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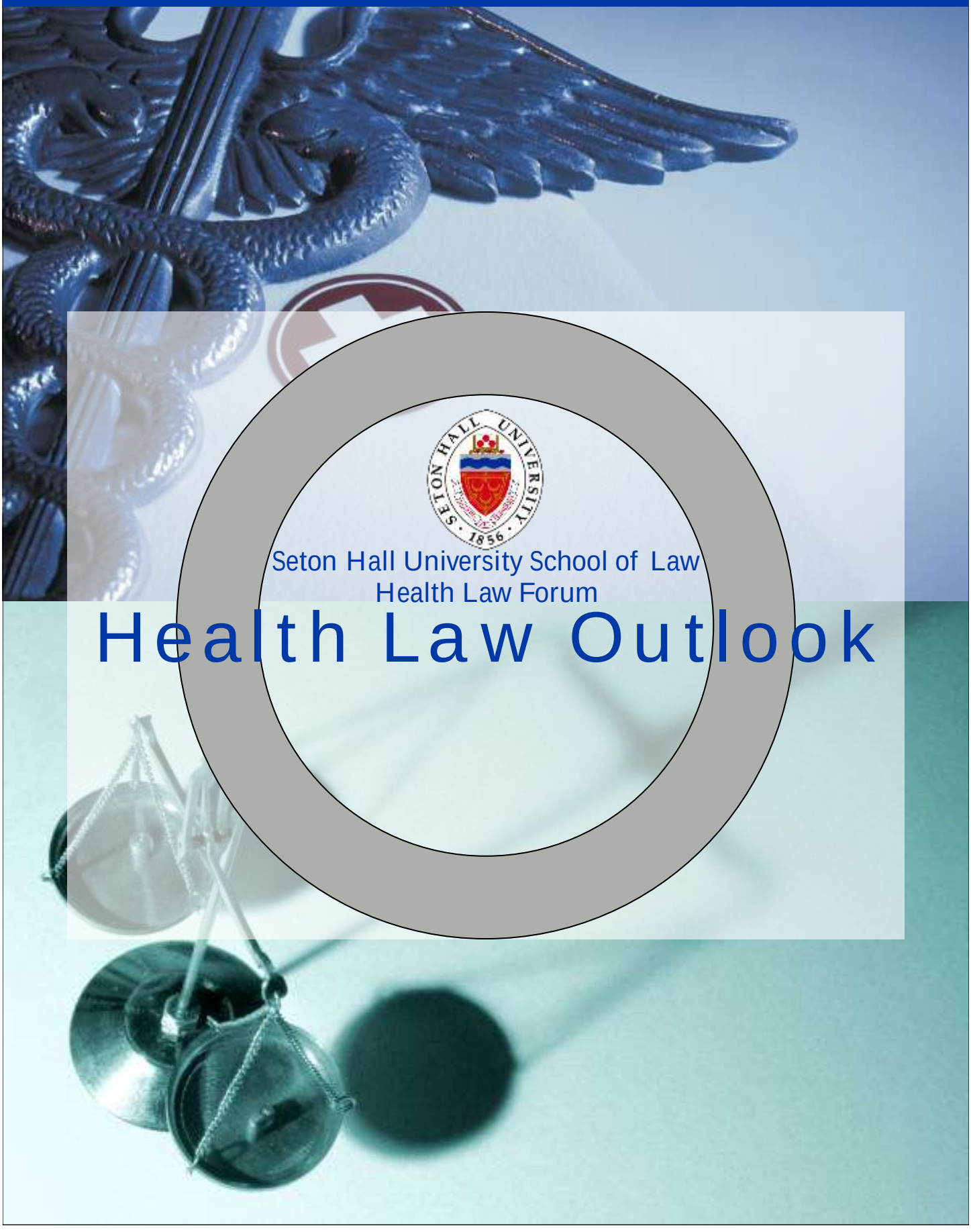


Seton Hall University School of Law
Health Law Forum

Health Law Outlook

Inside this issue:

Improving Health Outcomes and Reintegration for Reentering Offenders

Healthcare Reform and Coordinated Care Through Targeted Holistic Services

Jessica Huening
Jessica.huening@student.shu.edu

Corrections in the United States is characterized by high rates of recidivism and an enormous amount of spending. Nearly 95% of those incarcerated will reenter back into society; however, the vast majority of released individuals continue to cycle through the legal system throughout most of their lives.[1] A staggering $75 billion dollars was spent in 2008 among federal, state, and local governments, with the majority of that money used directly for incarceration costs.[2]

A complex set of individual and environmental factors impacts the health status of the offending population.[3] A lack of preventative care, a lack of coordinated and consistent care, and the effects of repeated and/or sustained periods of incarceration further complicates these factors. While returning offenders are heavy consumers of healthcare services, treatment for their health conditions declines after reentering the community.[4] Emergency room visits and hospitalizations provide the primary source of care for the offending population.[5] The result is ultimately individuals reentering into the community receive acute, fragmented care for chronic problems.[6]

Reentering into the community is often an extremely confusing and stressful period of time fraught with new challenges. Most individuals entering and leaving prisons come from, and are returned to, poor minority communities.[7] After being removed from their community for a substantial period of time, reentering offenders are suddenly confronted with the need to obtain what is necessary in order to survive and function: housing, employment, healthcare, and other services.[8] This is often in addition to managing significant health problems such as substance use and mental health disorders.[9]

Most returning offenders have limited to no savings, no immediate access to unemployment benefits, and no job prospects.[10] Additionally, up to 90% of individuals who are incarcerated at local and county jails have no insurance of any kind.[11] Ex-offenders face serious challenges finding a job in an increasingly competitive job market both due to their disclosed ex-offender status and general decreased lack of skills and experience. Indeed, up to 60% of individuals continue to be unemployed at a legitimate job one year after their release.[12]

It is no surprise that the time immediately following release is a critical period with a significantly increased risk of morbidity. In a Washington state study conducted from 1999-2003, the risk of death among former inmates during their first two weeks of release was found to be 12.7 % higher than among other state residents of the same age, race, and sex.[13] There is also a considerably higher prevalence of cardiovascular disease, cancer, liver disease, suicide, homicide, HIV, diabetes, and overdose among individuals released from prison than their incarcerated counterparts.[14] A lack of health insurance, difficulty obtaining care, the high prevalence of mental illness, and the detrimental psychological stress of reentry contributes to these problems.[15]

A coordinated holistic approach to care is most appropriate given the array of problems the offending population faces, and the dynamic relationship between health outcomes and criminal activity. Health problems influence reentry outcomes including housing, employment, family relationships, substance use, and recidivism.[16] Additionally, many predictors of poor health outcomes are also predictors for criminal activity.[17] Health care needs to be addressed in the reentry planning process, with a focus on continuity of care and linkages to appropriate services. [18]

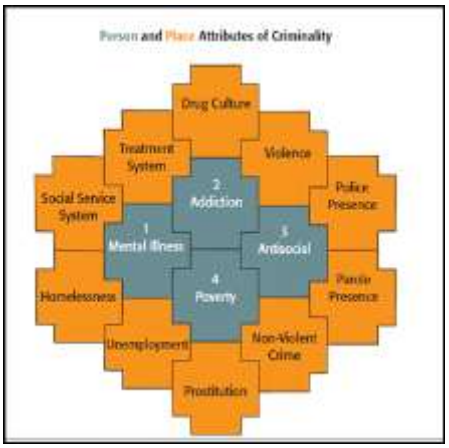


Figure 1: Factors Contributing to Justice-Involvement

Matthew Epperson, Nancy Wolff, Robert Morgan, William Fisher, B. Christopher Freuh & Jessica Huening. *The Next Generation of Behavioral Health and Criminal Justice Interventions: Improving Outcomes by Improving Intervention*, Center for Behavioral Health Services and Criminal Justice Research (2011).

Healthcare reform embraces a holistic approach to healthcare in several ways as legislated in the Patient Protection and Affordable Care Act (PPACA) signed into law by President Obama on March 23, 2010. Community health workers will encourage preventative health through education, guidance, and outreach in medically underserved racial and ethnic minority communities.[19] Information will be provided regarding the promotion of healthy be-

haviors, discouragement of risky health behaviors, guidance on enrolling in an applicable health plan, as well as referrals to community based programs that minimize fragmented care.[20] The Secretary of Health and Human Services is also responsible for planning and implementing a national outreach and education campaign to increase public awareness of health across the lifespan, such as the provision of information related to: utilizing health services to reduce health disparities and mitigate chronic disease, preventative services, healthy behaviors and proper nutrition, the negative effects of smoking and obesity, disease screening, health promotion, and disease prevention to healthcare providers participating in Federal programs.[21]

Additionally, PPACA dramatically expands Medicaid to include those individuals under the age of 65 at or below 133% of the federal poverty level in 2014.[22] This will include a substantial proportion of offenders returning to the community as those with the fewest financial resources often wind up in the criminal justice system.[23] The Center for Medicare and Medicaid Innovation will undertake many efforts to streamline patient care and reduce expenditures through information technology and the development of new patient care models.[24] The creation of community based medical homes and teams will be encouraged through grant funding. [25] These teams will assist community members and small-group practices treating chronic conditions in managing and coordinating care by connecting individuals to appropriate services and assisting with facilitating payments to providers. [26]

Starting January 1, 2011, PPACA has created a state option for the establishment of "health homes" for those on Medicaid with chronic problems.[27] Participation in the option is voluntary, however, matching federal grants are provided for the planning and development of the health homes, and States are reimbursed 90% of the Federal Medical Assistance Percentage for the first eight fiscal quarters.[28] Health homes provide comprehensive treatment and care in part through integrating and coordinating services with other specialists and providers such as clinics, behavioral health services, and substance abuse services.[29] Medicaid benchmark benefits have also been revised to include minimum essential coverage to include parity for mental health and addiction disorder treatment if care is provided through a managed care organization.[30]

To be effective for the offending population, however, education and coordination of traditional continuous care is likely to be just the beginning. To maximize improved health outcomes, the individual and environmental factors associated with criminality must be targeted and addressed (See Figure 1).[31] Individual factors are unique to the person and include mental illness, addiction, poverty, and antisocial beliefs and attitudes.[32] Environmental factors are conditions that increase risk of criminal justice involvement such as drug culture, homelessness, unemployment, violence, and prostitution.[33] Stress and trauma further aggravate the individual and the environmental factors associated with criminal behavior, as well as increases the likelihood that individuals will behave in ways harmful to themselves and the community.[34]

Policymakers can no longer afford to ignore the detrimental consequences of an overinflated prison population, the socioeconomic and racial disparities to accessing and obtaining appropriate healthcare, and the impact of individual and environmental factors on criminal thinking and behavior. [35] The correctional system in the United States is overwhelmed by a high number of offenders. The prison-industrial complex is more likely to be a site of trauma, rape and violence than a genuine source of rehabilitation.[36] Given the harms it is likely to impose on prisoners during their time under incarceration, it is imperative that it contribute to assuring continuous post-incarceration care.

There is no simple and straightforward solution to providing effective and affordable healthcare to ex-offenders. Healthcare reform provides states with the framework to adopt holistic diversion and reentry practices in order to improve health outcomes for the offending population. The efforts of recent trends in holistic legislation will be diminished, however, if the causes and effects of criminal thinking and behavior are not incorporated into case management, treatment plans, education outreach, and assistance provided with dollars allocated for healthcare spending. If these factors are successfully addressed then not only will health outcomes have the opportunity to improve, but so will the costs incurred by the correctional system through effective diversion and reduced recidivism. ☼

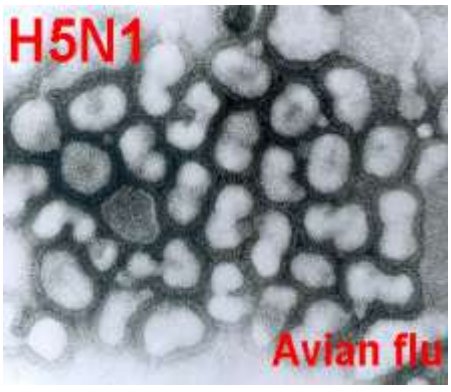
Regulating Health

Should regulations on the publication of recent Avian Flu research be imposed?

Melissa Rifai
Melissa.rifai@student.shu.edu

Scientific research has long been a boon to our society. It has lengthened human life expectancy, eradicated deadly communicable diseases, and cured people of illnesses that previously would have been deadly. Nevertheless, with every scientific discovery comes the potential for misuse. A transmittable strain of a deadly virus that falls into the wrong hands could lead to a pandemic, harming hundreds of thousands of people. We saw the misuse of a biological agent on a small scale with Anthrax in 2001, and recent studies on the H5N1 virus (commonly referred to as Avian Flu) elicit the same fear of misuse, called the "dual-use" concern.[1]

Avian Flu is a virus that is highly contagious among poultry.[2] Though it is not usually found in humans, the virus can be transmitted from infected poultry to humans as a result of close contact.[3] However, even humans infected with H5N1 do not generally pose a risk to other uninfected humans.[4]



Two recent studies, one led by Yoshihiro Kawaoka and the other by Ron Fouchier provide a model of the virus that is transmissible in ferrets.[5] The Fouchier paper reports on the transmissibility of the full H5N1 virus, while the Kawaoka paper "provides a method for producing a transmissible H5N1 reassortant virus."[6] The H5N1 strain used in the research was found to be highly communicable between mammals, and the ferret is considered the best available model of the flu virus in humans.[7]

The two studies could be replicated to create a highly transmissible virus that would pose serious threats to biosecurity.[8] For that reason, calls for the studies to remain unpublished or be redacted became plentiful.[9] On February 17, 2012, the World Health Organization (WHO) convened an expert meeting to discuss the issue of what portions of the studies should be published. Although they reached the decision that both the Kawaoka and Fouchier studies should be published in full, the meeting did not address the larger question of how to balance the threat of bioterrorism with the need for scientific research, and whether or not publication of medical research should be regulated.[10] It is not necessary to answer this larger question at this time.

This article argues that the benefits of publishing this Avian Flu research greatly outweigh the risk of bioterrorism. Disallowing or severely regulating the publication of this research would be a greater risk to public health than the threat of bioterrorism. For the following three reasons this research should be published in full: (1) studying the flu virus in ferrets does not dictate exactly how the flu will manifest in humans; (2) studying and understanding

Avian Flu is important for early detection and prevention of the disease as well as creating vaccinations, especially if it were to be used as a biological weapon; and (3) past scientific research that has posed a risk of bioterrorism has been published with no significant public health detriment.

Influenza Behavior in Ferrets is not an Exact Replica of Influenza Behavior in Humans

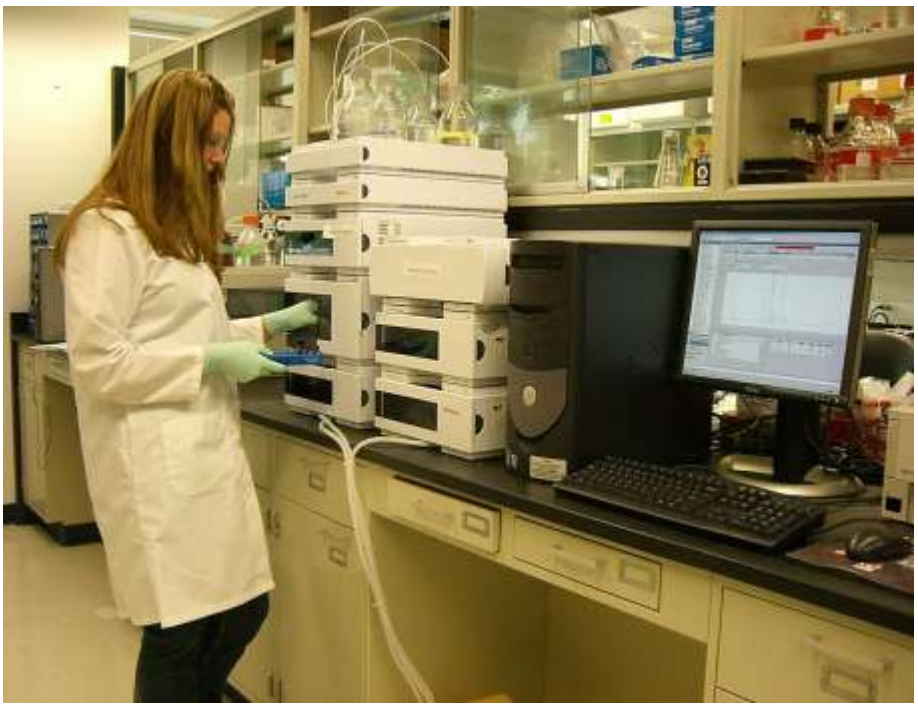
Two main differences in the manifestation of the Avian Flu exist between ferrets and humans: its communicability and its severity.[11] The communicability of this strain in ferrets has shown to be much greater than that in humans, but more research is required to know for sure whether the strain would be as transmissible in humans as it is in ferrets.[12] Because influenza is always mutating, it is not impossible that the strain would mutate naturally into the strain created by these studies.[13] Since the advancement of scientific research is largely based upon building on previous published research, imposing strict regulation on its publication would prevent researchers from being able to understand how the communi-

cability of the disease could change as the virus mutates. To prevent publication at this stage would be detrimental to the advancement of Avian Flu research.

Secondly, the strain of the virus appears to be less severe in ferrets than it is in humans.[14] The Centers for Disease Control and Prevention (CDC) states that 60% of people infected with the highly pathogenic form of the virus have died from the disease.[15] However, only a minority of strains of H5N1 is deadly in ferrets.[16] More research is needed to understand how the virus will behave in humans and whether the severity of this strain of the Avian Flu will mirror the manifestation in ferrets, or be more severe. Although ferrets provide a viable framework for understanding how influenza will behave, it is not an exact model. Preventing or regulating the publication of Avian Flu research, as some members of the scientific community have called for, would hinder scientists' ability to answer the questions of human communicability and severity, posing a risk to public health if the virus were to naturally mutate.

We Must be Able to Detect, Contain and Prevent the Virus Should it become a Biological Weapon

An outbreak of Avian Flu could manifest in a number of ways. Should Kawaoka and Fouchier's research fall into the wrong hands, it is important that the scientific community have information about how to detect, treat, and vaccinate against the virus. Without published research, we may be unable to find a way to treat or contain an Avian Flu pandemic if the flu mutates into a more communicable strain from human to human. If such a strain develops and is spread, whether naturally or through an act of terror, there will be a large public health issue at hand.



In 2009, a worldwide outbreak of the H1N1 virus infected an estimated 61 million people.[17] The virus was highly contagious and spread quickly, leading the WHO to declare it a pandemic.[18] Following the outbreak of the virus, the response to the pandemic was evaluated, concluding that the H1N1 pandemic "exposed vulnerabilities in public health capacities, limitations of scientific knowledge…and challenges in the communications among experts, policymakers and the public."[19] The evaluation concludes, "The world is ill-prepared for a severe influenza pandemic."[20] In order to rectify this, the WHO makes a number of recommendations including, but not limited to, "sharing of viruses and access to vaccines," "expanding influenza vaccine production capacity," and taking "measures to detect and promptly identify potential pandemic influenza viruses."[21]

In order to accomplish these goals and be better prepared for an Avian Flu pandemic, research must be conducted, and studies must be published and shared among the scientific community. Prohibiting the Fouchier and Kawaoka studies from being published in full would create a great risk to public health, resulting unpreparedness to combat an outbreak of the virus. The more time and opportunity that the scientific community has to research and understand the way that Avian Flu can mutate and spread, the better prepared it will be to deal with bioterrorism, or a natural mutation of the virus.

Scientific Research that has Posed a Risk of Bioterrorism has Been Published in the Past

Advances in medical research often ignite concerns of misuse, a phenomenon often called the "dual use concern."[22] In the context of Avian Flu, the dual-use concern is whether the biosecurity risks of publishing the Fouchier and Kawaoka studies in full outweigh the benefits of disseminating the research.[23] History has shown that publication of studies that pose a risk of bioterrorism is possible without the research being misused. For example, a study detailing the reconstruction of the 1918 influenza virus was published in full, and the threat of bioterrorism has not come to fruition.[24] In addition, the results of extensive research about the smallpox virus, as well as reserves of the smallpox virus have been around for almost 30 years and neither the research, nor the reserves of the virus, has been misused.[25]

In fact, there have been very few incidents of misuse of medical research in the United States. One such incident occurred in 1984 when a religious group used Salmonella typhimurium to contaminate restaurant salad bars in Oregon.[26] The group, running a legitimate clinical laboratory, used books that described "bacteria and other methods to make people ill," and learned to culture the bacteria with the help of a laboratory technician.[27] The misuse of the published results, and the aid from a member of the scientific community led to an estimated 751 infections, but there were no fatalities.[28] Considering these results, it is important to be cautious of bioterrorism, but the threat is not greater than that to public health that exists by not publishing research results, including those from the recent studies of Avian Flu.

"THE MORE TIME AND OPPORTUNITY THAT THE SCIENTIFIC COMMUNITY HAS TO RESEARCH AND UNDERSTAND THE WAY THAT AVIAN FLU CAN MUTATE AND SPREAD, THE BETTER PREPARED IT WILL BE TO DEAL WITH BIOTERRORISM, OR A NATURAL MUTATION OF THE VIRUS."

Conclusion

For the foregoing reasons, the publication of this Avian Flu research should not be strictly regulated or prohibited. Though the publication of scientific research often carries the dual-use concern, there have been relatively few instances of misuse in comparison to the vast amount of research that is published. Because the Kawaoka and Fouchier studies of Avian Flu in ferrets are not exact models of how the virus will behave in humans, and because there is a need to develop vaccines and ways to detect the virus if it were to mutate or be released in an act of bioterrorism, the threat of bioterrorism does not outweigh the public health interest in publication of results. ☼

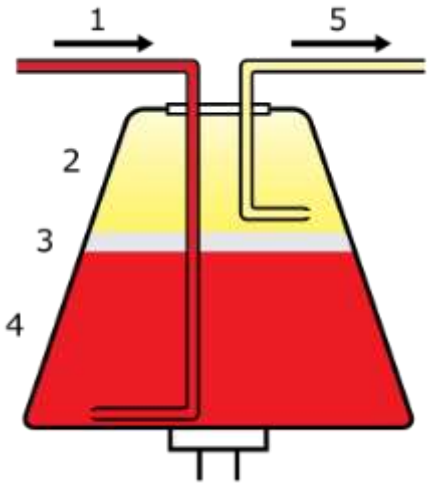
Flynn v. Holder: A Slippery Slope Towards Organ Compensation?

By Ryan Upchurch
Ryan.upchurch@student.shu.edu

In April 2010, Kumud Majumder suffered every parent's worst nightmare when he lost his son and only child, Arya, to leukemia.[1] Arya, whom Kumud described as "an angel who transformed my life" was only eleven years old when he passed.[2] His death was in part hastened by the inability to find a bone marrow match for transplant. Unfortunately, stories resembling Kumud's are far too commonplace. Over 100,000 Americans are diagnosed annually with serious blood and bone marrow disorders, with leukemia being the most prominent diagnosis.[3] Many of these individuals require a transplant of bone marrow cells to combat their particular malady.

Difficulty of Bone Marrow Matches

Finding matches for bone marrow recipients is a difficult proposition because there are various types of proteins present on bone marrow stem cells. Family members generally offer the best probability for a match, but even then the estimated success rate of 30% is paltry at best.[4] The difficulty in matching blood stem cells has led to striking statistics for those in need. An estimated 40,500 adults are diagnosed with leukemia annually as well as another 3,500 children.[5] Anywhere between 2,000 and 3,000 Americans die every year from a failure to achieve a suitable bone marrow match for their blood-based illness.[6]



Whole blood enters the centrifuge (1) and separates into plasma (2), leukocytes (3), and erythrocytes (4). Selected components are then drawn off (5).

Statistics illustrate distinctive success rates for people of different racial groups. Matches are rare for those of mixed-race parentage and African American descent, as they tend to possess a combination of African, Caucasian, and Native American genes.[7] Caucasian patients are successfully matched roughly 70% of the time, but this number drops to only about 40% for Americans of African descent.[8] A potential means of increasing the number of matches is to possibly enlarge the donor pool by offering some form of compensation. Until the *Flynn v. Holder* decision, this was presumed to be prohibited by the National Organ Transplantation Act ("NOTA").[9]

Flynn v. Holder: Legalizing Compensation for the Apheresis Method of Donation

On December 1, 2011, the Court of Appeals for the Ninth Circuit held in *Flynn v. Holder* that compensation for bone marrow stem cells derived from the "peripheral blood stem cell apheresis method" ("apheresis") was legal.[10] Additionally, the Court confirmed that compensation was still prohibited for donation of bone marrow through the more antiquated method of aspiration.[11]

The Court considered the distinctions between the two methods of marrow donation, apheresis and aspiration, in arriving at its ruling. Aspiration was described by the Court as a "painful, unpleasant procedure" in which thick needles are inserted into the cavities of the anesthetized donor's bones in order to extract the soft, fatty substance from within commonly known as bone marrow.[12] This procedure for bone marrow donation was in place in 1984 when Congress enacted the National Organ Transplant Act (NOTA), and it accounts for about one third of current donations.[13]

However, the newer method of apheresis has been developed since then. For apheresis, the donor is first injected with granulocyte colony-stimulating factor medication for five days prior to the procedure, which increases the amount of blood stem cells that exit from the marrow and enter into the bloodstream.[14] Afterwards, a collection needle is placed into the donor's vein.[15] The apheresis machine separates out the blood stem cells and the left over fluid is injected back into the donor. The stem cells taken from the donor will be replaced naturally by his or her body within three to six weeks.[16] The apheresis method of extraction is more common now, being used in about two thirds of all donations.[17]

On its face, NOTA prohibits any compensation for bone marrow.[18] However, the Ninth Circuit did not believe that the statute was applicable to the apheresis method of bone marrow donation because the Court likened the apheresis method to an ordinary blood donation.[19] NOTA's scope specifically excluded blood and its derivatives.[20] As the Court acknowledged, the only difference between an ordinary blood donation and a donor undergoing the apheresis method is that the latter involves the donor sitting for longer as well as the apheresis machine separating stem cells from the blood.[21] When the apheresis machine is used to sort and

collect plasma or platelets it is referred to as a "blood donation" or a "blood plasma donation."[22] When it is used to separate out blood stem cells, it is commonly known as a "bone marrow donation."[23]

Apheresis is a "Bone Marrow Donation" in Name Only

With respect to the newer apheresis method, the question before the court was whether a procedure commonly referred to as a "bone marrow donation" actually meant that bone marrow itself was involved. Under the apheresis method, none of the soft, fatty substance that is extracted through aspiration is present.[24] Rather, the apheresis machine merely separates blood stem cells from the blood that is extracted.[25] For the Court, the critical components were the actual material separated out and the location from which the material came. The donor would be providing his or her blood stem cells, not their bone marrow. Furthermore, these blood stem cells would come from the blood, not from within the cavities of the donor's bones. If compensating donors for their stem cells through this method was banned, the Court reasoned then that all compensated blood donations must be outlawed as well. However, the Senate Report had specifically excluded blood from the language of the statute.[26]

NOTA provides that "the term 'human organ' means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation."[27] Subsequently, the government raised the issue as to whether the blood stem cells fell under the statutory language of "or any subpart thereof" in reference to not just organs in their entirety but any subpart as well.[28] These blood stem cells do after all originate in the bone marrow before naturally moving into the bloodstream. Because the distance between actual bone marrow and the bloodstream is great enough, the Court found that this argument lacked merit.[29] Additionally, the drafters of NOTA could not have had the apheresis in mind because it had not yet been developed.[30]

"IN A SMALL BUT HIGHLY SUCCESSFUL STANFORD UNIVERSITY STUDY, DONORS OF KIDNEYS THEN PROVIDED THEIR BLOOD STEM CELLS FOR A BONE MARROW TRANSPLANT TO THE SAME PATIENT. EIGHT OF THE TWELVE PATIENTS WERE SUBSEQUENTLY FREED FROM THEIR NEED FOR LIFE-LONG IMMUNOSUPPRESSANT MEDICATIONS..."

A Slippery Slope Appears Likely

Perhaps the first thought to arise from this decision is that of the proverbial slippery slope. Opponents of organ commodification may be wary that the Ninth Circuit's interpretation could lead down a path towards black markets, harvesting of organs, and vast economic inequalities. On the other hand, NOTA is explicit in the limitations placed on remuneration for most body parts. Human kidneys, livers, hearts, lungs, pancreas and the ever important "any subpart thereof" are just some of the organs prohibited.[31] The Court's holding was much narrower than it may have appeared at first glance.[32] The issue then is whether the *Flynn* decision could in any way lead down a slippery slope towards relaxing or overruling NOTA in the future.

Generally a slippery slope can be thought of as a particular decision (decision A), which may be appealing now, but increases the probability that another broader decision (decision B) will be accepted later.[33] Due to its broader scope, decision B is usually opposed by some who initially wanted A.[34] However, many frameworks exist for different slippery slope arguments, and often times slippery slopes are composed of more than just two decisions. A slippery slope made up of three distinct decisions, or points, is a simple example of a multi-peaked preference slippery slope.[35]

The multi-peaked preference slippery slope provides the most plausible framework for the issue at hand. In this argument, the middle position is the least desirable of the three while either extreme offers a preferable option.[36] There are several subsets of multi-peaked preference slippery slopes. One is the basic equality version, in which both extremes (A & C) are preferred to the middle position (B) because getting to position B without then reaching position C may be unfairly discriminatory.[37] In applying this here, position A represents the way things were prior to *Flynn*, position B represents the current state of affairs legalizing compensation under apheresis, and position C represents removing the ban on compensation for all organs. The supporters of position B are happy with the ruling, but many of them hope to see a move from position B to position C as well. Position C's supporters are generally comprised of those afflicted by diseases to organs within NOTA's scope. For example, more than 83,000 Americans are currently on the waiting list for kidneys.[38] Roughly 13 of them die every day.[39] It may seem unjust to some that an individual has a potentially larger donor pool from which to find a match based upon the particular part of their body that is afflicted. Now that position B has been legalized, if a large enough percentage of people believe it is unjust

to not then reach position C, we could see a slippery slope. Nevertheless, position C might have to eventually be reached within the legislature given the broad scope of NOTA in limiting judicial interpretation.

Kidney transplants provide an interesting scenario to demonstrate the inequality of not moving from position B to position C. As is clear from NOTA, the donor offering their kidney cannot be compensated.[40] Yet, in an admittedly small but highly successful Stanford University study, donors of kidneys then provided their blood stem cells for a bone marrow transplant to the same patient.[41] Eight of the twelve patients were subsequently freed from their need for life-long immunosuppressant medications, which are used post-transplantation to prevent the donated organ from being rejected.[42] The immunosuppressant medications are expensive and include severe possible side effects.[43] One estimate places the price of such medications at anywhere between $2,000 and $4,000 per month, although insurance or Medicare can be used to offset some of this cost.[44]

The donor would still be ineligible for compensation after donating their kidney. However under *Flynn*, the donor could be compensated for their donated blood stem cells, which then liberate the recipient from expensive and often dangerous medications. This scenario, and the differing likelihoods of finding a donor match, serves as the best examples that we may be beginning down an equality slippery slope towards some form of organ compensation.

Conclusion

The *Flynn* decision is a monumental step forward for those afflicted by diseases of the blood or bone marrow. By legalizing compensation for donation through apheresis, the chances are increased that the donor pool will be expanded and many more matches can be made. This is especially true for mixed race and African American patients whose genetic makeup is more difficult to match for these kinds of transplants.

However, it may be premature to think that this will lead to any immediate change to the statutory construction. NOTA has the same effect it has had since 1984 and the legislature could even choose to simply add in "blood stem cell apheresis" to the statute if it so desired.[45] Perhaps in the near future, regenerative medicine will alleviate the need for most organ transplants as patients can have the requisite organ grown from their own stem cells.[46] A revitalized debate over organ commodification stemming from this decision is an important step for a slippery slope, though.

At any rate, *Flynn* is effectual and positive change and should be celebrated as such. It is only when *Flynn* is assessed in relation to other organs that it could be dismissed as presently being too narrow. Successful implementation of recompense for blood stem cells could still serve as a case study for those organs that remain prohibited by NOTA. For now, it may not initially appear that *Flynn* will lead to broader compensation, but one often cannot see where a slippery slope began until one has reached the bottom. ☼

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Student Contributors

Jessica Huening is a research associate at the Center for Behavioral Health Services and Criminal Justice Research (CBHS&CJR). There she is involved with several projects and works that seek to improve the availability and effectiveness of services for individuals with mental illnesses who are involved with the criminal justice system. Prior to her work at CBHS&CJR she worked as an IRB analyst at the Mount Sinai School of Medicine and as a research coordinator at the Nathan Kline Institute for Psychiatric Research. Her research interests include: the social systems of, and services provided for, vulnerable and high-risk populations involved with the criminal justice system; policy initiatives that affect individuals with mental illness and high-risk populations involved with the criminal justice system; healthcare law and ethics; and the regulations and policies concerning the use of human subjects in research.

Melissa Rifai is a first-year law student at Seton Hall University School of Law. She recently graduated with a Bachelor of Arts in Psychology from New York University. It was her background in psychology that piqued her interest in health law. She plans to pursue the health law concentration at Seton Hall.

Ryan Upchurch is a second-year student at Seton Hall University School of Law pursuing the Health Law Concentration. He graduated from Colgate University in 2010 with a major in History and a minor in Middle Eastern Studies & Islamic Civilization. He is currently externing with General Counsel at Saint Michael's Medical Center in Newark. Ryan plans on obtaining another externship for his third year, in order to further diversify his experience within health law.

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