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HEALTH LAW & POLICY

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Health Law & Policy

Fall 2009 Staff

Health Law & Policy (HLP) is a publication of American University Washington College of Law (WCL) and the Health Law Project LL.M. Program on Law & Government.

Letter from the Editors

Dear *Health Law & Policy* Reader*:*

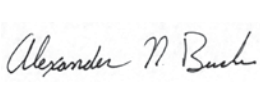
On behalf of the Editorial Board and staff, we proudly present Volume 3, Issue 2 of *Health Law & Policy*. Now on our sixth issue, this publication comes in the midst of a fervent and lively debate surrounding the potential overhaul of the American health care system. In light of this partisan environment, we continue to aspire to produce a scholarly product that includes opinions reflecting the diversity of voices affected by this debate.

As of the publication date for this issue, health care reform bills are still making their way through Congress and as of yet no bill has been submitted to President Obama for signature. A prominent issue currently facing policy makers and their constituents is the improvement of our health care system's ability to best accommodate gender differences. As a result, we have decided to dedicate a significant portion of this edition to our Spring 2009 Symposium entitled "Does SexX Really Matter? What A Difference An 'X' Makes!" This event featured a variety of topical issues involving women's health care research, genetics, and sexuality. The numerous panels included an eclectic body of experts from academia, research institutions, government, and private pharmaceutical and medical device companies.

In addition to the Symposium, this edition includes two timely student articles. One article examines various health care reform solutions for the uninsured, while the other analyzes the controversial issues involving genetic testing and its implementation in everyday medicine.

We want to extend our sincere gratitude to both our hard working staff that brought this publication to print and our advisor, Professor Corrine Parver, Esq., for her dedication both to this publication and to her students in furthering an understanding of health law issues. We hope you enjoy this issue and the topics discussed as much as we do.

Sincerely,



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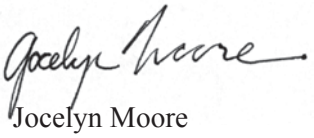

Jocelyn Moore
Editor-in-Chief

Does SexX Really Matter? What a Difference an "X" Makes!

Spring Health Law Symposium

March 3, 2009*

Welcome Remarks

Phyllis Greenberger, *President and CEO, Society for Women's Health Research*

Panel I—Will your Lawyer Deliver your Next Baby? The Effect of Rising Malpractice Insurance Costs on OB/GYNs

Sara Imershein, *M.D., FACOG*
Corrine Parver, *Practitioner-in-Residence and Executive Director, Health Law and Policy Program, Program on Law and Government, American University Washington College of Law*
Steve Pavsner, *Partner, Joseph Greenwald and Laake, PA*

Panel II—Your Mother's Medicine: a New Approach to the Health Care of Women Throughout Their Lifespan

Judith Waxman, *Vice President of Health and Reproductive Rights, National Women's Law Center*
Suzanne Mintz, *President and CEO, National Family Caregivers Association*

Keynote Address—Women's Health is a Human Right

Maureen McTeer, *Professor of Law, University of Ottawa School of Law*

Panel III—The R_{xx} Factor: Different on the Outside. Different on the Inside? Rethinking the Medical Model and Clinical Trials

Kathleen Uhl, *M.D., US Food & Drug Administration, Assistant Commissioner for Women's Health*
Katie O'Callaghan, *Division of Cardiovascular Devices, US FDA*
Rebecca Wolf , J.D., *Washington College of Law, American University, 2009*

Panel IV—When a Woman's Choice is Not a Choice

Lisa Brown, *Counsel, National Abortion Federation*
Dr. William Parker, *MD, MPH, Director of Family Planning for Washington Hospital Center*
Jill Morrison, *Senior Counsel, National Women's Law Center*

* Please contact panelists for sources cited.

Welcome Remarks

Phyllis Greenberger*:

I am going to start by giving a little bit of the history of the Society for Women's Health Research (Society) and how we got into the issue of clinical trials and sex based biology. Then I would like to talk about some of the barriers that we still face and some of the solutions that my organization thinks we can offer. For those of you who are not familiar with us, we are the only national non-profit organization whose mission is to improve the health of women through research, education, and advocacy. We were founded in 1990.

We focused our initial work on the inclusion of women and minorities in clinical trials and also on conditions that differently, disproportionately, or exclusively affected women. At that point in time women's health was exclusively defined as reproductive issues. The National Institute of Child and Human Development was the only organization doing research. That research focused on maternal issues. At other institutes and in private industry there was minimal or no focus on the other conditions that affected women differently or disproportionately. A few years after that initial focus, we started getting into the issue of biological differences between men and women. Since our inception we have been very influential at HHS, including at the FDA, NIH, and various other agencies. We have also influenced private industry, which does the bulk of pharmaceutical, device, diagnostic research.

The history of the inclusion of women in medical research is really one of exclusion. In 1977 the FDA banned the inclusion of women in clinical trials. To a great extent this exclusion was motivated by the thalidomide and DES tragedies. Although those tragedies had nothing to do with clinical trials, they had to do with harm to women, creating a feeling that women should not be included in clinical trials. This ban was meant to protect women and their fetuses, but what it actually resulted in was an era of what we refer to as the 'male norm' in clinical research. During that era most research was done on young, white, healthy males. It became common practice to extrapolate results from male subjects to women. I do not think it will come as any surprise that using the 'male norm' was not good for women's health.

In 1985 the United States Public Health Service determined that the lack of information on women in clinical trials was compromising women's health. To address this, in 1986 the NIH urged clinical researchers to include women in their studies and to analyze the results by sex. In 1990, with Congressional support, the Society spearheaded a Government Accountability Office (GAO) study. The study found that NIH was failing to implement its own guidelines. We knew NIH was not doing this, but we needed to make it official. We asked Congress to investigate the issue and discovered that NIH was not following its own mandate.[1] That was the beginning of the Society working with Congress to change laws.

There was not much progress at including women in research until two events took place in 1993. The first was the Revitalization Act, which required the inclusion of women in all clinical research and analysis of results by sex for Phase III trials. Second, the FDA established guidelines for the study and evaluation of gender differences in the clinical evaluation of drugs.[2] These guidelines did not encourage the inclusion of women in safety and dosing studies, which are Phase I and II, but required the inclusion of women in efficacy trials, which are Phase III.

We worked with the GAO again in 2001 to investigate what was being done at NIH and how much progress was being made. The investigation revealed a few things. The audit of the FDA records revealed that the FDA had not effectively overseen presentation and analysis of data related to sex differences and drug development.[3] In fact, there were a number of drugs that had been taken off the market after it was shown that they disproportionately caused adverse reactions in women. The analysis showed that 30 percent of study documents failed to fulfill requirements for

* Phyllis Greenberger is the President and CEO of the Society for Women's Health Research. The society has been instrumental in working with Capitol Hill and several administrations in trying to advance the way scientists, defenders, and policy makers approach various issues involving treatments, conditions, and research for women's health issues. Prior to that she was with the American Psychiatric Association. She was involved with the Clinton Health Reform Program and with the current administration's efforts to reform our health care system.

presentation of outcome data by sex. Nearly 40 percent did not include the required demographic information, demonstrating that the FDA had not effectively overseen the presentation and analysis of data. We believe that if the FDA had studied sex differences either the drugs would have stayed on the market, women would have been monitored, or the drugs would not have been prescribed for women.

In 2001 the board of directors of the Society decided that rather than just looking at conditions that differently, disproportionately, and exclusively affected women and inclusion in clinical trials, we should go more to the basic level and see if we could validate the concept of research looking into sex differences. At first we were not taken seriously. There we were, a group of women, telling researchers and doctors that they were doing research the wrong way and that some of the care they were providing was not appropriate for women. Then we went to the Institute of Medicine to convince them that this was an important study.[4] This process took a number of years, in part because we had to raise additional funds. In 2001, we released our report entitled *Exploring the Biological Contributions to Human Health: Does Sex Matter?* The report concluded that sex does matter. It matters in health and disease from "womb to tomb." It emphasized the need to carefully evaluate sex differences in medical research and incorporate those differences into clinical practice. Biological sex needs to be considered as a variable at all levels of research.

The inclusion of women in clinical research and the fact that scientists have begun finding differences between men and women in terms of susceptibility, prevalence, time of onset, severity, and response to treatment of various diseases and conditions, has led us to redefine women's health. Today's definition of women's health moves beyond the reproductive system and encompasses every disease and condition that affects women disproportionately or differently. Biological sex differences result from a combination of genetic, hormonal, physiological, and environmental factors. These differences have real world consequences for the diagnosis and treatment of diseases.

First let us look at heart disease. It was not until the Society had their first Sex Differences Conference on cardiovascular disease that anyone really started thinking that cardiovascular disease affects women. Heart disease kills 500,000 American women each year, over 50,000 more women than men, and strikes women, on the average, 10 years later. Women are more likely than men to have a second heart attack within a year after the first one. No one knows why. We do know there are significant sex differences in the anatomy and physiology of the heart and how heart disease manifests itself.

Another example of sex differences arises with neurological disorders. We have always known that men and women's brains are different, structurally and functionally. This may result from the effects of estrogen and testosterone during brain development and differences in response to steroid hormones in localized regions of the brain later in life. These differences can result in differing rates of certain neurological disorders in men and women. For example, women have higher rates of depression and anxiety disorders while men have higher rates of autism and ADHD.

The list goes on. In almost every category of disease – autoimmune, bone diseases, etc. – there are differences between men and women. While science has made great strides in understanding the basic biological differences, there is still a great deal to learn. We have reached a crossroads at which we need to examine how medical research is conducted and support programs and policies to promote the study of biological sex differences. We have spent more than a decade trying to raise awareness of the importance of sex differences in health and disease among research scientists, clinicians, funders, legislators, and the public. We have put together expert panels on various topics, published reports, and funded four interdisciplinary research networks. These four networks look at sex differences in cardiovascular, metabolic, neurological, and musculoskeletal diseases.

About two and a half years ago we launched a new scientific membership organization, the International Organization for the Study of Sex Differences, which brings together scientists to look at sex differences. We still face a lot of barriers. While there are a growing number of investigators doing research on sex differences and the literature is expanding, many scientists are still unaware that sex differences exist at every level. There are no consistent efforts among the NIH to encourage studies that elucidate sex differences of the basic biological mechanisms underlining these differences. By requiring that all grant proposals include plans for data by sex, the NIH could ensure that sex difference becomes a de facto priority in medical research. When the NIH interpreted the 1993 legislation, they interpreted it to require that women be included only in Phase III. We believe that inclusion needs to occur in Phase I and II, looking at toxicity and dosages.

There is also a problem in terms of the medical research. Scientific and medical journals do not require that authors report the sex of their studies' subjects, human or animal, or that results are analyzed by sex. As a result many published studies do not contribute to our knowledge of sex differences. If all scientific journals required analysis by sex, researchers would have to design their studies to detect sex differences. We believe that funders and institutional review boards should require that all research include women at all phases. Analysis of sex differences is not done routinely and in some cases the number of female participants is too small to obtain statistically significant data.

The 2007 review of published data from cardiovascular disease trials shows that, of the 628 reviewed studies, three-quarters did not include sex difference analysis, forty-one trials did not provide the sex of participants, and seventeen did not include women at all. At the basic research level, studies on animal models do not routinely include both sexes as subjects. We have been told that female animals are more expensive and more complicated, but that does not mean they should not be used.

Barriers to progress also exist at the health care provider level. Physicians need to be informed about sex differences to treat their patients effectively. In 2005 an American Heart Association national study of physician awareness showed that physicians remain largely unaware of sex differences in cardiovascular disease. Only eight percent of primary care physicians, thirteen percent of OBGYN's, and seventeen percent of cardiologists were aware that heart disease kills more women than men every year.

Currently how sex affects health and disease is not part of nursing and medical school curriculum. It is important that health care providers be trained in sex differences so they can appropriately evaluate, treat, and educate their

patients. Similarly, continuing medical education does not always include research that looks at sex differences. There is still physician bias. Female and male patients showing up at a clinic with the same symptoms may be treated differently. Doctors often fail to recognize women's risks for conditions such as heart disease, lung cancer, and osteoarthritis. Even when a physician diagnoses a condition such as heart disease, he or she is less likely to refer a female patient to diagnostics and treatment. Women get less aggressive treatment. Two alarming studies showed that even when male and female patients had the exact same conditions and symptoms the physicians' diagnoses were more aggressive for men.

Educating women about the importance of participation in clinical trials is another area that we continue to work in and fund. The only time we ever hear about clinical trials is when something goes wrong and it is on the front page of the paper. If our goal is to learn what works better in women and men, or children, or the elderly, or minorities, we need diverse participation in clinical trials. We need to educate women and physicians. Often physicians discourage people, both men and women, from entering clinical trials.

In a nine-year cardiovascular disease study, which asked women what is the greatest health problem facing women today, only eight percent identified heart disease. The number went up to thirteen percent in 2003 and twenty-one percent in 2006. Women fear breast cancer more than heart disease, but in reality they are much more vulnerable to heart disease and in many respects it is preventable. There are problems with how the media interprets scientific data from the published literature and reports study findings incorrectly. This contributes to patient confusion and lack of confidence. One example of this that is still controversial is the way in which the Women's Health Initiative (WHI) study was halted. We believe it is a perfect example of miscommunication leading to confusion. The WHI was a federally funded study to determine whether hormone replacement therapy reduces the risk of heart disease in post-menopausal women. Since the release of the initial results, contradictory information has come to light. Women are still confused as to whether hormone therapy is safe, whether taking calcium helps their bones, and whether low fat diets are beneficial for their health.

We are faced with a system where in many respects patients are forced to be their own health advocates as consumers in a complicated health care system. This works for only a fraction of educated consumers. For the majority of us it is extremely difficult enough to figure out the health care system, much less to develop a relationship with a provider. If a patient asks too many questions or appears to question the authority of the physician, the patient is often labeled as difficult.

Research teams need to think broadly about research questions, including sex as a variable in both basic and clinical research and requiring analysis in reporting results by sex. Journals also need to report by sex. Sometimes when an article is too long a journal will cut out the portion having to do with women or will simply refer to women as 'patients'. Often readers do not know whether women were included. Imagine you are a cardiologist reading an article in the popular journal, *Circulation*, about a major trial on cardiovascular disease, but the article only refers to males. Then there might be in a smaller journal, less popular among healthcare providers, in which the part on women is included.

Blood and tissue samples that are stored in repositories should indicate the sex and hormonal status of the donor. For women, this would include pre-pubescent, reproductive, pregnant, menopause, post-menopause statuses. As the Institutes of Medicine suggest, research needs to be conducted in individuals from womb to tomb. We need faster translation of basic research results into the clinic, not just in terms of better drugs and diagnostics, but in the adoption of new technologies that are affordable. We need to develop guidelines to educate providers on how sex differences impact the health and health care of women.

In closing we believe that the study of sex differences is the strongest approach to improve women's health. As sex differences research evolves and is translated into more personalized medical treatments, both sexes will equally benefit. Understanding the differences in how diseases manifest themselves in women also helps us understand the mechanism in men. We will all equally benefit from better health and health care.

Corrine Parver:

If you were to emphasize to policymakers that sex differences research benefits both men and women, rather than just women, would they be more responsive to the issue?

Phyllis Greenberger:

For many years we have been trying to convince the pharmaceutical industry that if they do not do testing on women in the early stages of drug development, we will find problems once the drugs are on the market. The industry would rather have a drug that is out there for everybody and worry about problems later, than spend more time and money doing complicated and costly trials that will only allow them to market the drug to half the population. Obtaining funds from Capitol Hill is a long shot. It is up to the NIH directors. Some NIH directors get it and are doing the right thing, but the majority of them do not.

We did a study a number of years ago looking at the percentage of proposals that were funded by the NIH. At that time only three percent related to sex difference research. The institutes that one would think would have more of a focus on women's issues, such as the Cancer Institute and the Heart Lung and Blood Institute, were the worst. Nobody is against knowing what works best and there are a lot of things that could be improved. We are still learning about sex differences in diagnostics, devices, and pharmaceuticals. We are concerned that if the NIH starts looking at comparative effectiveness without taking into consideration sex differences we may end up backtracking from the progress we have made so far.

1 *NIH Guide for Grants and Contracts,* National Institutes of Health, Bethesda, MD, 1986.
2 *Women Sufficiently Represented in New Drug Testing, But FDA Oversight Needs Improvement.* Rep. GAO-01-754, United States General Accounting Office, Washington, DC, 2001.
3 *Drug Safety: Most Drugs Withdrawn in Recent Years Had Greater Health Risks for Women.* Rep. GAO-01-286R, United States General Accounting Office, Washington, DC, 2001.
4 Wizemann, T.M. M.-L. Pardue, *Exploring the Biological Contributions to Human Health: Does Sex Matter?* Eds. 2001. Board on Health Sciences Policy, Institute of Medicine, Washington, DC.

Will Your Lawyer Deliver Your Next Baby? The Effect of Raising Malpractice Insurance Costs on OB/GYNs

> We are paying $135,000 in premiums a year, but are getting reimbursed less and less every year. The average OBGYN makes about $200,000 a year, works about 60 to 80 hours a week, and then goes home at night worrying about what he or she did wrong.

Dr. Sara Imershein*:

I am going to talk to you about how rising malpractice insurance costs affect physicians. If you are a parent you know that childbirth is a pretty scary situation for a family. One of the common complaints that we hear is that doctors perform too many Caesarian sections. The fetal heart rate monitor, which was designed in the 1970s by Dr. Hahn, is a way of monitoring heart rate changes of the unborn fetus. This was established as standard of care in the 1980s, not by any double blind, controlled, or crossover clinical study, but by legal precedents. No controlled medical studies have ever proven that women who have fetal monitoring have healthier babies than women who do not have fetal monitoring. However, to forgo fetal monitoring would be considered malpractice or negligence today. Anytime you look at a normal population of 100 people, five percent will fall outside the normal range.

Now let us take a group of women in labor. Discovering a fetal heart rate abnormality might show us an existing problem or a potential problem. We are talking about serious long term problems with long term effects. So let us say there is a five percent risk that a baby will be damaged if we do not intervene. If it is my baby, I want a Caesarian section because five percent is an awfully high number when you know that the baby can be delivered safely right away. That said, if only five percent of the babies have an actual abnormality, many unnecessary Caesarian sections are being performed. We know that three to five percent of all children born are going to be abnormal, regardless of what doctors do. It is like planting your garden: not every flower will bloom. We are going to be doing a lot of unnecessary Caesarians because mothers and fathers are not willing to take the risk.

The second thing I want to talk about in terms of why doctors feel squeezed in all directions is affordability, which is why you are going to be seeing fewer and fewer doctors like myself delivering babies. OBGYNs' overhead has gone up substantially in the last ten or twenty years. Generally speaking most of us run a business with overhead of about fifty to fifty-five percent. A fulltime OGBYN in Washington, DC pays about $135,000 a year in medical malpractice premiums. That covers up to one million dollars per malpractice event and up to three events per year. That is the same coverage that most of us had twenty years ago, but it does not cover a lot of the current lawsuit settlements or judgments.

As you all know, a lot of lawyers won't take a case unless it is a seven-figure case because it is very expensive to take a case to court. You have to put that expense up front if you are working on a contingency basis. You better be sure that it is worth a lot of your time to invest that money. We are paying $135,000 in premiums a year, but are getting reimbursed less and less every year. The average OBGYN makes about $200,000 a year, works about 60 to 80 hours a week, and then goes home at night worrying about what he or she did wrong.

If you deliver an average of 110 babies a year with an average payment of $2000 and your insurance is $135,000, do the math. You have $85,000 left after you pay your malpractice premiums. You then have to pay your office nurse, your receptionist, and your rent. We do gynecology also, but you can see that obstetrics is hardly a money-maker unless you are working a very high volume. The million dollar coverage is no longer adequate. Many doctors, when they receive a letter that they are being sued, go out and hire another lawyer in addition to their insurance company lawyer to make sure their insurance company is working on their behalf. Doctors do not want to go to court and risk being liable for excess of their malpractice insurance. It is not unusual to have to pay an additional legal fee to take care of that.

We also have many non-reimbursable expenses. Every time you make a phone call to your doctor's office, somebody has to look up your chart, pull out

* Dr. Sara Imershein graduated from the University of Pennsylvania magna cum laude and attended Emory University's Medical School. She completed her post doctoral training at NYU Bellevue Medical Center in New York City. For twenty-five years she has been in private practice with a specialty in OBGYN, Obstetrics and Gynecology in Washington, D.C. She is also an Assistant Clinical Professor at the George Washington University Medical School. She chairs the Health Information Management Committee at Sibley Hospital and has served on numerous committees for the American College of Obstetrics and Gynecologists, the DC Medical Society, and other health organizations and community groups. Currently she is also a student of health policy at the George Washington University School of Public Health and Health Sciences.

that record, and give it to the doctor for approval. Most law firms bill you for that; doctors get nothing. These are overhead expenses. If Joe calls to find out how his elderly mother is doing and spends several minutes explaining what is going on, the conversation is non-reimbursable. We are squeezed at both ends. Our overhead costs have gone up by forty percent in the last ten to twenty years. Our reimbursements have gone down by about forty percent as well. I received those numbers from the American Medical Association (AMA) yesterday. The average doctor is making less than fifty percent of what they used to and the average medical school student is graduating at thirty. If you go straight through in law school you are about twenty-five when you graduate. The average doctor puts seven or eight years into their training after college and graduates with a $250,000 debt. You cannot lower tuition by adding another student in medical school. You can always bring another chair into a law school and lower tuition a little bit by getting one more student to pay. The rate limiting step in medical school is usually the gross anatomy lab. It was thirty years after I graduated from Emory University Medical School before they enlarged their freshman class. They had to build a whole new building to accommodate the gross anatomy lab to enlarge their freshman class of medical students.

Between our increasing expenses and our decreasing reimbursement, a sense of depression has fallen over much of the medical community. There is also sense of hopelessness because many of us are making maybe twenty to fifty percent more than the nursing staff at our hospitals who are working very nice forty hour work weeks with time and a half for overtime. I don't want to whine. I love what I do. I love taking care of women.

Corrine Parver*:

I became interested in this topic when I was out for dinner one evening with a group of friends, some of whom were physicians. Somebody said that the University of Maryland had not sent a single one of their medical students into an OBGYN residency. This trend apparently has been repeated in many medical schools across the country. I was concerned on the one hand because I had a daughter who wanted to be a mother and a daughter-in-law who wanted to be a mother and I wondered who would be their doctors. At the same time I looked at it from the standpoint of the disproportionate effect that a shortage of OBGYNs might have on women of color. Everything that happens to Caucasian women, at least in this country, has a multiple effect on the negative side for women of color.

I began to do some research in this area a couple of years ago and found to my dismay that, from a legal standpoint, there was no literature on this particular topic. I thought, what is causing doctors not to go into OBGYN? I remember when my husband was a medical student and going through the different specialty trainings. He came home after his first day with an OBGYN, said "That is the kind of doctor I want to be. It is such a wonderful, happy, profession, and the women are happy and the babies are healthy", but he did not end up not going into that specialty. It left a big impression on me. Why are people not feeling the same way about the OBGYN specialty? Why do young doctors not want to be OBGYNs? Why do many practicing OBGYNs get out of obstetrics and end up just practicing the gynecological surgery and medical aspects of the specialty? Could one of the reasons be that lawsuits and high malpractice insurance costs are deterring and scaring people away from practicing OBGYN?

In our research on the affect of the medical malpractice insurance crisis on women of color, we took a look

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at five states across the country to get some data to begin the discussion of whether people are not going into this specialty because of increasing medical malpractice insurance rates. Our research was published in the 2007 *Journal of Health & Biomedical Law,* Suffolk University Law School. We were not able to come up with a specific conclusion as to whether that was the sole reason people are not choosing this specialty. We do know, as we heard from Dr. Imershein, about the rising cost of medical malpractice insurance, most specifically for obstetrics.

We wanted to see whether there is a barrier to access to care for women of color because of medical malpractice issues. The fact that minority women have a propensity to choose physicians of their own race and ethnicity has been demonstrated in several studies. Medically indigent women are four times more likely to receive care from non-white physicians than non-Hispanic white physicians. If you have a woman who wants to receive her care from a physician who is from the same race and ethnicity– you can see that her access to care could be completely blocked. There is also a perception, although it has been unsubstantiated, that poor women are more litigious than women of means. If you have statistics that show that African American women bear the brunt of the poverty in the United States, that would increase the fear of even minority physicians going into this particular specialty.

Another factor that we looked at was that medical malpractice insurance coverage in some states is forcing physicians to abandon the practice of medicine entirely. Years ago your family physicians, and other physicians, would work until they died in the office, or at least until they were eighty or eighty-five years of age. You just do not see that today. You see young physicians leaving the practice of medicine, as well as going out of the specialty of obstetrics. We looked at five states and tried to determine what the numbers were for physicians and to derive a correlation between numbers of physicians treating patients and access to care. We looked at California, Nevada, Arizona, Mississippi and Maryland. Some of these states have been labeled medical malpractice insurance 'crisis states' by the American Medical Association (AMA). The remaining states are showing some problem signs.

California is a heavily regulated state when it comes to medical malpractice. The Medical Injury Compensation Reform Act (MICRA) was passed in the mid-1970s and has been held up as the gold standard for other states. In looking at the female population, you can see that there are more women of color than Caucasian women in California. Eighty-one percent of women in California have health insurance, a national rank of thirty-fourth. Why is that number so low? It is so low because the proportion of women of color in that state is so high. Then we took a look at the number of physicians in each of these states. These statistics have just been updated; they are 2007 numbers. Of the 4,300 California OBGYNs, only 113 are African American. The ratio of black OBGYNs to black women is one to almost 11,000.

Maryland is also pretty heavily regulated. There has been a huge increase in medical malpractice insurance rates in that state. The non-Caucasian population is slightly smaller than that of California so we would expect to see better numbers. Indeed Maryland ranks fifteenth in the country for women with health insurance. One interesting statistic that we looked at was the high percentage of African-American, Hispanic, and Asian women in Maryland who receive routine check-ups. There are less than 1000 OBGYNs and of those only twenty-seven are African American. There is a ratio of one African American OBGYN per 30,000 African American women. This is a huge disparity. If you look back to the studies that showed that women prefer to be treated by physicians of their own race and ethnicity, you begin to see how difficult it is to achieve high access to care for women of color.

We looked at the effect of tort reform in 2000 on access to care in Mississippi. Mississippi ranks forty-third in terms of percentage of women who have health insurance. There were only six African American OBGYNs in 2006 in the entire state of Mississippi, a ratio of almost one in 90,000.

Arizona currently ranks fortieth for the percentage of women who have health insurance. Far fewer African American women receive routine checkups than in the other states that we looked at. Here the ratio is a little bit more positive. Fourteen out of the state's 221 OBGYNs are African American, for a ratio of around one per 5,000.

Nevada has similar non-Caucasian and Caucasian populations. It ranks forty-seventh for the number of women who receive preventive care, which is one of the lowest percentages of women who have health insurance. There were five black OBGYN's out of 231 in 2006, for a ratio of one in almost 15,000.

So as I said when I began, this was just a preliminary examination of the issue of access to care for women of color. Much more work has to be done in the area, but I found it personally very discouraging for all of us. I wonder how we can possibly encourage more women to enter this field. I would guess that the percentage of female OBGYNs today far exceeds that of twenty or thirty years ago, but it is a specialty that should be encouraged by medical schools. It is disappointing when you read about medical schools doing the exact opposite. We are continuing to look at this area and trying to determine whether greater tort reforms should be enacted.

Steve Pavsner*:

I think that both Professor Parver and Dr. Imershein have laid out the problem. It is a problem that clearly exists. It is often referred to the as the 'malpractice insurance crisis', and from my perspective, the emphasis should be on the word 'insurance.' In short, there are those with an interest in a certain outcome, who refer to it as the 'medical malpractice crisis.' I am going to show you some data to suggest that the emphasis should not be on the medical malpractice system or on the jury system, but that the emphasis should be on the insurance system.

Clearly doctors are facing a big problem and I think Dr. Imershein laid it out pretty clearly. The problem is multi-faceted. It involves skyrocketing consumer costs, health costs, and health insurance premium costs. Yet, despite the fact that as consumers we are paying a lot more for our health insurance, the persons delivering that healthcare to us are receiving less and being squeezed.

In some cases, as Professor Parver implied and Dr. Imershein suggested, OBGYNs are leaving the field. This raises some issues with respect to the profession and leads to the provocative title of this first panel of this symposium 'Will Your Lawyer Deliver Your Next Baby?' There are essentially four popular ways to explain this crisis. First, that there are frivolous lawsuits. Second, that we live in a litigious society and so not only are there frivolous lawsuits, but there are a lot more lawsuits. Third, that there are more plaintiffs' verdicts. This is the idea that often times a jury will return a plaintiffs' verdict out of sympathy, not because the evidence indicates that there should be a plaintiffs' verdict. Fourth, that when there is a verdict for a plaintiff, it tends to be for a high payout. This is something that Dr. Imershein certainly alluded to – this notion that if the OBGYN has limits, insurance limits of one million to three million dollars – that that might not be adequate in the case of what we lawyers refer to as a 'bad baby.' By 'bad baby' we mean a baby who has suffered some birth problem, oftentimes anoxia or hypoxia during the birth process. If it is not anoxia or hypoxia it could be something called shoulder dystocia that leaves a baby with a limp arm. The questions for us should be why does the malpractice insurance problem exist and what is the relative merit of these popular explanations.

One popular explanation was in a cartoon I saw. The cartoon reads, "[i]f you close your eyes and make an allegation someday it might come true." I thought this captured the notion that frivolous lawsuits are being filed. Specifically we are talking about lawsuits in the context of the delivery of babies, basically obstetrical problems. Of course we as lawyers know when we handle these sorts of cases that the last thing in the world we want to do is take a case that does not have substantial merit. We know that there are rules to sanction us if we bring a case to court that does not have substantial merit or file a case that does not have substantial merit. We know that as a practical matter if we file a frivolous case, because these cases are brought on a contingent fee basis and because there are substantial costs associated with bringing these cases, it is not in our economic interest to bring a case that does not have substantial merit. Additional hurdles that we have to meet before we can bring a case include pre-screening requirements. For example, in Maryland there is a requirement that we initially file a lawsuit before something called the Health Claims Alternative Dispute Resolution Office. As part of that, within a certain period of time, we are required to file something called a certificate of a qualifying expert, or qualified expert. This is essentially an affidavit by another physician in the field who says under oath, that "I have reviewed the facts of this case and in my opinion with reasonable medical probability Dr. Smith violated the standard of care and caused damage to the plaintiff." My point is that there are procedures in place, both in terms of our own self-interest and in terms of procedures imposed upon us by the system, which are intended to, and I would suggest in many cases do successfully, weed out and diminish this notion of frivolous lawsuits. We do not want to bring frivolous lawsuits and there are systems in place to discourage us from bringing frivolous lawsuits.

The second popular explanation is that we live in a very litigious society. It is true that we have a system of justice – and I would be willing to defend that system of justice that is designed to result in the peaceful resolution of disputes. If one party feels aggrieved by the actions of another, there is a peaceful process that exists to resolve the dispute. The process is designed to try to bring resolution to that dispute and to try to make people who feel aggrieved believe that they have some redress. This is an important process that is necessary to the very fabric of our system of justice. That system does require physicians, when we are talking about personal injury cases or medical malpractice cases, to become involved. From my own experience, in some sense many physicians enjoy being involved in that process for a number of reasons. One is the intellectual challenge and the other is that it tends to be remunerative and it helps compensate for the other

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problems that some physicians are facing with respect to being squeezed. The notion that we live in a litigious society holds some truth in the sense that we know that we have access to the courts. However there are no studies that suggest that there has been some explosion of litigation or that there has been any disproportionate increase in the number of lawsuits. Given that we have an increasing population, it stands to reason we would have an increasing absolute number of lawsuits, but there is nothing disproportionate about it. I am not aware of any studies that suggest there is any particular disproportionate explosion of litigation in the medical malpractice area.

If those two popular explanations do not explain the problem, then how about this notion that there are more plaintiffs' verdicts in medical malpractice cases? A pie chart presented at another conference that we had on a similar topic here at American University in 2005, by a gentleman by the name of Larry Smarr, the president of a major malpractice insurance company, Physicians Insurance Association of America (PIAA), attempted to explain the resolution of lawsuits that are brought in the United States. This was data from PIAA, so it relates to PIAA insurance. What Mr. Smarr indicated was that basically sixty-one percent of medical malpractice lawsuits are dismissed or dropped. There are some minimal administrative expenses that the insurance company incurs in reaching that resolution, but the cases are dropped or dismissed before they go through the full litigation process. In addition, a number of cases settle. Any insurance adjuster will tell you that they settle the cases they think they are going to lose. They do not settle the cases they think they are going to win. When they try those cases, as you would expect, there are many more verdicts for the defense than there are for the plaintiff. Why is that? Well as I indicated, they try the cases they think they are going to win and they settle the cases they think they are going to lose. You would expect that result. Of all the PIAA malpractice cases that are filed there are about thirty-three percent that represent plaintiff's verdicts. The overwhelming majority are dropped or dismissed and only about seven percent of them go to trial, where the substantial expenses are incurred.

The New York Times published an article not too long ago in which it looked at this particular phenomenon. They authors looked at the phenomenon of the increase in malpractice insurance premiums and the alleged relationship of that increase to increasing malpractice payouts. Their conclusion was that the payments for malpractice claims, although increasing, were not increasing at nearly the same rate as the increase in premiums. The question then becomes, what is the cause of the explosion in malpractice insurance premiums? I think the answer was presented right here by Larry Smarr of the PIAA at the conference I mentioned previously. He presented it in short form under the title *PIAA Data Sharing Project, Claim Payment Trends*. He presented the loss and loss-administration expenses from 1995 to 2003. Loss-administration expenses are basically paying the adjustors, paying the lawyers to defend the lawsuits, and paying the costs associated with getting experts involved in the lawsuits. They increased from ninety-seven percent in 1995 to 105 percent in 2003.

What does that mean? The insurance company takes in an insurance premium from the doctor and holds that premium. It does not pay a claim the day it takes in a premium. It may never pay a claim or it may pay a claim five or six years later. This is what the insurance business is all about. It is based upon taking in premiums and then hopefully not having claims, or paying out claims long after it has earned money on the premiums. So insurers take in the premiums, invest that money, and then pay out claims. They are prepared to pay out even more than a dollar for every dollar of claims. Why? Because those are absolute numbers; a dollar taken in and a dollar paid out. They separately account for the interest they earn on holding that premium dollar until they pay it out. You can see that as the insurance company starts to pay out a little more money, they reimburse fewer dollars to the policyholders. That is one of the cushions they have. Then they have a column called 'adjusted combined' in which they account for the combined expenses plus the policyholder dividends. "Adjusted combined," as you see, is merely the sum of "Combined"—which includes losses, loss administration expenses (LAE), and underwriting expenses—and "Underwriting Policy Holder Dividends"— which is to say, what they are reimbursing to the doctors to reduce the cost of the physicians' cost of malpractice insurance. And what you see when you read across the chart is that, from 1995 to 2003, there is absolutely no change. I mean it is not perfectly flat. You wouldn't expect it to be perfectly flat, but the ratio of dollars paid out to net dollars earned from premiums happens to be exactly the same in 1995 as it was in 2003.

But what changes dramatically is their net investment income, what they make in the market. Doctors and lawyers have no impact on a company's investment decisions. This is simply what the insurance companies decide to do with those premium dollars. The net investment income decreased by more than fifty percent over the period. It went from forty-six percent on the dollar all the way down to twenty-one percent. Then after accounting for income tax PIAA's net income took a nosedive from twenty-three cents on the dollar to a loss of two cents on the dollar. So in other words they lost money. But the question is why, and the answer I suggest is right in the data that Mr. Smarr presented. Step number one in fixing a problem is identifying the true cause, not establishing some bogeyman.

Medical Malpractice- Financial Update
Financial Ratios to Net Premiums Earned

	1995	1996	1997	1998	1999	2000	2001	2002	2003
Loss & LAE	97%	92%	92%	92%	91%	98%	112%	111%	105%
Underwriting Expense	15%	17%	19%	21%	22%	22%	22%	18%	17%
Combined	112%	109%	111%	114%	113%	120%	134%	129%	122%
Underwriting Policy Holder Dividends	10%	9%	7%	6%	6%	5%	3%	2%	0%
Adjusted Combined	122%	118%	118%	120%	119%	125%	137%	131%	122%
Net Investment Income	46%	43%	43%	42%	33%	32%	30%	18%	21%
FIT	7%	6%	6%	5%	2%	2%	0%	-3%	0%
Net Income	23%	19%	20%	16%	13%	6%	-7%	-11%	-2%

Your Mother's Medicine: A New Approach to the Health Care of Women Throughout Their Lifespan

Judy Waxman*:

I was part of the health care reform effort in the early 1990s with the Clinton Administration. We made some serious progress, but in the end there were many reasons why the effort failed. We will be facing some of the same issues today, but there also seems to be a feeling, at least among a lot of the people who were involved before, that this is the time there is a greater sense of urgency. The timing presents a golden opportunity.

There are a lot of reasons why we need health reform. Forty-six million Americans do not have health insurance. Costs are increasing astronomically and health care is becoming a larger and larger part of our Gross Domestic Product. Costs are increasing at a pace where if we do not figure out how to cover everybody and control costs at some point in the not so distant future, 100 percent of our Gross Domestic Product may be health care.

The National Women's Law Center is involved in a variety of issues that affect women. I am head of the Health and Reproductive Rights Group. For the last thirty-five years, we have done a lot of work on health care and display lots of information on our website, expanding the scope of what National Women's Law Center does. We issue a federal and state report card on "Making the Grade on Women's Health," which goes state by state looking at statistics on how women are actually faring. It is based on many different indicators, including what policies at a federal and state level might help women have better health.

Looking at health reform specifically, you might also notice that we have a special project on health reform and women. I will go into a little bit of detail on a few issues that women face. Health care for all and controlling costs for all will obviously help women.

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When we look a little more closely, we see that women have some special needs separate and apart from men. Affordability is one of them. The individual insurance market is detrimental to women. I will cover that and the general questions we should be asking about health reform.

First of all, let us take a look at insurance coverage patterns. More women have coverage than men at the moment. The real reason is that women have less income than men overall, and so Medicaid and other low income programs cover more women than men. In private insurance, the pattern is somewhat different. While men and women have private coverage at about the same percentages, more women than men are covered as dependents, which can affect their coverage. Furthermore, when you look at women by race, you can see that insurance coverage varies dramatically in terms of who actually has coverage. That, of course, is linked very much to poverty and levels of income.

If we are going to build on our current employer-based insurance system, then we have to figure out how to deal with part-time female workers. Building on the employer system is possibly a good way to go, but we must deal with it as a women's issue. It is true that women in the affordability gap generally use more services than men, due to their reproductive health needs and other issues. Obviously, it is not any individual man versus any individual woman, but across the board women tend to receive more health care. There is a large affordability gap, which is evidenced by family out-of-pocket costs and premiums; women wind up spending a whole lot more out of their pocket than men do. Women have more cost related access barriers and are less likely to take the medication prescribed to them. Women have more medical debt, which is one of the major causes of bankruptcy in this country.

Where do women get their health care coverage right now? Eighteen to sixty-four year olds get their coverage mostly from employer sponsored coverage. Seven percent are covered under the individual market. That is the group where, for example, you graduate law

school, you do not have a job yet, and your parents say you must have health insurance. You go online and you try to find out what plans are available. It is a brutal market because each individual is looked at separately. You are not in a big group where your medical costs are combined with everybody else's, sharing the risk, which is the whole point of insurance. It is pretty wide open in terms of what companies can do and what they can look at about you, whether they approve you or not, what you are charged, and so forth. We looked at this issue in terms of men versus women.

As I said, women generally use more services than men. However, we decided to do a study to see how women were charged in the individual market. We looked at plans in two states, which had similar criteria, so we were comparing apples to apples. What we found at ages twenty-five, forty, and fifty-five was that there were gigantic differences around the county in what women versus men were actually being charged. At age twenty-five women were being charged between six and forty-five percent more; at forty, between four and forty-eight percent more. Then, at fifty-five in some instances it switched and men were actually charged more. The numbers were all over the place and totally arbitrary. Should there be a difference? Should we all be in this together because any individual is not necessarily representative of the whole group? For example, in this country we do not rate by race. No matter what your race is, no matter if one race has certain problems that would cause medical expenses to be incurred and another race does not, we do not look race in insurance. We do not say, "we are going to charge you more because you're X."

We started to wonder with this vast variation between men and women, whether we should be charging by gender in this country at all. Of course, when we show these numbers to people, they always say "well, that is because of maternity care." What I want to tell you is, no it is not, because the plans that we picked expressly did not cover maternity care. It turns out that in the individual market, maternity care is mostly not covered. Only twelve percent of plans nationwide have comprehensive maternity coverage. Nine percent have something that they call maternity coverage, but it is more like, "we will give you $2000 towards whatever your expenses are." Twenty percent offer a supplemental maternity rider, meaning you buy the plan and if you want the maternity coverage you have to pay extra. Of course, you could not get it if you were already pregnant and some of them even have waiting periods. For example, you may have to wait six months to get pregnant after you start the plan.

There are additional challenges in the individual market. I wanted to mention that there are still nine states and DC in which insurers can reject applicants because they are survivors of domestic violence. The insurance company figures that they do not want to cover a person who may be victimized again and have medical expenses. We have also been hearing that once a woman has a Caesarian section, a company may not want her because she may have another one. She may never have children again, but they still do not want to take that chance. Obviously, ratings based on age, your general health status, and any pre-existing condition poses challenges in the individual market.

The reason I bring up all of these issues in terms of the individual market is because there are a lot of health care reform proposals that build on the individual market. Both former President Bush's and Senator McCain's plan proposed giving people tax credits to buy individual health insurance. I hope that some of the evidence I just laid out for you explains why the National Women's Law Center thinks that that is not in the best interest of consumers. We believe that there should be some kind of plan where as many of us as possible are basketed together because that is the point of insurance. Rather than each of us buying an individual plan and the company deciding what they want to cover, the company goes out and purchases a group plan.

I want to end with eight questions we should consider going forward. Will everybody be covered? Will the plan provide care that is affordable? Will there be comprehensive benefits? Does the plan adopt insurance market reforms to end unfair practices? Does the plan preserve or expand the role of public health insurance, as well as the employer sponsored health plan? Will disparities be addressed? Lastly, will the plan control costs while ensuring quality? Those are very big prescriptions we need to look out for, but we can do it.

Suzanne Mintz*:

There is not a family in the country that is not going to have some level of caregiving experience in the future. That is because people are living longer. Medical science has found ways to keep people alive longer, despite the fact that they have serious conditions. The nature of our society is such that the people who need the most care now are from the World War II generation. Boomers have fewer kids than the World War II generation had boomers. There are going to be fewer people around in twenty or thirty years to provide care for another family member or friend, which obviously raises issues of how care is going to be given to persons with chronic illnesses and disabilities in the country.

That gets to some of the issues that Judy Waxman was talking about: the need to improve quality and control costs. I want to ask you one other question before I get going. Has anybody heard of the term 'coordination' and 'continuity of care'? That is an issue you are going to hear a lot about in health care reform because the lack of it is one of the major drivers of increased costs. There have been a number of programs that show that when there is continuity and coordination of care, we actually reduce costs.

It has what I call 'the passability factor,' which is something that is going to be critical in all of the discussions. If reform does not save money, it most likely is not going to happen. The question put out by the program was "Does SexX Really Matter? What a difference an X makes!" I want to give you a brief background on the National Family Caregivers' Association (NFCA). We are the leading organization of and for family caregivers in the

* Suzanne Mintz is the President and Co-founder of The National Family Caregivers Association (NFCA). She took her personal experience with her husband's diagnosis of MS and its impact on their lives, and built a national organization to improve the lives of family caregivers. The National Family Caregivers Association has empowered hundreds of thousands of individual family caregivers to take their own lives and speak on behalf of themselves and their loved ones. In addition to her work with health care professionals, public policy makers and the media, she has transformed the lens through which we view family caregiving and helped to raise it from being considered solely a personal experience, to being one of the most important health care issues of our time. She is also a member of the Board of the National Health Council, the Board of Governors of the National Patient Safety Foundation, the Advisory Board of the Partnership to Fight Chronic Disease, and the Advisory Task of the National Transition for Care Coalition.

country. We reach across the life span and individual diagnoses to address the common needs and concerns of all family caregivers. Our mission is to empower family caregivers to act on behalf of themselves and their loved ones and to remove barriers to health and well-being. That is what I call a bottom-up and a top-down approach. You have to give people information and a sense of confidence in order for them to feel that they have a role to play and that their voices will be heard. Top-down obviously deals with the issues of health reform and bringing about systemic changes to our system.

I want to give you a short primer on family caregiving today. There are more than fifty million people in the country, who provide care to a loved-one who is chronically ill or disabled. That is about twenty percent of the population. The market value of these services is $375 billion per year that is provided for free. That could never be duplicated by the system. So, family caregivers are literally underpinning all of long-term care in the country. A typical family caregiver is a forty-six year old married woman, who works while also caring for her mother, but does not live with her. There are people who give a minimum amount of help. They may just be starting out, helping Mom with the groceries or taking over paying her bills. Then there are the people, of course, who are providing around-the-clock care for someone who has multiple chronic conditions, such as a soldier who has returned from Iraq and is disabled.

Family caregiving has become a huge issue for the business community because it causes businesses to lose between seventeen and thirty-four billion dollars every year. This is calculated in terms of lost productivity. For example, people making phone calls to find out how to get services while they are at work. They come in late and leave early. Then there is something called 'presenteeism' when you are there, but you are not there. All of those factors go into businesses choosing to help their family caregiving employees because it is easier to keep them and have them be productive. Initially, companies started providing things called INR, Information and Referral Services. It was not getting a whole lot of pickup and was not changing a lot. Some large employers are offering some very innovative programs, such as paying for immediate homecare if someone's homecare aid cannot come. Companies are offering flex time and using virtual communications to help people balance their home and work life issues.

I want to talk about the unmet needs of family caregivers. There is the lack of recognition and respect from the health care community, as well as from payors, that family caregivers have much higher rates of depression, chronic illness, and premature aging. Judy Waxman talked about women having higher rates of chronic illness, depression, and other mental problems. There is a correlation here. In a study done to find out about the impacts of stress researchers looked at parents of children with special needs for their study population. Specifically the study included women who had children with Down Syndrome, Cerebral Palsy, or mental retardation. They looked at young women because if you are trying to measure premature aging, it is a lot harder for those of us who have already aged. What they have found is that there is a slowing of or lack of growth in telomeres in the tips of fingers. These have to do with the renewal of neurons and other things that keep us younger. They found that under extreme stress, family caregivers can age as many as 10 years. The study was duplicated by a researcher looking at older caregivers and caregivers of people with Alzheimer's disease. This is extraordinarily stressful because you are dealing with a combination of physical and mental stress, making caregiving harder.

Another unmet need is that family caregivers are health care workers who receive absolutely no training. We do not get any education, we do not get peer support, and we certainly do not get paid or get vacation. If you think of family caregivers as part of the work force, which the Institute of Medicine did for its study on the work force around aging society, why would you hire us? Why would you want to hire somebody who is overly emotionally involved with the patient? There are reasons that surgeons do not operate on their own family members. Again, we are not trained for this job, we just popped into it. Fifty-nine percent of family caregivers are in the workforce. They are isolated from the other people who are doing the same jobs. If you look at it from that perspective, you realize that family caregivers have a whole lot of unmet needs and by extension so does the system that is using our services.

Caregiving is expensive. Caregiving families tend to have lower incomes than average, but have much higher out-of-pocket expenses than the average population. You get people who are being squeezed at both ends of the spectrum. We get more calls at NSCA for people trying to find out if there is any financial assistance for caregiving families. Unfortunately, we have to say no. Some states have some emergency funding for caregiving, but most do not. In Medicaid, there is a program called Cash and Counseling, which allows people to be their own managers in terms of getting services. In traditional Medicaid, people are given a plan of care and it is prescribed and provided by companies or services in the community. Under Cash and Counseling, they become their own boss, so money is literally given to the Medicaid recipient and they can go out and use the money to buy the services that they think they need. It is called Cash and Counseling because there is a counselor to assist with all of this. Under that program, in certain states, people have begun to pay the family member or friend doing the caregiving from their Cash and Counseling allowance.

I talked somewhat about the costs at business and some of the programs that are coming down the pike. Pitney Bowes is always mentioned as a company that has put together a really good program. Most big companies are putting together something these days. Certainly an unmet need of family caregivers is political power. We are an invisible population and because family caregivers are all doing their jobs separately, there is no cohesiveness or self-identity. If you ask someone if they are a family caregiver, they might say no. But, if you ask them if they are caring for somebody with a chronic illness or disability, they would say yes. People recognize the tasks they do, but they do not recognize the nomenclature. They do not recognize the label of family caregiving. I think that is for several reasons. So many people think this is just what you do for a family member, which of course is true, but we have twenty-first century medicine today and the care that is being requested is totally different. More people used to die of infectious and then penicillin and other medications came along allowing people to outlive infection. Now people live longer and get things like Alzheimer's or Parkinson's. People are surprised when I mention that the average age of death in 1900 was forty-seven. Today, the average age is around seventy-seven. If a person cared for a family-member in 1900, it was always for a short duration. Now, caregiving goes on for years. It can go on for fifteen or twenty years for someone with Alzheimer's. My

husband has Multiple Sclerosis, which is a disease of young adults. He was thirty-one when he was diagnosed. He is sixty-five now; do the math. We have been dealing with some aspect of having a chronic illness for over thirty years.

It is important for family caregivers to get political power, but it is very difficult to have them come together as a large force for change. One reason is that they do not see this as a political issue. Again, it is what you do. We got a quote from one woman in a focus group some years back that I have never forgotten. She said something to the effect of, "well, it sounds like you're turning this into a political issue. It's not, it's a personal issue. You're taking all the love out of it." My response was "no, it is because we love that we want to make things better." We really do have a shot with health care reform right now, which is extremely exciting. If you cannot get a huge group of family caregivers to come to Washington, you can bring their stories, which are extremely compelling.

I want to get to the essential question: does sex matter? These days in family caregiving, the answer is not so much. It used to be a seventy-five to twenty-five split: seventy-five percent of caregivers were women, twenty-five percent male. Now it is sixty-forty. Both are likely to be primary family caregivers, meaning the main person doing everything. Both equally provide help with what are called "instrumental activities of daily living," which has to do with grocery shopping, managing medications, and driving to the doctor. More women than men provide hands-on help such as helping someone get in and out of bed, helping them shower, and helping them use the toilet. Those, of course, are the activities that create more stress, which is what creates the situation in which family caregivers are more prone to chronic illness, depression, and premature aging. More men than women do long-distance caregiving. You live here, mom and dad live in Florida. You see a lot of people dealing with long distance. They are on the phone a lot and they will go down more often than they might have before. They might try to convince Mom that she should wear some sort of a buzzer system or, in some cases, install a monitoring device so that you can know if Mom gets out of bed at the regular time. The more technology, the more opportunities there are for monitoring people from a distance. That allows people to stay in their homes longer.

Both men and women caregivers report taking time off from work, adjusting their schedules, considering a job change, and refusing jobs that require a lot of travel. Both report not being aware of the benefits that they have at work. Even though companies are putting benefits in place, a lot of people are not taking advantage of them. More women talk about caregiving when they are at work. Men tend to keep quiet. There is always fear at work whether I should tell my boss.

Picking up on health care reform, there are opportunities for change. America has what we call an acute care system. If you are in a car accident, you're taken to the E.R. The people we are dealing with that cost Medicare, Medicaid, and private insurers the most money are those with chronic conditions. Changing the system to provide better chronic illness care that is coordinated and continuous across settings holds a great deal of promise for improving quality, lowering costs to the systems, and taking stress off family caregivers and their loved ones. I think it is essential that we support the critical role of family caregivers by providing some education, training, support, and, for those who need it, financial assistance. Those are small things compared to everything that family caregivers do. It will minimize errors and save enormous amounts of money. That is where NFCA is focusing its energies in terms of health care reform. There are many opportunities for students when you get out in the world in terms of being a lawyer dealing with health care. You can work for companies that provide health insurance. You can work in the field of tort reform, in terms of minimizing the number of suits and getting fairer equity in the system. People who have been affected by a medical error want more than anything else to make sure that nobody else is affected in the same way. They want financial equity. If someone's husband has died and he was the main breadwinner, there are certainly costs. If a child has become disabled because of a medical error, there are costs involved. You can always work on the Hill and focus on health care issues there. There are millions of opportunities for you. I hope that you will consider health care law as a really good opportunity for you down the road.

Women's Health is a Human Right

*Maureen McTeer**

It seems fitting that in this International Women's Week, when we mark women's achievements in all areas, that we should meet here at the Washington College of Law to speak of women's health and the legal and other challenges that still face women seeking care. We have a lot for which to thank the two founders of this law school. Ellen Spencer Mussey and Emma Gillett were not planning to make history when they began teaching three female students in their law offices in February, 1896.

They were realists and pragmatists, acutely aware that only they could ensure women had access to a legal education. They knew that if they did not act women would continue to be denied a chance to learn the law and to practice it as did men in their city and country.

Two years later, as their class prepared to enter their third and final year of legal studies, these two women again lead the way when another law school in the city refused to enrol their female students. Undaunted, they founded their own law school, whose letters of incorporation made it clear that this law school would be a place where women could learn the law as equals with men.

Two hundred and eleven years ago, the Washington College of Law made history, as the first of its kind to be founded by and for women, led by a woman Dean and celebrating the first and only all women graduating law class in America.

Thanks to their bold action, women in the U.S. and beyond enjoy the right to legal education and now form the majority of most graduating classes in law in North America.

In my country, four of the nine Justices of the Supreme Court of Canada,[1] including the Chief Justice, the Rt. Hon. Beverley McLachlin, are women. It is a legacy of which you must be truly proud as we meet at the WCL today as part of this year's health law symposium.

As a lawyer, a feminist, and a women's rights advocate, I am pleased indeed to be here with you today, as part of the Founders Day celebrations, to speak to the topic of women's health as a human right.

The whole concept of women's rights and equality with men is a fairly recent phenomenon –beginning in earnest only after the Second World War. Of note, this post War era also marked the beginning of the most active phase of the modern women's movement.[2]

Since then, a tremendous amount has been achieved for women and there has been a sea-change in how women and girls are treated in most of the developed world.

One area where progress has been slow, however, is that of access to health care by women and girls – especially in the developing world.[3]

Historically, your country and mine have played a leading role internationally to enhance the status of women. Our efforts have been both reactive and pro-active; and our goals have been to end discrimination against women generally and to set new standards and definitions that ensure legal equality for women and girls, and guarantee them the power to exercise those rights through access to education and especially to health care and women's health services.

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Seventy years ago, on Dec. 10, 1948, with Nazi atrocities barely ended, The Universal Declaration of Human Rights[4] (UDHR) established *fundamental* human rights for all. It promised respect for the dignity and worth of the human person, and most important for our purposes today, it committed us to the guarantee of equal rights to both women and men.

The thrust of this and subsequent international human rights treaties was to entitle women to precisely the *same* protection as men. But as time progressed, it became clear that the *"sameness principle"* (as this treatment came to be called) was insufficient to ensure women would be treated as equals with men.

Fundamentally, the sameness principle ignores women's biology and reproductive realities; and ignores discrimination against women due to religious and cultural biases throughout the world.

To quote Pierre Sané, the Secretary General of Amnesty International, in 1998, "International human rights law has been guilty of 'gender-blindness…. For too long it focused on the 'public' arena largely populated by men and neglected the so-called 'private' sphere of home, family, and community in which women are traditionally enclosed."[5]

And so the women's movement in the 1960s and early 1970s began to lobby to move us beyond the sameness principle, urging world leaders to recognize the fact that women live their lives with different and additional responsibilities and demands than men do, and that the clustering of their lives in the private or domestic sphere of society left many vulnerable, indeed powerless, to control their own destiny or participate fully in its realization. Betty Friedan, years before, had spoken of this exclusion and the despair and desperation it engendered in women.

But it took until the 1980s, for the world to act at which time the United Nations took up the rallying cry for change for women and became the major catalyst for change. Its various agencies urged governments around the world to guarantee equity, equality, justice and fairness for women.

Perhaps because of their additional responsibilities as mothers and nurturers, the global UN context for action originally focussed on women's sexual and reproductive rights.[6]

Between 1975 and 1995, the U.N. sponsored several international women's conferences, building upon the change begun in affluent countries to revive the women's movement in the 1960s and 1970s.

In 1975, at the Mexico City conference, *The United Nations Convention on the Elimination of All Forms of Discrimination Against Women* [7](CEDAW) was passed. This international human rights treaty would seek to improve women's status by focussing on women's rights within the historical UN agreements already in place.

Twenty years later, the Cairo conference on Population and Development[8] called on governments to raise the standards of living and quality of life for women.

For the first time, it was officially recognized that women's equality, education and health were crucial to development and that indeed without them, international development as a goal would be unattainable.

Governments came to realize that investing in women and girls was essential to their country's future success and prosperity, and reproductive health was firmly established within the context of human rights, with women's empowerment now the key to the protection of those rights.

The Cairo commitment paved the way for national governments to tackle long-standing reproductive health problems; and to create a legal and social culture globally that would ensure reproductive health and rights for women and girls.

The Cairo meeting was followed closely by the Beijing conference in 1995. This Fourth World Conference on Women adopted the *Beijing Platform for Action*[9] which remains the internationally agreed upon template for advancing women's status today.

The Platform reconfirmed that women's human rights included their right to decide on matters concerning their sexuality "including sexual & reproductive health, free of coercion, discrimination & violence…." It further stated that women's second class status contributed to their ill health in areas of reproduction and sexual health.

By the 1990s, then, women's reproductive health and the many factors which determine it throughout their life cycle – referred to as the "social determinants of health" were defined and monitored through the lens of human rights.

Yet despite all this effort, women's health and the systemic changes needed to ensure our full equality with men lagged behind.

In 2000, unhappy with progress towards achieving the goals of these major international women's conferences, then U.N. Secretary-General, Kofi Annan pushed for the passage of the Millennium Development Goals (MDGs)[10]. Ironically, none mentioned sexual and reproductive health as a specific goal.

But at the World Summit in 2005, the UN explicitly reaffirmed that universal access to reproductive health is critical to achieving the MDGs.[11]

The Millennium Project Report[12] that year called for bold action on women's health and rights – especially sexual and reproductive rights - insisting that one of the seventeen "Quick Win Solutions" was the expansion of access to sexual and reproductive health information and services worldwide.

This despite the "gag-rule" in place under the previous American Administration, which had such a profound effect on women's lives in the developing countries of the world. Still, little has changed since 2005.

To quote the 2008 U.N. Millennium Development Goals Report

> Maternal mortality remains unacceptably high across much of the developing world. In 2005, more than 500,000 women died during pregnancy, childbirth or in the six weeks after delivery. Ninety-nine per cent of these deaths occurred in the developing regions, with sub-Saharan Africa and Southern Asia accounting for 86 per cent of them. In sub-Saharan Africa, a woman's risk of dying from treatable or preventable complications of pregnancy and childbirth over the course of her lifetime is 1 in 22, compared to 1 in 7,300 in the developed regions. [13]

So where are we in terms of women's health and access to care today? Will we meet the MDG targets by 2015? According to the 2008 U.N.'s

Millennium Development Goals Report, greater effort is required. A bit of an understatement given the enormity of the challenge we face.

No one has described more accurately the challenge that lies ahead for all of us than SHA ZUKANG, the U.N.Under-Secretary-General for Economic and Social Affairs, who said:

> Ensuring gender equality and empowering women in all respects – desirable objectives in themselves – are required to combat poverty, hunger and disease and to ensure sustainable development. The limited progress in empowering women and achieving gender equality is a pervasive shortcoming that extends beyond the goal itself. Relative neglect of, and de facto bias against, women and girls continues to prevail in most countries. As an indispensable starting point for women's betterment in later life, all [113] countries that failed to achieve gender parity in primary and secondary enrolment by the target year of 2005 should make a renewed effort to do so as soon as possible. Improved support for women's self-employment, and rights to land and other assets, are key to countries' economic development. Above all, however, achieving gender equality requires that women have an equal role with men in decision-making at all levels, from the home to the pinnacles of economic and political power.[14]

And so what can we do to help?

You and I are fortunate women, blessed with both affluence and influence. We live in the Capitals of two of the world's great countries. We are educated. We are free. We have food. We have medicines. We have health care options second to none.

Most of us share the view that we achieve more by working together than we can ever achieve on our own. This concept of community is at the heart of the women's health movement. But the stark reality is that our good fortune is not shared by most of the women in the world.

Today, in our world, almost half a million women die each year from the preventable complications of pregnancy and birth. Half a million women, year in and year out whose potential and contributions are lost to the world forever. Almost all of these women live in poor and developing countries, the vast majority in Africa and Asia, where other diseases, especially HIV/AIDS increasingly have a woman's face.

Responding to such tragic statistics of loss of women's lives is not simply a question of extending health care. It is more basic. It requires us to reconfirm that women's health is a human right, not a special interest, and to recognize that women's health and wellbeing are affected by a wide range of factors – the so-called "social determinants of health". That is a deliberate health policy choice that our governments must make.

For we know that when women are poor their health suffers. When women eat little and eat last, their health and therefore their families' suffer. When women die in childbirth, die from easily preventable causes, their babies die too; and then too often, another woman, usually no more than a child herself, takes her mother's place – and continues the cycle of women trapped in illiteracy and poverty and often abuse, with no real hope of ever breaking free.

We have to help change that reality, break those cycles of poverty, build new hope and opportunity for women. That is the challenge that awaits us – you and me – lucky women who are truly committed to ensuring that women's health is indeed a human right.

Female Participant:

I previously worked on a study of gender parity systems within Sub-Saharan Africa and found that, regardless of the number of women that were participating in the legislative systems, there was a disproportionately small amount of pro-women's rights legislation actually passing through. This would suggest that it really is up to the developed world to push for these rights. What is your best suggestion for advancing that cause?

It is a little bit more difficult to do by giving the money to governments who are not pushing through the amount of legislation necessary. Is it necessary to put more money into private organizations and look toward development ventures that will promote women's health issues, especially now that there's been a change in the administration?

Maureen Mcteer:

My background is politics. My husband was a Foreign Minister, so we had an opportunity to travel the world extensively, including in Africa, and remain very involved in Africa. It is against that backdrop that I answer your question. I am not pretending to be an expert, but offer my personal view, limiting myself to Africa, because that was your focus.

There are several elements to aid and health, and the first is attitudinal. We should try not to always be the 'expert' arriving with all the answers. We have to recognize that most of the solutions have to be home-grown in order to really be effective. Indeed, the Non-Governmental Organizations (NGOs) had a tremendous role in convincing governments that this was the way to proceed. We hope to "train the trainers". It is within our tradition of aid in Canada. Sooner or later the trainers will go home. The women in Africa are very dynamic and involved in their communities. They are its natural leaders and have achieved change against the backdrop of their daily lives and cultures. For instance, there was a tribal law that prevented women from holding land. The world responded with what seemed at the time a very small step, by starting a system of micro-credit. Groups and governments began to provide small loans, usually no more than $100 each, directly to women who had no other access to credit. It became such a wonderful success story and all but .01% of these loans were repaid.

I mentioned previously the need for a solid public system of health care. If you live in a society where you have to pay to deliver your baby in a hospital or clinic with a qualified midwife, nurse, or doctor, then you will likely have to pay for all types of care. Further, pregnant women who are buried in their own village with no money, whose husbands decide whether to pay for a doctor or midwife, have a diminished chance of getting care at delivery. Serious labor troubles require obstetric care, such as a caesarian or some kind of intervention, which a birthing attendant cannot provide. First, the doctor and surgery are going to cost money. Second, there is likely no transportation to the clinic or hospital. Finally, if you die in the clinic, your husband and family must pay to transport you home for burial. For these reasons, women often reason it is better to deliver at home. Most women (53%) give birth without any professional help. These elements have to be

dealt with at the grassroots level. On the other hand, you have to work at the government level to look at the policy issues, as we are doing through White Ribbon Alliance. The two working hand-in-hand are absolutely essential. If we cannot succeed the way we are trying now, so fewer women die each year from preventable causes, then we will try to achieve it some other way.

Female Participant:

I would like to comment about the preventable causes of death in childbirth. One hundred and twenty to 150 years ago, the gender of the child who was born was not recorded, just whether the mother survived. We did not even pay attention to whether the baby survived. The preventable causes of death in childbirth are infection and hemorrhage, which are treatable in the United States and Canada. The number one health intervention is, singularly, and by far the education of women. Educated women educate their children, boys and girls, and it is the sons who will change things. The key issue is providing education to women by financing small community schools. As long as women's education is prohibited by social, cultural, and religious rules, we are not going to start saving their lives.

Maureen Mcteer:

Primary education for women and girls is so important that it is one of the Millennium Development Goals. A tension exists in achieving the eight Millennium Development Goals. The money goes to whichever goal has the largest voice. As an example, in September 2008, hundreds of women went to New York City as part of the White Ribbon Alliance for Safe Motherhood. We had a commitment that MDG #5 would be highlighted by world leaders at the U.N. General Assembly. Yet, despite solid commitments, both the photo ops and the money went to the Bill Clinton Foundation for AIDS. While it is true that that AIDS in Africa has a woman's face now, the focus was not on women and AIDS, maternal health, or saving women's lives. We have to be careful not to play one Millennium Development Goal against the other. Without education none of the other goals are going to fall into place.

1 http:///www.scc-csc.gc.ca.
2 For an historical perspective, see *inter alia,* Women's Rights, Human Rights: International Feminist Perspectives, Julie Peters and Andrea Wolper, eds. Routledge, New York, 1995; in particular Chapter 2, "Women's Human Rights: The Emergence of a Movement" by Elisabeth Friedman, 18-35; and Chapter 3, "Women's Rights and the United Nations" by Elissavet Stamatopoulou, 36-50.
3 The State of the World's Children: Maternal and Newborn Health, UNICEF Report 2009, available at http://www.unicef.org/sowc09.
4 http://www.un.org/en/document/udhr.
5 http://www.amnesty.org.
6 See chapter 25 of the book edited by Peters and Wolper – "International Human Rights and Women's Reproductive Health" by Rebecca J. Cook, 256-278.
7 For further information, see http://www.un.org/womenatch/daw/cedaw/history.htm.
8 For further information, see inter alia the following website – http://www.iisd.ca/Cairo.html.
9 For further information, see inter alia, http://www.un.org/womenwatch/daw/beijing.
10 http://www.un.org/millenniumgoals.
11 This was achieved by expanding Millennium Development Goal #3 on gender equality from its original focus on primary education to include the five following commitments, namely an end to impunity for violence against women; the goal of universal access to reproductive health; the right to own and inherit property; equal access to labor protections; and increased representation of women in government decision-making bodies. For further information, see inter alia http://www.un.org/summit2005.
12 See http://www.unmillenniumproject.org/who/index.htm.
13 http://www.un.org/millenniumgoals/2008 at p. 24.
14 Ibid. p. 5.

The R_{XX} Factor: Different on the Outside. Different on the Inside? Rethinking the Medical Model and Clinical Trials

Kathleen Uhl*:

I have been asked to talk today about the Food and Drug Administration (FDA) and the issue of women in clinical drug studies, including the impact of having women in those studies. I will give you a perspective from the FDA and go over some of the regulations that govern women in clinical studies. I will end with some food for thought as to what it might mean, from a broader perspective, to include women in clinical trials.

First of all I just want to tell you what the FDA is. I give numerous presentations at medical organizations where there are a lot of physicians, pharmacists, nurses, et cetera, many of whom think they know what the FDA is. Yet I often find that they are not exactly sure what the FDA does. The FDA is a regulatory agency first and foremost. We are not a research agency like NIH, and so our mission and what is written in law is very different from other agencies in the federal government. We are the oldest consumer protection agency and we have oversight over a trillion dollars worth of commerce. On a daily basis that means about a quarter of every dollar you spend is something that the FDA is responsible for regulating. Basically, the FDA receives and reviews research information from companies who want to manufacture products. We oversee pharmaceuticals, whether they are prescription or over-the-counter; medical devices, whether it be a tongue depressor or an implantable defibrillator – the full spectrum. We regulate vaccines and blood products. We regulate food. Most of the food in this country is regulated by FDA, but not all. There are numerous agencies involved with regulating food, but to make it easy: we do not regulate meat. We regulate cosmetics. We regulate personal care products. We regulate veterinary products. Lastly, we do inspections, inspections at ports. You have heard a lot about those recently, especially with the recent peanut butter incident and salmonella in tomatoes and cilantro. Those inspections at ports and inspections of research facilities are conducted by the FDA should those facilities want to submit information for approval.

Why is it important that we are even talking about women in clinical studies? What does it matter? According to the Institute of Medicine, nine drugs were withdrawn from the market for safety reasons over a four year period. Many of these drugs had greater health risks in women and the top four of them had health risks specifically in women. In several other products, there were health risks in both men and women. However, in these specific incidences, it is just women who were harmed by the use of the products.

For example, there was a particular drug called Tedasmil that was taken to an advisory committee. These are large public meetings with experts brought in to hold a public discussion of the data. Tedasmil is basically used for what is called atrial fibrillation or atrial flutter. It is a rapid heart rate condition. There were similarities in how both men's and women's bodies handled this drug and the drug worked equally well in both sexes. The problem was that there were twice as many female deaths in these clinical studies. The question was then taken to the advisory committee. The committee was asked what it should do given that the drug worked for what it was intended to be approved for, but there were questions as to whether it should be allowed onto the market. The company proposed specific dosing that would be different for men and women, but the advisory committee members unanimously said, "no, do not approve this product." As a result, the product has not been approved by the agency. This was a huge blow to the company because it takes hundreds of millions of dollars to develop a product and the fact that there are differences between men and women has substantial economic implications.

In 1977 there was a regulation that the FDA put forward that actually excluded women from clinical studies and specifically excluded women of childbearing

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potential from early-phase clinical studies. The problem with that was it was overly-interpreted to mean women should be excluded from clinical studies and that all phases of drug development should exclude women. There are multiple phases of drug development. Although this is not the purpose of this talk, it suffices to say that some of the earliest studies are very small – ten, fifteen study participants – and what they basically do is slowly increase the dose to see if there are any adverse effects. They are not meant to show whether the drug works. That is the step where women were supposed to be excluded; not the large, multi-phase-, multi-center-, multi-country-, 4,000-participant studies. Excluding women right off the top actually violates some ethical principles. It violates the principle of autonomy and quashes the ability of a woman to make her own decision as to whether she wants to assume the risks and the benefits of participating in such a clinical study. Advocacy groups lobbied hard to have the regulation changed because it denied women access to some important and innovative therapies.

What followed in the seventies and the eighties was the HIV epidemic and the exclusion of much-needed, yet experimental, products for not just a life-threatening, but also a lethal medical problem. This issued forced a change in these regulations. In addition, advances in cancers and cancer therapeutics were also a large reason for advocacy groups to lobby to have the regulation changed. In 1993, this particular regulation was changed, but only via a guideline, which is much lower down the threshold of, "is this something that has to be done?" versus a more voluntary rule. Evidently the guideline did reverse the policy and required pharmaceutical companies to collect information about the participants in their studies. Companies were also required to analyze the data to look at effectiveness, whether there were particular adverse consequences, and pharmacokinetics, which basically gets to the bottom line of dosing.

In the early nineties, the thought was that if we were concerned about exposure to women of childbearing potential – and, hence, the developing fetus – that that concern could be taken care of with the use of appropriate language in the research protocol. Subsequently, the agency enacted a regulation in 1998 requiring companies to report in a submission with the data broken down by age, sex, and race. It does not necessarily say they have to analyze the studies based on those factors, but that the participants are spanning the spectrum of the demographics of the population. Another regulation that the agency has is the clinical hold rule. This regulation allows the FDA to stop a study if people are excluded from participation based upon their reproductive capabilities. It is not permissible to exclude women of childbearing potential or men because they could potentially impregnate a woman and the clinical study could be put on hold as a result of such exclusions.

There certainly are challenges to studying women. For one, women are harder to study. Women ask questions and do not just take things at face value. There are facilities that do clinical studies for the industry who do not want to include women because it takes too long to enroll them in studies because they ask so many questions. Women are less homogenous, meaning they are more difficult to analyze. If the argument is that we want to have women in the clinical studies, we need to understand whether we are talking about females in general or boys versus girls. There may not be that much different between a seven-year-old female and a seven-year-old male. In contrast, there is a huge difference between a 12 year-old female and a 12 year-old male. For example, whether females are within their reproductive potential or where they are in their monthly cycle are both dramatic physiologic changes that can impact a woman's response to a medication or contribute to the adverse effects she may experience. Pregnancy is a whole other matter. Further, there is the issue of whether someone is perimenopausal or postmenopausal. If you look at this as a continuum, it is not enough to just say 'women' in clinical studies.

Women are also expensive. The argument around expense is that you may have to drive up your sample size and enroll more people if you are forced to enroll a specific number of women. There is also the whole issue around hormones. Women will continue to menstruate, get pregnant, and become menopausal. These factors influence the conduct of clinical studies. Another challenge is the fear of liability. This is what drove the 1977 exclusion of women, specifically the birth defects associated with thalidomide. This is the most apparent teratogenic compound that exists. The fear of birth defects with pharmacologic agents is real and was the basis for exclusion for a long time. There were also key cases around DES and the Dalkon Shield that forced companies to be extremely cautious when enrolling women in subsequent studies.

Why are women not in clinical studies? To exclude women intentionally is not permissible, but women are often not recruited. Then there is the aspect of the large volumes of data. Despite the IT-friendly society that we live in and the advances in our health information infrastructure, we are still in the dark ages when it comes to data standards. By this I mean one data set, one clinical study, cannot necessarily be pooled with another clinical study because of how certain data is reported. I will give you one very simple example. The easiest example of a data point is what sex a person is. In a clinical study, what we want to see is every female and every male categorized the exact same way with the exact same nomenclature. So for a male, it always says, "M" and for a female it always says, "F" and for unknown or not registered it says, "U." That is not the way studies are conducted. Any symbol can be used. Since you cannot pool information across studies, it is hard to even know the extent of women's participation in studies.

Katie O'Callaghan*:

Like Kathleen, I am from FDA. She is from the Center for Drug Evaluation & Research (CDER); I am from the Center for Devices & Radiological Health (CDRH). My remarks today do not necessarily reflect the official views of the FDA. Today you have heard about some of the regulatory background, the difference between the guidelines, and what we have statutory authority as an agency to do. Why is there still a problem with the most recent regulation? Why are we still not getting enough information on women? I am going to talk about the problem, some solutions that are

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being discussed, and identify the key players in the game that need to work together to change the paradigm.

I really like the session title that we were assigned – *Different on the Outside. Different on the Inside?* It would seem you would assume that there are differences rather than assume that there are not. From a scientific perspective, that affects how you design your studies, how you design your devices, and even how you treat patients. If you come in with the assumption that there are differences, you are going to treat women differently than men as opposed to treating all patients the same. A lot of the medical field does not take this approach, especially with cardiovascular disease. Here are some general examples – not necessarily cardiovascular-specific – that clearly show there is something different on the inside because there are differences in disease. For osteoporosis, depression, or auto-immune diseases, there are differences in how things that we do affect our body and how that interplays with the development of disease; like the impact of smoking on health.

More women develop and die from heart disease than men. This is relatively new knowledge in the science and medical fields. Let us start with some observations. Look at what we know about the outcomes of heart disease: more women die of it, women are more likely to die from a heart attack, more women are likely to die from heart failure and after having a heart attack, more women are likely to have another heart attack. Even when women are treated, there may be differences in how well the treatment works in terms of effectiveness or the types of side effects or adverse events. Why is this? Specialists say it is because the difference with female patients is that they are older when they develop heart disease and they have more co-morbidities like diabetes or obesity. Why are women being diagnosed so late? Let us take a look at access. Some relatively recent studies have uncovered disparities in health care delivery for men and women with heart disease. Women are less likely to get an EKG, which is a standard diagnostic test for heart disease. Other diagnostic tests are often less accurate in detecting heart disease in women. Women are less likely to be referred to a heart disease specialist. When women do get treatment, they are less likely to get the right treatment, such as clot-busting drugs or catheterization procedures.

Why are women not getting the right treatment? As it turns out, we are still in the learning phases, from a scientific perspective, when it comes to the biology. There is a lot being uncovered, but we are still learning about the ways in which women and men are different, biologically speaking, in diseases that affect both. For things like breast cancer or pregnancy-related complications we have a relatively good understanding about how women and men are different. But for things like heart disease, we have just been treating males and females the same when, in fact, there may be male-typical heart disease with some variation and female-typical heart disease with some variation.

What about solutions? Let us start with educating women; patient awareness. The red dress campaign is one example. There is also the 'Go Red for Women' campaign. There is a lot of overlap and collaboration between the medical professional societies, NIH, patient advocacy groups, and there is outreach to female patients who have heart disease. Slowly but surely there has been a measurable increase in how much the public knows about heart disease in women.

As a result of education programs, more female patients know they are at risk for heart disease. What about the referral bias and the delivery disparity issues that we were talking about earlier? We do need to educate providers, but if there is a referral bias issue we cannot just talk to the cardiologists; we have got to go a step back. We need to talk to the primary care doctors, the ER doctors, or the OB/GYNs which, for many women, is their primary care physician. We need to go to the medical schools. The Association of American Medical Colleges has actually been looking at integrating more gender-specific teaching into their curriculum. A medical professional society has put out practice guidelines and there have been a few that have come out for treating and diagnosing women with heart disease.

The next issue is what to put in those guidelines. How should we be diagnosing and treating women with heart disease? We need to talk about research. What do we know about the biological reasons for sex differences, both in the healthy female versus the healthy male and then in men and women with heart disease, and then how they respond to the treatment? We need to analyze the trial data that we have in the drug, device, and treatment trials and look for and report any differences. When we try to do that, the statisticians say, "there are not enough women." The signals are still within the margin of error. We need to get more women involved. How do we do that? Patient awareness. At that point we have completed the circle. I am trying to paint a picture of how there are many components of this system that are all operating under the current paradigm. The regulation and policy issue is one aspect of it, but really it is going to require all of these pieces coming together. Who is responsible? In my opinion, all of the above: patients, primary care and specialist medical providers, the research industry who are designing the medical devices and drugs, the FDA, NIH, and the payors.

Our panel is also talking about rethinking medical models and clinical trials. The FDA is trying to change the paradigm by putting out a guideline for trials and marketing applications for medical devices. We are talking with the industry about enrollment targets to include more women in trials, evaluating data to identify what information should be released to the public and what necessitates further study, identifying barriers to women enrolling in studies, assessing at what point in the study are they dropping out, figuring out ways to minimize that, and studying other systematic changes. We need more data about sex-based differences and this will come about with an FDA-industry partnership, through the NIH's work with academia to conduct studies, incentives from CMS and the other insurance providers, and practice guidelines from medical professional societies.

Rebecca Wolf*:

I will be discussing a two-part article about personalized medicine which I co-authored with Professor Corrine Parver, several other WCL students,

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and health law practitioners. I will be touching on a few of the pertinent health law issues addressed in these publications. I will be explaining the new technology of pharmacogenomics (juxtaposed against traditional model of one-size-fits-all medicine) which was made possible, in part, by the Human Genome Project that was completed in 2003. I will be discussing the benefits and concerns associated with personalized medicine, namely the exacerbation of gender inequities in clinical trials and concerns about genetic-based discrimination. In that vein, I will be describing some of the legal provisions which can protect individuals from genetic discrimination. Finally, I will conclude that pharmacogenomics is a promising new field of medical research which has the potential to revolutionize the field of medicine. However, it is important to consider and address gender inequities and clinical trials. In addition, potential genetic discrimination means that there is a need for scrupulous legal protection.

One-size-fits-all medicine is when the general population receives essentially the same treatment for a particular disease. The only tailoring that occurs is for adults, children, and the elderly. One-size-fits-all medicine does not provide additional information about how an individual patient will react to a particular type of treatment or what type of dosage would be beneficial given that patient's rate of drug metabolism. Two benefits of one-size-fits-all medicine are as follows: first, one-size-fits-all medicine is less costly in the short term than tailoring treatments for each individual patient; second, standardized treatment simplifies interventions.

However, there are many concerns associated with one-size-fits-all medicine. First, individual differences and drug metabolism can result in ineffective treatment or a drug overdose, in some patients. Second, ignoring genetic differences can result in serious side effects. In fact, only one-third of all drugs act as expected when prescribed. For instance, in the treatment of asthma, the same drug can provide relief for one patient and have serious side effects for another. In a heterogeneous population, such as in the United States, there will be less predictability of reaction to treatment due to a diverse gene pool.

Pharmacogenomics, or personalized medicine, is an alternative to one-size-fits-all medicine. It was made possible, in part, by the Human Genome Project. The Human Genome Project was an effort to decode the sequence of DNA and map the entire human genome. The Human Genome Project may ultimately give medical providers information about an individual's predisposition to developing a particular disease or the way in which an individual will react to a certain type of medical treatment. Personalized medicine is the marriage of genomic technologies and pharmaceuticals. The primary purpose of personalized medicine is to individualize medical treatment for each patient's DNA.

Unlike one-size-fits-all medicine, personalized medicine is much more likely to be beneficial and safe for a particular patient because a physician prescribes a particular drug and dosage based upon the individual's genotype. There are several benefits of personalized medicine. First, there is a potential for more effective treatments for each individual. Second, physicians may intervene at an earlier stage of a disease or even before a disease manifests based upon knowledge of a patient's predispositions. Third, personalized medicine may help researchers identify disease targets, speed clinical trials, and advance treatments for specific populations. However, as with any new technology, there are also associated concerns. Two concerns that I will be discussing are that personalized medicine could exacerbate gender inequities in medicine and that individuals will experience discrimination based upon their genetic information.

There is a historical lack of inclusion of women in medical research. Until the late 1980s, women were excluded from participating in clinical trials through explicit policies, practices, and severe neglect. In 1993, the NIH Revitalization Act required the inclusion of women in clinical studies, as well as the analysis of research results by gender. Now, more than fifteen years later, despite the NIH Revitalization Act, women remain excluded from clinical trials. As you can imagine, if women are excluded from clinical trials related to personalized medicine, then there will be a paucity of information about how to treat women on an individual basis.

In addition to exacerbating gender inequities, there is a concern that individuals will experience discrimination based upon their genetic information. Genetic discrimination occurs when people are treated unfairly because of differences in their DNA that increase their chances of getting a certain disease. For example, a health insurer might refuse to give coverage to a woman who has a genetic predisposition for breast cancer. Employers also could use DNA information to decide whether to hire or fire workers. This is particularly troubling in the current economic climate in which companies are trying to save money. To employers, it might be more cost-effective to employ someone who is not predisposed to a costly disease.

There are several existing legal protections against genetic discrimination. Title VII of the Civil Rights Act of 1964 prohibits all private employers with fifteen or more workers; labor organizations; employment agencies and federal, state and municipal government employers from discrimination on the basis of race, color, religion, sex or national origin. The statute does not specifically address discrimination based upon genetic information but Title VII may protect against discrimination on the basis of an individual's genetic makeup if that discrimination disproportionately impacts individuals belonging to a protected class. The Americans with Disabilities Act (ADA) prohibits discrimination in employment, public services, public accommodations and communication against individuals with disabilities. In March 1995, the Equal Employment Opportunities Commission issued an interpretation of the ADA that states: "[e]ntities that discriminate on the basis of genetic predisposition are regarding the individuals as having impairments and such individuals are covered by the ADA." However, because interpretation has not yet been tested in the legal arena, it remains an interpretative policy guideline.

The Health Insurance Portability and Accountability Act, or HIPAA, ensures that individuals who change health coverage are not denied or restricted in employment-related coverage on the basis of a preexisting condition. HIPAA was the first federal law to address the use of genetic information in the health insurance context. It prohibits group health plans and group health insurers from excluded individuals from coverage on the basis of genetic information unless there is an actual diagnosis of the condition related to the genetic information. In 2000, President Clinton signed an executive order prohibiting every federal department and agency from using genetic information in any hiring or promotion action.

Finally, and most recently, the Genetic Information Nondiscrimination Act (GINA) of 2008 prohibits the improper use of genetic information in

health insurance and employment. The Act prohibits group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to developing a disease in the future. It also bars employers from using individuals' genetic information when making hiring, firing, and job placement or promotion decisions.

In conclusion, pharmacogenomics is a promising new field of research which has the potential to revolutionize medicine as we know it. However, it is important to consider and address gender inequities in clinical trials. In addition, potential discrimination based upon genetic information means that there is a need for scrupulous legal protections.

Audience Question:

Is there anything happening now to address the refusal to include women in clinical trials? Will it be just the same kind of situation but with a new dynamic with pharmacogenomics or, in fact, will we resolve it? There seems to be a real opportunity for personalized medicine to exclude half of the country. Is something being done?

Kathleen Uhl:

It is interesting that you bring that question up because there are certainly genomic databases that exist and it is not that surprising that some of the data does not include information about sex. A large database of information on multiple patients with no information on their sex is not going to answer any of the questions that you have raised. It comes back to the issue of data standards. What are the standards that need to be collected for every patient, not just in research but at every clinical encounter? How do we develop a systematized manner of collecting health information so that a patient's sex is collected every time? That question is actually addressed through the health IT aspect of the stimulus package. Health IT is important, not just for the patients' electronic medical record with his or her practitioner, but also the accessibility of that record. Someone entering medical data in Washington, D.C. or Portland, Oregon will complete all the same fields for every encounter. That is still in the works. There are certainly systems that use electronic health records but yet there is no universal electronic health record.

Katie O'Callaghan:

Health IT has been getting a lot of attention as part of an overall health reform. It has potential to be part of the solution, because when everything is electronic, it may be easier to standardize data or at least access data. Often, for the data we receive at the agency level, it would be really burdensome to go back to the actual patient-level data and determine whether the patient was male or female. With electronic records it becomes much more accessible. There's also a Heart Act for Women which passed last year in the House and did not make it through the Senate, but is being reintroduced. The Agency for Healthcare Research and Quality, which creates disparities reports, would be charged with doing women-specific reports by utilizing information from various databases, nationwide information resources, and certainly anything that would become available via a health IT initiative.

Kathleen Uhl:

I want to comment about the use of the terminology 'excluded' versus 'not included', because they mean two different things. Women can be intentionally excluded from participation in studies, like they were in the 1970s. They were not allowed to participate in studies: totally excluded. In today's situation, and using cardiovascular health as an example, women are not included in the studies to the same extent that men are. They certainly are included. There are some great meta-analyses in medical literature that assess women's participation in large, multicenter cardiovascular studies and for drugs and devices. Women represent twenty to thirty percent of participants. Women are not expressly excluded but if the enrollment criteria states that participants must be under age sixty five, fewer women will be included, because they tend to develop heart disease at an older age than men.

It is a subtlety to say that, but there are people who would take exception to anyone saying women are excluded from studies because there is policy, regulation, and law that prohibits the exclusion of women from studies.

Katie O'Callaghan:

The other piece, as far as the genomics and personalized medicine go, is that there have been an increasing number of reports from the basic science research field finding that the receptor associated with this marker for heart disease is much more prevalent in women than in men. I think the more we start to learn about the genetic predisposition to disease, the more that may come into play.

Audience Question:

Last February, the Supreme Court ruled on a case that gave a huge amount of deferential authority to the FDA. Specifically, if something is reviewed and approved by the FDA then, even if it is defective and hurts somebody, they cannot bring a lawsuit. Now, I just wanted to know what your opinion of that is because what happens if there is another *Dalkon Shield* or DES case? Somebody who is injured by that cannot bring a lawsuit. I want to know what their remedy is. They cannot go to the court, they cannot get any relief or remedy for that or prevent this from happening again, and I wanted to know what your opinions were on that decision.

Katie O'Callaghan:

I do not know all the legal specifics of the court case from reading the news reports. I believe that the decision, in regards to preemption, is about not suing the company if the device or drug was used exactly as the label was written by the FDA for the approved use in patients. The issue with FDA trials and off-label marketing or usage of treatment is that the studies that FDA receives, reviews, and evaluates the treatment on are very specific and, oftentimes physicians use them in areas that are not studied. In those cases, I do not think that preemption would rule out medical malpractice suits. So if you are harmed as a result of off-label usage of a device, drug, or a biologic by your physician, medical malpractice is still not ruled out by preemption.

Moderator:

Dr. Uhl, you talked about the differences among women and how that creates a difficulty in women being part of clinical trials. I was wondering if you had any thoughts about how to address those differences to make it possible for women to be part of those clinical trials in a real, concrete way.

Kathleen Uhl:

Well, the reason I discussed that was two-fold: one, to let people see some of the barriers and two, to emphasize the heterogeneity of the female population. That is more the food-for-thought part of the talk. It is what we need to think about it if the game plan is to increase participation of women in studies and specifically, find out how applicable the data is to the entire female population? So, if we are just studying women who are under forty-five in a particular area, but there are women in their seventies or eighties that will be taking or using this same medical product, how applicable is that data? I do not have the answer to that, but I think that the way to answer those questions is probably not in the context of pharmaceutical or device-sponsored studies because, if that is the expectation, we will not see any new medical products on the market. If the expectation is, as Katie alluded to, some of these large claims databases that AHRQ, theAgency for Healthcare Research and Quality, or CMS have access to, then we will be able to better address the effects from medical product use, whether they are efficacy or safety, in different populations of women.

I also put it there to show that there will always be excuses as to why we do not study more women. If you want to counter them you have to know what they are in the first place and why people feel that way. Then you can go to the next step and say, "how do we improve the recruitment of women in clinical studies?" That is an entirely different focus that requires the next question to be "how do you promote recruitment and retention of women in clinical studies?"

Katie O'Callaghan:

As far as cardiovascular trials, the agency had a public workshop – two, actually; one in June and one in December – specifically looking at that. We got together a group of physicians via professional societies, patient advocacy groups, and several of the agencies under HHS: FDA, NIH, CMS, and AHRQ. When you look at anything, be it heart disease or prevention or any type of access to the healthcare system, there are a lot of disparities in women and men accessing healthcare. Then there are separate disease-specific or product-area-specific issues. For example, with heart disease, one thing that I learned from a think tank relates to body image and cultural issues. An ER doctor had mentioned that one of the reasons why he thought women might be less likely to get the EKG is because in a crowded ER, when you do not have a room available, a guy who has chest pain is comfortable with tearing his shirt off and strapping on all the electrodes for the EKG. If a woman has mild chest pain and is short of breath, she may not want to tear her shirt off. She is still fully cognizant. She is not falling on the ground and she does not necessarily know it is a heart attack. She is probably going to wait for the room. There are disease-specific issues but it is really very multifaceted and it is going to take collaboration from all the stakeholders to figure out what is needed for each specific area.

Kathleen Uhl:

The heterogeneous population of women has different requirements if you want them in clinical studies. For example, if you want to recruit women into a clinical study who are twenty to forty years old and have kids, unique issues arise. How are you going to get her into your clinical study? You have to provide childcare at the site of the clinical study. You probably have to provide transportation. For the aging female population, as shown by information presented earlier today talking about salary and income, older women are living below the poverty line. If you want to enroll older women, they are more likely to have a need for bus fare or cab fare to get to the site of the study. There is not a cookie-cutter approach to participant enrollment, yet this is the paradigm that has been followed in the research community.

Audience Question:

My question is about issues that are only related to women; namely, reproductive health. What is going on with the trials there? I know there were a lot of issues when birth control first came out and there are some moral/ethical dilemmas with those trials.

Kathleen Uhl:

It depends in which area you are referring. For example, there are a lot of studies ongoing for osteoporosis. Since there is certainly a great market for contraception, companies are still creating new contraceptives; whether they are drugs or devices or drug/device combinations.

The area of pregnancy is where there is really a dearth of information because of the liability aspect. We know pregnant women get sick. We know pregnant women need medical treatment. Whether they need diagnostic tests, they need treatment with medication or treatment with medical devices. The community of clinicians and the developers of these products are scared to death to touch pregnancy because of liability. There are very few products under development for use during pregnancy. There may be more in the medical device area because of use in labor and delivery, but when it comes to medication, there is a dearth of studies to collect that. We know women take medication when pregnant. There have actually been numerous workshops to discuss this and ask questions like "is it ethical to study the use of medical products in pregnancy?" The counter is, it is unethical not to. If the standard of care is to use this particular drug for a patient with asthma when pregnant, then how is it unethical to study the outcomes in the woman or in her developing fetus from that exposure? Though the ethics around it are substantial, the medical liability part is even larger. I think the other part around pregnancy is that it is a limited-term medical condition where the end result, in the majority of circumstances, is a healthy baby. The issues around pregnancy tend not to be embraced as much by the women's health advocacy community.

When a Woman's Choice is Not a Choice

Lisa Brown*:

My name is Lisa Brown and I am the general counsel for the National Abortion Federation (NAF). NAF is the professional association of abortion providers in the United States and Canada. Our members include clinics, doctor's offices, and hospitals who together care for more than half of the women who chose to have an abortion each year. The mission of NAF is to ensure safe, legal, and accessible abortion care to promote health and justice for women.

I am here today to talk about Medicaid and abortion care. I am going to begin my presentation with an overview of some statistics about the women who choose abortion in the United States and then talk a bit about the Medicaid system itself. I will conclude with an analysis of how the treatment of abortion care by Medicaid disproportionately impacts low income women and creates disparities in the ability of these women to exercise their choice of abortion when faced with an unintended pregnancy.

Despite the fact that abortion is a controversial political topic, it is also one of the safest and most common medical procedures provided in the United States. Nearly half of all pregnancies in the U.S. are unintended and four in ten of those pregnancies will end in abortion. This means that by age forty-five, almost one-third of American women will have had an abortion. In terms of numbers per year, in 2005 there were 1.21 million abortions provided in the United States. This is a common procedure that many American women will experience in their lives.

When in their pregnancies do women have abortions? Almost ninety percent of abortions are performed in the first trimester of pregnancy, which is the first twelve weeks after the first day of the last menstrual period. What are some of the general characteristics of women having abortions? The majority of women having abortions are in their twenties. Most abortions are obtained by those who have never married. Married women account for a lower proportion of abortions in part because they have low rates of unintended pregnancy. Those who do experience an unintended pregnancy are more likely than unmarried women to continue that pregnancy.

The largest racial ethnic identification of women having abortions is non-Hispanic white. However black and Hispanic women together make up more than half of women having abortions. This proportion is greater than their proportion in the population partly because they have a higher rate of unintended pregnancy.

Forty-three percent of women identify themselves as Protestant. The proportion of abortion patients who are Catholic is slightly lower than the Catholic proportion of the entire population. Thirteen percent of abortion patients say they are Born Again or Evangelical Christians. Twenty-two percent of abortion patients claim no religious identification. That is compared with only about sixteen percent of the general population that claims no religious identification.

The need for abortion spans the economic spectrum. However, low income women are over-represented among abortion patients. Some fifty-seven percent of women having abortions in 2000 were poor or low income, which means they were living at less than twice the poverty level. To put this into context, twenty-seven percent of women were living below 100 percent of the Federal Poverty Level, which means they earned approximately $900 a month to support an individual or $1,500 a month for a family of three. Only twenty-five percent of women reported living more than 300 percent above the Federal Poverty Level, which is still not a lot of income. A family of three would be earning approximately $4,500 per month.

* Lisa Brown is an alumna of WCL, Class of 2004. She is currently Counsel for the National Abortion Federation (NAF), a professional association of abortion providers in the United States and Canada. She works as part of the organization to ensure safe, legal, and accessible abortion care to promote health and justice for women. Ms. Brown specifically works with NAF's members and patients to facilitate their participation in the policy making process and to provide resources for state and regulatory battles nationwide.

In addition to being disproportionately low income, many women face significant barriers to obtaining abortion care. Eighty-seven percent of U.S. counties had no abortion provider in 2005, a number that has increased steadily since the 1970s. In non-metropolitan areas, ninety-seven percent of counties had no provider. As a result, many women must travel substantial distances to access this service. The Guttmacher Institute has found that about one in four women who have an abortion travel fifty miles or more for the procedure, a significant distance and a documented barrier to timely care.

Over the past several years, the abortion rate in the United States has declined. The rate of unintended pregnancy has remained generally the same across the whole population. Notably, however, the rate of unintended pregnancy has increased by twenty-nine percent among women living below the poverty level and sixteen percent of women who are poor account for thirty percent of unintended pregnancies.

Because a disproportionate number of low income women will experience an unintended pregnancy, they are also a population that is greatly affected by access to abortion services. Funding from state and federal Medicaid programs influence what choices are available for low income women seeking abortion care. Low income women disproportionately rely on the Medicaid system. Medicaid is the nation's state/federal health coverage program for the poor. It provides over twenty million low income women with basic health and long term care coverage. Eligibility for Medicaid is based on meeting federal income and categorical requirements. Under Medicaid, states receive federal matching funds to provide healthcare for low income individuals. In order to receive these funds, states must provide a certain core set of services to specific groups and individuals.

Over two-thirds of adults on Medicaid are women. Women are more likely to have lower incomes and to meet the eligibility criteria for Medicaid. Women are also more likely than the general population to be of reproductive age, poor, minorities, less educated, and parents. Nearly two-thirds of adult women on Medicaid are in their reproductive years and rely on Medicaid coverage for family planning and pregnancy related care.

State Medicaid programs must cover pregnant women with incomes up to 133% of the Federal Poverty Level - this is approximately $1,200 a month for one person - during pregnancy and up to sixty days postpartum. States may elect to cover women with incomes that are higher than those in the guidelines, and can receive federal matching funds for coverage of pregnant women with incomes up to 185% of the Federal Poverty Level. States have a wide variety of coverage limits from 133% of the Federal Poverty Level in some states to 275% in Minnesota. To put this in context, that is not a lot of money. For a family of three under the 2009 Federal Poverty Guidelines, 133% is $2,029 per month or a total income of $24,350 per year for the entire family.

Unless medically necessary services are specifically excluded or deemed optional by the Federal Government, states participating in the Medicaid program are mandated to reimburse Medicaid enrolled health care professionals for providing those services. Unfortunately, abortion has become one of the most ostracized medical procedures in the Medicaid system. Between the *Roe v. Wade* decision in 1973 and 1976, Medicaid paid for abortions without any express restrictions. In 1976, Representative Henry Hyde introduced an amendment to limit federal funding of abortion services. The Hyde Amendment, which is reapproved by Congress each year, allows federal funding for abortions only in cases of rape, incest, or life endangerment. This restriction was challenged in court and in 1980 the U.S. Supreme Court ruled in *Harris v. McRae* that the Hyde Amendment's prohibitions on abortion, including those on medically necessary abortion care, were constitutional.

The Court also upheld the right of a state participating in the Medicaid program to fund only those abortions for which it received federal funding rather than all medically necessary abortions. Justice Marshall strongly dissented on the basis that denying medically necessary care to poor women is equivalent to denying them access to legal abortion altogether. However, several state challenges have proven successful. Although there are still restrictions, several state constitutions provide greater protection than the federal constitution does. Lawsuits requiring Medicaid coverage using state funds for abortions in all or most medically necessary circumstances have been successful in thirteen states. Despite these lawsuits, the effect of the Hyde Amendment on low income women has been drastic. In thirty-three states and the District of Columbia, Medicaid only provides funding for abortions in cases of rape, incest, or life endangerment.

A low income woman seeking an abortion for other reasons, even those related to her health, is left with few options. Often women are forced to sell their possessions or use money set aside for rent or groceries to pay for an abortion. Six in ten low income women report wanting to have their abortion earlier. Without public funding, abortion is essentially not an option for many women. Studies have shown that eighteen to thirty-five percent of women who would have had an abortion carried their pregnancy to term in absence of funding. Across the country, private funders assist thousands of Medicaid enrolled or Medicaid eligible women with raising the money for abortion care each year.

The Hyde Amendment and restrictions on Medicaid funding also have a broad impact on abortion providers who find it difficult to find the funds to provide care for low income women and often charge on a sliding scale for those who should be covered by Medicaid. In states where Medicaid does cover all or most medically necessary abortions using state Medicaid dollars providers report a series of administrative barriers to receiving reimbursements, even for filing reimbursements with the Medicaid program. Providers report they often have to jump through many hoops and fill out extra paperwork for abortion procedures or face having their reimbursements routinely denied or held for up to a year when they legally should be covered. Women report being told by their Medicaid office that Medicaid would never cover abortion even in states where Medicaid is required to fund it in all or most health circumstances. This campaign of administrative barriers and disinformation adds to the confusion that the Medicaid system causes and the burden that these restrictions place on low income women.

In closing, Justice Brennan stated in his dissenting opinion in *Harris v. McRae* that the Hyde Amendment is an attempt to "impose the political majority's judgment" on a woman making a reproductive choice that the government disfavors. The Hyde Amendment "imposes that viewpoint only upon that segment of our society which, because of its position of political powerlessness, is least able to defend its privacy rights." *Harris v.*

McRae, 448 U.S. 297 (1980). NAF remains committed to ensuring that low income women have equal access to abortion services, regardless of their ability to pay or the Medicaid system in their state. Activists are working together across the country to raise awareness of the Hyde Amendment and its effect on low income women and NAF is a member of a broad campaign to educate members of Congress and the Administration about the harmful effects of the Hyde Amendment. To achieve reproductive equally for all women and ensure that each woman has the ability to make the choice that is right for her, restrictive barriers such as the Hyde Amendment must be abolished.

Dr. William Parker*:

I am going to continue with the theme of discussing the notion of choice, which for me is kind of a bad word. I think it is a notion that is antiquated when you look at the context in which most women make the decision of whether to continue their pregnancy.

I have laced the words together a little bit differently: abortion care, Medicaid, and disparity. Lisa laid out the fact that Medicaid is the system of social insurance for most people who meet the means test of being in poverty. It certainly describes poor women and women of color, but the two are not always the same. What I would like to do is try to connect some of the dots for you and review a few of the things she said, and maybe create a different context around them, particularly as they pertain to race and ethnicity. I will then talk specifically about how my practice as an abortion care provider has been impacted by the reality of Medicaid and the Hyde Amendment.

To very briefly summarize what Lisa said, about six million pregnancies happen annually, and about half of those are unintended. However, unintended does not necessarily mean unwanted. When we look at those unintended pregnancies, the majority of women who become pregnant, albeit unintended, will continue their pregnancies. Forty-eight percent of those unintended pregnancies will end in abortion. When we convert that to a rate, over time you can see that there has been a constant fall in the number of abortions. Everybody wants to take credit for that, from people who talk about abstinence-only education to people who create more effective means of contraception. Whatever the reason the rate is falling, we will take it.

Data examined in the aggregate does not always tell the whole story. You can look at unintended pregnancy as a proxy for the likelihood of a woman to continue to consider discontinuing her pregnancy. While unintended pregnancy rates have either stagnated or fallen when the data is disaggregated and unintended pregnancy rates are explored by various perimeters, one finds that in some sectors of the population unintended pregnancy has increased. This is evident particularly amongst poor women, while it has decreased amongst women with a higher income. While there has been a small decrease for women of means there has been larger increase for women with limited resources. It has shifted the dilemma of pregnancy decision-making to women who are more likely to have adverse circumstances affecting their reasoning. Women who experience unintended pregnancy are disproportionately poor. While sixteen percent women are poor, they account for thirty percent of unplanned pregnancies, a disproportionate share.

Now to introduce a different frame, that is that being in poverty and being a person of color is oftentimes synonymous, it is not always the same. When considering women of African-American descent, they account for twenty-six percent of the unintended pregnancies, while they make up fourteen percent of the population. A similar trend is true for Hispanic women. Again, Hispanic women represent a disproportionate share of unintended pregnancies compared to their portion of the population.

Unintended pregnancy is a proxy for the likelihood of a woman choosing to discontinue her pregnancy, but that does not necessarily mean an abortion, as we saw that in the majority of unintended pregnancies women continue their pregnancy. If we were to convert that disproportionate representation in poverty to a rate, it makes sense that when you look at women below the level of poverty, they have the highest rate of abortion. Because they have the highest rate of unintended pregnancy, they are more likely to be in a circumstance that will prompt them to consider abortion.

African-American women have the highest rate of abortion, followed by Latino women. Women of color represent the highest rate of abortion, which is counterintuitive when often times in the media the feminist movement has been perceived to be largely for white women. In reality, the notion that feminism empowers white women to have abortions would fly in the face of their numbers. It is amazing how forces that are against a woman's right to choose will spin this to say now we are talking about eugenic and genocidal notions in terms of who has abortions.

What prompts the rates that I have shown you? There has been some survey research of women who recently had abortions. When asked about the reasons why they chose to discontinue their pregnancies, most women gave multiple reasons. The average woman would give about five reasons why she chose to terminate her pregnancy. The majority of those reasons are related to the responsibilities that many women face by continuing a pregnancy that they materially, socially, and otherwise cannot afford. Most women have reasons that are related to their social economic status, trending towards the conclusion that women who rely on public assistance are affected in an adverse way by the Medicaid policies that restrict their access.

If you look at the reasons why a woman would delay having an abortion to a later gestational age in pregnancy, aside from not realizing that she is pregnant, the major reason is the difficulty arranging logistics, which is often a financial burden. You can now understand why women relying on public assistance who cannot access funding for abortion services delay the procedure. The relative safety of abortion is linked to the procedure occurring in the safest timeframe where there are least likely to be complications. If you look over time, even a week's increase in the gestational age makes a big difference in the risk for mortality and morbidity.

If you look at the number of deaths per 100,000 live births, death in the context of pregnancy, whether you're talking about abortion or childbirth, is a very rare thing. When it does occur, if you look at women who continue their pregnancy to term, their risk for death is roughly ten times more if you

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continue your pregnancy to term rather than if you have an abortion at any point. I am not advocating for a woman to discontinue a pregnancy, but it is to say that when women are forced to delay their decision-making for whatever reason, they exponentially or at least significantly increase their risk for morbidity and mortality, as demonstrated in published research by my friend at CDC, Dr. Linda Bartlett. She showed that when you delay the decision to have an abortion by even a week, you significantly increase a woman's risk. Hence, policies that selectively disadvantage some women over others devalue the lives of women who rely on public assistance, thereby by forcing them to take unnecessary risks when seeking abortions.

I have been able to see the implications of such policies first-hand over the last few years as an abortion provider. I want to present three cases that I have managed in the last year and give you the fact patterns. They are all three women of different backgrounds with different medical problems, but what they have in common is that they all rely on Medicaid funding for their health care. I will talk about these facts to give some texture to the complexity of abortion decision making and explain why we sought to have these women covered by Medicaid to have their procedure. I will also tell you the outcome of the coverage determination.

The first case was a twenty-five year old African American woman who had AIDS. She was in renal failure and on dialysis three times a week. She found that she was twelve weeks pregnant. The common medical wisdom is that she probably would not survive a pregnancy if she chose to continue. Initially, she made the decision to discontinue the pregnancy. Then she became conflicted and decided not to discontinue – but then ultimately decided that she wanted to be around for as long as she could to raise the two children that she already had. We approached Medicaid for permission to provide the services. Under the Hyde Amendment, as Lisa shared with you, there are three circumstances under which women can access Medicaid coverage for abortion services. The the people evaluating the case decided that the condition was life threatening to the mother and as a result, they authorized coverage for the procedure.

The next case was a thirty year old Hispanic woman who had one child and was nine weeks pregnant because her birth control method failed. Having an underlying condition that increased her risk for blood clots, she could not take birth control pills. She had not yet heard about the IUD, although she had by the time she met me. She also had a seizure disorder. In the management of her blood clotting condition and her seizure disorder, she was also on two medicines that were known to be teratogenic or had a high likelihood of causing birth defects. Now, the pregnancy would also increase her risk for having another blood clot that could go to her lungs and kill her. When we presented this case to Medicaid and they determined that although her story was very compelling there was no immediate, absolute threat to the life of the mother. There was no documented abnormality of the pregnancy even though she was on two medications that had a very high likelihood of causing birth defects. In that case, the procedure was not authorized and Medicaid refused to pay for her care.

The third case was a twenty-seven year old young Caucasian woman who had two kids, was 13 weeks pregnant, and was hospitalized because the heart valve that she had replaced began to leak, causing chest pain. She thought that she might be pregnant and was also on the blood thinner that was a known teratogen. She also had cocaine and alcohol binges, creating multiple teratogenic exposures. She also had a heart condition that would probably worsen with the progress of her pregnancy. We painted this medical picture for Medicaid and again the determination was that there was no immediate, absolute threat to the life of the mother or the fetus and the procedure was not authorized.

Now when I say that the procedure was not authorized, it does not mean that the care was not provided. It just means that we could not get the preauthorization to pay for the care that the woman needed. As a provider, when I have a woman who has need, my medical reasoning and decision-making should not be effected by the woman's ability to pay. On a daily basis, I try to make sure that it is not.

When a patient is faced with the dilemma of whether to sign a promissory note that might be demanded of her by an institution saying if we let you have this care, you have to agree that you are going to pay this money, for some it becomes cheaper to continue the pregnancy than to figure out where they are going to get the resources. It becomes quite clear how Medicaid policy with regard to the Hyde Amendment effects and compromises the care and well-being of women and my ability to provide the best care that I can as a provider.

It does so in a couple of ways. It imposes a financial barrier to health care that women would otherwise be entitled to as a part of their medical coverage, creating hardship. It also creates health disparities by imposing financial barriers that lead to differences in morbidity and mortality risks between groups on the basis of race and socioeconomic status. In other words, poor women have limited access to services. As I said earlier, poverty, race, and ethnicity are not always synonymous. Anything that delays the decision-making process results in women having to take increased and absolute risks with their lives.

Female Participant:

How long does it take to get a preauthorization?

Dr. William Parker:

Actually they try to do so in an expeditious manner. Usually because the answer is no, it does not take long, sometimes forty-eight hours. Most of the time, once you get someone to take the information, they will pledge a decision in twenty-four to forty-eight hours. We usually try to help navigate the maze for them. Most people do not know where to go or who to call. They do not usually have the numbers or the kind of diagnostic codes and all the other things that are required. There seems to be an air of whimsicality in the decision making. That is my assessment. They find ways to deny the most compelling cases and then cover things I would not expect.

Jill Morrison*:

Thank you for having me here. My purpose is to put to rest any doubts that the public scrutiny, the debate, the controversy, and the state intervention in pregnant women's lives is over once she decides whether to have a baby.

There have been numerous efforts to intervene in the lives of pregnant women. The most obvious example is efforts to prosecute pregnant women based solely on their drug use during pregnancy. At the National Women's Law Center (NWLC), where I work, we oppose such prosecutions. They are bad public health policy because they discourage pregnant women from seeking prenatal care and they violate the Constitution on several grounds. Our work on that issue relates closely to what I will discuss today, the prosecution of women for their birthing decisions and other actions during pregnancy. I decided not to focus on addiction because addiction is not a choice. It did not fit within the title *"When a Woman's Choice is Not a Choice,"* but as you can see, the issues are similar.

Because drug users are so stigmatized, it is sometimes difficult to have empathy for them as women who are equally deserving of reproductive justice. The cases I am going to discuss are far more empathetic. At the same time they expose and support the exact same misconceptions and arguments that we use to oppose punitive measures against pregnant addicts. We cite these same cases when we submit amicus briefs to courts explaining why prosecuting pregnant women for child abuse, child neglect, or homicide is rooted in sex discrimination. I am happy to report that every court to consider the issue has agreed that criminal laws were not intended to be used in this manner.

The question at issue is the same for cases involving both drug use and medical decision-making during pregnancy. Once pregnant, what is a woman's duty to ensure the best possible health outcome for her unborn child? What actions can be taken against her by a third party who believes that she is not acting in the best interest of her fetus? What are your rights when it comes to making medical decisions for yourself presuming that you are not pregnant? Well here are the principles that apply, presuming you are in support of Constitutional rights.

First I will talk about your rights regarding the acceptance and refusal of medical care. In *McFall v. Shimp*, a man refused to donate blood marrow to his cousin. He happened to be the only match for that cousin. So what was the outcome? The court decided he did not have to donate. Why? He has a right to bodily integrity. There is no right to receive a donation of bodily fluids, organs, or anything else from another person. *Cruzan* held that competent adults have a right to refuse medical care even if it results in their own death. These are core principles protecting bodily integrity and autonomy. Yet we have many examples of attempts to violate these principles where pregnant women are concerned.

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To begin, there are cases involving women's refusals to submit to Caesarian sections. In the leading case, *In Re A.C.*, Angela Carder struggled with cancer since the age of thirteen, but decided to get married and have a baby after going into remission. The cancer returned in the twenty-fifth week of her pregnancy and she lapsed into a coma. The hospital, George Washington University Hospital in Washington, D.C. was especially concerned about her declining condition given the fact that the fetus was viable. The hospital petitioned the court for an order to force Ms. Carter to have a Caesarian section despite the opposition of her husband and family. The court ordered the surgery. Ms. Carter's treating doctors refused to perform the surgery because they were aware of her wishes. A staff obstetrician grudgingly agreed to perform the surgery. In the meantime, Ms. Carter came out of the coma and was told about the planned surgery. When told she might die as a result, she said over and over again that she did not want it done. Despite this, a panel of the appeals court met and quickly upheld the lower court's decision. They performed a cesarean operation on her that she expressly did not want. The baby died within two hours of delivery. Angela Carter lasted another two days. There is no doubt whatsoever that the surgery hastened her death.

Her family requested a hearing from the court of appeals trying to make sure that no woman ever again was subjected to such treatment. The full D.C. Court of Appeals reversed the panel's decision. The court reviewed the other decisions that had refused to require organ donations between relatives and concluded a fetus cannot have rights in this respect superior to those of a person who has already been born.

Since that case, virtually every court has supported a pregnant woman's right to make medical decisions that may endanger the fetus or a pregnant woman's right to refuse treatment for the fetus' benefit. The case *In Re Baby Boy Doe* was technically rendered moot before the court could hear it because the mother had a vaginal birth, but the court heard the case anyway because it was apparent that this situation could arise again. In that case, the state claimed that the lower court was correct in ordering a woman to have a Caesarian section after balancing the state's interest in fetal life against the right of a pregnant woman to choose her own medical care. The appeals court rejected this argument finding that a woman's competent choice to refuse medical treatment as invasive as a Caesarian section must be honored even in circumstances where the choice may be harmful to her fetus.

One reported case to the contrary graphically illustrates the incredible violation of liberty and autonomy that occurs when the government oversteps its bounds. Laura Pemberton had previously had a Caesarian section, but wanted to give birth vaginally during her next pregnancy. This situation is called a VBAC, and many hospitals and doctors refuse to do them, claiming that they put women at risk of uterine rupture. Pemberton's doctor refused to attempt such a delivery and Pemberton decided to give birth at home. During her home birth, she became dehydrated and decided to go to the hospital for IV fluids. The attending physician at the hospital refused to give her IV fluids and instead called the hospital administration. The administration then called its lawyer, who then called the state's attorney. In the meantime, Laura Pemberton, who was full term and in labor, 'slipped' out of the hospital. What followed was an almost unbelievable

scene. A woman in labor is taken from her home to the hospital by law enforcement to submit to a court-ordered Caesarian section.

Ms. Pemberton sued, alleging a violation of her rights to bodily integrity and to refuse medical treatment. She lost, ironically enough, based on the court's application of *Roe v. Wade*. The court focused solely on the part of *Roe v. Wade* that says that the state has an interest in a viable fetus. The court concluded that because the state has an interest in a viable fetus, it could properly express that interest by ordering the Caesarian section to save the fetus's life. Of course, it is impossible to know whether Ms. Pemberton could have had a healthy delivery without the Caesarian section, but the evidence is certainly in her favor. Ms. Pemberton went on to deliver four children vaginally including a set of twins. So doctors don't always know best.

The case of Melissa Ann Rowland shows that the state is willing to go beyond mere aggressive intervention to criminal prosecution. Ms. Rowland was threatened with a homicide charge for not having a Caesarian section. Eventually the prosecutor dropped the charges, claiming that he did so only because Rowland was mentally ill.

Currently, a New Jersey Appeals Court is considering whether the state can base a child neglect proceeding solely on a pregnant woman's refusal to give advanced consent to a Caesarian section just in case any problems arose during delivery. Keep in mind that there was no indication that the woman would actually need a Caesarian section. As she went into labor, the hospital handed her a bunch of papers and she chose not to sign the one that says I will have a Caesarian section if it is needed. The state moved to terminate her parental rights alleging neglect. The state also moved against her husband because he agreed with her decision to withhold consent.

It is not just refusals to have Caesarian sections that evoke state intervention and criminal charges against pregnant women. Here are a few other cases that involve a pregnant woman's right to refuse medical care. In *In Re C.M.*, the New Jersey Division of Youth and Family Services filed a negligence complaint against an HIV positive woman because she refused to take medication during her pregnancy that would reduce the risk of her fetus being born with HIV. The court rejected the allegation of negligence stating that a pregnant woman's decision to refuse medical treatment that would benefit her fetus is a part of her constitutionally protected right to privacy. In *Taft v. Taft*, the Massachusetts Supreme Court vacated a lower court decision ordering Mrs. Taft to have her cervix sewn to prevent a possible miscarriage. She had a weak cervix and there is a surgery that can be done called a 'purse string' surgery. She did not want to have it, but Mr. Taft asked for a court order. The court refused to order the surgery.

Unfortunately, as you can see from these cases, often women are forced to vindicate their rights only after their rights have been violated. So they are doing so on behalf of others who may be in similar circumstances in the future. This raises the question of how many other women are subjected to such treatment and simply do not have the resources, the energy, the wherewithal, or the motivation to find an attorney and try to remedy the rights of others, especially considering that these women have a newborn baby at home. For every one of these cases that occurs that actually comes to court, just think of how many others are out there.

Why does this keep happening? These principles about bodily integrity and autonomy are deeply engrained in our constitutional jurisprudence. So why are states, prosecutors, and hospital administrators not getting the message? The United States Supreme Court once upheld a statute limiting women, but not men, to ten hour work days. According to the Court, the state presented adequate justification for the infringement on women's liberty because "healthy mothers are essential to vigorous offspring, the physical well being of women becomes an object of public interest and care in order to preserve the strength and vigor of the race."

If you have ever been visibly pregnant at any point in your life you are acutely aware of the public interest in pregnant women. When you are visibly pregnant, some people seem to think that you are public property. People believe they can touch you, they can give you advice, and tell you what to do and more importantly, what not to do. This is the interest that these state actions are actually reflecting. This is why those who are expected to uphold the law, prosecutors and other state officials, initiate prosecutions that they know are unconstitutional. This is why those who are best versed on principles of informed consent, doctors and hospital administrators, enthusiastically violate these principles when it comes to pregnant women.

Underlying these infringements on pregnant women's liberty is the discriminatory notion that women's best and perhaps only contribution to society is her fulfillment of her reproductive role. Women are expected to be self-sacrificing and altruistic; to submit their very lives for the sake of their children. A 'real' mother would not even want to assert the same liberty and autonomy rights as other individuals. Again, if this is something that you think is untrue or an overstatement, I would have to ask why we keep seeing these cases over and over again.

Regarding the Hyde Amendment, I was very interested Doctor in what you were saying about how arbitrarily these decisions are made. I was wondering if politically it would be more palatable to revise the regulations to broaden the medical bases for which what you call life endangerment as opposed to overturning the Hyde Amendment. And to Lisa, whether or not that would be possible. Although the movement has talked about overturning Hyde, I am so not optimistic about that. I know regulations are a lot easier to change than laws.

Dr. William Parker:

I think from a medical standpoint, the notion of what is considered an absolute versus a relative indication is important. It is almost like with medical expertise, you know the plan is fine. I think the Hyde Amendment has its greatest impact in terms of the way it introduces administrative delay. If you create a process that is even more nuanced, it still does not get around the notion that people bring the values to the decision making process that they bring. If I thought that refining the process would make a difference, I would be an advocate for that. At the end of the day what I find is that it will never trump the moral context in which many people process abortion care.

Lisa Brown:

I definitely agree with that in terms of the states that require Medicaid to fund all or most medically necessary abortions. They have found other

ways to make it difficult. Although it is not as difficult and you have more likelihood of having your abortion funded in one of those states than in a Hyde only state, we have providers in one state who all work together and all have found that they have completely different experiences with the Medicaid office depending on who they talk to, how big their clinic is, and how they interact with the Medicaid office on family planning and other issues besides just abortion.

If they already have a relationship with the Medicaid office, and the Medicaid office funds other procedures for them, then they are more likely to get their abortion procedures funded. Even then, the Medicaid office routinely loses their paperwork. There is a clinic in another state that actually physically goes to the Medicaid office and hands in their paperwork because it has gotten lost so much of the time.

Female Participant:

I have a question for Miss Morrison. Have you seen cases of women wanting to do home birth as opposed to delivering in the hospital? Have you ever seen litigation forcing a woman to go to a hospital on the day of delivery?

Jill Morrison:

I have not seen it litigated yet, but given the clash between some medical authorities and midwives in some states, I really do think it is just a matter of time. We are going to get to the point where doing anything against your doctor's advice can be a cause to bring child neglect or criminal proceedings against you.

Dr. William Parker:

One of the things that I have seen is the introduction of the notion of vicarious liability breeding contempt between midwives and obstetricians such that there are barriers to women if they make the decision for a home birth or if they make a decision to have their care with a midwife that decision becomes binding and absolute. It puts them on a path where, in some ways, they have restricted access to the interventional care that they can obtain with an obstetrician.

We had a forum in California where we sought to explore to what degree the statutory and regulatory mechanism of the state could intercede between insurance companies breeding these contemptuous relationships that ultimately penalize women. Basically what you are saying is if you want to have a certain type of birth experience and you make that decision, you are locked out of the health care system where we could optimize your outcome by creating this defensive posture for obstetricians. If I am having a conversation with Miss Morrison and she is a midwife and she says I have this patient who has a high blood pressure, what do you think I ought to do? If she mentions that we had a conversation, the concept of vicarious liability says that I am liable even though I've never met this patient. As a person who's practicing defensively, I say oops, I cannot talk to you. At the end of the day it is the woman who is in her care that pays.

Solutions for the Uninsured: Federal, State, and Local Initiatives

*Luke Chesek**

> After a spike in health care costs, starting in the mid-1990s, state and local governments began to take steps to provide health insurance to their residents in the absence of any genuine federal effort to provide coverage for the uninsured.

I. INTRODUCTION

Currently forty-six million Americans have no health insurance and "[i]n 2007, fifty-seven million Americans had difficulty paying their medical bills, up fourteen million from 2003."[1] These fifty-seven million citizens carried with them an average of two thousand dollars worth of medical debt.[2] While no one can deny the effects of being uninsured in our health care system, this dilemma has implications beyond those who cannot afford health insurance. As of 2007, half of American hospitals operated at a loss due in part to underpayments.[3] If the United States does not solve this problem, our market forces will cause many of these hospitals to go out of business. When a hospital shuts down, those who can afford health care begin to take a hit.

Both state and federal governments have made attempts at universal health care coverage. Hawaii established the Prepaid Health Care Act in 1975 that sought to cover all Hawaiians through employer mandates and subsidies for the poor.[4] In 1993, former First Lady Hillary Clinton spearheaded an attempt at universal coverage, but saw the program crushed by Congressional and special interest group opposition.

After a spike in health care costs, starting in the mid-1990s, state and local governments began to take steps to provide health insurance to their residents in the absence of any genuine federal effort to provide coverage for the uninsured. What is the result? States and localities around the country are implementing health insurance programs, behaving as our Founders intended, namely; like the engines of experimentation in government. However, certain realities are making it clear that state and local responses are inadequate to deal with some of the problems our current system faces. Furthermore, certain aspects of federal law, particularly the Employment Retirement Income Security Act (ERISA) and an IRS tax benefit make reform at the federal level necessary. This paper will explore the changes to health insurance taking place at the federal, state, and local levels, and conclude with a brief outlook on possible solutions taking shape today for the millions of uninsured Americans.

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II. FEDERAL INITIATIVES

A. Medicare

Medicare is the federal government's health insurance program for: "(1) people aged 65 or older; (2) people under age 65 with certain disabilities; and (3) people of all ages with End-Stage Renal Disease (permanent kidney failure requiring dialysis or transplant)."[5] In 1965, Medicare was created through amendments to the Social Security Act.[6] Due to the time period Medicare was enacted, its benefits tend to mirror the Blue Cross and Blue Shield plans in place in the 1960s, focusing on hospital and physician services.[7]

Medicare was originally split into two parts: Part A covered hospital insurance and Part B covered medical insurance. Eligible Medicare members do not pay out-of-pocket coverage for hospital insurance. The majority of members choose to enroll in the optional Part B of Medicare and paid a premium of $96.40 in 2009.[8] Enrollees in Medicare have the choice to enroll in the original Medicare plan or any one of the Medicare Advantage plans run by private insurers.[9]

The Medicare Modernization Act of 2003 (MMA) created Part D of Medicare, a prescription drug benefit program. This represented one of the largest increases in entitlement spending since the enactment of Medicare and Medicaid in the 1960s. At the time the MMA passed, two-thirds of Medicare beneficiaries were already receiving prescription drug coverage from their previous employers, Medicaid, or their enrollment in a Medicare+Choice plan.[10]

Part D essentially was designed "as a form catastrophic coverage."[11] Enrollment in Part D, like Part B, is voluntary, and it is private companies – not the federal government – that provide the drug benefit portion of the insurance policy.[12] Coverage under the plan is limited. Each beneficiary pays a monthly premium of thirty-five dollars, an annual deductible of $250, and is still responsible for a portion of their overall drug costs.[13] As of 2005, "beneficiaries [were] responsible for 25% of their drug costs between $250 and $2,250, 100% between $2,250 and $5,100, and 5% of their drug costs of $5,100 and over."[14] The monthly premium

payments are waived for low income Medicare beneficiaries whose incomes are below 135% of the federal poverty level, while limiting their cost-sharing responsibilities to no more than five dollars per prescription.[15]

MMA presented a dramatic change in treatment of Medicare beneficiaries. Breaking with thirty years of social insurance policy, the MMA provided a means-testing analysis that charged wealthier recipients more.[16] Prior to this change, all Medicare recipients paid the same for their Part B premiums regardless of income.[17] Under the changes embodied in the MMA, individuals "with adjusted gross incomes over $80,000 ($160,000 for joint filers) paid higher premiums for the same Part B benefit," and those with incomes below 135% of the poverty line paid substantially lower premiums.[18] While both sides of the political aisle have pushed for means-testing in the past, there are some who believe this could be an eventual deathtrap for any form of universal health care. As the argument goes, since participation in Part B is voluntary, wealthy Americans will eventually choose not to participate in Part B, leaving poorer and usually less healthy individuals to foot the program's bill.[19]

The MMA also amended provisions of Medicare with an aim towards privatization, under the assumption that market forces could help reduce the rising costs of the entitlement program. The MMA renamed Medicare+Choice as "Medicare Advantage." Medicare Advantage is the private option counterpart to the original Medicare plan. The problem with relying on the private sector to rein in costs is that the enactment of Medicare+Choice did not decrease costs: "[i]n 2003, Medicare paid private health plans participating in Medicare+Choice an average of four percent more than the average cost of a Medicare beneficiary under fee-for-service."[20] In 2005, Medicare Advantage did not deliver the cost-saving advantage many hoped it would. Instead, Medicare was paying 6.6% more for each of the five million beneficiaries enrolled in a private program than those enrolled in the original Medicare plan.[21]

One of the problems inherent in attempting to privatize health insurance is the reality of the marketplace surrounding health care. A book review of *The Health Care Mess: How We Got into It and What it Will Take to Get Out* by Julius B. Richmond and Rashi Fein, provides insights into the realities of the health care market. The authors explain that the normal forces of supply and demand do not operate the same in the health care system.[22] Richmond and Fein assert that after World War II, an increase in funding for the National Institutes of Health forced medical schools to become dependent on the federal government for research and training physicians.[23] The American Medical Association (AMA) successfully blocked attempts at government financing for delivery of care to patients, leaving personal care in a private market setting, representing the demand side of the medical system.[24] Academic medicine, coupled with a growing pharmaceutical and medical device industry, represented the supply side of the medical system.[25] This left the supply side unresponsive to changes in demand. While changes in demand should have brought about a decrease in cost, the supply side of medicine continued to "pump out more and more expensive therapies and procedures, with the attitude that more is better. . . [w]hile the AMA was standing guard against socialism, it got blindsided by capitalism."[26] The result was a system that could not keep up with the rising costs of care.[27] As legislatures work to reform health care, it is important to balance the need for government regulation while retaining a responsive supply and demand system.

B. Medicaid

Medicaid, which was enacted with Medicare in 1965,[28] accounts for one in every six health care dollars spent in the U.S.[29] The 2009 Congressional Budget Office (CBO) estimate predicts that Medicaid will provide health insurance to "nearly 68 million children, parents, pregnant women, seniors, and people with disabilities."[30] Medicaid is paid for in part through matching funds by the federal government, but is not administered by the federal government. Instead, each state sets up its own guidelines and is responsible for administering the program.[31] Medicaid sends its payments directly to each beneficiary's health care provider and, depending on the states' rules, individuals may be required make co-payments.[32]

There are some general guidelines for these state-run programs. Medicaid categorizes individuals into 'need' groups, some which are required to be covered under state plans.[33] The three most common groups include: special groups, the medically needy, and the categorically needy.[34] Special groups include, but are not limited to, qualified working disabled individuals, Medicare beneficiaries, women with cervical or breast cancer, and people with tuberculosis.[35] The medically needy consist of individuals who make too much money to be considered categorically needy.[36] If a state decides to enroll this class of individuals, Medicaid requires that it cover pregnant women through a sixty-day postpartum period, children under age eighteen, certain newborns for one year, and certain blind persons.[37] The categorically needy represent the following groups:

> Families who meet states' Aid to Families Dependent Children (AFDC) eligibility requirements in effect on July 16, 1996; pregnant women and children under age 6 whose family income is at or below 133% of the Federal poverty level; children ages 6 to 19 with family income up to 100% of the Federal poverty level; caretakers (relatives or legal guardians who take care of children under age 18 (or 19 if still in high school); Supplemental Security Income (SSI) recipients (or, in certain states, aged, blind, and disabled people who meet requirements that are more restrictive than those of the SSI programs); and individuals and couples who are living in medical institutions and who have monthly income up to 300% of the SSI income standard (Federal benefit rate).[38]

As the economy worsens, an increasing number of people are beginning to fall into these groups. Hence, the need for an effective and efficient Medicaid system, like all other aspects of health care, is growing.

C. Consolidated Omnibus Budget Reconciliation Act

In 1986, Congress passed the Consolidated Omnibus Budget Reconciliation Act (COBRA) health benefit provisions.[39] The law amended portions of ERISA, the Internal Revenue Code, and the Public Health Service Act. COBRA provides health insurance to employees who lose coverage when their employment is terminated.[40] The law requires certain employers to allow employees to remain temporarily covered under the employer's health insurance program after termination, and to notify employees of the availability of COBRA continuation.[41] An individual covered by COBRA will experience a spike in health care costs since employers usually only pay part of the health insurance premiums.[42] Under COBRA continuation, the newly unemployed are required pay the remaining premium payments,

but this cost is still notably lower than purchasing individual health insurance.[43]

There are three basic elements that determine COBRA applicability: plan coverage, qualified beneficiaries, and qualifying events. First, only employers who provide coverage to twenty or more employees, part-time (counted as a fraction equal to the part-time employee's hours worked divided by a full time employee's hours) and full-time, during "more than 50 percent of its typical business days in the previous calendar year..." are required to participate.[44] All employees and their dependents who were covered by an applicable group health plan, as well as certain retired employees, are considered qualified beneficiaries.[45] There are various qualifying events for employees, their spouses and children. Qualified beneficiaries are eligible for COBRA continuation if they are "voluntarily or involuntarily terminat[ed] . . . for reasons other than gross misconduct," or there was a reduction in the number of hours of employment that would, without COBRA continuation, cause the individual to lose health coverage.[46]

After an employee is terminated, he or she has a sixty day period in which to apply for care, which is measured from the later of either the coverage loss date or the date the COBRA election notice was provided.[47] Generally, COBRA allows beneficiaries to remain on their employer's group plan for a maximum of eighteen months. However, if another qualifying event occurs during this period, the individual may be able to extend coverage for a maximum of thirty six months.[48] The COBRA regulations do not prohibit group plans from continuing to cover employees beyond the established COBRA periods.[49]

When the American economy began to decline in late 2008, high unemployment rates forced Congress to take a close look at COBRA's continuation policy. COBRA did not provide a safety net for many recently terminated individuals because they were required to pay high premiums previously subsidized by their employer. American workers were finding "themselves in a 'Catch-22' of whether to elect COBRA in light of its costs or risk trying to get insurance in the individual market."[50] The American Recovery and Reinvestment Act of 2009 (ARRA) benefited recently unemployed individuals faced with this Catch-22 predicament. The ARRA extends a sixty-five percent subsidy of COBRA continuation premiums for a period of nine months for individuals involuntarily terminated between September 1, 2008 and December 31, 2009.[51] Another provision covers workers who were involuntarily terminated between September 1, 2008 and February 17, 2009, but originally decided against enrolling in COBRA.[52] These former employees were given an extra sixty days to enroll in COBRA in order to take advantage of the subsidy.[53] While the subsidy is not taxable for the year received, individuals with an adjusted gross income above $125,000 ($250,000 for joint filings) are obliged to repay the government, in whole or in part, through tax return cuts.[54] Under these changes, qualifying employers must subsidize the premium payments of former employees.[55] The ARRA allows companies to recoup some of these payments by "offsetting its payroll tax deposits or claiming the subsidy as an overpayment at the end of the payroll quarter."[56]

The ARRA goes a long way in achieving COBRA's mission to protect employees in between jobs, but with continuing unemployment, Congress and the Administration will face new difficulties when the nine month COBRA grace period runs out. Unless those individuals covered under the ARRA's COBRA extension find employment, these Americans will soon join the ranks of the uninsured. The uncertain economy increases the pressure to reform health care.

D. Children's Health Insurance Program

The Children's Health Insurance Program (CHIP), formerly known as the State Children's Health care Insurance Program (SCHIP), is jointly financed by the federal and state governments and is administered by the states.[57] Specifically, "[w]ithin broad federal guidelines, each [s]tate determines the design of its program, eligibility groups, benefit packages, payment levels for coverage, and administrative and operating procedures."[58] SCHIP began insuring children in 1997 through its inclusion in the Balanced Budget Act.[59]

The law attempts to encourage states to provide health coverage for children of families that do not qualify for Medicaid, but also cannot afford to purchase private health insurance.[60] In its first ten years of existence, SCHIP has allocated approximately twenty billion dollars to the states,[61] and has so far covered over five million children.[62] In order to provide this coverage, states receive what is known as an 'enhanced' federal match. This enhanced match is greater than what a state receives through Medicaid.[63] However, the law caps the match rate for states that provide coverage for those families with incomes greater than 300% of the poverty line.[64]

Since the law's enactment, states are responsible for determining SCHIP income eligibility levels.[65] As private insurers began to increase the cost of health coverage, states responded accordingly to cover more families by raising the eligibility levels and requiring families to pay a share of the premiums based on income levels.[66] The Bush Administration pushed back in 2007 in a letter issued by the Center for Medicare and Medicaid Services (CMS) to state health officials, demanding limitations on a state's ability to set its own income eligibility standards.[67] The letter, dated August 17, 2007, burdened states with "additional requirements . . . states must meet in order to cover children under SCHIP plans, including plans that CMS had previously approved."[68] As a result, tens of thousands of children were denied health care coverage.[69] CMS issued a second letter to the states on May 7, 2008, restating the policy set forth in the August 17, 2007 letter.[70]

The law's mandate extended for only ten years and its reauthorization was a subject for debate during the 2007 Congressional session. The Bush Administration and the Democratic Congress reached an impasse while debating the terms of any new enactment of SCHIP. As such, they extended the law's 1997 version through March of 2009, after the nation's next election cycle.[71] After the 2008 elections, Democrats in Congress planned to make reauthorization of SCHIP one of its first priorities. After quick passage through both the House and Senate, President Barack Obama, on February 4, 2009, signed into law the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA). Calling it a "down payment on my commitment to cover every single American," the reauthorization would "provide health care to millions of children across the country and [will go] into effect on April 1, 2009."[72] The signing of CHIPRA into law ensures financing for CHIP through fiscal year 2013.[73] Although the major health coverage program for low-income children is Medicaid, with about twenty nine million enrollees,[74] currently, seven million children are enrolled in

CHIP, with the CBO estimating 4.1 million children will join the program by 2013.[75]

For uninsured children whose parents are not poor enough to qualify for Medicaid but not rich enough to afford insurance, this program will ensure that their health care needs are met for the immediate future. President Obama issued a memorandum to CMS on February 4, 2009 – the day CHIPRA was signed into law – directing CMS to disregard President Bush's prior directives. In essence, states have more flexibility, or at least as much flexibility as they did prior to the Bush Administration's directives to determine income eligibility levels for their families. With this dual plan of action by the Obama Administration, and the program's general popularity, universal health insurance for children is creeping closer to reality in America.

E. Tax Exemption for Non-Profit Hospitals

The IRS, through § 501(c)(3) of the IRC, grants non-profit hospitals a tax break that some estimates predict decreases tax revenues by twenty billion dollars.[76] The public policy, generating free care for the poor, was reflected in the regulation's original language which required that the hospital be, "operated to the extent of its financial ability for those not able to pay for the services rendered." The IRS, from the enactment of this tax break in the 1950s until 1969, used a 'charity care' analysis in determining whether a hospital was qualified to receive the tax benefit.[77] In 1969, the IRS abandoned the 'charity care' standard in issuing Revenue Ruling 69545, in favor of a 'community benefit' standard.[78]

The original language of § 501(c)(3) represented a way to cover uninsured indigents through the tax code. By changing the analysis from whether the hospital was providing 'charity care' to whether it was providing a 'community benefit', it is less clear what exactly the federal government is subsidizing. Non-profit hospitals pushed for this change, not because they were overburdened by the requirement to provide free care, but because they believed that the Medicare and Medicaid systems would eliminate the need for non-profits to provide services free of charge.[79]

Since the 'community benefit' standard was enacted nearly forty years ago, the health care sector has undergone major overhauls. This raises tough questions. What exactly is the federal government subsidizing in providing this tax relief? If the public policy behind § 501(c)(3) is to provide care for the indigent, what benefit is it providing to said population? Medicaid provides health insurance to the indigent, but forty-six million Americans are still uninsured. Additionally, the media has reported accounts of non-profit hospitals charging more for services rendered for the uninsured than those with health insurance.[80] Uninsured patients are "cross-subsidiz[ing] the deep discounts that hospitals negotiate with private health insurers to provide care for insured patients."[81] Law suits brought on behalf of these patients have failed to establish a real basis for legal relief.[82]

Today, although it is difficult to differentiate between for-profit and non-profit hospitals, only one is subsidized by the taxpayers.[83]

> [T]he vagueness of the existing federal community benefit standard and its historically lax enforcement mean that we do not really know what or how much beneficial conduct flows from the tax exemption and its foregone revenue, or whether that conduct is closely related to improving access and health outcomes for the uninsured or other groups.[84]

This reality has caused some to call for reforming § 501(c)(3). Some reformers call for a return to the 'charity care' analysis, accompanied with strict enforcement.[85] This is exactly the approach the Texas legislature took by requiring hospitals to account for the 'charity care' they provide.[86] Problems still exist with this approach. Specifically, measuring and accounting for charity care would cause administrative headaches and discourage hospitals from providing current benefits to the community not amounting to 'charity care'. Meanwhile, a return to a pre-Medicare analysis may not help the uninsured get access to health care.[87]

Other models call for a flexible tax exemption to measure the variety of ways a hospital could provide community benefits, or even the outright repeal of § 501(c)(3) in favor of tax credits that could be applied to both for-profit and non-profit hospitals.[88] The former would require hospitals to set up a robust accounting system for the community benefits it provides, while the latter may bankrupt non-profit hospitals that rely heavily on the IRS subsidy.[89] I.R.C. § 501(c)(3) essentially is IRS-created health policy. Any federal attempt to provide coverage for the uninsured must take into consideration the tax code's effect on coverage.

III. STATE INITIATIVES

As health care costs continue to eat away at our nation's savings, (or perhaps more accurately, our debt-financed assets) over twenty states have attempted to fix the problem. Maine and Massachusetts have taken the lead in setting up comprehensive plans intended to eventually provide its residents with universal health care coverage. California is in the process of attempting to draft a comprehensive plan, but its struggles demonstrate the limits of state power during these troubling economic times. Although budget problems are currently choking off any new spending initiatives in California, Governor Schwarzenegger has supported the President's push for health care reform this year.[90]

A. Maine Takes the First Step

Maine became the first state since Hawaii in 1975 to pass a comprehensive health care statute with the goal of providing its citizens access to health care by 2009.[91] The Dirigo Health Reform Act established an independent executive agency "to arrange for the provision of comprehensive, affordable health care coverage to eligible small employers, including the self-employed, their employees and dependents, and individuals on a voluntary basis. Dirigo Health Agency is responsible for monitoring and improving the quality of health care in this State."[92] This Act has "contribute[d] to a reduction in uninsured adults to one of the lowest rates in the nation."[93]

The Dirigo Health Agency oversees the DirigoChoice health plan, the state's public sponsored option, and the Maine Quality Forum, which "promotes quality of care initiatives."[94] DirigoChoice can serve as health insurance for small businesses and individuals alike.[95] The program is currently only available for small employers with two to fifty employees, sole proprietors, and individuals.[96] Some benefits of DirigoChoice include no pre-existing condition restrictions, discounts from twenty to eighty percent off the monthly cost of health care depending on income and family size, reductions in deductibles and annual out-of-pocket expenses

depending on discount level, routine preventive care, inpatient/outpatient services, prescription drug coverage, maternity care, child care, childhood immunizations, emergency care, mental health services, no deductible for preventive care or prescription drugs, smoking cessation education programs, domestic partner coverage, extensive provider network, out of network coverage (at greater out of pocket cost), and no referral requirement to see a specialist.[97] DirigoChoice represents one of the most expansive forms of insurance coverage available.

People earning less than 300% of the federal poverty level are eligible for a sliding scale subsidy for DirigoChoice. As of 2007, DirigoChoice had a "maximum deductible of $1,250 and lower sliding-scale deductibles and premiums available to people below 300 percent of the federal poverty level."[98] The plan may suffer from its voluntary aspects. Employers that do not provide health insurance to their employees may voluntarily pay a fee covering sixty percent of their employees' premiums.[99] As of December 2, 2006, only 13,290 residents of Maine had enrolled in DirigoChoice, even though Maine had approximately 130,000 uninsured citizens.[100]

Maine's health care initiative will be funded by employer and individual contributions, general state funds, Medicaid, and the recovery of bad debt and charity care. Nevertheless, the results are nowhere close to the program's initial goals. When DirigoChoice was created, the government estimated that 31,000 people would enroll by the end of 2005.[101] According to a New York Times article published on April 30, 2007, only 18,800 people had signed up for DirigoChoice. Such paltry numbers in comparison to the state's original high hopes has forced Maine's leadership to attempt reform again.

Premiums have become too expensive for many individuals. Prices are increasing instead of decreasing because many of the people who signed up for this voluntary program have significant medical costs. The program lacks enough enrollees to bring down costs because healthy people do not yet see the need for such comprehensive coverage.[102] To cure this problem, Governor Baldacci laid out proposals that would require people to have insurance, employers to offer insurance, or subject both to financial penalties if they fail to abide.[103]

Some critics want to see the program scale back its comprehensive coverage. Jim McGregor, Executive Vice President of the Maine Merchants Association argued that, "[i]t's a Cadillac policy, and we ought to be trying to fund a Ford Escort policy."[104] While Mr. McGregor's concerns reflect a pragmatic approach, Maine has utterly rejected such a tactic. In fact, Maine's State Health Plan for 2008-2009 indicates a desire to maintain the same comprehensive program while still attempting to make strides in other areas such as oral care.[105] Maine's plan to tackle rising costs while still delivering improved health care is to implement an integrated care model that consists of two steps: "(1) the design and implementation of a Patient Centered Medical Home (PCMH) pilot; and (2) the continuation of the work of the Maine Center for Disease Control (CDC/DHHS) and MaineCare to raise awareness and inspire action on addressing the relationship between depression and the prevention and treatment of chronic diseases."[106]

Maine faces substantial obstacles in making the plan available to all its residents. Certain cost-cutting measures implemented by the plan mean lower costs to insurers.[107] Rather than allow the insurers to collect these savings, the state decided to charge insurers for these savings.[108] In 2005 and 2006, Maine charged insurers $43.7 million and $34.3 million, respectively, for alleged cost savings to the insurance companies.[109] The insurance companies complained that they owed much less, but lost in state court.[110] The case is now on appeal and the financing strategy has been scrapped in favor of imposing lower-cost surcharges.[111] This incident underscores the battle states will face in attempting to dictate the profit of insurers.

Furthermore, Maine's large rural, poor, and elderly populations have significant health needs and many businesses are not large enough to afford voluntary payments to employees for health insurance.[112] Insurance companies no longer find it profitable to do business in Maine where Anthem Blue Cross Blue Shield controls a vast portion of the marketplace.[113] If Maine does not figure out how to tackle this problem soon, the lack of competition could make it difficult to keep costs low.[114]

B. The Massachusetts Mandate

On April 12, 2006, Massachusetts passed the most comprehensive attempt at universal health care in our nation's history. The plan includes an individual mandate that requires every person to obtain health care coverage or risk tax penalties.[115] The Massachusetts Health Care Reform Plan (the plan) subsidizes individuals with income levels between 300% of the poverty level, with some expansions to MassHealth, an existing program for poor adults and children.[116] The law also contains a controversial measure with regards to the ERISA. The plan requires employers who neglect to provide coverage for individuals to pay an annual fee of $295 per uninsured employee to the state. These measures have been challenged in the courts under the allegation that such state provisions are preempted by ERISA.[117] More litigation on this issue is likely to follow.

Massachusetts, through a quasi-governmental entity known as the Commonwealth Insurance Connector (Connector), provides six different subsidized insurance programs.[118] The Connector works as the central nerve system through which individuals purchase a plan from one of these six programs.[119] The six plans were chosen "based on their ability to provide comparable services similar to what would be purchased on the open market and are portable upon a change in employment."[120] Beneficiaries of the program pay subsidized premiums based on a sliding-scale means test (akin to the changes adopted to Medicare through the MMA) up to three hundred percent of the federal poverty level.[121] Fully subsidized premiums are available only to those enrollees with income less than 100% of the federal poverty level.[122]

The six health insurance programs cover a wide array of services including "inpatient and outpatient care, mental health and substance abuse treatment, vision care, dental care, hospice care, emergency care, and certain rehabilitation services."[123] At conception, the plan was expected to cost 1.2 billion over its first three years, but it experienced a budget shortfall of $153 million as of April, 2008.[124] The system is funded through a "complex scheme involving Medicaid expansion to cover children, a Medicaid 1115 waiver, and the mandate schedule."[125] As a result of the shortfall, Massachusetts Governor Deval Patrick's request of $869 million is almost double the amount originally planned for the 2008-2009 fiscal year.[126]

These financing shortfalls should not be overlooked as mere growing pains. Instead, they reflect the necessity for a program that accurately

predicts the actual amount of uninsured individuals. Former Massachusetts Governor Mitt Romney, who signed the plan into law, originally thought there were 400,000 uninsured individuals in Massachusetts.[127] In 2008, this figure increased to 650,000 as uninsured citizens came "out of the proverbial woodwork to buy insurance rather than face tax penalties."[128] The state was forced to foot the bill for the premium because the majority of these previously unaccounted for individuals were poor.[129] Furthermore, Massachusetts already had in place a 'free-care' pool to pay hospitals for treating the poor. With the plan, legislators assumed the state would save anywhere between $500 and $600 million due to a decline in uncompensated hospital care.[130] Those savings never came to fruition.

Even acknowledging its shortcomings, the health care solution enacted by the Massachusetts legislature still represents the best attempt at providing universal coverage to its citizens. As of 2008, 340,000 formerly uninsured residents have signed up for insurance programs either through a private insurance company or through the Connector.[131] As more residents sign up, cost control issues are expected to decline. If costs can somehow be reigned in, the program may achieve its goal of universal health coverage for the residents of Massachusetts.

C. California Tries to Follow Suit

Governor Arnold Schwarzenegger, on January 8, 2007,[132] unveiled what would be the largest attempt at health insurance coverage since the creation of Medicare and Medicaid in 1965.[133] The program faces the daunting task of providing insurance to 6.5 million uninsured Californians.[134] Governor Schwarzenegger's plan revolves around three main elements: (1) prevention, health promotion, and wellness; (2) coverage for all Californians; and (3) affordability and cost containment.[135]

The Governor began promoting the first element of this plan in his acting days. He intends to incentivize healthy behavior such as gym memberships and weight management programs.[136] In addition, the plan proposes to reduce premiums for participation in healthy activities.[137] These incentives are "linked to a health risk assessment and follow-up doctor visit[s]."[138] The Governor proposes additional measures to address two preventable causes of high health care costs. The proposed plan seeks to develop a diabetes treatment model and implement what is known as 'evidence-based' measures to reduce medical errors.[139]

The Governor's second goal is to provide health coverage for all Californians. To achieve this result, he has proposed an ambitious five-part plan:

> (1) Expansion of the Medi-Cal and Health Families programs to cover all uninsured children with family incomes below 300% of the federal poverty level; (2) mandated purchase of health insurance by all legal adult residents of California and expanded medical coverage for undocumented persons in California; (3) provision of payment assistance for lower-income adults through a state purchasing pool; (4) a mandated minimum level of coverage with a $5,000 deductible plan and maximum out-of-pocket costs of $7,500 per person ($10,000 per family); and (5) a "pay-or-play" mandate requiring all employers with 10 or more employees to provide health coverage or pay a 4% payroll contribution to the cost of coverage, as well as a contribution to the state health plan of 4% gross revenues by hospitals and 2% of gross revenues by physicians.[140]

With the fifth element in his plan raising ERISA questions discussed below, the Governor may have to rethink the viability of this plan.

The Governor introduced a complex system of cost-saving measures and mandates on provider spending. These measures include: (1) a set of tax breaks for contributions to Health Savings Accounts; (2) a mandate that forces patient care to account for eighty five percent of every dollar a health plan, insurer, or hospital receives from premiums and health spending; (3) an expansion of electronic submission of documents between insurers and beneficiaries; (4) universal electronic prescriptions by 2010; and (5) incentives for quality health care through pay-for-performance measures.[141] Whether these provisions would successfully fund an insurance plan for millions of uninsured Californians remains to be seen.

Concerns about the financial health of Governor's Schwarzenegger's proposal are well-founded. The most recent plan, the Health Care Security and Reduction Act (HCSRA), proposed to finance health coverage through: (1) an employer contribution based on the size of payroll and number of uninsured employees; (2) expected contributions from counties totaling one billion dollars; (3) a raise in cigarette tax to $1.75 per pack; and (4) a mandated four percent contribution from hospital revenues into a state-controlled fund.[142] However, California's Legislative Analyst's Office, an independent state agency, found that "by the fifth year, the program's costs would exceed revenues by $300 million, and by as much as $1.5 billion a year further down the road."[143] The state Senate committee did not pass HCSRA because it was deemed too expensive.[144]

California's budget shortfalls, exacerbated by the economic recession, forced the legislature to put universal health care on the backburner. Although Governor Schwarzenegger remains committed to providing Californians with universal health care, he faces an uphill battle. California is an example of a state not having the financial capacity to deal with a major health care overhaul during times of economic hardship. Obliging states to fund large entitlement programs, such as universal health care, creates long-term problems for state budget-planners, especially when the economy is not producing tax revenue to pay for such programs.

D. Problems with Employer Mandates: Preempted by ERISA?

On January 12, 2006, Maryland successfully overrode the governor's veto, and passed the Fair Share Health Care Fund Act (the Act).[145] Employers with at least 10,000 workers that spend less than eight percent on non-profit payroll (less than six percent for-profit payroll) on health insurance cost are required to contribute to the state Medicaid program.[146] In early 2005, prior to passage of the Act, the Retail Industry Leaders Association (RILA) challenged the Act on its constitutionality and preemption by ERISA. ERISA contains a preemption clause that states, "ERISA shall supersede any and all State laws insofar as they relate to any ERISA-covered employer benefit plan."[147] The preemption clause ensures that only one set of regulations governed employee benefit plans.[148] In *Shaw v. Delta Air Lines, Inc.,* the Supreme Court declared that "a law 'relates to' an ERISA plan if it has either 'reference to' or 'connection with' such a plan."[149]

The United States District Court in Maryland, in a July 19, 2009 decision, determined that the Act was constitutional but preempted by ERISA because it had a "connection with" an ERISA plan.[150] The court essentially looked at two criteria: the objectives of ERISA and the effect of the state law on ERISA plans.[151] The court reasoned that the ERISA preemption clause was intended to avoid a multiplicity of regulations and concluded that, "[T]he intended effect of the Act is to force the employer to increase its contribution to its health benefit plan, which is an ERISA plan, and the actual effect of the Act will be to coerce [the employer] into doing so."[152] The court's decision was affirmed in the Fourth Circuit.

The Fourth Circuit's decision sent shockwaves through state legislatures, as states have either attempted to pass employer "Pay-or-Play"[153] laws or at least debated the possibility. The Massachusetts Pay-or-Play provision, if challenged, will probably be preempted by ERISA due to the fact that it "mandates employer health care financing."[154]

With states struggling to find ways to pay for health insurance programs, this is yet another indication of the need for federal intervention in health care. The issue has not gone unnoticed on Capitol Hill. Senator John Kerry of Massachusetts "said he wanted to require employers to provide insurance to their employers."[155] Bringing to fruition Senator Kerry's hopes would go a long way to cure the ERISA-created hassle for state programs trying to effectuate change in our health care system.

"With states struggling to find ways to pay for health insurance programs, this is yet another indication of the need for federal intervention in health care."

IV. LOCAL INITIATIVES

While much attention is drawn to the debate over universal health care at the state and national level, local initiatives are also emerging. The following is a brief look at local initiatives taking place in California and Maryland. The county-level programs in California stress coverage for children. Howard County, Maryland is beginning its attempt to provide health coverage for the uninsured at all ages.

A. Californians Take the Lead at the County Level

In California, as many as twenty five counties operate what is known as a Children's Health Initiative (CHI).[156] CHI has two basic goals: (1) increasing outreach to uninsured children eligible for state-provided health insurance programs; and (2) developing a new insurance program known as Healthy Kids for children who would otherwise be ineligible for the state-administered programs.[157] California, the nation's largest state, has suffered immensely from a drop in employer-based coverage, increasing poverty rates, and rising immigration.[158] These factors have forced a shift of responsibility in financing health insurance for families.

The California Medical Association reported that in 2007, twenty percent of Californians were uninsured, a remarkable 6.6 million people (the largest uninsured population of the states), sixteen percent of whom are children aged zero to eighteen.[159] An estimated two-thirds of these children are eligible for existing programs, but have not yet enrolled in Medicaid or SCHIP (entitled Medi-Cal and Healthy Families, respectively).[160] The remaining third fail to qualify because their family's income does not qualify or, more commonly, the family has undocumented immigration status.[161] These facts underscore the need to fulfill the two goals of California's local initiatives: to educate the public of existing programs and to provide insurance for those who fall through the current system's cracks. The existing state programs have "restrictions on providing assistance to undocumented families, and child health advocates sought alternatives to ensure that the estimated 200,000 or so ineligible children without coverage could obtain care."[162]

In 2001, Santa Clara County launched the first CHI and Healthy Kids programs, followed closely by Alameda, San Francisco, and San Mateo Counties.[163] The program was launched in only six months, using a mix of public and private funding.[164] Currently, twenty-six counties operate Healthy Kids programs. Other counties offer CalKids benefits.[165] Furthermore, children appear to be faring better as a result of government insurance displacing employer-based coverage. For example, "[p]ublic program expansions have more than offset major decreases in employer-based coverage, resulting in an estimated net decrease of 117,000 uninsured children between 2001 and 2003."[166]

The rapid pace of growth for these programs spurred further efforts to both consolidate resources and vary approaches. Regional efforts to consolidate county programs are underway and three CHIs have initially opted to utilize CaliforniaKids, a nonprofit private insurance plan for undocumented immigrant children aged two to eighteen.[167] CaliforniaKids is available statewide, offering primary coverage and subsidized premiums to qualified children.[168]

Although CaliforniaKids has served more than 62,000 children statewide,[169] Marin County hopes to leave CaliforniaKids behind and aims to offer a Healthy Kids program.[170] The Healthy Kids program, run by CHIs, has been successful in enrolling more than 85,000 children whose immigrant status precluded them from

coverage under federal and state insurance programs.[171] Furthermore, these county-wide initiatives enrolled countless more children in the state-run health insurance programs to ensure that California inches "closer to universal coverage for children."[172]

B. Howard County, Maryland

Howard County, Maryland attempted to build a low-cost health care program to serve its estimated 15,000 uninsured adults.[173] The program launched on October 1, 2008.[174] Healthy Howard, as the program is called, "offers care for as little as $50 a month." [175] Although applicants inundated the program when it first went online, most were denied because they were eligible for state or federal programs and were consequently directed to those programs. This is a sign that information is not being disseminated regarding government-sponsored health insurance at the federal or local level.[176] As a result, approximately 109 of the 1,500 uninsured but eligible individuals were receiving health care through Healthy Howard.[177] Howard County is ready to take some bold marketing steps to attract the uninsured to the program. These steps include "plans to increase outreach efforts to local college students and small businesses. They are even resorting to cold cash – offering some nonprofit community groups $20 for each person they help recruit for the program."[178]

V. THE AMERICAN RECOVERY AND REINVESTMENT ACT, THE OBAMA ADMINISTRATION, AND CONGRESS: HOPE FOR THE FUTURE?

A. The American Recovery and Reinvestment Act (ARRA)

President Obama kept his campaign promise by signing the ARRA into law. The ARRA provides $19.2 billion to support the development of health information technology (HIT).[179] The ARRA also goes a long way to address long-term cost-containment issues, such as HIT and research in best practices. The AARA sets aside ten billion dollars for the National Institutes of Health; two billion dollars for Community Health Centers with$1.5 billion of that amount allotted for construction, renovation, equipment and HIT, and $500 million for operations; and $1.1 billion for Comparative Effectiveness Research.[180] Another $500 million was set aside to expand the primary care work force, with $300 million going to the National Health Service Corp. and $200 million allotted for primary care training programs contained within the Public Health Services Act.[181] Furthermore, the ARRA provides an additional $500 million to the Indian Health Service for renovation, HIT, and health services. Another $338 million will go to "Medicare spending to block payment reductions for teaching hospitals and hospice providers and to make technical corrections for long-term care hospital payments."[182]

While the ARRA went a long way to place a 'down payment' on health reform, the steps taken were mostly to counteract the economic recession while the task of true health care reform remains with Congress. This could prove to be a tough fight. As of this paper's publication date, five Congressional panels have passed comprehensive health reform bills.[183] While this represents a significant step forward towards passing legislation, Congress must still reconcile some of the more contentious issues – a public option and an individual mandate being two of the major ones – before the proverbial 'mission accomplished' flag can fly above Washington.

The plan President Obama touted on the campaign trial would cost approximately $1.2 trillion over ten years,[184] but would not guarantee coverage to all Americans. The Lewin Group, a leading consulting and health policy analysis firm, estimates that in order to cover all Americans the cost will be between $1.5 and $1.7 trillion dollars over ten years.[185] This price tag has drawn criticism from Republican lawmakers.[186] It will be difficult, but not impossible, to pass a major overhaul of our health care system. The President, through the ARRA, asked Congress to place $634 billion into a reserve for health care reform.[187] However, Congress has yet to appropriate this money into such a fund.

B. Health Care Reform Legislation

As President Obama has called upon Congress to provide a health care proposal, many commentators are expecting a tough political fight.[188] In recent years, several proposals have floated around Congress. In April of 2007, the late Senator Edward Kennedy (D-Mass.) and Congressman John Dingell (D-Mich.) introduced the "Medicare for All" bill, which included an individual mandate and the offering of Medicare to those under sixty-five during a five year phasing-in process.[189] Those ages fifty-five and sixty-five and children under the age of twenty-five would be eligible for coverage.[190] Enrollees would then be able to choose any of the private insurance plans available to federal employees through the Federal Employee Health Benefit Program (FEHBP). The estimated cost is $600 billion per year paid for by payroll taxes and general revenues.[191]

Representative Pete Stark (D-Calif.) proposed "AmeriCare" as an alternative, while Senator Ron Wyden (D-Ore.) introduced the "Healthy Americans Act" in 2006.[192] Stark and Wyden's proposals claimed to cover nearly all Americans.[193] Stark's proposal would turn Medicare into the primary source of insurance coverage for all Americans. The AmeriCare proposal estimated that administrative costs of health insurance would decline by seventy-four billion in 2007.[194] Stark's proposal underscores what many believe a single-payer system would accomplish by slashing the administrative costs associated with private health insurance. Wyden's proposal, on the contrary, would set up regional purchasing pools called Health Help Agencies.[195] People would purchase private insurance in these large regional groups that were estimated to cut administrative costs by fifty-seven billion in 2007.[196]

While neither of these proposals became law, they underscore the debate on Capitol Hill. Some liberal Democrats urge for the creation of a single payer system, while moderate Democrats and Republicans are pushing for more personal choice in order to supplement and encourage participation in the private health insurance market. With five Congressional bills having passed their respective committees, a number of options still linger that could find themselves into the final draft. The Senate Finance Committee balked at a public option and chose instead to propose a system of consumer-driven cooperatives established with six billion federal dollars.[197]

The jury is still out on whether cooperatives can successfully compete with the private insurance market to force down costs. In the rural west, insurance cooperatives have existed for quite some time with success – notwithstanding Republican Senator Orrin Hatch's characterization of cooperatives "as another way of saying a government plan."[198] Cooperatives are completely member-owned.[199] In Idaho, "a consumer-

governed, nonprofit health care provider — Group Health Cooperative of Puget Sound — offers extensive [health] coverage at some of the lowest premiums in the nation."[200] Cooperatives are also a uniquely American solution to health insurance. Many western Americans purchase "their tents, sleeping bags and bikes from the nation's largest consumer co-op, REI, founded in Seattle in 1938, now with 3.5 million active members. It's consistently rated one of the best places to work in the United States."[201] Whether 'co-ops' can assuage both Republican desires for there not to be a public option and the Democratic desire to create some entity that can keep the insurance industry honest is difficult to foresee.

What could be the most intriguing aspect to this battle is how Democrats decide to try and pass health care reform. The Democratic Party holds a significant majority in the House, such that initiatives like a public option are sure to come out of House bills. Liberal Democrats, such as Portland, Oregon Representative Earl Blumenauer, continue to hope for a public option claiming: "[i]t would be very hard for me to [vote for a bill without a public option]."[202] However, Republican opposition in the Senate remains committed to seeing the government stay out of the insurance business.[203] Olympia Snow, the lone Republican senator from Maine, who voted in support of the Senate Finance Committee's bill, may turn out to be the key determinant of any final bill.[204] Her continual insistence that a final bill not include a government sponsored insurance option – coupled with Blue Dog Democrats' similar instincts and the desire to have the appearance of bi-partisan support – underscore the difficulty of reconciling bills coming out of the House and Senate.

The ARRA barely passed muster in the Senate, and health reform will be an even harder fight tempting Democrats to use a process called 'reconciliation' to pass major health care reform. If Congress takes the normal route, Democrats risk a Republican filibuster unless they can count on Arlen Spector's allegiance to his new party. Reconciliation would erase the need for sixty 'yea' votes, and allow health reform to pass by a simple majority. Reconciliation is more properly termed 'budget reconciliation' and would place any health reform proposal in a budget resolution that only requires a simple majority vote in the Senate.[205] Reconciliation is still an available option and "the Obama administration has made it clear that they will push something through, using reconciliation if necessary, and in effect put Democrats who don't go along on the spot."[206]

If Democrats can pass health care reform through the reconciliation process there will undoubtedly be little concessions made to the Republican Party. Such a proposal would most likely include a public health insurance plan to compete with the private market, and perhaps a program mandated employers to provide a minimum amount of health coverage.[207] Senator John D. Rockefeller IV, a Democrat from West Virginia, hopes to see a public option in any final legislation while Senator John Kerry hopes to push through an employer mandate to provide health insurance for their employees.[208]

Senators are allowed, under current rules, to attack provisions of a reconciliation piece that are "merely incidental to budgetary concerns, [but] nobody is quite sure how the Senate parliamentarian would rule on such items as tighter regulation of private insurers or creation of a new public plan to improve the coordination of care."[209] Democrats may attempt to establish a bill that allows for the normal Congressional procedures with a clause that would eventually bring the proposal into the reconciliation process if Democrats and Republicans cannot agree on a bill.[210] One concern with the reconciliation process is the divisive affect it may have on the country. The Republican base would certainly feel cheated, and the President's goal of bringing the country together may never come to fruition. Conservatives may forever hold a grudge against the President for his failure to reign in a Democratic Congress unwilling to compromise, ferociously attacking any further attempts at reform in other fields. Either way, the fight for health care reform is under way.

VI. CONCLUSION

A. Universal Coverage for Children a Far Easier Task

Providing coverage for children seems to be a more feasible goal than providing coverage for all Americans. This makes sense in light of the American value of self-reliance. In order to create a universal health care system, the public will have to accept the fact that the government, not the individual, will be the guarantor of health care. The public seems more willing to accept a government initiative to ensure health care for children because children lack the self-reliance necessary to provide health insurance for themselves.

The ease with which Congressional Democrats passed the reauthorization of SCHIP (now known as CHIP) is a telling sign that America is getting used to the idea of universal health care. However, comparing a program that provides insurance to children, who

"The public seems more willing to accept a government initiative to ensure health care for children because children lack the self-reliance necessary to provide health insurance for themselves."

have no control over their parents' income, to a true universal system of health care may not be warranted. There still seems to be a general fear of an all-powerful federal program governing something as private as a person's health care. Perhaps, as more and more people experience the benefits of CHIP, we can expect the nation to turn the corner and warm to the idea of universal health care.

B. Facets of a Solution

1. Make the Public Aware of the Health Care Coverage Available

All levels of government seem to be failing when it comes to community outreach and education. In 2006, twelve million non-elderly uninsured Americans were eligible for existing state or federal health programs, but failed to enroll.[211] The government should take note of the problems created by failed outreach. Arkansas currently offers coverage through small businesses but the program enrolls a mere 5,000 people while having the capacity to accommodate ten times as many.[212] Massachusetts currently imposes a tax penalty on 167,000 individuals because of their failure to enroll in either a private or public insurance program. In Maryland, Healthy Howard has only been able to enroll 109 out of an estimated 13,500 uninsured constituents.[213] If outreach programs do not address these inadequacies, any initiative is bound to fail to provide health coverage to the uninsured.

2. Fix the Tax Code

The tax break created under IRC § 501(c)(3) was enacted before the existence of Medicare and Medicaid and needs reevaluation. While the language was amended to reflect these federal health insurance programs, the IRS has still failed to rationalize the change in light of the public policy concerns behind the subsidy. The original policy goal was to provide medical care for those who could not afford it. While Medicare and Medicaid provide health insurance for a large portion of the population, millions still slip through the cracks. There are forty-six million uninsured Americans who cannot afford health care. The tax benefit provided to non-profit hospitals would more accurately address public policy concerns if the benefit were granted according to the hospital's provision of medical services to the uninsured at a discounted rate.

The twenty billion dollar subsidy for non-profit hospitals is still merely "a drop in the bucket in terms of the amount needed to address the access problems faced by the insured."[214] Any change to IRS rulings or enforcement policy would not substantially address the health care problems we face as a nation. Still, every little bit helps. As Congress and the Administration lay out their plans for reform, it is important that they address a myriad of potential areas for reform, including the tax code.

3. Get Everyone in the Pool

To spread risk and decrease per-capita costs of health insurance, the healthy and young need to jump into the insurance pool. Outreach programs will not force young, healthy individuals to allocate monthly rent money for a benefit they cannot foresee using. Hence, some sort of mandate may be necessary. In Massachusetts, the individual mandate had more success than Maine's original coverage plan, forcing the Maine legislature to consider implementing an individual mandate.

While during the presidential election campaign then Senator Hillary Clinton (D-NY) supported an individual mandate on the campaign trail, President Obama shied away from such a federal declaration. Instead, the President believes we can provide affordable health care to all through cost cutting measures such as: allowing more generic drugs and drugs from other developed countries to enter the American marketplace, subsidizing the costs of catastrophic care for insurers, preventing insurers from overcharging doctors for their medical malpractice insurance, requiring large employers who do not provide health coverage to pay into a worker's health care savings account, requiring insurance companies to cover pre-existing conditions, providing a small business health insurance tax credit so they can also provide insurance to their employees, and promoting initiatives such as investments in HIT and quality of care.[215]

4. Health Care Reform Does Not Need to Completely Overhaul the System

Whether the President's program would be enough to bring substantial numbers of the uninsured into the risk pool remains uncertain. Massachusetts Governor Patrick, after experiencing frustrations with rising premium costs even with an individual mandate, told reporters prior to the 2008 election, "[t]he next administration in Washington should give serious consideration to a single-payer universal health care solution."[216] Such a solution would no doubt lower administrative costs in the future, but at what cost?

Currently there are a myriad of ways in which Americans get their health care, ranging from Veterans benefits, Medicare, Medicaid, employer-sponsored plans, and private insurance. In a New Yorker piece

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entitled *Getting There From Here: How Should Obama Reform Health Care?*, Atul Gawande takes the reader through a history of universal health care developments around the world. Contrary to popular beliefs, universal health care reform in countries like Great Britain, France, Switzerland, and Australia did not come about with drastic changes to the systems already in place.[217] Instead, each country merely built around and expanded the pre-existing insurance programs.[218] The plan that President Obama proposes seems to do just that by providing a mix of tax benefits and incentives for employer-sponsored health insurance, as well as the possibility of expanding existing federal programs. With the addition of a few cost-containing measures such as investments in the quality of care, preventive care, and HIT, change could be right around the corner.

C. Federalism is Working like the Founders Planned, Now its Time for Washington to Take Action

In the health care context, federalism is working out as planned: experimental, slow and painful – at the expense of millions of uninsured Americans. States and localities are initiating programs for universal health care while Congress debates how such a system would work. The results are mixed. Local initiatives in California seem promising and reflect a truly American solution with a combination of private and public funding. This cannot be mistaken for a belief that local solutions can rescue the almost fifty million Americans without health insurance. Historically states and localities were the first to enact fair labor standards at the start of the twentieth century. It was not until after numerous court battles, the Great Depression, and the election of Franklin Roosevelt that a national plan was created to provide some sort of safety net and floor for employees' wages.

When comparing the current economic situation to the crisis that precipitated the New Deal, there are some stark differences. First, states and localities are not waiting for the federal government to solve their problems. Akin to the early years of the twentieth century, states are taking the lead in ensuring a safety net exists. This time the target is health care, not fair labor standards. Furthermore, ERISA represents a legal tug of war between the states and the federal government. Prior to the New Deal, Supreme Court decisions made it very difficult for the federal government to enact national workers' rights laws. Although we face almost the opposite problem today – with federal courts denying states the power to mandate employer contributions to health coverage programs – both court challenges underscore the need for federal action. With regard to the enactment of fair labor standards, too many states were not willing to enact their own workers' rights laws. Today states are unable to fully incorporate employers into a health insurance solution due to ERISA preemption. This dramatically weakens states' abilities to provide coverage to the uninsured, as employer provided health care represents one of the largest facets of American health insurance.

The current economic recession, like the Great Depression, is increasing the number of uninsured citizens in America. Since the federal government is one of the few players that can access the capital needed to provide health insurance to those forty-six million uninsured, it only makes sense for it to take responsibility for the costs and risks associated with a government administered health insurance program. As the benefits and drawbacks of such a system battle each other in the marketplace of ideas, federalism seems to be doing its job. It is unclear how these debates will be resolved, but one thing is certain: history and the realities of the day point in the direction of a federal solution.

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Protecting the Marks of Life: Genetic Testing and the Personalization of Health Care

*Michael L. Wilson**

Mark and Jennifer Jones recently gave birth to Sarah, a seemingly healthy newborn baby girl. During the pregnancy, the Jones' physician learns that both Mark and Jennifer have relatives who have been diagnosed with cystic fibrosis. Cystic fibrosis is a hereditary disease, and the Jones's physician recommends that Sarah be tested for the genetic abnormalities that lead to the disease later in life. A small sample of Sarah's blood is taken and sent to the hospital laboratory. The hospital laboratory analyzes 87 of the most common genetic mutations that can lead to Cystic Fibrosis. Unfortunately the tests conclude that Sarah, although not currently displaying any symptoms, will contract the disease early in her life. After receiving these results, Mark, Jennifer, the Jones' doctor, and a genetic counselor discuss the results. The doctor reviews all the medical options for a young child who has cystic fibrosis, and stresses how a well-balanced, high-calorie, high-protein diet can help manage many of the symptoms. The Jones' take the doctor's advice to heart, and follow his advice in the care and early upbringing of Sarah.[1]

The above scenario is an example of a genetic test performed through routine medical practice and is presented, along with examples of other beneficial genetic tests, on the United States Department of Health and Humans Services' (HHS) Personalized Health Care Initiative website.[2] This is an example of an ideal scenario where a genetic test can be performed in the course of everyday medical practice, and in this case, is a routine genetic test performed on all newborn infants in many states.[3] The benefits of performing a test for cystic fibrosis are undoubtedly of enormous and can lead to careful lifestyle planning and a much improved and prolonged life for the individuals affected.[4]

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In contrast, what if the genetic testing described above were performed with a larger or alternative focus in mind? What if, instead of, or in addition to cystic fibrosis, genetic testing reveals that Sarah will have a sixty percent chance of developing a severe mental illness such as schizophrenia by the time she is thirty? What if genetic testing reveals if she will have a seventy percent likelihood of developing Alzheimer's by the time she is seventy? What if there is not a cure or well-proven treatment to reduce the effects of these debilitating conditions? Sarah could end up marked for life.

Many of the fears associated with 'genetic marking' have played out in science fiction works—primarily based on the fear that genetic testing could predict the potential intelligence, strength, or talents of a particular individual and thus evolve into a new system of discrimination and class distinction.[5] The real fear still persists that Sarah, or individuals like her who receive genetic testing, might be discriminated against because of a genetic propensity to develop one or more of a vast number of hereditary diseases in their life.[6]

Perhaps an individual may exercise a right not to be informed about non-curable genetic diseases or they may decline to know about any genetic abnormalities whatsoever. But can an individual or the parent of an individual decline all testing? If the testing is performed, and the individual declines to be informed of the results, what might happen if the information is somehow disseminated to others, i.e., employers or insurance companies or others who may exploit such information for criminal purposes? What about the possibilities that the genetic diseases are never manifest?

As the practices and procedures of medicine are evolving into a new ideology based on the treatment of the individual pursuant to a 'personalized health care' approach, there has never been a more important time to ensure that the identities and private information of those whose genes are being tested are thoroughly respected and safe-guarded.

This article will examine the progress being made toward the development of personalized health care

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medical systems based on the use of genetic testing, the current and pending laws required to protect the genetic privacy of every human being, and the effects of these systems on the American health care system in general.

I. The Personalized Health Care Initiative

> The Personalized Health Care Initiative will improve the safety, quality and effectiveness of healthcare for every patient in the U.S. By using "genomics", or the identification of genes and how they relate to drug treatment, personalized health care will enable medicine to be tailored to each person's needs. Healthcare that is proactive, instead of reactive, gives the patient the opportunity to become more involved in their own wellness.[7]

On March 23, 2007, former Secretary of Health and Human Services, Mike Leavitt, identified a strategy for achieving gene-based medical care combined with the use of health information technology, something he referred to as "Personalized Health Care" (the Initiative).[8] Secretary Leavitt commented that the "initiative has the potential to transform the quality, safety and value of health care for patients in the future."[9] The idea behind this initiative is to take advantage of scientific breakthroughs resulting from the human genome combined with recent technological advancements to exchange and manage medical information. This will result in an increased ability to provide correct treatment to each individual patient at just the right time. [10] Secretary Leavitt continued,

> Gene-based medicine can help individuals identify their particular susceptibilities to disease while they are well and take effective preventive steps. In the future, it will help detect the onset of disease much earlier, enabling treatment to prevent disease progression, and can help bring about medical products that are tailored more precisely to the needs of each individual… In the future, we'll understand diseases at a new level…We'll know them as gene- or molecular-based diseases. And that will give us new kinds of treatments that will be effective for both the very specific condition and the individual patient. [11]

Upon announcing this important initiative, Secretary Leavitt further identified the implementation steps that the Federal Government was already taking.[12] He also emphasized that there is much work remaining to build a system capable of delivering effective personalized health care.[13] In identifying the steps that HHS is taking to lay the foundation for the Initiative, Secretary Leavitt established that "HHS is engaged in a broad review of the implications for privacy protection as health information technology is increasingly adopted, including needs for genetic information, and the anticipated effect on the confidentiality, privacy and security of individually identifiable health information."[14]

> HHS seeks to advance the Initiative through two guiding principles:
>
> Provide federal leadership supporting research addressing individual aspects of disease and disease prevention with the ultimate goal of shaping preventive and diagnostic care to match each person's unique genetic characteristics.
>
> Create a "network of networks" to aggregate anonymous health care data to help researchers establish patterns and identify genetic "definitions" to existing diseases.[15]

With or without a federal initiative, it seems inevitable that the practice of medicine is undoubtedly on course to shift from a broad disease prevention and treatment approach to a personalized approach where each individual is treated based on his unique conditions and needs—and, principally, genetics. The advantages the Initiative offers include specific funding for the shift in medical practice and the benefit of Congressional oversight to assure that protective measures are put in place for the protection of privacy.

II. Privacy Concerns

Privacy concerns in genetic testing and health care are not new. As a result of modern advances in genetic testing, individuals fear not only what they might discover about themselves but what others, like employers or health insurance providers, might discover about them.[16] Due to recent advancements in technology many of these past fears are perhaps closer than ever before.

The Personalized Medicine Coalition (PMC), "an independent, non-profit group that works to advance the understanding and adoption of personalized medicine for the ultimate benefit of patients,"[17] came out in support of the Initiative.[18] However, the PMC quickly identified many of the privacy concerns that must be overcome in order for the Initiative to come to fruition.[19] In identifying these obstacles, the PMC pointed out that "[s]everal surveys have been conducted to gauge public opinion around the use and protection of genetic information … [t]he surveys revealed that more than two-thirds of the public is

concerned about potential misuse of genetic information." [20] About one-third of the public are of the opinion that if legal protections are not put in place, concerns revolving around privacy could prevent individuals from utilizing or participating in any genetic research.[21] The concern is that greater technological advances will be made without equal advances in protective measures.

PMC expounds upon the data gathered in the surveys by identifying the specific concerns of the general population:

> PMC believes that all genetic information, including family history, deserves strong and enforceable protections against misuse in health insurance and employment, and PMC supports passage of the Genetic Information Nondiscrimination Act. The benefits of personalized medicine can only be fully realized when the fear of genetic discrimination, and its actual practice, are eliminated from the healthcare system.[22]

The concerns presented by PMC and many other groups who cautiously support the advancement of personalized medical care are just now being addressed.

III. The Genetic Information Nondiscrimination Act

On May 21, 2008, Congress passed, and former President George W. Bush signed into law, the Genetic Information Nondiscrimination Act of 2008 (GINA), as a solution for many of the concerns associated with genetic testing and personalized health care.[23]

GINA is modeled after Title VII of the 1964 Civil Rights Act. [24] GINA protects employees, job applicants and family members by prohibiting employers and health insurers from requesting, requiring, or even buying genetic information about them. Additionally, GINA strictly prohibits health insurers from purchasing genetic information for underwriting purposes.[25]

a. Employment Discrimination

The Equal Employment Opportunity Commission (EEOC) has been charged with promulgating regulations to enforce GINA. In the realm of employment discrimination, GINA brings in a whole new world of enforcement for the Equal Employment Opportunity Commission.

Particular difficulty in enforcing GINA revolves around six loopholes or exceptions to its prohibition on the use or collection of genetic information.[26] These include: the inadvertent acquisition of medical information (the so called water cooler exception), health or genetic services, genetic monitoring of the biological effects of toxic substances, Federal or state Family and Medical Leave Acts, compliance, commercially and publicly available records, and law enforcement.[27] These exceptions leave significant leeway for an employer to obtain information and use that information to discriminate against an employee. The position of the EEOC, however, is that an employment decision based on genetic testing is in violation of the law.[28] The idea is that any test which purports to predict future disabilities, whether it is accurate or not, is unlikely to be relevant to the employee's present ability to perform his or her job."[29]

Another issue is that the EEOC has very little experience with regulating genetic information.[30] One notable case took place in 2001, when the EEOC filed its first lawsuit challenging genetic testing. The case took place in the Eastern District of Wisconsin and the parties' settled for $2.2 million.[31] The allegation presented by the EEOC was that the company had "violated the ADA by requiring dozens of employees to provide blood samples in medical exams after they submitted claims for work-related carpal tunnel syndrome."[32] The blood from the medical exams was secretly used in tests to determine if an employee had any possible genetic predisposition for carpal tunnel syndrome.[33]

With the passage of GINA, the number of employee genetic discrimination cases may rise significantly. Though the number of U.S. companies that are conducting medical tests of employees is dropping, according to surveys by the American Management Association, at least some companies were conducting tests that might be in violation of GINA.[34] The American Management Association found that three percent of companies reported medical testing for breast or colon cancer, two percent for sickle-cell anemia, and one percent for Huntington's disease; all of which can have genetic links.[35] In addition, these surveys found that fifteen percent of companies collected family medical histories which can reveal hereditary genetic predispositions for specific diseases.[36] Employers need to take urgent measures to ensure that employees and all necessary parties are sufficiently instructed on the nondiscriminatory measures within GINA and adequately warned about the consequences of violating GINA.[37]

b. Insurance Discrimination

> GINA fills in the gaps of current federal law such that all health insurers-whether governmental, private, group or individual-would be forbidden to discriminate on the basis of genetic information. Health insurers may not use genetic information to determine eligibility or set premiums. They cannot use genetic information to impose enrollment restrictions or adjust premium or contribution amounts. Health insurers may not require or even request genetic testing or test results, except as necessary for treatment, payment or health care operations. This includes requesting, requiring or purchasing genetic information prior to enrollment.[38]

Though GINA's health insurance protection provisions appear to be near watertight, it will be important for lawmakers to keep an eye on insurance companies to ensure they do not navigate around the provisions of GINA. Careful attention will be required to assure GINA's exceptions are not exploited at the expense of otherwise qualifying individuals.

The passage of GINA is a step in the right direction to protect private information that may be collected in the course of practicing personalized health care, but problems and questions persist. One concern associated with the privacy of genetic information collected in the course of personalized health care is that the information could still find its way into the hands of an employer or insurance provider through one of the loopholes.

IV. Beyond GINA's Reach

While necessary privacy protections must be, and are being put in place, greater measures must be taken in order to overcome the general public mistrust of genetic testing. The measures must both resolve and dispel public concerns and misconceptions revolving around genetic testing.

a. The Right Not to be Tested/Right Not to Know

What about an individual's right not to be tested or right to not know? While much remains to be seen regarding this particular issue, legal precedent says that "adults are free to refuse even potentially beneficial testing and treatment… children [however,] can be treated without their [parent's] consent (and over their parents' refusal) to prevent serious imminent harm."[39] Currently, there is a great discord among the states as to whether genetic testing is mandatory or can be refused.[40] Some states have no provision on refusing genetic testing, while others provide criminal penalties for parents who refuse to have their children genetically tested.[41]

"The idea behind mandatory newborn screening is a benevolent one—to try to ensure that all children get the benefits of screening for PKU and hypothyroidism, for which early treatment can make a dramatic difference in the child's well-being by preventing mental retardation."[42] However, little evidence suggests that it is necessary for a newborn screening program to be mandatory to ensure that children are screened.[43] Rather, evidence suggests that a voluntary program is more effective and reaches a higher percentage of children.[44]

Though it may be difficult to comprehend where such a requirement would be initiated, making adults undergo genetic testing for any reason would appear to be even less effective and may only create more distrust in the system. Further, for adults who are tested, many may wish to exercise a right not to know the results of their tests.

> [G]iving a patient a right to refuse genetic testing, or its results, is justified as vindicating a patient's autonomy, a 'basic bioethical principle.'… [T]hough such choices are often justified by a rational interest in remaining free of the psychological harm that might follow from receiving test results, the right to assess that harm and make a choice whether to know lies solely with the patient.[45]

Another consideration is whether the individual being tested, or the parent of the child who is tested, is capable of living with the knowledge that he, or his child, is plagued with a genetic identity that will likely lead to disease. Parents who are carriers of genetic diseases may feel desperate and guilty for passing on a disease to their children.[46] "Studies have shown that knowing that one is at risk for genetic conditions or even learning that one does not have [a defective gene] strongly affects self-perception and life experiences."[47] Many individuals, for example, suffer from depression when they learn that they have a gene responsible for causing Huntington disease (HD)—some have gone so far as to commit suicide.[48] "Not surprisingly, many who were at risk [for HD] and discover they do not carry the mutation feel liberated. But, after having lived with a sense of being at risk, some have difficulty adjusting to the knowledge that they will not develop HD."[49]

At the very least, regulations should be considered to allow individuals, including children (through parents), to exercise the right not to be tested for genetic disorders for which there is no cure or effective treatment.

b. The Use of Genetic Information in Criminal Proceedings

Some concerns loom as to what might be done with the genetic information collected. What if genetic propensities were introduced as evidence in criminal trials? This type of concern is found in the area of neuroscience and is associated with analyzing images of the brain with an MRI.

> What if you could do a brain scan and determine to a high probability whether a criminal defendant was a psychopath, with, for example, a 60-70 percent chance of recidivism within five years instead of only 20-30 percent? Would that make a difference to a judge or a jury? What if you were a juror in a capital case in the sentencing phase? Would you want to know if someone is a psychopath or not if it affects his odds of committing another murder? How would we want to use that information? ... What if you can say that…particular 12-year-olds will be psychopaths while the others won't be? What do you do with the children you are confident will be psychopaths?[50]

This type of ethical dilemma is further implicated by advancements in genetic testing. What if you could determine that an individual will likely have a propensity (aside from simply having XY sex chromosomes as opposed to XX sex chromosomes) to commit some form of violent crime based on the presence of certain DNA structures? Certainly it provides a basis for taking preventive measures by implementing lifestyle adjustments—much like the result of discovering the likely risk for certain diseases like cystic fibrosis. Should this information ever be presented in a court of law, or disseminated to police officers? These are questions that must be answered by the judiciary, or perhaps more preferably by Congress, before these problems come to light.

c. A Revival of Eugenics?

In the 1927 case *Buck v. Bell*, the United States Supreme Court upheld a Virginia statute that allowed for the forced sterilization of 'feeble minded' and epileptic individuals that were committed to state institutions.[51] Specifically, the hearing procedure conducted before sterilization could be performed was found to satisfy the Fourteenth Amendment because it did not deny equal protection to inmates in state institutions.[52] In his majority opinion, Justice Holmes wrote:

> It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. Three generations of imbeciles are enough.[53]

What if genetic testing were used today for the same or similar purpose? Though genetic testing is unlikely to lead to forced sterilization of those who are 'genetically unfit,' a more realistic possibility is de-facto sterilization where health care is denied to those considered unfit to reproduce. Although this example is extreme, and would be unlikely to arise under GINA, it illustrates the possibility that the results of genetic testing might need to be protected from health care providers who have no apparent need for the information.

V. Further Action Necessary to Implement Personalized Health Care

In additional to privacy concerns, the implementation of an effective personalized health care plan will require other important measures. Many of these measures were laid out by the Personalized Medicine Coalition. These include educating physicians and other health care professionals who will be responsible for treating patients and implementing sufficient technology information systems to aid in the sharing of information.

> PMC believes that extensive education will be required for practicing physicians, medical school students, and a range of healthcare professionals, to enable them to apply an ever-expanding set of molecular approaches for individualized care for their patients. Towards that end, PMC is collaborating with its member organizations that have expertise in genetics and education to develop a unique set of curricula.[54]

Educating responsible parties appears to be one the biggest tasks at hand. Chief amongst the education requirements should be an assurance that health care personnel can effectively communicate the rights of patients receiving genetic testing. This direct communication will further aid in the protection of privacy.

Another area of concern is establishing sufficient health care information technology (HIT) systems such that information can be easily communicated between the appropriate parties.

> PMC actively supports the creation of a national health information network that enables the interoperable exchange of digital biomedical information securely between a diverse set of stakeholders in the healthcare ecosystem. This infrastructure should also take into account the unique needs of the basic, clinical and translational research community. PMC supports the examination of potential incentive structures to induce investment in HIT by all healthcare providers, from solo practitioners to large hospitals.[55]

The implementation of adequate HIT systems raises various concerns. Effective measures, including legislation, must be put in place to ensure the protection of information that is stored or transferred over such systems.

A final concern and stated goal of the HHS Initiative is ensuring the accuracy and validity of genetic tests.[56] Specific verification and testing measures require implementation. Further, penalties for laboratories that continually produce wrong results require contemplation.

Among the remaining steps of implementing the Initiative, great care and concern still needs to be made for privacy. As new measures are taken and new technological feats are reached, careful analysis of privacy protection needs to be made at each milestone. Still, it is appropriate to consider a far reaching privacy measure at this early stage. Namely, Congress should consider creating penalties for any party who sells the genetic information of another or who seeks the genetic information of another to make a profit or with malicious intent.

VI. Personalized Health Care, GINA, and Health Care Reform

President Barack Obama declared his commitment to ensuring that comprehensive health care reform is passed within this year with the stated goal of controlling rising health care costs.[57] Given the President's determination, carefully assuring that a personalized health care initiative is implemented could significantly contribute to the realization of this goal.

a. Cost Savings Under the Initiative

The Initiative will ensure that the practice of medicine evolves into a practice focused on the individual. As more accurate information about a patient is produced, through genetic testing, the costs of treating certain illnesses and conditions may be greatly reduced. The further use of typical hit and miss treatment strategies could be completely abolished and replaced with more narrow and individualized treatment plans. This necessarily leads to a much more effective and cost efficient system. No more time or money need be wasted in 'attempting' to treat individuals.

b. Why GINA Further Necessitates Coverage for All

GINA now makes it illegal for health insurance companies to raise insurance premiums for, or otherwise discriminate against, the class of individuals found to have a genetic propensity for certain illnesses or for the class of individuals who have a family history for certain illnesses.[58] Insurers might choose to quadruple the premiums of or refuse to sell a policy to the third class of individuals—those who are diagnosed with illnesses through routine medical care.[59] Moreover, if a member of this third class "is enrolled in an employer-sponsored group health plan, insurers could raise the rates for everyone in the group."[60]

> Researchers have argued that:
>
> In making such distinctions, GINA is emblematic of this country's piecemeal and inconsistent approach to health care policy, which makes little sense and leaves many Americans without access to care or in danger of financial ruin if they seek care. Our recent history is replete with examples of similar half-measures in health policy. The Emergency Medical Treatment and Active Labor Act (EMTALA) of 1986 ensures that neither the poor nor the sick can be denied emergency medical treatment, but it leaves those without insurance completely on their own when it comes to follow-up care. So when a patient presents at the emergency room with a myocardial infarction with ST-segment elevation, she will receive a lifesaving coronary-artery stent, but she may not be able to afford Plavix (clopidogrel) — which she must take to avert in-stent restenosis — and may not have access to follow-up care, which might enable her to modify her risk factors for heart disease. Medicare might help if the patient is 1 day past her 65th birthday, but not if she is 1 day shy of it. Medicaid might help if her income is lower than the qualifying threshold in her state, but not if she earns $1 more.[61]

Rather than leave out individuals who may have a genetic predisposition for a disease but only find out through routine medical care, the researchers argue that the better solution is outright prohibition of medical underwriting—a prohibition on setting health insurance premiums based upon any health care information.[62]

> Moreover, to ensure that the costs of bad health are shared equitably, all Americans would have to be in the same risk pool. This would mean enacting a health insurance mandate either for employers or, if health insurance could be made affordable, for individuals — and specifying a minimum set of benefits that everyone would be required to have. Given the growing disparity between the cost of modern medicine and the incomes of many Americans, enforcing such a mandate would be difficult. Even with income-based subsidies, an individual mandate could place an undue financial burden on many families. Nonetheless, bringing everyone into the same risk pool is an important long-term goal.[63]

The goals of comprehensive health care reform, as stated by President Obama, may go a long way in ensuring that health care costs for any individual do not escalate out of control.

VII. Conclusion

The practice of medicine is on the verge of moving into a new frontier of personalized health care. The HHS Initiative indeed promises to enthrone a revolutionary approach to the practice of medicine where the focus is on the individual needs of each patient as determined by genetic screening. As the practice of medicine shifts into this new frontier, it is important that the government ensure the protection of each individual's genetic privacy.

GINA provides a substantial step towards protecting an individual's private genetic information against the possibilities of being used for employment or health care insurance discrimination. The beginning steps have been taken, but much needs to be done to ensure that each individual maintains his or her rights regarding genetic testing and the right to not be tested or the right to not know test results. Further, it is of vital importance that Congress keeps a close eye on the progress being made within this field and on the efforts of those who would seek to thwart the laws.

As medicine moves into this new realm of personalized health care, it would be a huge advantage for all parties involved, especially the federal government, to take advantage of the opportunities that personalized health care offers. Specifically, as health care reform is considered and established, the cost benefits of carefully implementing personalized health care initiatives cannot be ignored.

The words of Professor Henry T. Greeley of Stanford University Law School apply: "although this stuff is really interesting, we need make sure it works before we use it. Let's make sure we understand what it can and can't do. And, as a society, we don't do patience very well."[64] Let us be patient and careful in protecting the rights of all mankind.

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The Recession Drives Up Medicaid Enrollment and Drives Down States' Ability to Fund the Program

Jessica Ritsick, 2L

The Kaiser Family Foundation's Commission on Medicaid and the Uninsured recently released a report stating that enrollment in Medicaid has increased due to the current recession. Many insured individuals receive heath care benefits through their employers. With the unemployment rate increasing, however, employer-based health insurance coverage is on the decline. Left with the option of no insurance at all or paying out-of-pocket for private insurance, many of the recently unemployed have found themselves with a third option: Medicaid. Those who are eligible for the program are flocking to receive coverage.

The Federal government shares Medicaid funding with state governments. Many state budgets have been unable to cover the surge of new enrollees in the program and fear their upcoming budgets will not be able to shoulder these costs. The states found some relief in last spring's stimulus plan, but many still worry that there is not enough money appropriated in their budgets to adequately cover patients without sending their own state finances into the red. Additionally, the stimulus funds came with strings attached: states using the funds cannot restrict eligibility or complicate the coverage application process.

Many states are facing the challenge of finding or re-appropriating funds in their budgets. Other states are considering cutting benefits or provider payments – an option that does not violate the terms of the stimulus plan, but could dramatically impact the care of Medicaid recipients. Many doctors already refuse to treat Medicaid patients because the payments are so low that physicians end up operating at a loss.

When unemployment increases, disposable income decreases. The economy declines and state budgets have less financial cushion. Unfortunately, the recession disproportionately affects the poor and unemployed.

The Genetic Fountain of Youth

Molly Elizabeth Conway, 2L

For centuries, explorers have searched for a source of eternal youth. While many of these rituals and explorations would be considered bizarre and mythical today, researchers recently found an internal pathway that, with genetic manipulation, may lead to longevity in mice – and potentially humans.

For decades, scientists have known that reducing caloric intake in experimental organisms leads to a significantly longer lifespan. Recently, however, researchers at the University College London successfully delayed the onset of many age-related diseases and increased longevity in mice by genetically blocking the S6 Kinase protein, a protein that is activated in response to food consumption. The mice were found to have delayed markers of aging and lived twenty percent longer than the non-genetically modified mice.

Other researchers have demonstrated that similar longevity benefits in mice could be achieved by manipulating the S6 Kinase protein through the use of a drug known

to block the protein's action. The drug, Metformin, is one of the most commonly prescribed drugs in the United States. Metformin is used to treat Type II Diabetes and Polycystic Ovarian Syndrome. One of the drug's effects is to alter signaling pathways in cells, 'tricking' the cells into thinking they have fewer nutrients. Researchers hope to find that drugs like Metformin will produce similar results to the manipulation of the S6 Kinase protein by deceiving cells into a starvation response, analogous to what is observed in long-lived calorie restricted animals. Eventually, researchers would like to test the drug's effects on the lifespan of humans.

As the research of the phenomenon in humans continues, perhaps one day we will have our very own Fountain of Youth available at your local pharmacy.

The "Gluten-Free" Struggle

Colin Rettammel, 2L

In January 2007, the United States Food and Drug Administration "FDA) proposed a regulation to define the term 'gluten-free' for voluntary labeling. Nearly three years later, the regulation remains in draft form and as a result, there is no clear legal standard for disclosing levels of gluten in food products. The lack of government regulation for labeling products as gluten-free continues to cause serious problems for the United States population who suffer from Celiac Disease.

Celiac Disease is a chronic disorder where an immune system reaction to gluten proteins causes inflammation of the small intestine. Individuals who are genetically predisposed to Celiac Disease suffer from symptoms triggered when they ingest gluten-containing products – found predominantly in wheat, rye, and barley. There is no cure for Celiac Disease, but experts say that the disease can be effectively managed through strict dietary measures. Thus, individuals who suffer from Celiac Disease – who commonly cannot tolerate even trace amounts of gluten – rely heavily on labels to inform them as to whether a product is safe to consume.

Although knowledge of Celiac Disease has been prevalent in the United States for more than fifty years, it is not considered an allergy and was not covered under the *Food Allergen Labeling and Consumer Protection Act of 2004* (FALCPA). While FALCPA did not establish regulations for gluten-related labeling, it did mandate that the FDA define the term 'gluten-free' within four years of the law's enactment date. The FDA continues to struggle with a comprehensive definition and has now missed that deadline by more than a year. The struggle lies in where to draw the line for gluten-free. The FDA would like to place the gluten ceiling at 20 parts per million (ppm), stating that this is the level current technology can reliably identify. However, the proposed regulation has been met with criticism from many groups who believe this standard is not strong enough and is potentially unsafe. Two independent gluten free certification organizations, the Gluten-Free Certification Organization and the Celiac Sprue Association each say that they reliably certify products that are under 10 ppm. As the FDA struggles with its definition, millions of Americans continue to rely upon unregulated product labels.

The Physician Fee Schedule Debate

Molly Elizabeth Conway, 2L

Medicare is a government-run health insurance program for individuals sixty-five years of age or older, individuals under the age of sixty-five who have certain disabilities, and individuals of all ages who have End-Stage Renal Disease.

Medicare is an entitlement program. It must be fully-funded each year and eligible individuals may not be turned away. In fiscal year 2009, Medicare is estimated to cost a total of $492 billion – three percent of the Gross Domestic Product of the United States – while covering about forty-five million individuals. Physicians who serve the Medicare population are reimbursed on a physician fee schedule established through the *Omnibus Budget Reconciliation Act of 1989* (P.L. 101-239). The physician fee schedule is determined by the Sustainable Growth Rate (SGR), a formula designed to provide payments to physicians in accordance with the costs of providing those services. As established by law, each year the reimbursement rates are calculated using the SGR. Since 2002, this formula has resulted in a negative update in payments, leading to concern from physicians and providers.

A decrease in payment would likely lead to increased costs for all patients, including those privately insured, so that physicians can cover the loss suffered from serving the Medicare population. It could also potentially lead to a refusal by physicians to accept Medicare patients. Congress has acted to prevent these reductions each year since 2003. However, the manner in which they have 'paid for' these adjustments has only allowed the issue to snowball. In order to find funds to pay for the current year's adjustment, Congress increases the reduction in payment for the following year. Next year, Congress would do the same thing, thereby continually increasing the reductions that physicians face annually.

Finding a 'fix' has been at the forefront of the health care debate this year. Several proposals have surfaced, including using a formula other than SRG or just appropriating funds to ensure that doctors are reimbursed at a level sufficient to sustain operations. There are few issues brought before Congress that are truly non-partisan. The issue of the physician fee schedule under Medicare is one of those issues and it will be interesting to see what direction Congress takes to fix this problem.

The Fat Tax: Banning Bake Sales and Penalties for Drinking Soda

Jessica Ritsick, 2L

According to experts at Johns Hopkins University, the obesity epidemic in the United States is a full-fledged 'public health crisis' – beginning in childhood and continuing through adulthood. In response to this crisis, schools across the country have locked up soda and snack vending machines until after school hours to force children to eat healthier lunches. Some schools have banned vending machines altogether, even though contracts with these companies provide additional funding to the schools. The New York City Education Department placed a ban on bake sales – limiting them to once-a-month and only allowing dark fudge brownies and lemon squares to be sold after the lunch hour.

President Obama, who has been spotted at 'quick fix' hamburger restaurants such as Five Guys and Ray's Hell Burger, among other places,

supports proposing a 'sin tax' on so-called junk food, especially soda. Proponents of the tax note that, just as the United States taxes and regulates items such as tobacco and alcohol, other potentially harmful food products should also be regulated. Others suggest cutting corn-production subsidies – a reason high-fructose corn syrup permeates so many foods on store shelves – and instead subsidizing organic and fresh fruits and vegetables. Opponents believe that the federal government already over-taxes citizens. They also contend that taxing and regulating non-drug items constitutes an over-stepping of the government's federal power and a potential slippery slope into further regulation.

Most Americans agree that obesity is becoming a crisis in the United States – but what they cannot agree upon is how much regulation is too much regulation.

Cutting Health Care Costs – The Re-importation of Drugs Debate

Colin Rettammel, 2L

The United States health care system has been at the forefront of policy discussions since President Barack Obama took office in January, 2009. Even with this attention to health care reform, the *Pharmaceutical Market Access and Drug Safety Act* is one piece of legislation that has gone largely unnoticed. This bill was introduced by Senators Byron Dorgan (D-ND), John McCain (R-AZ), and Olympia Snowe (R-ME), as a bi-partisan effort to lower the cost of prescription drugs.

The bill would allow drug wholesalers and licensed pharmacies in the United States to re-import prescription drugs originally manufactured in the United States from Canada, Europe, Australia, New Zealand, and Japan. Because many countries impose price controls on the drugs that they import from the United States, the sponsors believe that re-importing prescription drugs at a lower price will pass savings directly on to customers without any inconvenience. The sponsors also state that measures will be taken to ensure that the imported medications are safe, including mandating that only FDA-approved drugs be re-imported and sold.

Many critics of the bill claim that not only are the safety measures inadequate, but that the bill could potentially harm pharmaceutical research and development. The American Enterprise Institute for Public Policy Research argues that the best defense against counterfeit drugs, which are easier to produce outside the United States, is the ban on large-scale drug importation. Thus, the reasoning is that if wholesalers are allowed to import foreign drugs, then counterfeit drugs will find their way into the market, as there is no technology that would allow for the easy detection of such drugs at the border. Along with the security fears is the concern that pharmaceutical companies would potentially lose money due to price controls placed on their products, money that could be spent on research. Even if some countries chose to raise prices to encourage research, other countries could undercut those prices to attract resellers.

While there is much argument about the actual implications of the legislation, there appears to be little room for compromise. The bill will likely be discussed on the Senate floor in the midst of the health care reform debates, as its sponsors are trying to take advantage of the current national spotlight on health care.

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