laws in the United States assume a person has not consented to organ donation absent express consent by the person or by a family member. The burden of obtaining consent is largely placed on health care professionals.¹ However, a majority of states have experimented with “opt out” provisions for certain organs from the 1960’s to the early 2000’s.² These presumed consent statutes assumed that a decedent had consented to the posthumous donation of organs, unless an objection was made by either the person while alive or by a family member after the person’s death.³ Since the 2006 Revised Uniform Anatomical Gift Act, which eliminated the presumed consent provisions found in the 1987 version, states have uniformly abandoned presumed consent statutes in favor of less controversial--and arguably less effective--means of organ procurement.⁴ However, the rest of the world has not followed. Many countries in Europe and the Middle East have included “opt out” provisions in their organ donation laws.⁵ While a delicate balance must be achieved between presumed consent’s effectiveness of organ donation and the ethical concerns raised in an “opt- out” system, today’s tired and ineffective system of organ donation is in desperate need of an overhaul, and presumed consent statutes may be

an effective remedy.

The shortage of organs in the United States is a monumental crisis for patients and physicians alike. Although 95% of the national population indicates support for organ donation, only 42% have committed to be organ and tissue donors.⁶ The gap between the supply of available organs and the patients needing a transplant widens each year. Over the last 25

ALTHOUGH 95% OF THE NATIONAL POPULATION INDICATES SUPPORT FOR ORGAN DONATION, ONLY 42% HAVE COMMITTED TO BE ORGAN AND TISSUE DONORS

years, the number of transplants more than doubled, but the waiting list grew about six-fold.⁷ Today, over 110,000 people are on a waiting list for an organ, and roughly 18 of those people will perish each day.⁸ In 2011, a total of 6,669 patients died while waiting desperately for the arrival of a matching organ.⁹

Federally Imposed Limitations To Organ Donation

In promoting different and more controversial organ donation policies, it is critical to provide the two major influences up-

on state organ donation laws. The federal government prohibits the sale of human organs under § 274 (e) of the National Organ Transplant Act (NOTA).¹⁰ NOTA provides that it is “unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.” While seemingly straightforward on its face, NOTA affects many other types of possible organ procurement legislation that are less controversial than a blatant sale of an organ. Various proposed benefits for organ donors including half price drivers licenses, estate tax credits, and partial coverage of funeral expenses could run afoul with NOTA’s ban on valuable consideration for organs.

Similarly, the Uniform Anatomical Gift Act (UAGA) was drafted by the National Conference of Commissioners on Uniform State Laws and attempted to harmonize state laws regarding organ donation.¹² While itself not legally binding, history has shown that the UAGA heavily influences state legislation. The UAGA was originally enacted in 1968 and was promptly adopted by all 50 states.¹³ The first revision was in 1987 and more than half of the states

'Are you in or out?'

adopted the revision in full.¹⁴ The latest revision, occurring in 2007, has been adopted by over 30 states.

History of Presumed Consent Legislation in the United States

Presumed consent statutes were present in nearly every state from the 1960's to the early 2000's. The statutes were initially intended as a way to address the serious shortage of corneas and organs throughout the nation.¹⁵ While most of the early statutes were limited to cornea or pituitary gland removal, the implications were drastic.¹⁶ Seven years after Georgia adopted a presumed consent statute, the number of cornea transplants skyrocketed from 25 to 1,000.¹⁷ During a nine-year period after Florida enacted a presumed consent statute, cornea transplants increased from 500 to 3000.¹⁸ Similarly, in Alabama, presumed consent statutes resulted in the state having more corneas than it needed for transplantation.¹⁹

Despite the success of the presumed consent statutes, federal courts began hearing complaints about certain states' statutes violating due process. Firstly, in *Brotherton v. Cleveland*, the Sixth Circuit found the wife of the decedent had a property right over the cornea and organs.²⁰ The wife of the decedent had informed the hos-

pital that she did not consent to an anatomical gift.²¹ Nevertheless, the coroner's office removed the decedent's corneas without inquiring about any possible objection.²² The 6th Circuit, in interpreting the Ohio presumed consent statute, found that the wife of the decedent clearly had a possessory right to the body and an anatomical gift could not be made with the presence of her objection.²³ Similarly, the Ninth Circuit found a procedural due process right in regards to the removal of organs.²⁴ In *Newman v.*

A TWENTY-TWO-COUNTRY COMPARISON INDICATED THAT PRESUMED CONSENT STATUTES MAY INCREASE ORGAN TRANSPLANTATION BY 25-30%.

Sathyavaglswaran, a coroner avoided any efforts to speak with family members about the removal of organs so he could not be halted by any objections.²⁵ The circuit court once again concluded that a procedural due process right exists when dealing with the removal of organs. However, in both of these cases, the rights awarded to the plaintiffs by the courts were already given to the plaintiffs in the presumed consent statutes. These cases were not a referendum by the courts as to the validity of "opt out" provisions,

but merely a strict statutory interpretation of the presumed consent statutes themselves. Nonetheless, the drafters of the 2006 UAGA eliminated presumed consent provisions, citing multiple lawsuits regarding property rights of surviving family members as their reasoning.²⁶ Subsequent state organ donation statutes began eliminating their presumed consent provisions.

Current State Approaches Intending To Increase Organ Donation Are Insufficient

After the numerous lawsuits nationwide challenging presumed consent provisions, states began introducing new methods to increase the numbers of donors. Initially, a few states gave public recognition and honors to organ donors. The Maine legislature passed an Organ Donor Awareness Day in 1999, making December 3rd a day in which the Governor of Maine publicly recognizes one donor, recipient, or listed person per year during the Organ Donor Awareness Day celebration.²⁷ In New York, Governor Pataki signed legislation establishing the New York State Gift of Life Medal of Honor program.²⁸ The program was created to "recognize the selfless life-saving contributions of organ

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and tissue donors.”²⁹ A medal is presented to families of deceased donors and to the living donors of organs, bone, bone marrow, and blood stem cells.³⁰

More recently, a number of state legislatures are attempting to enact statutes forcing people to contemplate organ donation. In 2008, Governor Codey passed the “New Jersey Hero Act.”³¹ The act requires New Jersey residents, when applying for a driver’s license, to make a decision regarding organ donation.³² If a person does not wish to become a donor or designate a decision maker on their behalf, they must check off a box acknowledging that they have reviewed the importance of making an organ donation decision.³³ To further the consent of donation, the act requires mandatory organ donation education for high school students. The Act also provides for a much needed online donor registry via electronic signatures.³⁴

Similarly, in 2012, the New York legislature passed “Lauren’s Law” aimed at increasing the low number of organ donors through its driver’s license applications.³⁵ The measure would change the application of a driver’s license and include a section that applicants “must fill out” by either joining the organ donor registry or choosing to “skip this ques-

tion.”³⁶ A member of the Save Lives Now New York Foundation, who pushed for the measure, explained, “We want people to just have a momentary contemplation of the decision, even if the decision is that they don’t want to help right now.”³⁷

However, the inclusions of the aforementioned provisions have only gradually affected the donor rate in the respective states. While the Hero Act raised the donor rate from 18 to 31 percent, New Jersey is still 11 points behind the national average of 42 percent.³⁸ With 95 percent of the national population supporting organ donation, but only 42 percent of that population designating themselves as organ donors, it is clear that “opt in” provisions relying on the generosity of donors are insufficient.

Presumed Consent Provisions Found in Europe and Asia Have Been Effective

In Europe and Asia, where organ shortages are comparable to the United States, many countries have adopted presumed consent provisions. A twenty-two country comparison indicated that presumed consent statutes may increase organ transplantation by 25 -30%.³⁹ Singapore first performed a kidney transplant in 1970, but shortly thereafter found its voluntary system of organ donation was

not supplying enough organs.⁴⁰ In June of 1987, Singapore passed the Human Organ Transplant Act, instilling a system of presumed consent limited to kidney donations.⁴¹ After the adoption of presumed consent provisions, kidney procurement jumped from 4.7 per year to 31.3.⁴² Spain’s presumed consent provision, which has helped Spain attain the world’s highest rate of actual donation, considers any decedent a possible donor as long as a formally registered opposition has not been filed.⁴³ Belgium passed a similar law in 1987 and, after twenty years of implementation, less than 2 percent of the Belgian population registered an objection to their status of organ donor.⁴⁴ Similarly, Austria has enacted provisions that procure organs irrespective of relative’s objections so long as a registered objection had not been filed.⁴⁵ The procurement rate quadrupled within 8 years of the provision and is currently twice as high as the procurement rate in the United States.⁴⁶ Conversely, when Denmark switched from an “opt out” provision to an “opt in” provision, donation rate fell by 50 percent.⁴⁷

Presumed Consent Statutes Are An Effective Remedy to the United State’s Organ Shortage

While advances in technology and medicine have kept

‘Are you in or out?’

people alive much longer than in the past, similar progress in organ donation policy has not followed. With waiting lists growing larger each year, policies reliant on altruism and tragedy have proven insufficient. Federal courts have made clear that a due process right exists in the removal of organs. However, an “opt out” system does not violate such a right—it embraces it. Statutes requiring an honest effort by doctors and hospital administrators in finding dissenters within the family further the constitutional rights of the decedent along with family members and ensure the best possible chance of harvesting invaluable organs. A presumed consent statute does not foreclose someone’s wishes against donating organs if they did not elect to opt out; rather, their wishes live on with their family. With Europe and other parts of the world adapting successful and progressive presumed consent statutes, the United States should adapt a similar system. The 110,000 people on the waiting list deserve it.

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The Social Responsibility of Federally Funded Health Care for Undocumented Immigrants

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- 5 *Id.* Mr. Jimenez's cousin and legal guardian, Montejó Gaspar, filed a civil suit in Florida. However, the jury decided that Martin Memorial Medical Center did not act unreasonably when it "deported" Mr. Jimenez against his will. Montejó Gaspar had sought nearly \$1 million to cover the costs of provided care for Mr. Jimenez in Guatemala.
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- 9 Pursuant to the Emergency Medical Treatment And Leave Act (EMTALA), all hospitals receiving federal Medicare funds are required to provide emergency care to all patients, regardless of immigration status. *See* EMTALA, 42

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 - 12 See generally Lori A. Nessel, *Disposable Workers: Applying a Human Rights Framework to Analyze Duties Owed to Seriously Injured or Ill Migrants*, 19 IND. J. GLOBAL LEG. STUD. 61 (2012) (reporting that “[i]n the newest frontier of privatized immigration enforcement, hospitals are acting unilaterally, or in concert with private transport companies, to deport seriously ill or catastrophically injured migrants.”). The practice of forcibly and coercively deporting undocumented immigrants is commonly referred to as “medical repatriation” or “medical deportation.”
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- Reproductive Ramifications: The U.S. Refusal to Ratify the Convention on the Elimination of All Forms of Discrimination against Women and the Damaging Collateral Consequences on the Right to Choose**
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- 2 [http://www.un.org/womenwatch/daw/cedaw/text/
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- 3 *Id.*
- 4 I am incredibly grateful to Professor Alice Ristroff for her help and advice on these constitutional issues.
- 5 U.S.C.A. Const. Art. II § 2, cl. 2 (West).
- 6 *See* U.S. Const. amend. XIV, § 5. The power of Congress to create legislation under Section Five of the Fourteenth Amendment is different than the Senate's power to ratify and implement treaties. In *City of Boerne v. Flores*, 521 U.S. 507 (1997) Congress overstepped its enforcement powers of the Fourteenth Amendment. The Court used the "congruence and proportionality" test it had previously articulated in *U.S. v. Morrison*, 529 U.S. 598 (2000). This test of ensuring that Congress does not overstep its constitutionally imposed limits of enumerated powers does not apply to the treaty powers of the federal government.
- 7 *See Case v. Bowles*, 327 U.S. 92, 102 (1946); *Gibbons v. Ogden*, 22 U.S. 1, 129-30 (1824).
- 8 *See, Gonzales v. Carhart*, 550 U.S. 124 (2007); *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992); *Roe v. Wade*, 410 U.S. 113 (1973) holding modified by *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992).

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- 18 Mayer, 23 Hastings Const. L.Q. at 789.
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- 20 *See, United States v. Virginia*, 518 U.S. 515 (1996); *Craig v. Boren*, 429 U.S. 190 (1976). *See also*, Mayer, 23 Hastings Const. L.Q. at 821-22 critiquing the Equal Protection Clause's apparent failure to protect women's rights.
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Playing Doctor: How the FDA's Regulation of Access to Experimental Drugs Limits Patient Autonomy

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- 4 *Id.*
- 5 Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Treatment Use and Sale, 52 Fed. Reg. 19,466 (May 22, 1987). Commonly known as the Treatment IND application, this was the FDA's somewhat belated attempt at responding to rising criticism of its drug approval process.
- 6 Olufs, Rimmerman, and Crimp all attest to the inadequacy of the currently available remedies in 1987-88.

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- 12 21 C.F.R. §312.34 (the 1987 Treatment IND) and its replacement (the 2009 regulations, to be codified at §312 and §316). Section 312.305 of the 2009 regulations functions as the most significant obstacle.
- 13 Pub. L. No. 87-781, 76 Stat. 780 (1962).
- 14 21 C.F.R. §355(b)(5).
- 15 *Id.* at § 312.305. To qualify for access to a clinical trial, a potential participant must meet the strict clinical guidelines set out by the FDA (which are then usually supplemented by the drug sponsor to specifically tailor the trial). These guidelines set baselines for health, age, gender, and the presence of any co-morbidities.
- 16 Most studies self-select for subjects afflicted only with the specific disease targeted by the drug, with any other conditions seen as potentially complicating or obscuring any data gathered. Those who are seriously or terminally ill rarely have only one significant medical condition (serious illness usually includes multiple co-morbidities), and would thus be disqualified from most clinical trials. Two excellent resources on co-morbidity and its impact on healthcare decisions—up to and including trial participation—are M. van den Akker, et al, *Multimorbidity in General Practice: Prevalence, Incidence, and Determinants of Co-occurring Chronic and Recurrent Diseases*, J Clin Epidemiol, 51:367–375 (1998), and M. Fortin, et al, *Prevalence of Multimorbidity Among Adults Seen In Family Practice*, Ann Fam Med, 3:223–8 (2005).
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- 18 21 C.F.R. §312. Codified in 1987 but substantially amended by the 2009 regulations.
- 19 *Id.* at §312.305(a)(2).
- 20 *Id.* at §312.305(b)(2). Section 312.305 generally establishes a new multi-step program (to be discussed in detail below) for access for those excluded from participating in a clinical trial, but this is the key provision that inserts the FDA into the physician-patient relationship.
- 21 *Id.*
- 22 *See supra* note 16.
- 23 21 U.S.C. §360bbb(b) (2010). Subsection (b)(1) requires an individual patient's doctor to determine that: 1) the patient has exhausted treatment options, and 2) the "probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition."
- 24 *Id.* §360bbb(1)-(3).
- 25 *See supra* note 16. See also *Abigail-Alliance.org*.
- 26 *See* Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. 40,900, 40,901 (Aug. 13, 2009). Later codified in 21 C.F.R. §§312 & 316.
- 27 *Id.*
- 28 *See* 71 Fed. Reg. at 75,150-51.
- 29 *Id.* at 75,151.
- 30 *See supra* note 125.
- 31 *Id.* at 40,940.
- 32 Charging for Investigational Drugs Under an Investigational New Drug Application, 74 Fed. Reg. 40,872 (Aug. 13, 2009). Only allowing recovery of direct costs still functions to limit industry incentive to participate.
- 33 *See* 21 C.F.R. §312.8(d)(1)-(2) (2011).
- 34 *Id.* at §312.310(c)(2) (2011).
- 35 21 C.F.R. §312.305(a)(2) (2011).
- 36 21 C.F.R. §312.305(a)(2) (2011).
- 37 As mandated by §360bbb of the FDAMA.
- 38 *See supra* note 23.
- 39 21 U. S.C. §360bbb(b)(2) (2010).
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- 47 See §360bbb(1)-(3). Subsections (b)(1) and (b)(2) are especially relevant in this delegation of authority.
- 48 *Id.* Subsection (b)(1) delegates decisional authority for individual patient treatment to the physician, and (b)(2) reiterates the information-gathering and aggregating duties of the FDA. The two subsections, both in their language and clear intent, contemplate a separation of the duties incumbent upon treating physicians and the FDA.
- 49 See *FDA v. Brown & Williamson Tob. Corp.*, 529 U.S. 120 (2000). The Court held that an agency could not simply assume that Congress had assigned it a new authority without explicit statutory language. In *Brown*, the FDA had created not only a more involved and extensive role for itself, it had embarked on a regulatory scheme which ran counter to any action it had taken in the past. In essence, the agency completely reversed its regulatory stance. The Court found that this action, because it took place in the absence of explicit statutory authorization, was an invalid exercise of agency authority.
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- 52 *Id.*
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- 55 21 C.F.R. §312.8(d)(1)-(2) (2011).
- 56 See Benjamin R. Rossen, *FDA's Proposed Regulations to Expand Access to Investigational Drugs for Treatment Use: The Status Quo in the Guise of Reform*, 64 Food & Drug L.J. 183 (2009).
- 57 Although it falls outside the scope of this article, one proven solution to the problem of covering the increased costs generated by expanded access is a single-payer healthcare system. Single-payer health systems in Western Europe and Japan—because they function as a lone, somewhat monolithic entity—have far greater bargaining power with the pharmaceutical manufacturer and thus usually pay far less than comparable U.S. providers. In essence, a single-payer health system in the U.S. could presumably negotiate far lower prices for experimental drugs, while still allowing the manufacturer to recover at the new (though lower) market rate. See generally T.R. Reid, *The Healing of America: A Global Quest for Better, Cheaper, and Fairer Health Care* (2010).
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- 63 §312.60. The section makes the physician responsible for many of the tasks the drug sponsor would shoulder in the clinical trials context.
- 64 §312.70. Loss of investigator status would be especially devastating for a physician practicing in a research or academic setting.
- 65 See *supra* note 63.
- 66 §312.60. On a comparative note, both Britain and Germany have significantly faster rates of access to experimental drugs because they place much of the decisional burden on the prescribing physician. In both countries, the treating doctor is expected to decide—typically without the input of any regulatory body—whether the new drug is appropriate for her patient. Neither country has reported significant adverse event outcomes as a result of having the physician function as an intermediary between the patient and the

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Student Contributors



Daniel Gilbert is a first year law student at Seton Hall University School of Law. He received a B.A. in English from Gettysburg College in Pennsylvania. He previously worked with a number of veteran organizations, particularly Wounded Warrior Project and The United War Veterans

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Anthony W. Liberatore is a third-year student at Seton Hall University School of Law pursuing the Health Law Concentration. He graduated from Loyola University Maryland (formerly known as Loyola College in Maryland) in 2007 with a major in Sociology and a minor in Political

Science. His health care experience includes an internship at the Baltimore City Health Department, volunteer experience in a community hospital emergency room, and research on the medical treatment of seriously ill and injured undocumented workers in the United States.



Elijah Bresley is a second-year law student at Seton Hall University School of Law. He recently graduated the College of Wooster with a major in Political Science in 2011. His interests in this health law issues piqued when he studied abroad in Yaoundé, Cameroon and saw first hand the im-

portance of health issues and standards, especially on an international level.



Melissa Cartine is a third-year law student at Seton Hall University School of Law pursuing the Health Law concentration. She graduated from New York University with a Bachelor of Arts in Psychology in 2009. Before beginning law

school, Melissa worked for Grand Street Settlement's College and Career Discovery Program, where she helped high school students from lower-income families develop post-secondary school plans. Currently, Melissa helps individuals who have been wrongfully denied unemployment insurance obtain such benefits at the Unemployment Insurance Advocacy Project in New York City. In addition, she has served as a Student Senator, and as the Secretary of the Health Law Forum. Melissa was also an intern to the Honorable James G. Troiano at the Superior Court of New Jersey – Family Division.



Phillip DeFedele 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 of medical professionals has given him an intense interest in the field of medicine as well as the policies and legislation that regulate

pharmaceuticals, medical devices, disease control and prevention, and medical research. He also plans to focus on international health regulations governing these fields due to his extensive travel experiences.

Student Contributors



Nina Schuman is a first year law student pursuing the health law concentration. Nina earned her B.A. in Economics and a concentration in pre-medicine from Emory University in 2008. While at Emory, she interned at the CDC, which sparked her interest in public health. She decided not

to pursue medical school, but instead earned a Master's Degree in Public Health from Boston University, with a focus on Health Policy and Management. After graduating from BU, she worked at Mount Sinai Hospital for two years in the Department of Surgery as a Quality Improvement Analyst and later promoted as Project Manager. She became interested in the legal side of health care after working with the Risk Management Department at the hospital.



Melody Hsiou is a third-year J.D. student who is graduating in May 2013 with a Health Law Concentration. Prior to attending Seton Hall, she received her M.P.H. in Sociomedical Studies and Health Promotion from Columbia University. She has a B.S. in Physiological Sci-

ence with a Public Health minor from the University of California, Los Angeles. Melody is currently an intern at the New York State Office of Attorney General Healthcare Bureau. She has previously held internships at Horizon Blue Cross Blue Shield and the U.S. Department of Health and Human Services Region II Office of General Counsel.



Ben Smith is a third-year student at Seton Hall University School of Law. He graduated from the University of Georgia with a B.A. in English and Philosophy. After graduation, he became certified and worked as a Paramedic in the Emergency Room at Kennestone Hospital in Atlanta, GA. During his time at Kennestone Hospital, Ben served on the Shared Governance and Error Prevention Boards,

which involved working with the general counsel for the Hospital. These interactions led to his interest in the interplay between regulatory compliance and healthcare delivery.



Suzan Y. Sanal, class of 2014, is in pursuit of a health law concentration, writes for Seton Hall's Health Reform Watch blog, and holds the position of Student Bar Association representative for the Health Law Forum student group. Her interests in health law include studying health care compliance, analyzing the Patient Protection and Affordable Care Act, and promoting health care consumerism.



Robert Granzen is a second-year law student at Seton Hall University School of Law pursuing the Health Law concentration. He graduated from Seton Hall University in 2011 with a degree in Political Science. He plans to pursue a legal career in health law, focusing on corporate compliance and regulatory work.



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