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Letter from the Editors

Welcome to the Spring 2013 volume of the *Health Law & Policy Brief*. In this issue, we reflect on the rapidly evolving regulatory framework in both the healthcare and pharmaceutical industries, as well as examine a number of public policy concerns related to maintaining health for our nation's citizens.

As the United States witnesses the cavalier march of healthcare costs to levels previously unseen, both political and industry leaders are looking for innovative ways to contain those costs and reverse this troubling course. In the delivery of healthcare services, the emphasis is on better care coordination, enhanced communication between providers, and value-based purchasing by the federal government. Likewise, the pharmaceutical industry is dealing with an ongoing struggle between brand-name and generic drugs, as the government attempts to encourage research and development by brand-name manufacturers while reducing often exorbitant drug costs through generic substitution. Adding to the complexity of the pharmaceutical industry is the unique role of biologics and their sensitive manufacturing processes, as well as the recently implemented Physician Payment Sunshine Act, which requires drug manufacturers to report payments to physicians in an effort to increase transparency in the sector.

Consequently, the time is ripe for law and public policy students and practioners alike to engage in critical analyses of our current healthcare regime and develop creative solutions to some of these pressing problems. It will take the collective effort of many minds to develop real, long-lasting, and workable routes toward correcting the U.S. healthcare system. The pages that follow represent but a small sliver of the intensive thought these matters will require.

On behalf of the *Health Law & Policy Brief* Editorial Board, we would like to specially thank our staff members, whose tireless effort toward reviewing and editing these pieces ensures that we continually produce relevant, high-quality articles on health law issues. This volume would not be possible without their hard work and dedication. For questions or information about the *Health Law & Policy Brief*, please visit our new website at www.healthlawpolicy.org.

Best,

Jake & Katherine

Community Water Fluoridation Around the Nation: Significant Case Law and Legislation

*Jeff Wurzburg and Corrine Propas Parver**

I. INTRODUCTION

Community water fluoridation, heralded in the United States as one of the great public health successes of the twentieth century,[1] is recognized as an essential mechanism to improve oral health, regardless of one's socioeconomic background.[2] Courts across the United States have consistently supported community water fluoridation as a constitutional means of protecting public health; this Article reviews both the legal history and the chronology of fluoridation as a public health measure.

The U.S. began discovering fluoride's oral health benefits in the 1930s and, in 1945, Grand Rapids, Michigan, became the first city in the nation to fluoridate its water supply.[3] Following the example of Grand Rapids, many states, cities, and municipalities over the last sixty-eight years passed legislation requiring and implementing community water fluoridation. By 2010, seventy-three percent of the U.S. population, or a total of 204.3 million people, had access to optimally fluoridated water in community water systems.[4]

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Scientific studies have demonstrated conclusively that adding a low level of fluoride to community drinking water reduces the rate of dental caries among children and adults.[5] The American Dental Association ("ADA") states that "drinking optimally fluoridated water is one of the safest and most cost-effective public health measures for preventing, controlling, and in some cases reversing, tooth decay."[6] Many institutions support community water fluoridation including the ADA, American Medical Association, American Academy of Pediatrics, the American Academy of Family Physicians, the American Public Health Association, the American College of Dentists, and many other medical and public health organizations.

Fluoride exposure during early childhood, while teeth are developing within the jaw, can lead to fluorosis, which is a change in the appearance of tooth enamel.[7] The U.S. government's recommendations for the optimal level of fluoridation balance both protecting from dental caries and limiting the likelihood of dental fluorosis.[8] However, opponents of fluoridation point not only to fluorosis, but also allege that fluoridation can lead to increased risk of cancer, heart disease, osteoporosis and bone fracture, acquired immunodeficiency syndrome, low intelligence, Alzheimer's disease, allergic reactions, Down Syndrome, and other claims,[9] despite reviews from the government and the National Research Council that do not support these claims.[10]

From the beginning, opponents of fluoridation have strived to influence community water fluoridation policies in the public dialogue, courts, and state and local governments. While the percentage of the nation's population with community water fluoridation continues to increase, the number of cities and towns that elect to discontinue water fluoridation is also slowly increasing.[11]

Despite attempts to prevent community water fluoridation through court challenges and ballot initiatives, it has received consistent approval in the courts as a proper means of advancing public health and welfare. In addition, federal guidelines reinforce longstanding government support for community water fluoridation at safe and effective levels.

This Article examines the present status of community water fluoridation in the U.S. Initially, it provides a history of community water fluoridation. Secondly, this Article examines the present state of community water fluoridation at the state and local level. The third section examines the legal challenges mounted against community water fluoridation. The fourth section examines the legal theories employed by opponents of community water fluoridation, and how the courts have addressed them. As community water fluoridation remains a timely public health issue, the final section examines the current efforts both to expand and curtail community water fluoridation.

II. COMMUNITY WATER FLUORIDATION: A HISTORICAL PERSPECTIVE

According to the ADA, tooth decay is "the destruction of [the] tooth enamel."[12] Bacteria in the mouth produce acids that, over time, destroy the tooth enamel, leading to tooth decay.[13] Dental caries have long been a serious problem in the United States,[14] remaining a common and costly health problem among all age groups.[15] The reduction of dental caries in the United States during the twentieth century was a major accomplishment.[16] At the beginning of the twentieth century, tooth extraction was the common treatment for dental caries.[17] While today obesity acts as a barrier for many young Americans to serve in the nation's military,[18] during the first and second world wars, the requirement that soldiers have six opposing teeth was a common impediment for military service.[19] During earlier parts of the twentieth century, three in ten Americans above the age of forty-five had lost all of their natural teeth.[20] More than twenty-five percent of children aged two to five, and fifty percent of children aged twelve to fifteen, are affected by tooth decay.[21] According to the Centers for Disease Control and Prevention ("CDC"), approximately fifty percent of all children, and two-thirds of children age twelve to nineteen from lower-income families, have suffered from tooth decay.[22]

Tooth decay and caries often lead to other health problems, such as "constant pain, malnourishment, [and] loss of teeth."[23] Problems that start in childhood can persist and worsen in adulthood.[24] Poor children are disproportionately affected by pain from tooth decay.[25] Children from families earning less than $10,000 a year have twelve times more "restricted activity days" as a result of dental pain than children of wealthier families.[26]

Fluoride, a natural mineral found in water sources,[27] prevents caries and re-mineralizes tooth surfaces.[28] Dr. Frederick McKay is credited with the discovery of fluoride's effect on teeth. His research began after noticing many of his patients had brown stains on their teeth in Colorado Springs, Colorado.[29] The residents had many explanations, including "eating too much pork, consuming inferior milk, and drinking calcium-rich water."[30] Dental researcher Dr. G.V. Black, dean of the Northwestern University Dental School in Chicago,[31] joined Dr. McKay's research to focus on the cause of this 'Colorado Brown Stain.'[32] The research revealed that teeth afflicted by 'Colorado Brown Stain' were resistant to decay.[33] Dr. McKay subsequently joined Dr. Grover Kempf of the United States Public Health Service to examine reports of similar tooth staining in Bauxite, Arkansas.[34] Notably, they found that the brown stains were common with children in Bauxite, but nonexistent in a town only five miles away.[35] ALCOA's chief chemist, H. V. Churchill, then undertook an examination of Bauxite's water using more advanced technology called photospectrographic analysis.[36] The test presented evidence that the water had high levels of fluoride.[37] Additional water samples from other towns led to the conclusion that fluoride was the reason behind the discoloration.[38]

Dr. H. Trendley Dean, head of the Dental Hygiene Unit at the National Institutes of Health, subsequently found that "fluoride levels of up to 1.0 ppm in drinking water did not cause enamel fluorosis in most people, and only mild enamel fluorosis in a small percentage of people."[39] As a result of Dr. Dean's research and his discussions with the Michigan Department of

Health, the City of Grand Rapids, Michigan, became the first city in the world to fluoridate its drinking water.[40] Dental caries among Grand Rapids children dropped more than sixty percent following the addition of fluoride to its water supply.[41]

Community water fluoridation has been implemented at the state level under the general welfare and police powers retained by the states. To date, the following thirteen states have enacted various statutory requirements for fluoridation of their community water systems: Arkansas, California, Connecticut, Delaware, Georgia, Illinois, Kentucky, Louisiana, Minnesota, Nebraska, Nevada, Ohio, and South Dakota. Legislation ranges from requiring fluoridation to providing an option for municipalities to fluoridate their water supply. In many instances, statewide legislation makes fluoridation of water supplies contingent upon attaining a certain population level. In addition, the overwhelming majority of the nation's largest cities have enacted ordinances requiring fluoridation of their water systems.[42]

III. BACKGROUND ON FLUORIDATION AS A PUBLIC HEALTH MEASURE

The United States supports community water fluoridation based on studies that consistently provide that water fluoridation is a safe and effective modality to prevent tooth decay in both children and adults.[43] Fluoridation reduces decay in children, adolescents, and adults by about twenty-five percent across one's lifespan,[44] and has substantially reduced the rate of edentulism, losing one's teeth, among seniors.[45] Today, fluoridated water reaches seventy-three percent of the U.S. population that is on a community water system.[46] HHS's Healthy People 2020 initiative set a goal of eighty percent of Americans served by community water systems to have optimally fluoridated water by 2020.[47]

Implemented as a public health measure, community water fluoridation is "the adjustment of the existing, naturally occurring fluoride levels in drinking water to an optimal fluoride level recommended by the U.S. Public Health Service for the prevention of tooth decay."[48] Fluoride prevents tooth decay by fortifying healthy teeth against corrosive acid, re-mineralizing decayed teeth, and limiting the ability of bacteria to attack the teeth.[49] When fluoride is added to drinking water, it is retained in dental plaque and saliva.[50]

The cost-effectiveness of community water fluoridation is now well documented.[51] Providing all Americans with fluoridated water could save up to $1 billion per year in dental costs.[52] For communities with more than 20,000 people, the cost is a mere fifty cents per resident.[53] Even in small communities, fluoridation costs three dollars per resident.[54] In addition, the Center for Disease Control (CDC) estimates that each dollar invested in the fluoridation creates approximately thirty-eight dollars of savings in dental treatment costs.[55]

Additionally, in five to seventeen year olds, tooth decay is five times as common as asthma, and seven times as common as hay fever.[56] Community water fluoridation is an intervention to prevent tooth decay in adults and children without regard to socioeconomic status or access to care.[57] The ADA has stated that "[c]ommunity water fluoridation is the single most effective public health measure to prevent tooth decay."[58] Former United States Surgeon General David Satcher stated that the fluoridation of community water is "an inexpensive means of improving oral health that benefits all residents of a community, young and old, rich and poor alike."[59] According to the ADA, tooth decay is reduced by twenty to forty percent as a result of community water fluoridation.[60] Public officials have argued that water fluoridation remains important because many Americans cannot afford dental care.[61]

Notwithstanding the well-documented scientific basis for community water fluoridation, those opposed to fluoridation continue to fight efforts to increase Americans' access to fluoridated water. Two organizations leading this campaign are the Fluoride Action Network[62] and Citizens for Safe Drinking Water.[63] In *The Case Against Fluoride*, Fluoride Action Network's Executive Director, Paul Connett, argued that the benefits of fluoride have been overstated and that other explanations, including regular brushing and sealants, account for the decline in caries.[64]

Scientists do agree that the decline in caries can, in part, be attributed to the increased use of fluoride toothpaste, and note that ingestion of fluoride by young children while teeth are developing under the gums can lead to clinical dental fluorosis.[65] Yet the World Health Organization (WHO) notes that ingestion of fluoride after age six will not cause dental fluorosis.[66] Regardless, opponents continue to allege that fluoridation can lead to increased risk of cancer, heart disease, osteoporosis and bone fracture, low intelligence, acquired immunodeficiency syndrome, Alzheimer's disease, Down Syndrome, allergic reactions, and other claims,[67] despite the U.S. government, the National Research Council, and academic reviews denying these claims.[68] As just one example, a recent study from Harvard University and the National Cancer Institute failed to provide a link between fluoride and bone cancer.[69]

IV. REGULATION AND IMPLEMENTATION OF COMMUNITY WATER FLUORIDATION

Although the U.S. Public Health Service recommends fluoridation to prevent tooth decay, the decision to add fluoride is a decentralized decision and is not mandated by any federal agency.[70] Most water supplies contain some natural fluoride.[71] The optimal level of fluoride in drinking water prevents tooth decay in children and adults and limits children's chances to develop dental fluorosis in teeth forming under the gums. In the 1950's drinking water was the sole source of fluoride exposure. Studies were constantly conducted regarding water consumption and caries experience across different climates and geographic regions in the United States. In 1962, the U.S. Public Health Service recommended an optimum range of fluoride concentration of 0.7-1.2 mg/L, with the lower concentration applying to warmer climates (where water consumption was higher) and the higher concentration applying to colder climates.[72]

Over the past several decades, many factors, including the advent of air conditioning, have reduced geographical differences in water intake. Recent studies failed to associate the total water intake of children and measures of maximum daily temperature, suggesting that the temperature-based approach was unnecessary given the current conditions.[73] Also, Americans currently receive fluoride from multiple sources in addition to drinking water, including food, dental products and pesticides.[74] On January 7, 2011, the U.S. Department of Health and Human Services (HHS) announced that it was proposing a change in the recommended level for community water fluoridation to a single level for the nation of 0.7 mg/L, to achieve the best balance of protection from dental caries while limiting the risk of dental fluorosis.[75]

Although many communities add fluoride to drinking water to strengthen teeth, some communities must treat their water to remove excess amounts of fluoride, which often is present naturally in water. The Environmental Protection Agency (EPA) regulates the maximum amount of fluoride that may be present in drinking water supplies to protect against adverse health effects, as required by the Safe Drinking Water Act ("SDWA"), passed by Congress in 1974. The SDWA requires the EPA to determine contaminant's levels in drinking water at which no adverse health effects are likely to occur. This is referred to as a non-enforceable health-based maximum contaminant goal (MCLG).[76] The EPA also determines a maximum contaminant level (MCL), which is the maximum permissible level of a contaminant in drinking water delivered to any user of a public water system. These levels are enforceable standards.[77] States are granted "primacy" to control their water systems as long as they have adopted standards as stringent as the EPA's.[78]

In a statement released jointly with HHS the day it proposed its new recommendation for the optimal level of fluoride in drinking water, the EPA announced that it was initiating review of the maximum amount of fluoride allowed in drinking water, which is presently 4.0 mg/L. The agencies acknowledged that they were guided by the same scientific assessments and findings of the National Academies of Science (NAS), including information that individuals now receive fluoride from many sources, including "dental products such as toothpaste and mouth rinses, prescription fluoride supplements, and professionally applied fluoride products."[79]

Following the joint announcement, the ADA "commended" the new recommendation and complimented the government's reaffirmation of the benefits of community water fluoridation.[80] A week later, the Grand Rapids Press published an editorial supporting the continued benefits of community water fluoridation, remarking that the new guidelines "suggest fluoride should be adjusted, not discarded."[81]

Because there is no federal water fluoridation requirement, and access to fluoridated water is determined by state and local laws, a complex regulatory web surrounds community water fluoridation. Some states, using their police power, have legislated fluoridation of water. The thirteen states that specifically require fluoridation of community water systems to promote equitable access to optimal fluoride levels by residents across the state include: Arkansas, California, Connecticut, Delaware, Georgia, Illinois, Kentucky, Louisiana, Minnesota, Nebraska, Nevada, Ohio, and South Dakota. The type of requirement varies, with some states including an opt-out provision that allows water systems an exclusion from the requirement. Other state statutes condition fluoridation on the acquisition of capital to fund the fluoridation.

California is an example of a state that requires fluoridation of community water systems. Section 116409 of the California Health and Safety Code states that fluoridation is a "paramount issue of statewide concern"[82] and specifically preempts any "local government regulations, ordinances, and initiatives."[83] Any public water system that has at least 10,000 service connections must be fluoridated.[84] The statute has additional requirements with regard to equipment maintenance, capital cost estimates, testing, record keeping and reporting.[85] The statute also allows for a rate increase, which maintains the system through an application to the Public Utilities Commission.[86] Section 116415 exempts a public water system that fails to raise capital and associated costs from sources other than ratepayers, shareholders, local taxpayers, bondholders, or any fees or charges levied by the water system from the requirements.[87]

States with similar requirement statutes are Arkansas,[88] Connecticut,[89] Delaware,[90] Georgia,[91] Illinois,[92] Kentucky,[93] Louisiana,[94] Minnesota,[95] Nebraska,[96] Nevada,[97] Ohio,[98] and South Dakota.[99] An examination of the statutes reveals each jurisdiction's unique approach to fluoridation. For instance, Nevada's requirement is only applicable to counties with populations over 400,000, and a water system serving over 100,000 people.[100] By comparison, Connecticut's requirement applies to water supplies serving 20,000 people,[101] and South Dakota requires fluoridation for municipal water supplies serving a population of 500 or more, but offers an exception where the naturally occurring level of fluoride is sufficient with the rules of the Department of Environment and Natural Resources.[102] Kentucky requires fluoridation for water systems that serve 3,000 people or more.[103] Those receiving water from smaller water systems are also covered, as the statute requires water systems serving between 1,500-3,000 to provide supplemental fluoridation if "adequate fluoride feed equipment is available from the Cabinet for Human Resources, Department for Health Services, and there are competently trained or certified personnel at the community water system."[104]

In response to the new federal recommendations announced by HHS on January 7, 2011, Illinois amended its state statute mandating fluoridation.[105] The statute now requires the Department of Public Health to incorporate in their rules "the recommendations on optimal fluoridation for community water levels as proposed and adopted by the U.S. Department of Health and Human Services."[106]

Other state fluoride requirements contain opt-out clauses. To date, there has not been research surrounding the effects that opt-out clauses have on access to fluoridated water. For instance, Delaware required a referendum if the water supply was not fluoridated before May 26, 1974.[107] The statute provides specific requirements for the referendum, including that it shall be conducted by the Board of Elections;[108] the Division of Public Health must also provide an educational campaign

about fluoridation.[109] The referendum must occur within sixty days of the Division of Public Health providing notice to the water supplier and the local government.[110] After the referendum, the statute states that it is "conclusively decided" for a period of three years.[111]

If a public water system in Louisiana has never been fluoridated, a vote on an exemption from the requirement is conditioned upon the receipt of a petition containing the signatures of fifteen percent of registered voters.[112] A referendum's results are controlling for four years.[113] Louisiana's requirement also provides an exemption where funding is not made available.[114]

Similarly, Georgia's fluoridation statute allows a municipality or county to opt-out through a referendum after a petition signed by ten percent of the registered voters is submitted.[115] Georgia's law also provides an exemption where funds are not made available for "the cost of the fluoridation equipment, the installation of such equipment, and the materials and chemicals required for six months of fluoridation of such potable public water supplies."[116] The Georgia statute is unique because it provides a tax deduction for people allergic to fluoridated water to purchase a device that removes fluoride from the drinking water.[117]

Nebraska provided an opt-out clause that exempts its citizens from fluoridating "if the voters of the city or village adopted an ordinance, after April 18, 2008, but before June 1, 2010, to prohibit the addition of fluoride to such water supply."[118] Cities or villages that have 1,000 residents after June 1, 2010 may pass an ordinance prohibiting fluoridation, thereafter placing it on the ballot for a referendum at the next statewide election.[119]

In addition to state statutes, many cities and municipalities have developed their own ordinances to regulate water fluoridation. Forty-three of the largest fifty American cities fluoridate their water systems.[120] Until recently, San Jose was the largest municipality in the country without fluoridated water.[121] On November 15, 2011, the board of the Santa Clara Valley Water District voted in favor of fluoridating the water supply for most residents of the county.[122]

V. LEGAL CHALLENGES TO COMMUNITY WATER FLUORIDATION

To date, courts have consistently upheld fluoridation programs.[123] Moreover, the United States Supreme Court has declined to grant certiorari in cases surrounding water fluoridation.[124] A current review of federal jurisprudence reveals that no community water fluoridation challenge has originated in a federal court.

Even so, opponents of community water fluoridation have utilized the judicial branch as a mechanism to prevent the addition of fluoride to drinking water. Opponents of fluoridation have challenged fluoridation efforts using several different legal arguments, including: abuse of municipal authority;[125] due process clause violations;[126] a violation of fundamental liberties;[127] petition initiatives and re-votes;[128] preemption;[129] push for FDA approval;[130] the right to privacy;[131] state police power;[132] unlicensed practice of medicine/ compulsory medicine;[133] and claiming fluoridation is unnecessary, unsafe, and wasteful.[134]

Legal challenges to community water fluoridation began quickly in the years following the addition of fluoridation in Grand Rapids, Michigan,[135] and continue today.[136] The challenges have included a number of legal theories, which have failed. This section briefly identifies and explains each theory advocated in fluoride litigation.

The United States Supreme Court has stated that "public health" means "the health of the community."[137] The seminal case surrounding the use of the state's police power to protect public health is *Jacobson v. Commonwealth of Massachusetts*.[138] There, Mr. Jacobson challenged the constitutionality of a compulsory smallpox vaccine statute by the City of Cambridge.[139] The Supreme Court held that the statute was a valid exercise of the state's police power to regulate the health and safety of its citizens. The Court noted:

> If there is any such power in the judiciary to review legislative action in respect of a matter affecting the general welfare, it can only be when that which the legislature has done comes within the rule that, if a statute purporting to have been enacted to protect

> the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge, and thereby give effect to the Constitution.[140]

State courts have repeatedly upheld the constitutionality of community water fluoridation. The U.S. Supreme Court has never heard a challenge to a state's police power to fluoridate community water. In *Young v. Board of Health of Borough of Somerville*, the New Jersey Supreme Court provided a concise history of the legal challenges:

> The courts throughout the nation have been virtually unanimous in resisting these as well as other arguments, and in upholding fluoridation of drinking water as a valid public health measure whenever a challenge has been presented. . . . The unanimity of appellate state court holdings is matched only by the frequency and persistent regularity with which the United States Supreme Court has declined review.[141]

A. Significant Case Law and Legal Theories

In one of the early challenges to community water fluoridation, the Court of Appeals of California heard the case of *DeAryan v. Butler* in 1953.[142] There, the plaintiff alleged that the 1951 resolution adopted by the City of San Diego to add fluoride to the public water supply was unconstitutional.[143] The court disagreed, finding that the resolution was a valid exercise of the city's police power, "so long as it was not unreasonable or an abuse of discretion."[144] Citing to *Jacobson*, the court stated that a legislature's determination that regulation is necessary for "the protection or preservation of health is conclusive on the courts except only to the limitation that it must be a reasonable determination, not an abuse of discretion, and must not infringe on rights secured by the Constitution."[145]

Coshow v. City of Escondido provided a constitutional challenge of whether the City of Escondido could add hydrofluorosilicic acid to the city's water supply as a means of fluoridation.[146] The Court of Appeals, Fourth District, held that Coshow failed to state a cause of action evidencing a violation of fundamental constitutional rights.[147] To comply with the California Safe Drinking Water Act, the City of Escondido directed its staff to fluoridate the water supply.[148] Coshow asserted he was:

> [b]eing forced, without his consent, to drink the municipal water containing a drug – HFSA [fluoride] – that has never been tested or approved by the FDA to treat dental caries and which is dangerous to his health and the health of other residents.[149]

Coshow's challenge was not timely because he did not challenge the decision to use HFSA to fluoridate the water prior to the Department of Health's decision.[150] The Court noted that a timely challenge should have been made at the administrative level.[151] Coshow alleged that water fluoridation was forced medication, which violated his right to bodily integrity and privacy.[152] The court failed to find a fundamental right to "drinking water uncontaminated with HFSA."[153] Instead, it noted that "courts throughout the United States have uniformly upheld the constitutionality of adding fluoride to the public water supply as a reasonable and proper exercise of the police power in the interest of public health."[154] As well, it noted the absence of precedent recognizing due process claims based on drinking water purer than the requirements of federal and state drinking water standards.[155]

The court next examined Coshow's claim that fluoridation is forced medication. In rejecting this argument, the court noted that fluoridation "stops with the water faucet."[156] The court distinguished fluoridation from invasive treatments where the state seeks to override individual freedom, and further stated that Coshow retained the freedom not to drink fluoridated water.[157] In addition, it is the function of the Department of Health to ensure that the level of any chemicals added to the water is safe.[158] The court also discarded Coshow's claim based on fluoride having not been approved by the FDA to treat dental caries.[159] The FDA's regulation of fluoride in bottled water and other products does not extend to public supplies of drinking water.[160]

With regard to Coshow's due process challenge, the court stated that there is "no fundamental right to privacy at stake" when the challenged action relates to health and safety,[161] and thus the rational basis test must be satisfied.[162] In finding the rational basis test to be satisfied, the court offered a strong endorsement of community water fluoridation:

> [w]ater fluoridation is integrally related to a strong state interest – public health – and the manner of accomplishing this objective is a cost-effective way of providing dental protection to residents.[163]

Even though challengers to community water fluoridation often allege it is not a valid exercise of the state's police power, courts nonetheless have uniformly held that water fluoridation is a valid utilization of a state's police power.[164] In *Kraus v. City of Cleveland*, the plaintiff argued that prevention or treatment of tooth diseases was not a matter of public health, and that a valid exercise of the police powers requires a contagious or infectious disease.[165] The court rejected this contention, noting that laws relating to "child labor, minimum wages for women and minors and maximum hours for women and minors" have all been upheld as state police powers.[166] The court also cited an Oklahoma case challenging fluoridation, which found that "[t]he relation of dental hygiene to the health of the body generally is now so well recognized as to warrant judicial notice."[167] The court later referenced the advancement of science as a basis for modifications in the law:

> Under our modern existence the law must change and expand with mechanical and scientific progress. What did not concern public health yesterday, because of an inability of science to cope with the problem at hand, may very well become a matter of public health due to scientific achievement and progress. The use of fluoridation to prevent dental caries is an excellent example of this proposition.[168]

Another charge that has been levied against community water fluoridation is that it infringes on due process rights.[169] The U.S. Supreme Court has held that "[t]he guarantee of due process of law includes a substantive component which prohibits the government from infringing on certain 'fundamental' liberty interests unless the infringement is narrowly tailored to serve a compelling state interest."[170] In *Pure Water Committee of Western Maryland, Inc. v. Mayor and City Council of Cumberland, Maryland*, the plaintiffs asserted that fluoridated municipal water was forced, nonconsensual, medication, and therefore violated their due process.[171] The court distinguished water fluoridation from "the type of invasive and highly personalized medical treatments involved in the cases in which the Supreme Court has recognized a liberty interest in freedom from unwanted medical treatments."[172] The court stated it was unclear whether a liberty interest existed in being free from water fluoridation because plaintiffs retained the choice to not drink the fluoridated water.[173]

When presented with such claims, courts have noted the difference between an invasive medical procedure that overrides personal freedom and adding approved chemicals to public drinking water.[174] "Fluoridation occurs before it enters each household and stops with the water faucet."[175] A person may avoid fluoridated water by purchasing bottled water[176] or by filtering, boiling, or mixing it with purifying spirits.[177]

In *Dowell v. City of Tulsa*, the court rejected the argument of compulsory medication and stated that the city of Tulsa:

> is no more practicing medicine or dentistry or manufacturing, preparing, compounding or selling a drug, than a mother would be who furnishes her children a well-balanced diet, including foods containing vitamin D and calcium to harden bones and prevent rickets, or lean meat and milk to prevent pellagra. No one would contend that this is practicing medicine or administering drugs.[178]

Plaintiffs have also alleged that, because fluoridation has never been proven "safe and effective" by the FDA, it violates constitutional protections.[179] In *City of Watsonville,* the voters passed a ballot initiative, Measure S, prohibiting the introduction of any substance into the city's drinking water unless it was found to be safe and effective by the FDA.[180] The

court found that, because the FDA does not regulate additives to public water supplies, Measure S was targeting fluoridation, as required by California state law, and struck down the initiative.[181]

Community water fluoridation has also been at issue in First Amendment cases.[182] In *Readey v. St. Louis County Water Co.*, eight taxpayers challenged a 1959 ordinance requiring fluoridation of the St. Louis County water system.[183] The taxpayers alleged that "the ordinance is unconstitutional because it prohibits certain county residents from practicing their religious beliefs."[184] A Missouri attorney filed an amicus curie brief, asserting that the ordinance was unconstitutional because it subjects Christian Scientists in St. Louis County to forced medication against their religious beliefs.[185] The Supreme Court of Missouri decided the case on technical grounds, finding the issue was not before them, as it had not been raised in the case below or preserved for appeal.[186] The court upheld the St. Louis ordinance requiring the fluoridation of water.[187]

In another case, *Exner v. American Medical Association*, the plaintiff alleged defamation based on an article written about fluoridation. Dr. Frederick Exner, an avowed anti-fluoridation advocate, had been contracted as an expert witness, was published in multiple books and magazines, and had been asked to guest lecture on fluoridation.[188] In October 1965, the Director of Public Information for the American Medical Association (AMA) published an article challenging the views espoused by Dr. Exner. Dr. Exner sued the AMA for defamation.[189] The Washington Court of Appeals granted summary judgment in favor of the AMA, finding that Dr. Exner had become a "public figure in regard to the limited issue of fluoridation."[190] Therefore, because the court found the article to "have commented fairly on the plaintiff's position on fluoridation and not to have attacked his personal character or medical competence,"[191] the AMA's article was not defamatory in nature.

Similarly, plaintiffs who argue that fluoridation violates their right to privacy have also been unsuccessful in preventing community water fluoridation.[192] The plaintiff in *Quiles v. City of Boynton Beach* alleged that fluoridation of the community water supply violated his right to privacy under the Florida Constitution.[193] The court notably distinguished that water fluoridation does not seek to introduce fluoride into Quile's bloodstream and thereby "stops with Quile's water faucet."[194] Because Quile had not been compelled to drink the water, he was "free to filter it, boil it, distill it, mix it with purifying spirits, or purchase bottled drinking water."[195]

Challengers have also argued that water fluoridation is unnecessary, unsafe and wasteful.[196] In *Rovin v. Pennsylvania Public Utility Commission*, the plaintiff, a local dentist, brought a claim against the Philadelphia Suburban Water Company on the grounds that it was violating the Public Utility Code by failing to provide safe and reasonable water service.[197] Rovin argued that, because only some of the residents serviced by the utility were receiving fluoridated water, it was "unsafe, inadequate and unreasonable" because the customers who were not receiving fluoridated water "[were]denied the benefits of fluoridated water."[198] In addition, the customers receiving fluoridated water "might be harmed if their pediatricians prescribe a fluoride supplement."[199] Rovin was concerned that, because customers would not know whether their source of water contained fluoride, it was possible that they could simultaneously receive a fluoride supplement from their dentist, resulting in fluorosis.[200] The court agreed with the decision of the Public Utility Commission that there was no evidence supporting Rovin's petition. Rovin offered no proof of an adverse event to a customer, and the company provided testimony that the water was safe.[201]

Plaintiffs have also contended that community water fluoridation is an abuse of municipal authority.[202] In these cases, plaintiffs have argued that the governing body lacked the authority to require fluoridation. Typically, these cases have not been successful. For example, the court in *Young v. Board of Health of Borough of Somerville* held that the New Jersey legislature had specifically granted the power to enact policies to promote public health and prevent disease in N.J.S.A. 26:1A-37,[203] and in turn, the Department of Health decided to promote fluoridation of water supplies.[204] Where a policy decision is made at the

state level, "the proper function of local boards of health is undoubtedly to implement and carry out such decisions."[205]

There are instances, however, in which courts have ruled that governing bodies have overstepped their power. In *Parkland Light & Water Company v. Tacoma-Pierce County Board of Health*, private water companies successfully challenged the Washington Board of Health's requirement that municipal water districts fluoridate their water system, arguing that it exceeded its authority. The legislature had previously delegated the ability to fluoridate water systems to local water districts after a majority vote of its board of commissioners.[206] Therefore, because the resolution conflicted with state law, the Board of Health's resolution requiring fluoridation was invalid.[207] The legislature has not changed the law since this decision.

Challengers have also attacked the procedures surrounding the implementation of water fluoridation.[208] Following the City of Port Angeles's decision to fluoridate the city water supply, advocacy organizations sued the city, alleging that the State Environmental Policy Act required an environmental review.[209] Despite the prior determination that fluoridation was categorically exempt from environmental review, the challengers argued that "fluoridation could have significant detrimental effects on public health and, therefore, an environmental impact statement should be prepared."[210] The Washington Court of Appeals held that, because the Department of Health oversees fluoridation of public water, it is categorically exempted by state law from State Environmental Protection Act review.[211]

In *Potratz v. Commonwealth of Pennsylvania Department of Environmental Protection*, James Potratz challenged the Department of Environmental Protection and the Erie Water Authority's (DEPEWA) decision to issue operations permits to fluoridation facilities.[212] Potratz alleged that the DEPEWA failed to protect the waters of the Commonwealth, as required by the Pennsylvania Constitution.[213] The respondents argued that the decision to add fluoride to the water supply was determined when they issued the construction permit, not at the time of the operations permit, and therefore the Doctrine of Administrative Finality prevented Potratz from challenging the operations permit.[214] The operations permit was issued a year and a half after the construction permit, and after the construction of the fluoridation facility, which cost $285,498.78.[215] The court noted that, at the construction permit stage, the DEPEWA was required to submit water quality analyses[216] and that the construction permit was an approval at the fluoridation process.[217] Therefore, the doctrine of Administrative Finality precluded a collateral attack of an administrative decision that could have been raised at the time of the construction permit.

Where fluoridation has been approved by voter referendums, opponents of community water fluoridation have challenged the referendums and requested re-votes.[218] For example, after San Antonio residents approved water fluoridation in a November 7, 2000 special election, residents sued to have the vote declared void.[219] Texas law provides the City Council with the power to determine whether to fluoridate the water supply.[220] A city government's ordinance may not be revised unless it is determined to be arbitrary, unreasonable, and a clear abuse of power.[221] The court in *Thompson v. Bexar County Elections* noted that the City Council was not provided with materials that the risks associated with fluoridation were unreasonable, and that at most, the issue is debatable.[222] Nonetheless, the court held that the City Council's decision to hold a special election "[was] a valid constitutional exercise of the City's police powers."[223]

The citizens of Davis County, Utah, also voted in favor of water fluoridation in November 2000. A group of Davis County citizens sought a revote and filed an initiative petition.[224] Subsequently, in *Utahns for Better Dental Health-Davis ("UFBDH") v. Davis County Clerk*, UFBDH challenged the constitutionality of a revote, and sought declaratory judgment and injunctive relief.[225] The District Court agreed with UFBDH, finding that allowing the petition to be "placed on the ballot would be a 'misuse [of] the people's direct legislative power'" and would "thwart the will of a majority of Davis County voters."[226] Both the District Court and Court of Appeals denied UFBDH's request for attorney damages.[227] In contrast, the Utah Supreme Court

granted attorney fees, finding that preventing an unconstitutional initiative petition provided value to voters, especially in consideration of the costs of a campaign.[228]

In an attempt to stop water fluoridation in Port Angeles, Washington, two advocacy organizations filed separate initiatives.[229] The City Council declined to either enact or refer the initiatives to the ballot, as requested by the organizations.[230] Instead, the city pursued a declaratory judgment action alleging that the initiatives were administrative in nature because they attempted to administer the details of the city's existing water system.[231] The Washington legislature vested the power to decide whether to fluoridate with the Board of Commissioners of a water district.[232] The court in *City of Port Angeles v. Our Water-Our Choice* agreed that the decision by the City of Port Angeles to fluoridate the water system was administrative in nature,[233] and affirmed that the initiative was beyond the local initiative power.[234]

Citizen groups have also utilized preemption when attempting to prevent water fluoridation.[235] In November 2002, the citizens of the City of Watsonville, California, passed a voter initiative entitled Measure S for the purpose of stopping the city's fluoridation efforts.[236] Measure S directly conflicted with the California Department of Health regulations that required the fluoridation of the city's water system.[237] The city sought a declaratory judgment and injunctive relief that Measure S was not preempted by California law.[238] The court in *City of Watsonville v. State Department of Health Services* found that the California legislature clearly intended to preempt local government regulations regarding the fluoridation of drinking water.[239] The city argued that a conflict did not exist because it lacked the funds to properly fluoridate its water system and did not have 10,000 hookups, a requirement of the California regulation.[240] The court rejected this argument, noting that Measure S "purports to regulate an area that is fully occupied by express provisions of the state law."[241] In supporting the belief that fluoridation of public water systems is a statewide concern, the court cited the language of the legislature: "[p]romotion of the public health of Californians of all ages by protection and maintenance of dental health through the fluoridation of drinking water is a paramount issue of statewide concern."[242] A timely consideration of the court was the cost of healthcare. The court cited the legislative history to support the state's concern of the importance of water fluoridation, which discussed the cost to the Medi-Cal and Denti-Cal programs of tooth decay.[243] Ultimately, the court found that California law preempted Measure S.

VI. THE PRESENT STATE OF COMMUNITY WATER FLUORIDATION

A *New York Times* staff editorial on March 18, 2012 noted that challenges to community water fluoridation in public dialog focus on "costs involved, improper government control over a personal decision, and potential health dangers."[244] This occurs in the context of a 2007 CDC report, revealing the first increase in forty years of caries amongst preschool age children.[245] Not only are children developing caries in more teeth, but the caries tend to be so severe that anesthesia is required during some procedures.[246] One of the reasons posited for this increase is that many children are drinking bottled water instead of fluoridated tap water.[247] The CDC notes that "[b]ottled water may not have a sufficient amount of fluoride, which is important for preventing tooth decay and promoting oral health."[248]

Nevertheless, opposition to community water fluoridation in public dialog shows no signs of relenting. With the courthouse doors severely limited in terms of legal challenges, opponents of community water fluoridation will continue to target cities and municipalities legislatively in their efforts to prevent fluoridation. One city that recently voted to end fluoridation of its drinking water was Fairbanks, Alaska. A report prepared for the Fairbanks City Council found that "[a]lthough claims have been made that adding fluoride to drinking water has been one of the main reasons for this decline, the data indicate that in many countries and communities progress in preventing caries has been made without fluoridated water."[249] The Fairbanks Fluoride Task Force recommended the cessation of adding additional fluoride to the city's drinking water "because of the fluoride content of the city's ground water and the alternate sources of

fluoride available in the community."[250] However, the report also noted that "water fluoridation may be an important element of an effective dental health program in many communities."[251]

On June 5, 2012, New Hampshire Governor John Lynch signed legislation that made New Hampshire the first state in the nation to require notification on the water system's consumer confidence report about mixing infant formula with fluoridated water.[252] Beginning August 4, 2012, consumer confidence reports were required to contain the statement: "[y]our public water supply is fluoridated. According to the Centers for Disease Control and Prevention, if your child under the age of 6 months is exclusively consuming infant formula reconstituted with fluoridated water, there may be an increased chance of dental fluorosis. Consult your child's health care provider for more information."[253] This statement actually misquotes the CDC by deleting the important modifier "mild" to describe the type of dental fluorosis associated with fluoridated water.[254] Mild dental fluorosis is, in fact, associated with lower rates of tooth decay and higher perceptions of oral-health related quality of life.[255]

On July 24, 2012, the City of Milwaukee's Common Council passed a resolution requiring a more informative infant advisory notice to be included on quarterly municipal service bills and annual quality water reports.[256] The enacted notice summarizes American Academy of Pediatric (AAP) guidance and provides a link to further information at the AAP website. It also summarizes guidance from the CDC about both dental fluorosis and use of infant formula, including the following:

> [i]f breastfeeding is not possible, parents should consult a pediatrician about an appropriate infant formula option. Parents should be aware that there may be an increased chance of mild dental fluorosis if the child is exclusively consuming infant formula reconstituted with fluoridated water. Dental fluorosis is a term that covers a range of visible changes to the enamel surface of the tooth.[257]

These examples demonstrate that, as the fluoridation debate moves forward, advocates on both sides will continue to utilize intense and possibly misleading rhetoric to influence the oral health of millions of Americans.

Notably, educating the public about fluoridation was addressed in the 2010 federal health reform law, the Affordable Care Act (ACA). In Section 399LL of the ACA, the Oral Healthcare Prevention Education Campaign, the Secretary of HHS is required to "utilize science-based strategies to convey oral health prevention messages that include, but are not limited to, community water fluoridation and dental sealants."[258]

Education, while a critically important strategy, may not achieve an optimal public health impact.[259] Additional scientific evidence can assist in informing the decision to fluoridate a community's water, but such choices often are not made purely on the basis of science.[260]

In an era of increasingly tight state and local government budgets, anti-fluoridation advocates argue that stopping community water fluoridation will save money. That argument was used in early October 2011, when Pinellas County, Florida, voted to end adding fluoride to its water.[261] The result of this action was that 700,000 residents would no longer receive fluoride through their water supply.[262] However, in November 2012, two of the commissioners that supported ending community water fluoridation were defeated in their re-election bids.[263] Later that month, the 2011 decision was overturned.[264]

Dr. Bill Maas, a respected authority on community water fluoridation believes:

> This decision demonstrates a disconnect in public policy making whereby public water system authorities are aware of the direct costs of fluoridating the water, but not the positive externality or external benefit of improved dental health and lower health care costs. The savings are "external" to the perceived scope of responsibility of the decision-makers. When considering whether discontinuing fluoridation would save money, the water system authorities may not consider the negative externalities or external costs to the members of the

community served by the public water supply when their dental care expenses increase to treat tooth decay that would have been prevented if fluoridation had continued. A broader perspective would consider the total cost-benefit calculation to the community, but because over 90% of dental care expenses are paid by private funds, local decision-makers are often unaware of how their decision affects dental care costs.[265]

Other policymakers are becoming increasingly aware of the impact of the fluoridation decision on Medicaid costs. Studies in New York,[266] Texas,[267] and Louisiana[268] found that fluoridation substantially reduced dental treatment costs among children and youth in the Medicaid program. Annual per person Medicaid treatment cost savings in these states ranged from $27.6 to $66.8 (in 2010 dollars). The number of procedures related to treatment of tooth decay per child in the New York State Medicaid program was thirty-three percent higher in less fluoridated counties than in predominantly fluoridated counties.[269] In Louisiana, more severe tooth decay among young children in non-fluoridated parishes required that treatment be provided under general anesthesia in a hospital operating room three times as often as young children living in fluoridated parishes.[270]

Court decisions have reinforced the understanding that community water fluoridation is a cost-effective, equitable and safe measure to protect communities from dental decay, and the health problems and costly restorative services that follow. Therefore, educational efforts directed to both policymakers and the public alike to reinforce this understanding is both timely and appropriate.

[1] *Ten Great Public Health Achievements—United States, 1900–1999*, Ctrs. for Disease Control & Prevention Weekly Morbidity & Mortality Rep., Apr. 2, 1999, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm.

[2] U.S. Pub. Health Serv., Dep't of Health & Human Servs., Oral Health in America: A Report of the Surgeon General 3 (2000), *available at* http://silk.nih.gov/public/hck1ocv.@www.surgeon.fullrpt.pdf.

[3] *The Story of Fluoridation*, Nat'l Inst. of Dental & Craniofacial Research, http://www.nidcr.nih.gov/oralhealth/topics/fluoride/thestoryoffluoridation.htm, (last visited Mar. 11, 2013).

[4] *2010 Water Fluoridation Statistics*, Ctrs. for Disease Control & Prevention, http://www.cdc.gov/fluoridation/statistics/2010stats.htm (last updated July 27, 2012).

[5] *See Community Water Fluoridation: Questions and Answers*, Ctrs. for Disease Control & Prevention, http://www.cdc.gov/fluoridation/fact_sheets/cwf_qa.htm (last updated Oct. 22, 2012).

[6] *Fluoride & Fluoridation*, Am. Dental Ass'n, http://www.ada.org/2467.aspx (last visited Mar. 11, 2013).

[7] Eugenio D. Beltrán-Aguilar et al., *Prevalence and Severity of Dental Fluorosis in the United States, 1999–2004*, Nat'l Ctr. for Health Statistics Data Brief (Nov. 2010), *available at* http://www.cdc.gov/nchs/data/databriefs/db53.pdf.

[8] *Id.*

[9] *Achievements in Public Health, 1900–1999: Fluoridation of Drinking Water to Prevent Dental Caries*, Ctrs. for Disease Control & Prevention, Weekly Morbidity & Mortality Rep. (Oct. 22, 1999), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm [hereinafter *Achievements in Public Health*].

[10] *See* Nat'l Research Council, Fluoride in Drinking Water: A Scientific Review of EPA's Standards 4-8 (2006), *available at* http://www.actionpa.org/fluoride/nrc/NRC-2006.pdf.

[11] Lizette Alvarez, *More Places Change Course on Fluoride in Water*, NY Times (Oct. 13, 2011), http://www.nytimes.com/2011/10/14/us/more-places-change-course-on-fluoride-in-water.html?pagewanted=print; Kim Murphy, *Fluoride, Portland City Council to Back Water Treatment*, L.A. Times (Sept. 6, 2011), http://articles.latimes.com/2012/sep/06/nation/la-na-nn-portland-fluoride-water-20120907) (reporting that the number of fluoride treated community water systems has grown by 42 million since 2000).

[12] *Decay*, MouthHealthy, http://www.mouthhealthy.org/en/az-topics/d/decay.aspx (last visited Mar. 11, 2013).

[13] *Id.*

[14] *Tooth Decay*, Nat'l Insts. of Health, http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=129&key=T#T (last visited Mar. 11, 2012) [hereinafter *Tooth Decay Fact Sheet*].

[15] Am. Dental Ass'n, Fluoridation Facts 16 (2005), *available at* http://www.ada.org/sections/newsAndEvents/pdfs/fluoridation_facts.pdf.

[16] *See Achievements in Public Health, supra* note 9 (citing Brian A. Burt, *Influences for Change in the Dental Health Status of Populations: An Historical Perspective,* 38 J. Pub. Health Dentistry 272 (1978)).

[17] *See id.*

[18] John M. Shalikashvili & Hugh Shelton, *The Latest National Security Threat: Obesity*, Wash. Post (Apr. 30, 2010), *available at* http://www.washingtonpost.com/wpdyn/content/article/2010/04/29/AR2010042903669_pf.html.

[19] *Achievements in Public Health*, *supra* note 9 (citing Rollo H. Britten & George St. J. Perrott, *Summary of Physical Findings on Men Drafted in World War*, 56 Pub. Health Reps. 41 (1941); Henry Klein, *The Dental Status and Dental Needs of Young Adult Males, Rejectable, or Acceptable for Military Service, According to Selective*

Service Dental Requirements, 56 Pub. Health Reps. 1369 (1941)).

[20] *Tooth Decay Fact Sheet*, supra note 14.

[21] Nat'l Ctr. for Chronic Disease Prevention & Health Promotion, Ctrs. for Disease Control & Prevention, Oral Health at a Glance: Preventing Cavities, Gum Disease, Tooth Loss, and Oral Cancers 2 (2011), *available at* http://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2011/Oral-Health-AAG-PDF-508.pdf.

[22] *Id.*

[23] Jacqueline Fox, *The Epidemic of Children's Dental Diseases: Putting Teeth Into the Law*, 11 Yale J. Health Policy L. & Ethics 223, 225 (2011).

[24] *Id.*

[25] *Id.* at 227 (citing U.S. Gen. Acct'g Off., Report to Congressional Requesters: Oral Health: Dental Disease is a Chronic Problem Among Low-Income Populations 3-4 (2000), *available at* http://www.gao.gov/new.items/he00072.pdf [hereinafter GAO Oral Health Report].

[26] Fox, *supra* note 23, at 227 (citing GAO Oral Health Report, *supra* note 25, at 9).

[27] *Fluoridation Basics*, Ctrs. for Disease Control & Prevention, http://www.cdc.gov/fluoridation/benefits/background.htm (last visited Mar. 11, 2013).

[28] *Id.*

[29] *The Story of Fluoridation*, *supra* note 3.

[30] *Id.*

[31] Fluoridation Facts, *supra* note 15.

[32] *The Story of Fluoridation*, *supra* note 3.

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] *See* Am. Dental Ass'n, *Water Fluoridation Status of the 50 Largest U.S. Cities*, *available at* http://www.ada.org/sections/newsAndEvents/pdfs/ Fluoridation_Status_of_50_Largest_U.S._Cities.pdf (last visited Oct. 29, 2011).

[43] Dr. Howard K. Koh & Nancy Stoner, *Protecting Our Drinking Water and Health*, The Whitehouse Petitions (Sept. 23, 2011) *available at* https://petitions.whitehouse.gov/petition/prohibit-all-federal-agencies-promoting-endorsing-or-funding-fluoridation-public-drinking-water/SRYL4NwC?utm_source=wethepeople&utm_medium=response&utm_campaign=fluoride (last visited Aug. 28, 2012).

[44] *See* S.O. Griffin et al., *Effectiveness of Fluoride in Preventing Caries in Adults*, 86 J. Dental Res. 410 (2007).

[45] Eugenio D. Beltran-Aguilar, DMD, et al., *Surveillance for Dental Caries, Dental Sealants, Tooth Retention, Edentulism, and Enamel Fluorosis–United States, 1988-1994 and 1999-2002*, (2005) *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5403a1.htm (last visited April 13, 2012).

[46] *2010 Water Fluoridation Statistics*, supra note 4.

[47] *Fluoridation Basics*, *supra* note 27.

[48] *Fluoride & Fluoridation*, *supra* note 6.

[49] Brian Resnick, *What Do We Know About Fluoride?*, The Atlantic (Feb. 9, 2012) http://www.theatlantic.com/health/archive/2012/02/what-do-we-know-about-fluoride/252683/.

[50] *WHO: Water Fluoridation*, World Health Organization, ttp://www.who.int/water_sanitation_health/oralhealth/en/index2.html (last visited March 15, 2012).

[51] *See Fluoridation Facts*, *supra* note 15 (citing BA White et al., *Issues in the Economic Evaluation of Community Water Fluoridation*, 53 J. Dental Educ. 646 (1989).

[52] Fox, *supra* note 23, at 239 (citing *The Cost of Delay: State Dental Policies Fail One in Five Children*, Pew Center on the States 2 (2010) *available at* www.pewtrusts.org/uploadedFiles/Cost_of_Delay_web.pdf).

[53] *Fluoridation Basics*, *supra* note 27.

[54] *Fluoridation Facts*, *supra* note 15.

[55] *Fluoridation Basics*, *supra* note 27.

[56] *ADA Statement Commemorating the 60th Anniversary of Community Water Fluoridation* (2005), *available at* http://www.ada.org/sections/newsAndEvents/pdfs/fluoridation_facts.pdf (last visited April 1, 2012) [hereinafter *60th Anniversary*].

[57] *Ten Great Public Health Achievements–United States, 1900-1999*, Center for Disease Control and Prevention Weekly Morbidity and Mortality Report (April 2, 1999) *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm (citing Brian A Burt & Steven A Eklund, Dentistry, Dental Practice, and the Community 204-20 (6 ed. 1999)).

[58] *60th Anniversary*, *supra* note 56.

[59] *Oral Health in America: A Report of the Surgeon General – Executive Summary*, U.S. Dep't of Health and Human Serv., Nat'l Inst. of Dental and Craniofacial Res., Nat'l Inst. of Health (2000).

[60] *60th Anniversary*, *supra* note 56.

[61] Lizette Alvarez, *Looking to Save Money, More Places Decide to Stop Fluoridating the Water*, NY Times (Oct. 13, 2011), http://www.nytimes.com/2011/10/14/us/more-places-change-course-on-fluoride-in-water.html?pagewanted=all.

[62] *See* Fluoride Action Network, http://www.fluoridealert.org/ (last visited Mar. 1, 2013) (announcing the organization's mission to oppose community fluoridation of water).

[63] *See Citizens for Safe Drinking Water*, NoFluoride.com, http://www.nofluoride.com/ (last visited Mar. 1, 2013) (announcing the organization's mission to oppose community fluoridation of water).

[64] *See* Paul Connett et al., The Case Against Fluoride: How Hazardous Waste Ended Up in Our Drinking Water and Bad Science and Powerful Politics That Keep it There (2010); Brian Resnick, *What Do We Know About Fluoride?*, The Atlantic (Feb. 9, 2012), http://www.theatlantic.com/health/archive/2012/02/what-do-we-know-about-fluoride/252683/ (discussing a Florida county's decision to stop fluoridating its water supply).

[65] *See* Beltran-Aguilar et al., *supra* note 7 (stating that this is characterized by blemishes to the teeth).

[66] *WHO: Water-Related Diseases*, World Health Org., http://www.who.int/water_sanitation_health/diseases/fluorosis/en/ (last visited Mar. 1, 2013) (providing background information regarding fluorosis).

[67] *See Achievements in Public Health*, *supra* note 9 (discussing the history and impact of community water fluoridation as a public health success).
[68] Nat'l Research Council of the Nat'l Academies, Fluoride in Drinking Water: A Scientific Review of EPA's Standards (2006).
[69] Kate Zernike, *In New Jersey, a Battle Over Fluoridation Bill, and the Facts*, NY Times (Mar. 2, 2012), http://www.nytimes.com/2012/03/03/nyregion/in-new-jersey-a-battle-over-fluoridation-and-the-facts.html?pagewanted=all (discussing legislative efforts in New Jersey to add fluoride to the water supply).
[70] *See* Mary Tiemann, Cong. Research Serv., RL 33280, Fluoride in Drinking Water: A Review of Fluoridation and Regulation Issues (2008) (discussing the health concerns and regulatory processes surrounding community water fluoridation).
[71] Basic Information about Fluoride in Drinking Water, U.S. Envtl Prot. Agency, http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm (last updated May 21, 2012) [hereinafter Basic Information] (providing answers to frequently asked questions about regulated drinking water contaminants).
[72] *See* U.S. Dep't of Health, Educ., & Welfare Pub. Health. Serv., Public Health Service Drinking Water Standards (1962) (defining standards for fluoride in drinking water at a range of temperatures).
[73] *See* Eugenio D. Beltrán-Aguilar et al., *Lack of Association Between Daily Temperature and Children's Water Intake in the United States—1999-2004*, Ctrs for Disease Control & Prevention, http://www.cdc.gov/fluoridation/fact_sheets/totalwaterintake.htm (last visited Mar. 1, 2013) (reconciling conflicting study results regarding the correlation between daily temperature and the water intake of children aged one through ten).
[74] *See* National Research Council, Fluoride in Drinking Water: A Scientific Review of EPA's Standards 3 (2006) (listing the major sources of exposure to fluoride).
[75] *See HHS & EPA Announce New Scientific Assessments & Actions on Fluoride*, U.S. Dep't of Health & Human Servs. (Jan. 7, 2011), http://www.hhs.gov/news/press/2011pres/01/20110107a.html (announcing the agencies' decision to recommend a lower concentration of fluoride in drinking water in order to continue achieving public health goals).
[76] Basic Information, *supra* note 71 (providing answers to frequently asked questions about regulated drinking water contaminants).
[77] *See* U.S. Envtl. Prot. Agency, EPA 816-F-04-030, Understanding the Safe Drinking Water Act (2004) (providing general information regarding the Safe Drinking Water Act).
[78] *See id.*
[79] *Community Water Fluoridation: Questions and Answers*, Ctrs. for Disease Control & Prevention, http://www.cdc.gov/fluoridation/fact_sheets/cwf_qa.htm (providing answers to frequently asked questions about community water fluoridation) (last updated Oct. 22, 2012).
[80] Craig Palmer, *ADA Commends New Fluoride Recommendations*, Am. Dental Ass'n (Jan. 7, 2011), http://www.ada.org/news/5196.aspx (announcing the American Dental Association's response to the new government community fluoridation recommendations).
[81] Grand Rapids Press Editorial Board, *Why Fluoride in Water Should Be Adjusted, Not Rejected*, Grand Rapids Press (last updated Jan. 14, 2011, 6:35 AM), http://www.mlive.com/opinion/grand-rapids/index.ssf/2011/01/editorial_why_fluoride_levels.html (announcing the newspaper's support for the new government community fluoridation recommendations).
[82] Cal. Health & Safety Code § 116409(a) (West 2013) (listing the legislative findings and declarations).
[83] *Id.* § 116409(b).
[84] *Id.* § 116410(a) (enacting the provisions of the California Safe Drinking Water Act).
[85] *Id.* § 116410(b)(2).
[86] *Id.* § 116410(d).
[87] *Id.* § 116415(a)(1)(A) (providing an exception to the state's community water fluoridation requirements).
[88] Ark. Code Ann., § 20-17-136 (2011).
[89] Conn. Gen. Stat. § 19a-38 (2013).
[90] Del. Code. Ann. Tit. 16, § 124 (West 2013).
[91] Ga. Code Ann. § 12-5-175 (West 2012).
[92] 415 Ill. Comp. Stat. 40/7a (West 2013).
[93] Ky. Rev. Stat. Ann. § 211.190(11) (West 2012).
[94] La. Rev. Stat. Ann. § 40:5.11 (West 2012).
[95] Minn. Stat. Ann. § 144.145 (West 2012).
[96] Neb. Rev. Stat. § 71-3305 (2012).
[97] Nev. Rev. Stat. Ann. § 445A.055 (West 2011).
[98] Ohio Rev. Code Ann. § 6109.20 (West 2012).
[99] S.D. Codified Laws § 34-24A-3 (2013).
[100] Nev. Rev. Stat. Ann. § 445A.055 (West 2011).
[101] Conn. Gen. Stat. § 19a-38 (West 2013).
[102] S.D. Codified Laws § 34-24A-3 (2013).
[103] 902 Ky. Admin. Reg. § 115:010 (Section 1(1)) (2013).
[104] *Id.* Section 1(3).
[105] *See ISDS-Supported Bill on Fluoridation Signed*, Am. Dental Ass'n (Aug. 15, 2011), http://www.ada.org/news/6139.aspx (last visited March 6, 2013) (explaining that the Illinois statute, which previously established the minimum fluoridation level at 0.9 ppm, was being changed to conform with new federal guidelines of 0.7 ppm).
[106] 415 Ill. Comp. Stat. Ann. § 40/7a (2013).
[107] Del. Code. Ann. Tit. 16 § 124(b) (West 2013).
[108] *Id.* § 124(b)(4).
[109] *Id.* § 124(b)(1).
[110] *Id.* § 124(b)(1).
[111] *Id.* § 124(b)(5).
[112] La. Rev. Stat. Ann. § 40:5.11 (B)(4)(a) (2012).
[113] *Id.* § 40:5.11 (B)(4)(d).
[114] *Id.* § 40:5.11(B)(3).
[115] Ga. Code Ann. § 12-5-175(a) (West 2012).
[116] *Id.* § 12-5-175(b).
[117] *Id.* § 12-5-175(c).
[118] Neb. Rev. Stat. § 71-3305(2) (2012).
[119] *Id.* § 71-3305(3).
[120] *Water System FAQ*, The Pew Ctr. on the States, www.pewstates.org (last visited March 17, 2012).
[121] *Fluoride OK'd for San Jose Drinking Water*, Assoc. Press (Nov. 17, 2011), http://www.boston.com/lifestyle/health/articles/2011/11/17/fluoride_okd_for_san_jose_drinking_water/ (last visited March 6, 2013).

[122] *Id.*

[123] Edwin Pratt et al., *Fluoridation at Fifty: What Have We Learned*, 30 J.L. Med. & Ethics 117, 119 (2002).

[124] Thompson v. Bexar Cnty. Elections, Nos. Civ.A.SA-00-CA-1527, Civ.A.SA-00-CA-1542, 2002 WL 1492276, at *6 (W.D. Tex. Mar. 21, 2002).

[125] Parkland Light & Water Co. v. Tacoma-Pierce Cnty. Bd. of Health, 90 P.3d 37, 39 (Wash. 2004); Citizens for Safe Drinking Water v. San Diego City Council, No. D036647, 2002 Cal. App. LEXIS 4975, at *3 (Ct. App. Jan. 11, 2002); Young v. Bd. of Health, 293 A.2d 164 (N.J. 1972).

[126] Coshow v. City of Escondido, 34 Cal. Rptr. 3d 19, 19 (Ct. App. 2005); Pure Water Comm. v. Mayor of Cumberland, No. Civ. JFM-01-2611, 2003 WL 22095654 (D. Md. Sept. 4, 2003); *Thompson*, 2002 WL 1492276; Safe Water Ass'n, Inc. v. City of Fond Du Lac, 516 N.W.2d 13, 17 (Wis. Ct. App. 1994); Ill. Pure Water Comm., Inc. v. Dir. of Public Health, 470 N.E.2d 988, 989 (Ill. 1984); Minn. State Bd. of Health v. City of Brainerd, 241 N.W.2d 624, 633 (Minn. 1976); Bd. of Health v. Mayor of N. Adams, 334 N.E.2d 34, 36 (Mass. 1975); Ill. Pure Water Comm., Inc. v. Yoder, 286 N.E.2d 155, 157 (Ill. App. Ct. 1972); Graybeal v. McNevin, 439 S.W.2d 323, 325 (Ky. Ct. App. 1969); Attaya v. Town of Gonzales, 192 So. 2d 188 (La. Ct. App. 1966); Hall v. Bates, 148 S.E. 2d 345, 347 (S.C. 1966); Schuringa v. City of Chic., 198 N.E.2d 326, 328 (Ill. 1964); City Comm'n of Fort Pierce v. State *ex rel.* Altenhoff, 143 So. 2d 879 (Fla. Dist. Ct. App. 1962); Readey v. St. Louis Water Co., 352 S.W.2d 622, 629 (Mo. 1961); Baer v. City of Bend, 292 P.2d 134, 135 (Ore. 1956); Kaul v. City of Chehalis, 277 P.2d 352 (Wash. 1954).

[127] *Coshow*, 34 Cal. Rptr. 3d 19; *Thompson*, 2002 WL 1492276; *Dir. of Public Health*, 470 N.E.2d 988.

[128] City of Port Angeles v. Our Water-Our Choice!, 239 P.3d 589 (Wash. 2010); Utahns for Better Dental Health-Davis, Inc. v. Davis Cnty. Clerk, 175 P.3d 1036 (Utah 2007); City of Watsonville v. State Dep't of Health Serv., 35 Cal. Rptr. 3d 216 (Ct. App. 2005); Balke v. City of Manchester, 834 A.2d 306 (N.H. 2003); *Thompson*, 2002 WL 1492276; *Citizens for Safe Drinking Water*, 2002 Cal. App. LEXIS 4975 ; Burt v. Blumenauer, 675 P.2d 51 (Ore. Ct. App. 1983); City of Cuyahoga Falls v. McAvoy, 1979 Ohio App. LEXIS 12500 (Ohio Ct. Ap. 1979); Oregon Anti-Fluoridation Council v. Myers, 554 P.2d 177 (Ore. 1976); Turner v. Barnhardt, 497 P.2d 970 (N.M. 1972); Williams v. Rowe, 283 A.2d 881 (Pa. Comm. Ct. 1971); Hacker v. Common Council of Ithaca, 266 N.Y.S.2d 927 (N.Y. Sup. Ct. 1966); Landt v. City of Wisconsin Dells, 141 N.W.2d 245 (Wis. 1966); Hughes v. City of Lincoln, 232 Cal. App. 2d 741 (Ct. App. 1965); Stroupe v. Eller, 138 S.E.2d 240 (N.C. 1964); State *ex. rel.* Whittington v. Strahm, 374 S.W.2d 127 (Mo. 1963); *Readey*, 352 S.W.2d 622.

[129] *City of Watsonville*, 35 Cal. Rptr. 3d 216; *Citizens for Safe Drinking Water*, 2002 Cal. App. LEXIS 4975.

[130] *City of Watsonville*, 35 Cal. Rptr. 3d 216; *Coshow*, 34 Cal. Rptr. 3d 19; Froncek v. City of Milwaukee, 69 N.W.2d 242 (Wis. 1955).

[131] *Coshow*, 34 Cal. Rptr. 3d 19; Quiles v. City of Boynton Beach, 802 So.2d 397 (Fla. Dist. Ct. App. 2001); *City of Fond Du Lac*, 516 N.W.2d 13; *City of Brainerd*, 241 N.W.2d 624.

[132] *See* Parkland Light & Water Co. v. Tacoma Pierce Co. Bo. of Health, 90 P.3d 37, 39 (Wash. 2004); *Quiles*, 802 So.2d at 398-99; *Dir. of Pub. Health*, 470 N.E.2d at 992; Safe Water Found. of Tex. v. City of Houston, 661 S.W.2d 190, 192 (Tex. App. 1983); *McAvoy*, 1979 Ohio App. LEXIS 12500, at *11; *City of Brainerd*, 241 N.W.2d at 630; City of Canton v. Whitman, 337 N.E.2d 766, 772 (Ohio 1975); Akire v. Cashman, 350 F. Supp. 360, 362 (S.D. Ohio 1972); Ill. Pure Water Comm., Inc. v. Yoder, 286 N.E.2d 155, 157, 162 (Ill. App. Ct. 1972); Beck v. City Council of Beverly Hills, 30 Cal. App. 3d 112, 115 (1972); Hall v. Bates, 148 S.E.2d 345, 348, 349-50 (S.C. 1966); Wilson v. City of Mountlake Terrace, 417 P.2d 632, 634-35 (Wash. 1966); Paduano v. City of New York, 257 N.Y.S.2d 531, 540 (Sup. Ct. 1965); Rogowski v. City of Detroit, 132 N.W.2d 16, 18 (Mich. 1965); Schuringa v. City of Chic., 198 N.E.2d 326, 328, 329 (Ill. 1964); City Comm'n of Fort Pierce v. State *ex rel*. Altenhoff, 143 So.2d 879, 883 (Fla. Dist. Ct. App. 1962); *Readey*, 352 S.W.2d at 623, 627-28; Wilson v. City of Council Bluffs, 110 N.W.2d 569, 572 (Iowa 1961); Baer v. City of Bend, 292 P.2d 134, 141 (Or. 1956); Froncek v. City of Milwaukee, 69 N.W.2d 242, 282 (Wis. 1955); Chapman v. City of Shreveport, 74 So.2d 142, 143, 145, 146 (La. 1954); Dowell v. City of Tulsa, 273 P.2d 859, 860 (Okla.1954); Kaul v. City of Chehalis, 277 P.2d 352, 356 (Wash. 1954). *See generally City of Fond Du Lac*, 516 N.W.2d at 17 (rejecting the argument that the city's adoption of fluoridation ordinance was an impermissible exercise of police power); Kraus v. City of Cleveland, 127 N.E.2d 609, 610, 613 (Ohio 1955) (holding that a municipality could fluoridate its municipally-owned water supply as a proper exercise of police power); DeAryan v. Butler, 260 P.2d 98, 102 (Cal. Ct. App. 1953) (holding that the addition of fluoride to water was a valid exercise of police power as long as it was not unreasonable or an abuse of discretion to do so).

[133] *See Coshow*, 34 Cal. Rptr.3d at 25; Pure Water Comm. v. Mayor of Cumberland, No. Civ. JFM-01-2611, 2003 WL 22095654, at *9-10 (D. Md. Sept. 4, 2003); *Thompson*, 2002 WL 1492276, at *2; *Quiles*, 802 So.2d at 398; Rovin v. Pa. Pub. Util. Comm'r, 502 A.2d 785, 786 (Pa. Comm. Ct. 1986); *Brainerd*, 241 N.W.2d at 631; *Yoder*, 286 N.E.2d at 157; Young v. Bd. of Health of Borough of Somerville, 293 A.2d 164, 165 (N.J. 1972); Graybeal v. McNevin, 439 S.W.2d 323, 325 (Ky. Ct. App. 1969); Attaya v. Town of Gonzales, 192 So.2d 188, 189 (La. Ct. App. 1966); *Beck*, 30 Cal. App. 3d at 114; *Paduano*, 257 N.Y.S.2d at 537; Rogowski v. City of Detroit, 132 N.W.2d 16, 28 (Mich. 1965); *State* ex rel. *Altenhoff*, 143 So.2d at 881; *Readey*, 352 S.W.2d at 623; *Baer*, 292 P.2d at 136; Teeter v. City of LaPorte, 139 N.E.2d 158, 159-60 (Ind. 1956); *Froncek*, 69 N.W.2d at 246; *Kraus*, 127 N.E.2d at 610; *City of* McGurren v. City of Fargo, 66 N.W.2d 207, 209 (N.D. 1954); *Dowell*, 273 P.2d at 861; *Kaul*, 277 P.2d at 357.

[134] *See McGurren*, 66 N.W.2d at 209; Crotty v. City of Cinncinati, 361 N.E.2d 1340, 1341 (Ohio 1977); *Hall*, 148 S.E.2d at 346; *Rovin*, 502 A.2d at 786; Sheffer v. City of Harrisburg, 60 PA D.&C.2d 725, 726-27 (Pa. Comm. Pl. 1971).

[135] *See DeAryan*, 119 Cal. App. 2d 674 (water fluoridation challenge in 1953).

[136] *See* City of Port Angeles v. Our Water-Our Choice!, 239 P.3d 589 (Wash. 2010) (water fluoridation challenge in 2010).
[137] Whitman v. Am. Trucking Ass'n, Inc., 531 U.S. 457, 465-66 (2001).
[138] Jacobson v. Massachusetts, 197 U.S. 11 (1905).
[139] *Id.* at 12.
[140] *Id*. at 31 (citing Mugler v. Kansas, 123 U.S. 623, 661 (1887)).
[141] Young v. Bd. of Health of Borough of Somerville, 293 A.2d 164, 165 (N.J. 1972).
[142] DeAryan v. Butler, 260 P.2d 98, 102 (1953).
[143] *Id.*
[144] *Id.* at 101-02.
[145] *Id.* at 102.
[146] Coshow v. City of Escondido, 34 Cal. Rptr. 3d 19, 22 (Ct. App. 2005).
[147] *Id.*
[148] *Id.*
[149] *Id.* at 25-26.
[150] *Id.* at 29.
[151] *Id.*
[152] *Id.* at 29-30.
[153] *Id*.
[154] *Id.* at 30 (citing Beck v. City Council of Beverly Hills, 30 Cal. App. 3d 112, 115 (1973)).
[155] *Id.*
[156] *Id.* at 31-32.
[157] *Id.*
[158] *Id.* at 32-33.
[159] *Id.* at 33-34.
[160] *Id.* at 33.
[161] *Id.* at 32 (citing Wilson v. California, 110 Cal. App. 3d 317, 322 (1980)).
[162] *Id*. at 33.
[163] *Id*. at 33.
[164] *See generally* Parkland Light & Water Co. v. Tacoma Pierce Cnty. Bd. of Health, 90 P.3d 37 (Wash. 2004); Quiles v. City of Boynton Beach, 802 So.2d 397 (Fla. Dist. Ct. App. 2001); Safe Water Ass'n, Inc. v. City of Fond Du Lac, 516 N.W.2d 13 (Wis. Ct. App. 1994); Ill. Pure Water Comm., Inc. v. Dir. of Public Health, 470 N.E.2d 988 (Ill. 1984); Safe Water Found. of Tex. v. City of Houston, 661 S.W.2d 190 (Tex. App. 1983); City of Cuyahoga Falls v. McAvoy, 1979 Ohio App. LEXIS 12500 (Oh. Ct. App. 1979); Minn. State Bd. of Health v. City of Brainerd, 241 N.W.2d 624 (Minn. 1976); City of Canton v. Whitman, 337 N.E.2d 766 (Ohio 1975); Akire v. Cashman, 350 F. Supp. 360 (S.D. Ohio 1972); Beck v. City Council of Beverly Hills, 30 Cal. App. 3d 112 (1972); Ill. Pure Water Comm., Inc. v. Yoder, 286 N.E.2d 155 (Ill. App. Ct. 1972); Hall v. Bates, 148 S.E.2d 345 (S.C. 1966); Wilson v. City of Mountlake Terrace, 417 P.2d 632 (Wash. 1966); Paduano v. City of New York, 257 N.Y.S.2d 531 (Sup. Ct. 1965); Rogowski v. City of Detroit, 132 N.W.2d 16 (Mich. 1965); Schuringa v. City of Chicago, 198 N.E.2d 326 (Ill. 1964); City Comm'n of Fort Pierce v. State *ex rel.* Altenhoff, 143 So.2d 879 (Fla. Dist. Ct. App. 1962); Readey v. St. Louis Cnty. Water Co., 352 S.W.2d 622 (Mo. 1961); Wilson v. City of Council Bluffs, 110 N.W.2d 569 (Iowa 1961); Baer v. City of Bend, 292 P.2d 134 (Or. 1956); Froncek v. City of Milwaukee, 69 N.W. 2d 242 (Wis. 1955); Kraus v. City of Cleveland, 127 N.E.2d 609 (Ohio 1955); Chapman v. City of Shreveport, 74 So.2d 142 (La. 1954); Dowell v. City of Tulsa, 273 P.2d 859 (Okla.1954); Kaul v. City of Chehalis, 277 P.2d 352 (Wash. 1954); DeAryan v. Butler, 119 Cal. App. 2d 674 (Cal. Dist. Ct. App. 1953).
[165] *Kraus*, 127 N.E.2d at 610.
[166] *Id.* at 611.
[167] *Id.* (citing *Dowell*, 273 P.2d at 863).
[168] *Id.* at 612.
[169] *See, e.g.*, Coshow v. City of Escondido, 34 Cal. Rptr. 3d 19 (Ct. App. 2005); Pure Water Comm. v. Mayor of Cumberland, No. Civ. JFM-01-2611, 2003 WL 22095654 (D. Md. Sept. 4, 2003); Thompson v. Bexar Cnty. Elections, Nos. Civ.A.SA-00-CA-1527, Civ.A.SA-00-CA-1542, 2002 WL 1492276 (W.D. Tex. Mar. 21, 2002); *City of Fond Du Lac*, 516 N.W.2d 13; *Dir. of Public Health*, 470 N.E.2d 988; *City of Brainerd*, 241 N.W.2d 624; Bd. of Health of N. Adams v. Mayor of N. Adams, 334 N.E.2d 34 (Mass. 1975); *Yoder*, 286 N.E.2d 155; Graybeal v. McNevin, 439 S.W.2d 323 (Ky. Ct. App. 1969); Attaya v. Town of Gonzales, 192 So.2d 188 (La. Ct. App. 1966); *Bates*, 148 S.E. 2d 345; *Schuringa*, 198 N.E.2d 326; *State* ex rel. *Altenhoff*, 143 So.2d 879; *Readey*, 352 S.W.2d 622; *Baer*, 292 P.2d 134; *Kaul*, 277 P.2d 352.
[170] *Coshow*, 34 Cal. Rptr. 19 (citing Washington v. Glucksberg, 521 U.S. 702, 721 (2007)).
[171] *Mayor Cumberland*, 2003 WL 22095654 at *9-10.
[172] *Id.* at *11.
[173] *Id.* at *12.
[174] *See Coshow*, 34 Cal. Rptr. 3d 19; *see* also Quiles v. City of Boynton Beach, 802 So.2d 397, 399 (Fla. Dist. Ct. App. 2001).
[175] *Coshow*, 34 Cal. Rptr. 3d 19.
[176] *Mayor of Cumberland*, 2003 WL 22095654 at * 11.
[177] *Quiles*, 802 So.2d at 399.
[178] Dowell v. City of Tulsa, 273 P.2d 859, 864 (Okla. 1954).
[179] City of Watsonville v. State Dep't of Health Servs., 35 Cal. Rptr. 3d 216 (Ct. App. 2005); *Coshow*, 34 Cal. Rptr. 3d 19; Froncek v. City of Milwaukee, 69 N.W.2d 242 (Wis. 1955).
[180] *City of Watsonville*, 35 Cal. Rptr. 3d at 218.
[181] *Id.* at 219.
[182] Exner v. Am. Med. Ass'n, 529 P.2d 863 (Wash. Ct. App. 1974); Readey v. City of St. Louis Cnty. Water Co., 352 S.W.2d 622 (1961); Baer v. City of Bend, 292 P.2d 134 (Ore. 1956); Kraus v. City of Cleveland, 127 N.E.2d 609 (Ohio 1955); Dowell v. City of Tulsa, 273 P.2d 859 (Okla. 1954); Kaul v. City of Chehalis, 277 P.2d 352 (Wash. 1954).
[183] *Readey*, 352 S.W.2d at 623.
[184] *Id.* at 628.
[185] *Id.*
[186] *Id.*
[187] *Id.* at 632
[188] *Exner*, 529 P.2d at 865.
[189] *Id.* at 865.
[190] *Id.* at 870.
[191] *Id.* at 867.
[192] Coshow v. City of Escondido, 34 Cal. Rptr. 3d 19 (Ct. App. 2005); Quiles v. City of Boynton Beach, 802 So.2d 397 (2001); Safe Water Ass'n v. City of Fond Du Lac, 516

N.W.2d 13 (Wis. Ct. App. 1994); Minn. State Bd. of Health v. City of Brainerd, 241 N.W.2d 624 (Minn. 1976).
[193] *Quiles*, 802 So.2d at 399.
[194] *Id.*
[195] *Id.*
[196] Rovin v. Pa. Pub. Util. Comm'n, 502 A.2d 785 (1986); Crotty v. City of Cincinnati, 361 N.E.2d 1340 (Ohio 1977); Sheffer v. City of Harrisburg, 60 PA D.&C.2d 725 (Pa. Comm. Pl. 1971); Hall v. Bates, 148 S.E.2d 345 (S.C. 1966); McGurren v. City of Fargo, 66 N.W.2d 207 (N.D. 1954).
[197] *Rovin*, 502 A.2d at 785.
[198] *Id.* at 786.
[199] *Id.*
[200] *Id.* at 786-87.
[201] *Id.* at 787.
[202] Parkland Light & Water Co. v. Tacoma Pierce Cnty. Bd. of Health, 90 P.3d 37(Wash. 2004); Citizens for Safe Drinking Water v. San Diego City Council, No. D036647, 2002 Cal. App. LEXIS 4975 (Ct. App. Jan. 11, 2002); Young v. Bd. of Health of Borough of Somerville, 293 A.2d 164 (N.J. 1972).
[203] *Young*, 293 A.2d at 166.
[204] *Id.*
[205] *Id.* at 167.
[206] Wash. Rev. Code § 57.08/012; *Parkland Light & Water Co.*, 90 P.3d at 39.
[207] *Parkland Light & Water Co.*, 90 P.3d at 40.
[208] Clallam Cnty. Citizens for Safe Drinking Water v. City of Port Angeles, 151 P.3d 1079 (2007); Potratz v. Pa. DEP, 897 A.2d 16 (Pa. 2006); Balke v. City of Machester, 834 A.2d 306 (N.H. 2003); Village of Tully v. Harris, 119 A.D.2d 7 (N.Y. App. Div. 1986); Akinhead v. Borough of W. View, 442 A.2d 364 (Pa. 1982); Brown v. City of Canton, 414 N.E.2d 412 (Ohio 1980); City of Port Clinton Pub. Water Supply v. McAvoy, 1980 WL 351576 (Ohio Ct. App. 1980); Paduano v. City of New York, 257 N.Y.S.2d 531 (Sup. Ct. 1965).
[209] *Clallam Cnty. Citizens for Safe Drinking Water*, 151 P.3d at 1080.
[210] *Id.* at 1081.
[211] *Id.* at 1082.
[212] *Potratz*, 897 A.2d at 17.
[213] *Id.* at 17-18.
[214] *Id.* at 18.
[215] *Id.* at 21-22.
[216] *Id.* at 21.
[217] *Id.* at 23.
[218] *See generally* City of Port Angeles v. Our Water-Our Choice!, 239 P.3d 589, 592 (Wash. 2010) (challenging a city council vote to approve fluoridation with two initiatives); Utahns for Better Dental Health-Davis, Inc. v. Davis Cnty. Clerk, 175 P.3d 1036, 1037 (Utah 2007) (noting in passing the question heard and decided below of the constitutionality of a revote); City of Watsonville v. State Dep't. of Health Servs., 35 Cal. Rptr. 3d 216 (Ct. App. 2005) (questioning preemption by state law requiring fluoridation over local referendum banning the same); Balke v. City of Manchester, 834 A.2d 306, 307-08 (N.H. 2003) (challenging city referendum approving fluoridation which includes the water systems of other municipalities); Thompson v. Bexar Cnty. Elections, Nos. Civ. A.SA-00-CA-1527, Civ.A.SA-00-CA-1542, 2002 WL 1492276 (W.D. Tex. Mar. 21, 2002) (arguing in two parts: Plaintiffs sought to invalidate fluoridation ordinance as unconstitutional, and void the special election on the ordinance for voting irregularities); Citizens for Safe Drinking Water v. San Diego City Council, No. D036647, 2002 Cal. App. LEXIS 4975 (Ct. App. Jan. 11, 2002) (discussing authority granted by city code initiatives regarding fluoride versus state law governing community water services); Burt v. Blumenauer, 672 P.2d 51 (Ore. Ct. App. 1983) (deciding whether public health offices may expend funds or participating in a debate about fluoridation initiative); City of Cuyahoga Falls v. McAvoy, 1979 Ohio App. LEXIS 12500 (Ohio Ct. Ap. 1979) (dealing with challenges by local referendums to state regulations of water supplies); Oregon Anti-Fluoridation Council v. Myers, 554 P.2d 177, 178 (Ore. 1976) (challenging Secretary of State's omission from voting pamphlet certain details about the health risks of fluoride additions); Turner v. Barnhardt, 497 P.2d 970 (N.M. 1972) (claiming full text of voter approved initiative on fluorination of water not placed on ballot); Williams v. Rowe, 283 A.2d 881, 882 (Pa. Comm. Ct. 1971) (stating that it was a clerk's failure to prepare petition to prevent fluoride additions to the water supply); Hacker v. Common Council of Ithaca, 266 N.Y.S.2d 927, 929-30 (Sup. Ct. 1966) (deciding whether a voter petition to amend a city ordinance authorizing fluoridation is legal); Landt v. City of Wisconsin Dells, 141 N.W.2d 245 (Wis. 1966); Hughes v. City of Lincoln, 232 Cal. App. 2d 741, 742 (Ct. App. 1965) (petitioning to compel mayor and city council to repeal and prevent fluoridation resolution); Stroupe v. Eller, 138 S.E.2d 240, 242 (N.C. 1964) (arguing to enjoin city fluoridation ordinance); State *ex. rel.* Whittington v. Strahm, 374 S.W.2d 127, 128-29 (Mo. 1963) (pressing city counsel to take action on referendum to overturn fluoridation ordinance, arguing ordinance is amendable by referendum); Readey v. St. Louis Cnty. Water Co., 352 S.W.2d 622, 623 (Mo. 1961) (demanding that city council refrain from enforcing city ordinance to fluorinate water supply due to constitutional concerns).
[219] *See Thompson*, 2002 WL 1492276, at *1 (claiming election irregularities "tainted" the election results).
[220] *See id.* at *5 (providing that such city council action is within the authority to protect the health ,safety, and welfare of the public).
[221] *See id.* (outlining the presumption of validity city ordinances are afforded).
[222] *See id.*
[223] *See id.* (lacking these materials does not undermine reasonableness of the council's decision in protecting the publics' welfare).
[224] *See* Utahns For Better Dental Health-Davis, Inc. v. Davis Cn.ty Clerk, 175 P.3d 1036, 1037 (2007) (requesting the same question to be placed on the ballot in the next general election).
[225] *Id.*
[226] *See id.* at 1037-38 (holding that placing the vote on the ballet violates the law governing initiatives and referenda).

[227] *See id.* at 1040 (stressing that the lower court erred because the case did not deal with mere interpretation of a petition but implication of a fundamental right).
[228] *See id.* at 1040-41 (asserting the sentiment of the Oregon Supreme Court, which noted the benefit to the public in defending the integrity of initiatives).
[229] *See* City of Port Angeles v. Our-Water Our Choice!, 239 P.3d 589, 591-92 (2010) (petitioning to make the right to public water a property right, and making treatment of the water supply, effecting physical or mental human functions a crime).
[230] *Id.* at 592.
[231] *Id.*
[232] *See id.* at 592-94 (noting that states have the power to grant and delegate such authority to local governments).
[233] *See id.* at 595 (holding that the initiatives look to impact management of the water system).
[234] *See id.* at 595-96 (articulating that the initiatives attempt to control, limit and set standards for water treatment, which interferes with an existing regulatory system).
[235] *See generally* City of Watsonville v. State Dep't of Health Servs., 35 Cal. Rptr. 3d, 216, 220 (2005) (questing whether a chartered city ordinance and regulations related to municipal issues are in violation of state authority); Citizens for Safe Drinking Water v. San Diego City Council, No. D036647, 2002 Cal. App. LEXIS 4975, at *1, 8 (Ct. App. Jan. 11, 2002) (noting that the chartered city of San Diego is "autonomous over municipal affairs" with the sole exceptions of federal and state constitutions and state law which preempts).
[236] *City of Watsonville,* 35 Cal. Rptr. 3d at 218.
[237] *Id.* at 219.
[238] *Id.*
[239] *Id.* at 220.
[240] *Id.* at 221.
[241] *Id.* at 222.
[242] *Id.*
[243] *Id.* at 223-24.
[244] *Fluoridation Debate, Redux*, NY Times (March 18, 2012), http://www.nytimes.com/2012/03/18/opinion/sunday/fluoridation-debate-redux.html.
[245] Catherine Saint Louis, *Preschools in Surgery for a Mouthful of Cavities*, NY Times (March 6, 2012), http://www.nytimes.com/2012/03/06/health/rise-in-preschool-cavities-prompts-anesthesia-use.html?pagewanted=all.
[246] *Id.*
[247] *Id.*
[248] *Bottled Water and Fluoride*, Ctrs. for Disease Control & Prevention, *available at* http://www.cdc.gov/fluoridation/fact_sheets/bottled_water.htm (last visited March 10, 2013).
[249] Fairbanks Fluoride Task Force, *Report of the Fairbanks Fluoride Task Force*, 13 (Apr. 25, 2011), *available at* http://www.fairbanksalaska.us/wp-content/uploads/2011/07/20110425finalreport.pdf.
[250] *Id.* at 6.
[251] *Id.*
[252] N.H. Rev. Stat. Ann. § 485:14-b (2012).
[253] *Id.*
254 *Overview: Infant Formula and Fluorosis*, Cntrs for Disease Control & Prevention, *available at* http://www.cdc.gov/fluoridation/safety/infant_formula.htm (last visited March 12, 2013).
[255] H. Ilda & J.V. Kumar, *The Association Between Enamel Fluorosis and Dental Caries in U.S. Schoolchildren*, 140 J. Am. Dental Ass'n, 855 (2009); *see also* O. Chankanka et al., *A Literature Review of Aesthetic Perceptions of Dental Fluorosis and Relationships with Psychosocial Aspects/Oral Health-Related Quality of Life*, 38 Cmty. Dental & Oral Epidemiology 97 (2010).
[256] Milwaukee Common Council, Resolution 120187 (July 24, 2012), *available at* http://milwaukee.legistar.com/ViewReport.ashx?M=R&N=Text&GID=5&ID=1197632&GUID=B80EE033-A64C-4081-BC26-2A91A6E08911&Title=Legislation+Text (last visited March 12, 2013).
[257] *Id.*
[258] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, Section 399LL (2010).
[259] T.R. Frieden, *A Framework for Public Health Action: The Health Impact Pyramid.* 100 Am. J. Pub. Health 590 (2010).
[260] Tiemann, *supra* note 70.
[261] Rick Jervis, *Florida's Pinellas County Rejects Fluoride in Drinking Water*, USA Today (Oct. 6, 2011), http://www.usatoday.com/news/nation/story/2011-10-05/pinellas-county-florida-votes-no-fluoride-in-drinking-water/50673318/1.
[262] *Id.*
[263] Sue Carlton, *Lessons Learned After the Fluoride Fever Breaks*, Tampa Bay Times (Nov. 30, 2012), http://www.tampabay.com/news/politics/sue-carlton-lessons-learned-after-the-fluoride-fever-breaks/1263826.
[264] *Id.*
[265] *Comments of William Maas, DDS, MPH, Advisor to the Pew Children's Dental Campaign* (Feb. 4, 2013).
[266] J.V. Kumar et al., *Geographic Variation in Medicaid Claims for Dental Procedures in New York State: Role of Fluoridation Under Contemporary Conditions*, 125 Pub. Health Rep. 647 (2010).
[267] Texas Department of Health, *Water Fluoridation Costs in Texas: Texas Health Steps (EPSDT-Medicaid)* (2000), *available at* www.dshs.state.tx.us/dental/pdf/fluoridation.pdf.
[268] *Water Fluoridation and Costs of Medicaid Treatment for Dental Decay-Louisiana, 1995-1996*, Ctrs. for Disease Control & Prevention, Morbidity & Mortality Weekly Rep. (1999), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4834a2.htm [hereinafter *Louisiana, 1995-1996*].
[269] J.V. Kumar et al., *supra* note 266.
[270] *Louisiana, 1995-1996*, *supra* note 268.

The Electronic Health Revolution How Health Information Technology Is Changing Medicine—and the Obstacles in Its Way

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I. INTRODUCTION

Hospitals have long been on the cutting edge of technological innovations, both in the operating room and the administrator's office. It is the area in between—where patients are monitored and instructed, and where care is managed—that the medical profession has been a laggard. As a result, medical care within the United States is frighteningly less organized, integrated, and streamlined than is ideal for an industry that, at one time or another, will service nearly every person in the country.

Fortunately, the medical profession is improving through the utilization of health information technology. Many changes stem from the implementation and improvement of electronic health records (EHRs), resulting in improved integration between care providers, such as primary care physicians (PCPs), hospital staff, specialists, and pharmacists. This paper will survey the changing medical landscape resulting from the EHR revolution. The biggest advantages of EHR technology go beyond the ease of electronic recordkeeping and into the integration and interoperability that EHR systems allow. When properly utilized, applications of EHR systems can reduce administrative costs and burdens, improve care quality, reduce mistakes, and provide a boon for public health research.

And yet, there are pitfalls and roadblocks that must be addressed. The dual issues of privacy and information security, resistance to changing procedures, technologies and high startup costs, and unexpected hiccups in early adoption stand in the way of an easy transition. Each of these issues will be examined, and recommendations will be made for a more robust and successfully integrated health system. EHRs and the greater health information technology changes occurring around us can revolutionize healthcare delivery if the systems can be implemented as envisioned—but whether that will happen remains to be seen.

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II. ELEMENTS OF THE ELECTRONIC HEALTH REVOLUTION

In order to understand the overhaul that the electronic health revolution is bringing, it is helpful to understand a few of the most important technological changes that are making an impact on the medical profession. This section will focus on electronic health records (EHRs), health information exchanges (HIEs), and patient safety organizations (PSOs).

A. Electronic Health Records

Electronic health records are most easily described as a one-stop-shop for medical data on a particular patient. An EHR can consist of patient demographics, medical history, clinical notes, symptoms, diagnoses, current medications, vital signs, laboratory data, and radiology reports.[1] In essence, EHRs allow hospitals and physician offices to reduce large paper files into neat, easy-to-access electronic ones.

It is helpful to note the distinction between EHRs and electronic medical records (EMR). EMRs are essentially an electronic version of the paper records held within a medical practice.[2] EMRs contain patient medical and treatment histories, and are

essentially proprietary. But EMRs are not meant to be interoperable, and thus are not easily transferred between settings. In order to transfer EMR data to another practice, hospital or even department, the data must often be printed out.[3] In this way, EMRs are only marginally better than paper records. EHRs, conversely, are *designed to be transferred between care providers and practice settings*.[4] EHRs thus have the potential to improve care coordination and quality in a way that EMRs cannot. For this reason, this paper will only look at EHRs.

Electronic health records have been around since the 1960s. In the latter half of that decade, various academic hospitals developed proprietary systems for use in their medical centers.[5] The Department of Veterans' Affairs (VA) began to use its own EHR system in the 1970s, known as VistA.[6] Though EHR systems have been around for half a century, adoption has been relatively slow. Among hospitals, adoption of at least a basic EHR system was seen in only 13.4% of non-federal acute care hospitals in 2008.[7] By 2011, however, this number had jumped to 34.8%.[8] As time progresses and the benefits of EHR systems become more apparent to non-adopters, this number will likely increase at an even greater rate.

Hospitals without EHRs often have separate file systems for each of their departments, such that one hand does not know what the other is doing.[9] This can occur even when these departments store information in electronic format. To transmit patient data from a doctor to the pharmacy, for example, the information may be faxed over and manually entered into the pharmacist's computer. At best, this lack of coordination results in wasted time and effort, while in the worst case scenario it can result in harm to the patient. EHR systems allow medical professionals quick and easy access to patient records to verify, edit, or insert information. EHRs underpin much of the electronic health revolution as patient care goes online.

EHRs also offer the opportunity for patients to monitor and review their personal health records. This will allow patients to ensure their information is accurate and can also encourage patients to be involved in their healthcare decisions. The Indian Health Service, for example, is in the process of implementing a personal health record through their EHR system, eventually allowing patients to view information about health conditions, message care providers with questions, and refill prescriptions online.[10]

B. Health Information Exchanges

Health Information Exchanges (HIEs) are another tool in the electronic health arsenal. They are essentially an outgrowth of EHRs in that they allow EHR data to be shared across platforms and among stakeholders through interoperability.[11] This exchange can improve patient health and safety by reducing errors in transcription and transfer of patient records, while also offering the potential for lower administrative costs. One aspect of the Health Information Technology for Economic and Clinical Health Act (HITECH)[12] was the provision of $2 billion for the development of HIEs.[13] A large part of this funding was intended to promote more "meaningful use" of EHR in ways that require HIEs. E-prescribing, for example, requires the exchange of health information between the prescribing doctor and the pharmacy. Health information exchange allows this transfer to occur entirely electronically.

HIEs have already shown themselves to be useful. During Hurricane Sandy in October 2012, many patients in New York-area hospitals had to be relocated. Such a transition would once have required frantic calls to other providers and patient family members in order to piece together a working medical history and current diagnosis. With an integrated HIE, however, administrators were able to call upon a patient's record simply by accessing that information online through the exchange.[14] This was possible because New York has a statewide HIE, known as the Statewide Health Information Network of New York (SHIN-NY), which tracks hospital admittances, allowing providers access to required patient information.[15] HIEs are already an integral part of the electronic health revolution, and have great potential to improve patient safety and reduce administrative costs as their development continues.

C. Patient Safety Organizations

The Patient Safety and Quality Improvement Act (PSQIA)[16] introduced Patient Safety Organizations as a method of improving the quality and safety

of medical care.[17] PSOs accomplish this goal by allowing healthcare providers to share and aggregate data to flag problem areas and reduce risks to patients.[18] To become a PSO, the mission and primary activity of an entity must be the undertaking of activities to improve patient safety and healthcare quality.[19] The Agency for Healthcare Research and Quality (AHRQ) currently recognizes 76 PSOs as meeting the requirements.[20] One aspect of the Patient Protection and Affordable Care Act (ACA)[21] is a push to reduce hospital readmissions. Hospitals with high risk-adjusted readmission rates are encouraged to work with PSOs to improve patient safety.[22] Much like HIEs, PSOs function by aggregating large quantities of patient data to form an overall picture of care quality, specifically with the goal of reducing adverse events. In this way, PSOs are yet another aspect of the electronic health revolution that seeks to improve the healthcare system.

III. POTENTIAL BENEFITS OF THE REVOLUTION

These changes in the practice of medicine hold great promise. The ability to integrate records across providers and practice settings means that emergency room (ER) doctors can know a patient's medical history simply by calling up his or her EHR, even if the patient has never been to that hospital before. The computing power behind electronic records means that certain medical knowledge, such as adverse drug interactions and treatment cycles, can be left to the patient's record to monitor, reducing mistakes, and freeing up personnel for other tasks. Even more, EHRs—when the information is anonymized and aggregated across population groups—can potentially revolutionize public health research and reporting. This section analyzes some of the many benefits that the revolution holds for the health care industry and for society.

A. Better Outcomes and Fewer Mistakes

The dream of EHRs begins with the hope that widespread adoption of EHR systems will improve patient outcomes. A study by Kaiser Permanente found that use of EHRs was associated with improved recognition of diabetic patients in need of greater drug treatment as well as better control of disease risk factors among sicker patients.[23] Another study of U.S. nurses found that those who used comprehensive EHR systems reported better care and outcomes and encountered fewer patient safety issues and adverse drug reactions.[24] EHR systems can automatically flag potential areas of concern and remind medical professionals—who can be overworked or unfamiliar with a patient—to double check areas they may otherwise overlook.[25] A properly implemented and maintained EHR system has the potential to revolutionize care quality in many settings.

With prescription drugs, electronic systems can provide doctors with alerts when they use confusing or inappropriate abbreviations in prescriptions and can check for drug allergy interactions, drug-drug interactions, and duplicate drugs.[26] EHRs have also been shown to reduce medication errors through the use of electronic checklists when entering medication histories.[27] With complete integration of EHRs through HIEs and interoperable systems, medication errors can be reduced even further. Where a clinician using a basic electronic system has the advantage of an electronic checklist, he or she still must often rely on the patient to provide a complete, accurate medication history. Integrated HIEs allow the clinician to call upon the patient's record from all past encounters with the healthcare system, greatly reducing the chance of forgetting a past medication.[28] This possibility demonstrates one of the greatest promises of EHR systems—the ability for systems to "speak" to one another, instantly confirming the safety and necessity of medical care, thereby reducing redundancy, improving outcomes, and minimizing mistakes attributable to human error.

B. Public Health

One of the most promising potentialities of the electronic health revolution is in the area of public health. The health information of one individual may only be useful to that person, but when identifying information is removed and the health data is aggregated with the records of countless other individuals, the data can help society at large. Public health researchers can take aggregated data and spot potential disease outbreaks, find dangerous drug interactions, and improve quality of care in the greater community. The Centers for Disease Control

and Prevention (CDC) sees EHRs as a "game changer" in public health reporting, given the delay and burden of manual reporting of potential disease outbreaks.[29] Electronic data transfer allows public health officials to pinpoint problem areas more quickly, while automatic electronic reporting allows providers to share anonymized information that they didn't know would be relevant to researchers.[30] Quick, easy access to aggregated health information stands to benefit public health in significant ways.

C.A Positive Outlook

As more providers implement EHR systems and electronic systems become the norm, resistance to the technology is likely to drop. Both doctors and patients will be more likely to accept the need for EHRs and see the benefits of integrated records systems. As systems are improved and standardized, interoperability is likely to improve, unlocking the greatest benefits of all. EHRs are poised to improve care quality and reduce mistakes as the technology matures, and some of these benefits are already evident among early adopters.[31] The dream of interoperable health IT requires widespread adoption before all of the care-improving aspects of EHRs can be achieved.[32] Once EHR adoption reaches critical mass, they will be poised to revolutionize the American healthcare industry in a number of ways.

IV. CONCERNS MOVING FORWARD

Even with the advantages of the electronic health revolution, there are still a number of drawbacks that must be acknowledged. As with any electronic information system, privacy and security are at the forefront of many people's minds. Apprehension about who will have access to which records and when—as well as concerns about unauthorized access to protected information—follow whenever personal information is being used in new ways.[33] Change also breeds resistance, and EHRs are no exception. Hospitals and physician practices worry about the cost and burden of implementing these new systems, and some practitioners have shown resistance to making the change.[34] There are also some unexpected costs in the early stages of widespread EHR adoption, including an increase in reimbursement requests for expensive tests and procedures coinciding with the implementation of EHR systems.[35]

A. Privacy Concerns

Privacy is usually one of the first concerns people have when discussing a system that integrates and shares personal data. EHR systems are no different. One concern is that the move to integrated EHRs may dissuade a certain set of patients from seeing the doctor altogether.[36] These patients would be a small minority, but those with a strong distrust of the electronic transition may have a real and significant fear of having their records converted into EHRs.[37] For them, doctors in the short run can do little more than provide assurances that patient data privacy and security are taken seriously and explain how EHRs work generally.[38]

Other patients will see the benefits of electronic systems,[39] including the ability to e-prescribe necessary medicines and the reduced number of redundant forms required in office waiting rooms. But these same patients may be on the fence about the larger integrated nature of EHR systems. They may be grateful that they don't have to take a paper prescription down to the pharmacy to have it filled, but they may be uncomfortable with one specialist having access to the records created during a visit with a different physician. In this way, some patients may be protective of their medical records in a way limits the usefulness of EHR.

Records need not be shared with any and all in the medical profession, but it is entirely plausible that a cardiologist could benefit from a patient's records created by that patient's PCP.[40] In fact, the integration of one system of records among all of a patient's providers is one of the main tenets of an EHR system via HIEs. Past diagnoses may bear on current examinations and prescriptions much more heavily than a patient can realize, and integrated, interoperable EHR systems are a necessary part of maximizing patient benefit. Much like a loan financer who needs access to an applicant's bank records and income statements, medical staff need open access to relevant parts of a patient's medical record in order to effectively diagnose and treat any issues that may exist.

Many of these privacy concerns arise when patients are concerned about potentially authorized access to their medical records. Patients may be uncomfortable with the ease at which their records are accessible by a member of the medical profession, even if the medical or diagnostic benefit to the patient is quite large. These worries are likely to dissipate as EHR systems become not only standard, but obligatory. Hopefully, as more patients see the advantages of integrated EHRs, they will be more open to them.

B. Records Security

It is impossible to create a perfectly secure computer system, and so there will always be a struggle between the poles of security and accessibility.[41] The more restrictive a system is, the more likely it is to be secure from outside threats (though the most advanced cyber threats will always be a step ahead of the most advanced security), but such security comes at the cost of ease of accessibility. Likewise, an open, accessible, and efficient system of interoperable records will likely be less secure than it otherwise could be. The goal of the implementation of EHR systems is to balance the two aspects so that EHRs can be used to facilitate healthcare decision making and reduce administrative burdens while also maintaining patient confidence in the integrity of their protected health information (PHI).

Even in the relatively short history of widespread EHR use, there have been a number of high profile data breaches.[42] What is most interesting about these breaches is that many occurred not through hacking into secure systems, but through old fashioned loss, theft of physical media, or simple user error. For example, in 2006, the Social Security numbers (SSNs) and birth dates of 26.5 million veterans were compromised when a laptop was stolen from a VA employee.[43] Similarly, the theft of a National Institutes of Health (NIH) laptop from a researcher's car in 2008 resulted in the breach of clinical trial information including SSNs of 1,200 participants.[44] In the private sector, names and diagnoses of almost 20,000 Stanford Hospital emergency room patients were posted online after a job applicant sought help on converting the data into a bar graph.[45]

Encryption of laptops containing sensitive health information, which is *de facto* required,[46] can help prevent breaches, such as the theft of workplace computers containing sensitive data. So can disaggregation of information about participants in clinical studies and of patient data used as a sample. However, these procedures are not always followed, and there are still exceptions in the law that make some of these requirements less than mandatory.[47] Physical theft is not a new problem with EHRs, as it has long existed with paper records, but EHRs allow individual data breaches to involve thousands or millions of records, rather than the few paper records a thief can physically carry.

To be sure, a thief is most likely to value the stolen laptop for its worth as a resalable item or for personal information that has direct monetary value, such as SSNs or payment information.[48] But there are a number of entities that would find great value in the health information itself, including employers and potential employers, creditors, marketers, and health insurers.[49] Each of these entities could use the information to make decisions that affect the individual whose information is stolen, as well as the confidence of the public at large.[50] Even worse, blackmailers and paparazzi have already used celebrity and public officials' PHI for nefarious purposes. Former U.K. Prime Minister Gordon Brown alleged that The Sun newspaper illegally accessed his son's medical records and wrote a story on his cystic fibrosis.[51] While a patient at the UCLA Health System, Farrah Fawcett set up a sting operation to catch one of the hospital's employees who was illegally accessing and disclosing her health information.[52] In the case of internal leaks of celebrity PHI, especially, encryption and data storage standards will have little effect against employees who have access to the information anyway and wish to use it for unsavory reasons.[53]

C. Impact of HIPAA

The Health Insurance Portability and Accountability Act of 1996[54] (HIPAA) was designed with both paper and electronic health records in mind. It contains provisions that require "covered entities"[55] to make electronic health information secure[56] and limit access to and disclosure of patient records.[57] HIPAA functions as a privacy floor in that it does not automatically preempt more-restrictive state

laws. Instead, when determining the privacy standard to apply in a given state, a medical practice must compare HIPAA with the relevant state law and comply with the stricter of the two.[58] While HIPAA seems like a positive development in medical records privacy and security, it has not entirely lived up to expectations. There is no private right of action to remedy a HIPAA violation, so all potential violations must be prosecuted by the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR).[59] Thus, there is no personal remedy for the aggrieved patient or patients whose records were used improperly.[60]

Because electronic records are used more widely and for different purposes than when HIPAA was originally introduced, the HITECH Act was developed as a vehicle for updating HIPAA privacy and security rules. Under HITECH, HIPAA's rules apply directly to business associates—contractors and third parties with access to patient health information—rendering them subject to penalties for violations.[61] Previously, business associates were only liable to the covered entity with whom they were contracted. HITECH also introduced new breach notification rules, whereby breaches of confidentiality involving 500 or more persons require reporting to the news media, and those involving fewer than 500 persons must be reported to HHS.[62] EHR disclosure rules under HIPAA have been tightened by HITECH as well, so that a patient can request that disclosure of PHI be restricted in certain cases, and that such disclosure be limited to the minimum amount necessary for a given purpose.[63] Health care providers must also document disclosures of patient information for three years and make that information available at the patient's request.[64]

Though HITECH is a positive step in HIPAA's development, it patches without solving the enforcement problem. While HITECH allows states' attorneys general to bring civil actions for violations,[65] it still does not provide a private right of action. Therefore, aggrieved patients can still do little more than report their concerns to a government entity and hope that the government follows up on the complaint.[66] Patients who either lack faith in the efficacy of this enforcement system or who seek more control over recourse for violations of their privacy will find the HIPAA-HITECH scheme insufficient, which may in turn harm public confidence in a health information technology structure. Regulators must be vigilant and react swiftly to reports of violations if they are to instill confidence in the privacy and security of patient records.

D. Financially Motivated Resistance

Although EHR systems have the potential for greater efficiencies in the practice of medicine, many medical professionals will likely resist changing their system from the status quo absent some form of incentive. In some cases, resistance stems directly from the cost of implementation.[67] Some smaller practices are likely to balk at the size of the bill associated with installation, training, and startup of EHR systems.[68] The cost can be up to $50,000 per clinician, and many doctors don't see the potential for much additional return on that investment.[69] The result is a wait-and-see attitude, which drags down integration among providers when some have EHR and some do not. The long-term goals of better care quality and reduced administrative burden that comes with an integrated EHR system cannot be met unless there is widespread use of EHRs.[70]

To incentivize providers, the federal government has implemented financial bonuses to practices that achieve "meaningful use" of EHR.[71] To achieve meaningful use, a practice must comply with a host of requirements laid out over three implementation stages.[72] For example, eligible medical professionals must achieve twenty of twenty-five meaningful use objectives in the first stage, while hospitals must achieve nineteen of twenty-four total objectives in stage one.[73] Stage two, which begins in 2014, attempts to move from data collection to actually improving care. Eligible professionals must meet seventeen core requirements and three of six menu objectives, while hospitals must complete sixteen core requirements and three of six menu objectives.[74] Recommended health care policy domains include patient safety, care coordination, and efficient use of resources.[75]

Those providers who meet the developing requirements can see financial incentives through Medicare and Medicaid. Medicare providers,

including physicians, podiatrists, dentists, optometrists, and chiropractors,[76] are eligible for up to $44,000 in incentives over a period of up to five years for achieving meaningful use.[77] Under Medicaid, physicians, dentists, certified nurse midwives, nurse practitioners, and physician assistants[78] may receive up to $63,750 over six years.[79] The flip side of this incentive program is that providers who fail to meet the meaningful use criteria by 2015 will face reimbursement *reductions.*[80] The goal of this carrot-and-stick program is to normalize the use of EHR systems so that the program reaches critical mass and integration and interoperability can be achieved among providers.[81]

E. Resistance to Change

Though many hospitals and practices are making the transition to EHR systems—influenced by the combination of financial incentives for achieving meaningful use of EHRs and reimbursement penalties for failure to do so—individual doctors are left with the responsibility to actually use the systems on a daily basis.[82] As with any significant change, the shift from handwritten notes and sometimes-illegible prescriptions to comments tapped out on a keyboard and checkboxes selected on a tablet PC, has not been universally welcomed by the medical profession. Substantial change comes with the cost of unfamiliarity, and this contrast is starkest for those physicians who have been in practice for many decades.[83] However, while the transition may be met with resistance, and though there will be hiccups and wrinkles along the way, integrated, interoperable EHRs hold great promise once their use becomes second nature to the medical profession.

Some physicians feel that the use of EHRs cheapens the doctor-patient interaction.[84] One doctor sees the use of a laptop to take clinical notes as a barrier between her and the patient.[85] To her, the use of an electronic system of data management is not necessarily worth the costs of the transitional period.[86] Many of the concerns of physician distraction during appointments will be minimized once doctors become familiar with EHR systems, and many other worries about clunky menu searching and box checking will be reduced as EHR software is further developed and upgraded with interface concerns in mind. As with any technological adoption, comfort and speed of use will improve over time, and along with that, the resistance to change will dissipate as use becomes normalized.[87] The transition to EHR systems was always going to encounter resistance due to human nature. However, for those doctors who enter practice in the age of EHR, as well as for the physicians who take the time to use and better understand EHR systems and their benefits, the medical profession will likely find that the change is not as arduous as once thought.[88] Indeed, another characteristic of human nature, alongside resistance to change, is adaptability to changing situations.

F. Unexpected Cost Increases

The introduction of EHRs was hailed as a way to significantly reduce medical costs. With the establishment of the Office of the National Coordinator for Health Information Technology (ONC) in 2004, President George W. Bush estimated that EHR systems could reduce healthcare costs by 20% annually.[89] Likewise, a 2005 RAND analysis predicted more than $81 billion in annual savings.[90] Intuitively, EHRs should be able to reduce costs by streamlining care, reducing duplicative tests and procedures, and cutting out administrative costs and waste, including printing costs and physical records maintenance and storage. However, the ease of use of EHR systems can sometimes incentivize more testing and documentation, driving up costs for Medicare and private insurers, as well as those individuals who pay out-of-pocket.

Medicare reimbursements rose by $1 billion between 2005 and 2010, driven in part by a shift in how hospitals assign billing codes to emergency room patients.[91] In one case in 2009, a New York hospital reported a 43% rise in the number of ER patients requiring the highest level of care, coinciding with the hospital's introducing of EHRs.[92] A hospital in Tennessee reported an 82% increase in the highest-coded ER patients in 2010, the year that hospital switched to EHRs.[93] The hospitals say that the increases are due to improved coding accuracy under the electronic system, and that they were actually underbilling before they switched to EHRs; but federal regulators are concerned that hospitals are "upcoding," or reporting higher levels of care than

may be necessary, or even performed.[94] In a letter to several major hospital trade associations, the Obama administration expressed concern that some hospitals are using EHR systems to report a higher intensity of care or severity of patient condition without providing a corresponding improvement in care quality.[95]

Payments have also risen in part due to the ease of "cloning" documentation in EHR systems. Cloning allows doctors to cut and paste exam findings and diagnoses from one patient to another through a key stroke or a button press.[96] Where doctors once had to scribble notes for each individual patient, electronic systems allow them to use past patient notes as a template, incentivizing cloning as a time-saving measure and potential tool for greater reimbursements. Some payers have begun to push back against cloning, such as Medicare contractor National Government Services, which reported to physicians that it would not pay for claims submitted with cloned documentation.[97]

Another aspect of EHRs that has increased reimbursements stems from the design of the software and the incentives for a provider to use EHRs to maximize profits. Providers can set EHR systems to automatically prompt doctors to click through checklists that indicate a comprehensive patient examination has taken place, even where very few checks have been performed.[98] Systems can also be programmed to allow doctors to insert pre-created "findings" into a patient's record using a pre-filled template.[99] While EHRs are intended to reduce the burden on physicians when completing patient records, they should not be used as a shortcut for actually performing tests. In one telling example, a patient visited a Virginia hospital with a kidney stone, and emerged with a bill that showed examinations that had not been performed.[100]

The likely explanation is that the hospital's EHR system included a template that automatically fills in exam information that has not necessarily been completed.[101] While a sophisticated patient poring over his or her own records may notice such a discrepancy, a large insurance provider or Medicare contractor will not be able to check the accuracy of every bill. This will either increase the administrative costs for those payers, as they must hire additional personnel to audit providers, or will raise the reimbursements granted to providers, in turn raising the costs of Medicare or private insurance to keep up.[102]

While widespread implementation of EHR systems is likely to reduce medical costs in some ways—through better information sharing and integration, for example—the early returns have also shown the potential for increased costs in some other ways. The ease of upcoding, cut-and-paste examinations, and using templates for procedures not actually completed have dampened the cost-saving fervor of EHRs in the early going. Fortunately, these problems have been identified[103] and solutions are likely to be introduced as standards and regulations catch up to the technology.[104]

G. Several Speed Bumps Remain

As EHRs move into the mainstream, however, they will likely become more of a target for bad actors who seek the information they contain for any number of nefarious reasons. PHI of celebrities and public figures could be used in any number of ways that would harm that person's reputation. Where theft of medical records used to require physical intrusion into the records storage of a medical center, a determined hacker can now theoretically access a patient's entire file using a laptop with an internet connection. It is a principle of technological development that no matter how strict the security regime is surrounding a product or software, black hats will always outpace the security fixes. EHR security schemes can only be designed to eliminate the most common kinds of intrusions and reduce the more determined ones.

These concerns should not stunt the growth of EHRs, however. Online banking is analogous to the rise of integrated EHR systems—though users are rightly worried about information security, it has not slowed the adoption of online and mobile banking.[105] Convenience and functionality overcome apprehension in the long run. But healthcare providers should not simply ignore security because they cannot eliminate all intrusions. There are certain "best practices" that, if followed, will create a reasonably secure records system.[106] Encryption of records can go a long way towards limiting

unauthorized access to patient information.[107] Annual security compliance assessments can alert providers to potential problem areas.[108] Maintaining electronic records requires administrators to keep up with current best practices in the industry.

V. THE FUTURE OF THE ELECTRONIC HEALTH REVOLUTION

The electronic health revolution is now in full throttle. Adoption rates among doctors are increasing faster each year.[109] Whether for better or worse, EHRs are here to stay. The federal push to achieve meaningful use, including financial incentives and penalties for noncompliance, signals that the U.S. government is fully behind the move to the electronic space.[110] There has been a learning curve within practices that have implemented electronic systems, and indeed within the industry at large. And, even if the industry achieves 100% adoption rates in the future, all concerns about EHRs will not be allayed. Electronic records are inevitably at risk of being compromised, and issues of proper coding and reimbursement for services will need to be resolved as the technology matures. This section will reinforce both the advantages and drawbacks of the electronic health revolution before providing a brief discussion of some of the next steps that will help to improve the health IT infrastructure.

The idea of EHRs has been around for decades and systems have been in place for years, though we are still in the formative period of the technology. Slow adoption and high costs, coupled with resistance by the healthcare industry, have partially undermined the growth of EHR systems and the bounty that can come with them. The dam obstructing full implementation may finally have been broken, however, with the recent federal initiative to make the use of EHRs widespread. But although the profession has made significant strides in adoption of EHRs, there is still a large amount of work to be done before many advantages can be fully realized.

A. Multifunctional Systems

As discussed above, implementation rates of basic EHR systems have risen rapidly over the past few years. However, these systems are not necessarily "multifunctional," which means that they are not providing the optimal level of information integration. In fact, a recent survey found that only 27% of doctors reported their EHRs as "multifunctional."[111] Multifunctional systems go beyond simply acting as an electronic repository for patient information; rather, it provides physicians with decision support, allowing the systems to act as an extra set of eyes.[112] The shortage of decision support within American EHRs is one area in which future advancements can be made. Providers that currently have EHR systems cannot be complacent—just as security improvements are a necessary part of maintaining computer systems, functionality improvements should be made over time to ensure that a provider's EHR system is providing the appropriate level of support.[113]

B. Interoperable Systems

Another important aspect of EHRs that must be addressed is one that is at the core of the electronic health revolution: achieving interoperability. Many commentators speak of interoperable systems as the goal of advancements in heath IT, but fail to consider how it will be achieved. Currently, there are over 700 separate vendors that make certified EHR products.[114] While marketplace competition generally cultivates innovation, the EHR space is inundated with a dizzying array of products with proprietary user interfaces. A practitioner seeking a new EHR vendor for his or her practice will be faced with over 1750 separate products from which to choose.[115] Not only are there simply too many options to make a fully informed choice, but several larger companies are attempting to stifle the growth of newcomers, threatening the disruptive innovation that one would hope to see in such a robust market.[116]

Too many distinct systems can be harmful to interoperability and, without some form of standardization—likely coming from the federal government or a management organization such as HIMSS—true interoperability is likely far down the road. One approach to minimizing this problem is to create a set of flexible standards rather than requiring one specific software infrastructure. In this way, vendors would be free to design their software as they see fit, but with guarantees that their systems would be able to speak with those of another

vendor.[117] If we are to achieve the greatest promises of EHRs, we must first ensure that IT systems are able to communicate with one another.

C. Falling Costs and Increased Efficiency

As time goes on, EHR systems are likely to reduce costs in a number of ways. As the technology matures, prices for the system software would likely decrease. More importantly, the costs associated with lost time spent clicking through clunky menus will disappear as interfaces are streamlined.[118] At the same time that EHR software is optimized, the use of EHR systems will become second nature for healthcare professionals. This will increase the input and usage speeds of EHRs, and when coupled with the coming influx of health IT data analysts,[119] providers are likely to see a substantial increase in efficiency of use and decrease in associated costs over the long run. Over time, providers may look back at the learning curve faced during EHR adoption as trivial in comparison to the efficiency boon gained.

D. Mobile EHRs

Even as EHR systems are coming online in practices, there is already a move to use mobile devices to access and manage records. In fact, 70% of providers say that they are currently using smartphones and tablets to access their EHR software.[120] Doctors like mobile access to EHRs because it allows for more efficient use of time and easier and quicker access to patient records, especially as doctors quickly move from one exam room to another.[121] With the ability to access patient information on the go, however, comes an increased risk of theft or unauthorized access of that data. Health IT professionals say that encryption and other methods of restricting access to mobile health data will be key moving forward as mobile EHRs become more widely used.[122] However, these fears may be mitigated somewhat by the large number of practitioners who say their mobile EHR systems do not have the capability to store patient data on the device.[123] If mobile EHR systems do not allow for the storage of patient information, data theft will be a much smaller problem for the technology.

While many practices are already utilizing mobile EHR systems for day-to-day care activities,[124] the next step for the platform is the development of mobile applications for use by patients.[125] These patient-oriented applications can allow patients to access test results, schedule and manage appointments, email their doctor, or seek prescription refills all from their mobile device. It is clear that mobile EHRs are only going to increase in prevalence over time given the ubiquity of mobile computing devices, and they have the potential to better integrate patient and doctor to coordinate and manage care.

E. Lingering Problems

No matter how mature the technology becomes, there are certain issues with EHRs that will not easily go away. Patients as a class will likely become more comfortable with their records being in electronic form as time goes on, mitigating the privacy issue. However, concerns about records security will endure long after electronic records become the norm. Just as our societal comfort with the internet as a do-all tool has not meant we are any safer from hackers,[126] neither will 100% adoption of EHRs in the medical profession mean that our information is any safer than before. Data security will always require vigilance on the part of the providers who maintain EHRs.

Another issue that will endure long after EHRs mature is that of data stability and crashes. Reliability of purely-electronic systems is a sticking point in the developing electronic economy, and storing patient data not only on computer servers but at times offsite in the cloud means that, if something goes wrong in the system, access will be severely limited if not cut off entirely. Provider networks must be prepared to function without electronic access in case of an emergency. The Mayo Clinic, for example, has backup measures in place in the event of an EHR failure, including the ability to call for rapid system repairs and even to revert to paper records if necessary.[127] Just as it is impossible to protect a system fully from unwanted intrusions, it is impossible to make a system crash proof. Providers must therefore maintain a Plan B in case a system goes down. The "electronic" aspect of the electronic health revolution means that the same problems that affect all technologies will linger.

VI. CONCLUSION

The road traveled by the electronic health revolution has not been entirely smooth. Though there are numerous substantial benefits to fully integrated EHR systems, a number of drawbacks remain. Some, like patient comfort with privacy issues, will likely dissipate somewhat over time. Others, like protection from security risks, will require perpetual vigilance for system operators. Still, despite the growing pains faced by the healthcare industry as it moves to full adoption of EHRs and related health information technologies, the long term benefits seen by the transition are likely to greatly outweigh the negatives. Improved quality of care and reduced medical errors alone will overshadow the existing drawbacks. Time will tell, however, whether the electronic health revolution will progress smoothly over the coming years and whether the dream of an interoperable EHR infrastructure will be realized.

[1] *Electronic Health Record*, Healthcare Information and Management Systems Society, http://www.himss.org/library/ehr/?navItemNumber=13261 (last visited Mar. 22, 2013).

[2] Peter Garrett and Joshua Seidman, *EMR vs EHR—What is the Difference?*, Health IT Buzz (Jan. 4, 2011), http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference/.

[3] *Id.*

[4] *Id.*

[5] Jim Atherton, *Development of the Electronic Health Record*, 13 American Medical Assoc. J. of Ethics v. 3, 186, at 187 (2011), *available at* http://virtualmentor.ama-assn.org/2011/03/pdf/mhst1-1103.pdf.

[6] *See id.* (stating that VistA "is consistently well reviewed for reducing medical errors and improving health-record component integration").

[7] Dustin Charles, Michael Furukawa, & Meghan Hufstader, Electronic Health Record Systems and Intent to Attest to Meaningful Use Among Non-Federal Acute Care Hospitals in the United States: 2008-2011, Office of the National Coordinator for Health Information Technology, ONC Data Brief No. 1, 4 (2012), *available at* http://www.healthit.gov/media/pdf/ONC_Data_Brief_AHA_2011.pdf.

[8] *See id.* (finding that the large jump is mostly attributable to the federal government's push to adoption of EHRs by using Medicare and Medicaid payment incentives.

[9] *See* John Hazewinkel, *Digital Health Care Reform Under the HITECH Act*, 90 Mich. B.J. 33, 34 (2011) (explaining how the health care industry lags behind other industries in its use of information technology for its core business, i.e., clinical care, while it is used extensively for other functions, such as processing claims for payment).

[10] Mary Mosquera, *Indian Health Service Creates PHR System*, GovernmentHealthIT (Oct. 29, 2012), http://www.govhealthit.com/news/indian-health-service-creates-phr-system.

[11] *Health Information Exchange*, HealthIT.gov, http://www.healthit.gov/providers-professionals/health-information-exchange (last visited Mar. 7, 2013).

[12] The Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted as Title XIII of the American Recovery and Reinvestment Act (ARRA) of 2009, Pub. L. 111-5, 123 Stat. 226 (2009).

[13] Health Information Exchanges Part 1: The Basics 55, Healthcare Information Management Systems Society, *available at* http://www.himss.org/content/files/HIMSS_HIE_Presentation_HIE_TheBasics.pdf.

[14] *See* Dan Bowman, *HIE Critical to Care Continuity in Natural Disasters*, FierceHealthIT (Nov. 2, 2012), http://www.fiercehealthit.com/story/health-information-exchange-critical-care-continuity-natural-disasters/2012-11-02.

[15] *Id.*

[16] 42 U.S.C. § 201 et. seq., Pub. L. 109-41, 119 Stat. 424 (2005).

[17] *Welcome to AHRQ's Patient Safety Organization Web Site*, Agency for Healthcare Research and Quality, http://www.pso.ahrq.gov/ (last visited Oct. 25, 2012).

[18] *What is a Patient Safety Organization (PSO)?*, Agency for Healthcare Research and Quality, http://www.pso.ahrq.gov/psos/overview.htm (last visited Mar. 7, 2013).

[19] *See* 42 C.F.R. § 3.102(b) (including having "appropriately qualified workforce members" and not qualifying as a "health insurance issuer").

[20] *Alphabetical Directory of Listed Patient Safety Organizations*, Agency for Healthcare Research and Quality, http://www.pso.ahrq.gov/listing/alphalist.htm (last visited Mar. 7, 2013).

[21] Pub. L. 111-148, 124 Stat. 119 (2010).

[22] *Resources for Reducing Unnecessary Hospital Readmissions*, Agency for Healthcare Research and Quality, http://www.pso.ahrq.gov/readmin/readminres.htm#tools (last visited Mar. 7, 2013).

[23] Mary Reed, et al., *Outpatient Electronic Health Records and the Clinical Care and Outcomes of Patients With Diabetes Mellitus*, Annals of Internal Medicine (Oct. 2, 2012), *available at* http://www.ncbi.nlm.nih.gov/pubmed/23027319.

[24] Ann Kutney-Lee & Deena Kelly, *The Effect of Hospital Electronic Health Record Adoption on Nurse-Assessed Quality of Care and Patient Safety*, 41 J. of Nursing Admin. 11, 466, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3236066/.

[25] *See* Ed Susman, *EMR Cuts Rx Errors for HIV Hospital Patients*, Medpage Today, Oct. 20, 2012, http://www.medpagetoday.com/MeetingCoverage/IDWeek/35442?utm_content=&utm_medium=email&utm_campaign=DailyHeadlines&utm_source=WC&xid=NL_DHE_2012-10-22&eun=g419441d0r&userid=419441&email=mdhirsch@comcast.net&mu_id=5518887 (noting that a lack of familiarity with complex antiretroviral regimens was the main cause of medical error before implementing electronic systems).

[26] Andrew Klein, *Newer Electronic Health Record Systems Reduce Rx Errors, but Doctors Find the Switch Difficult*, Weill Cornell Medical College (May 26, 2011),

available at http://weill.cornell.edu/news/releases/wcmc/wcmc_2011/05_25_11.shtml.

[27] *See* Ken Terry, *Electronic Checklists Help Prevent Medical Errors*, Information Week (Oct. 19, 2012), *available at* http://www.informationweek.com/healthcare/patient/electronic-checklists-help-prevent-medic/240009348 (noting that handwritten medication histories have more errors than electronically recorded entries).

[28] *Id.*

[29] Neil Versel, *CDC Sees EHRs as Public Health 'Game Changer'*, Information Week (Apr. 6, 2011), *available at* http://www.informationweek.com/healthcare/interoperability/cdc-sees-ehrs-as-public-health-game-chan/229401061.

[30] *See id.*

[31] *See, e.g.*, *supra* notes 23-27.

[32] Systems that are able to "speak" with one another are the ultimate goal of EHRs, but before systems can communicate, they have to be implemented in the first place. If a patient's specialist seeks the records from a PCP, but that PCP doesn't have electronic records at all, electronic distribution is impossible. There's no way to get interoperability without first implementing the infrastructure.

[33] A Harris Interactive poll recently found that 63% of Americans fear that a hacker will steal their personal data used in EHRs, a decrease of only 1% from 2010. The same study found that 85% of Americans have "some kind" of EHR anxiety, including fear of information loss, damage, or corruption. *See* Robert Lowes, *Fear of Data Theft Blunts Public Acceptance of EHRs*, Medscape (Aug. 24, 2012), http://www.medscape.com/viewarticle/769778.

[34] One doctor theorized that the shift to EHRs is being resisted because it takes away some of the humanity—and, likely, some autonomy—associated with a purely face-to-face interaction. *See* Richard Reese, *Why Doctors Don't Like Electronic Health Records*, The Health Care Blog (Oct. 7, 2011), http://thehealthcareblog.com/blog/2011/10/07/why-doctors-dont-like-electronic-health-records/#more-32729 ("You cannot look a computer in the eye. You cannot read its body language. You cannot talk to an algorithm. You cannot sympathize or empathize with it. . . .We choose not to be reduced to data-entry clerks sorting through undigested computer bytes.").

[35] *See* Fred Schulte, *Growth of electronic medical records eases path to inflated bills*, Center for Public Integrity (Sept. 19, 2012), http://www.publicintegrity.org/2012/09/19/10812/growth-electronic-medical-records-eases-path-inflated-bills ("Interviews with hospital administrators, doctors and health information technology professionals confirmed that digital billing gear often prompts higher coding, though many in the medical field argue that they are simply recouping money that they previously failed to collect.").

[36] *See* Emily Badger, *Can Privacy, Electronic Medical Records Coexist?*, Pacific Standard (June 15, 2011), http://www.psmag.com/health/can-health-privacy-electronic-medical-records-coexist-32350/ (suggesting that privacy concerns could be the biggest hindrance to widespread implementation of electronic health records).

[37] *Patients Fear EHRs Increase Chances for Medical Data to be Stolen*, Atlanticon (Sept. 5, 2012), http://www.atlanticon.net/blog/2012/09/05/patients-fear-ehrs-increase-chances-for-medical-data-to-be-stolen/.

[38] Anne Zeiger, *Patients might leave your practice if they fear EHR data isn't secure*, EHR Outlook, http://www.ehroutlook.com/trends/Patients-might-leave-your-practice-if-they-fear-EHR-data-isnt-secure_182.html (last visited Nov. 2, 2012).

[39] In fact, a 2007 WSJ/Harris Interactive Poll found that even at that early stage in EHR development, most respondents agreed that improved information sharing via electronic systems would improve care and 63% agreed that sharing of such records could decrease medical errors. However, about one-quarter of adults were unsure about the benefits of EHRs. *See* Beckey Bright, *Benefits of Electronic Health Records Seen as Outweighing Privacy Risks*, Wall St. J., Nov. 29, 2007, http://online.wsj.com/article/SB119565244262500549.html.

[40] Patient transfers are another area in which record sharing is necessary to improve safety and coordination. Think of a patient who was recently treated for congestive heart failure and has been discharged to a nursing home. Medical care does not stop at the door—rather, the nursing home staff will need the patient's records in order to make the discharge transition as safe as possible. *See* Paul Cerrato, *National Health Information Exchange: Why the Delay?*, Information Week (Nov. 5, 2012), http://www.informationweek.com/healthcare/interoperability/national-health-information-exchange-why/240044378.

[41] A "perfectly secure" computer would require that no user could access the data held within it. Likewise, a perfectly accessible computer would have no way of preventing access by anyone. The balancing maneuver requires determining an acceptable location on the continuum between the two for a given purpose. *See* Michelle McNickle, *4 Best Practices: Combat Health Data Breaches*, Information Week (Nov. 1, 2012), http://www.informationweek.com/healthcare/security-privacy/4-best-practices-combat-health-data-brea/240012739 ("[D]ata is liquid; it needs to move around so much that it's impossible to completely eliminate breaches.") (statement of Doug Pollack, chief strategy officer at ID Experts).

[42] Less well-known is that nearly 20 million patient records have been compromised within the past two years alone. *See id*.

[43] Susan R. Gering, *Electronic Health Records: How to Avoid Digital Disaster*, 16 Mich. St. U. J. Med. & L. 297, 309 (2012).

[44] Rick Weiss & Ellen Nakashima, *Stolen NIH Laptop Held Social Security Numbers*, Wash. Post, Apr. 10, 2008, http://www.washingtonpost.com/wp-dyn/content/article/2008/04/09/AR2008040903680.html.

[45] Darius Tahir, *Can Electronic Medical Records Improve Our Health Without Jeopardizing Our Privacy?*, The New Republic, Nov. 25, 2011, http://www.tnr.com/blog/jonathan-cohn/97801/electronic-medical-records-privacy-stanford.

[46] *See* Breach Notification for Unsecured Protected Health Information, 74 Fed. Reg. 42,741-42,742 (Aug. 24, 2009) (to be codified at 45 C.F.R. 160) ("[I]f a covered entity chooses to encrypt protected health information to comply

with the Security Rule, does so pursuant to this guidance, and subsequently discovers a breach of that encrypted information, the covered entity will not be required to provide breach notification. . . . [I]f a covered entity has decided to use a method other than encryption. . .that is not specified in this guidance to safeguard protected health information. . . following a breach of this information, the covered entity would have to provide breach notification to affected individuals.").

[47] *See id*. ("[B]ecause these are addressable implementation specifications, a covered entity may be in compliance with the Security Rule even if it reasonably decides not to encrypt electronic protected health information and instead uses a comparable method to safeguard the information.").

[48] *See* Verizon, DBIR Industry Snapshot: Healthcare 1 (2012), *available at* http://www.verizonbusiness.com/resources/reports/rp_dbir-industry-snapshot-healthcare_en_xg.pdf ("The vast majority of attackers seek information from which they can directly or indirectly profit. This includes personal and payment information. . . .").

[49] *See* Gering, *supra* note 43, at 310–11.

[50] *See* Badger, *supra* note 36 ("The associated dangers aren't just about privacy on principle. An insurance company that learns of a particular illness might decline to cover you. An employer who realizes that your costly medical condition is weighing down the group health plan might find other cause to fire you.").

[51] Jennifer Dennard, *Personal Health Information and the Rupert Murdoch Effect*, Healthcare IT News, July 13, 2011, http://www.healthcareitnews.com/blog/personal-health-information-and-rupert-murdoch-effect.

[52] *Id*. (listing Britney Spears and Maria Shriver as among the list of celebrity patients that have been targets of unauthorized leaks of protected health information).

[53] *See* Verizon, *supra* note 48, at 2 ("Insider jobs [are] much less frequent, but they can't be ignored. When employees do go rogue, their ready access to and knowledge of information assets means they can do quite a bit of damage without expending a lot of effort.").

[54] Pub. L. 104-191, 110 Stat. 1936 (1996).

[55] *See* 45 C.F.R. § 160.103 (A "covered entity" is either (1) a health plan, (2) a health care clearinghouse, or (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by the regulations).

[56] *See* 45 C.F.R. §§ 164.306-18.

[57] *See* 45 C.F.R. §§ 164.502-10.

[58] *Does the HIPAA Privacy Rule Preempt State Laws?*, HHS.gov, *available at* http://www.hhs.gov/hipaafaq/state/399.html (last visited Nov. 3, 2012) (noting that the Privacy Rule does not preempt state laws where a state law "relates to the privacy of individually identifiable health information and provides greater privacy protections or privacy rights with respect to such information.").

[59] *See* Acara v. Banks, 470 F.3d 569, 571 (5th Cir. 2006) ("HIPAA does not contain any express language conferring privacy rights upon a specific class of individuals. Instead, it focuses on regulating persons that have access to individually identifiable medical information and who conduct certain electronic health care transactions. . . . HIPAA limits enforcement of the statute to the Secretary of Health and Human Services.").

[60] *See Case Examples and Resolution Agreements*, HHS.gov, *available at* http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/index.html (last visited Nov. 3, 2012) (highlighting a number of settlements and resolution agreements with HIPAA violators).

[61] *What Changes in HIPAA Compliance Requirements Were Made by the HITECH Act?*, HRSA.gov, *available at* http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/PrivacyandSecurity/compliancereqs.html.

[62] Hazewinkel, *supra* note 9, at 35.

[63] *What changes in HIPAA compliance requirements were made by the HITECH Act?*, *supra* note 61.

[64] *Id.*

[65] Hazewinkel, *supra* note 9, at 35.

[66] *See, e.g.*, *Health Information Privacy Complaint*, Dept. of Health and Human Svcs., Office for Civil Rights, *available at* http://www.hhs.gov/ocr/privacy/hipaa/complaints/hipcomplaintform.pdf (An aggrieved individual must fill out the HHS form and file it with the appropriate OCR regional office within 180 days from when the individual learned of the grievance); *see also How to File a Complaint*, U.S. Dep't of Health & Human Servs., http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html (last visited Mar. 26, 2013).

[67] Perhaps somewhat ironically, 69% of physicians participating in a survey conducted by the Bipartisan Policy Center said that electronic information exchange will improve efficiencies in their practices. Thus, many doctors recognize the longer-term advantages of electronic systems, but the startup costs are still a barrier for some. *See* Bipartisan Policy Center Health Information Technology Initiative, Clinician Perspectives on Electronic Health Information Sharing for Transitions of Care 12 (2012), *available at* http://bipartisanpolicy.org/sites/default/files/Clinician%20Survery_format%20(2).pdf; *see also id.* at 13 (indicating that the same survey also revealed that 69% of respondents saw the cost of setting up and maintaining interfaces and exchanges as a major barrier to clinical information sharing).

[68] Gering, *supra* note 43, at 311–12.

[69] Lena H. Sun, *Despite Incentives, Doctors Are Wary About Switching to Electronic Health Records*, Wash. Post, Mar. 14, 2011, http://articles.washingtonpost.com/2011-03-14/national/35207018_1_electronic-records-doctors-computerized-records.

[70] The Bipartisan Policy Center survey found that 80% of clinicians surveyed felt that HIE will improve care quality, and 80% also said HIE would improve coordination. *See* Bipartisan Policy Center, *supra* note 67, at 12.

[71] *See Electronic Health Record (EHR) Incentive Program FAQs*, Centers for Medicare and Medicaid Services, *available at* https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/FAQsRemediatedandRevised.pdf (last visited Nov. 2, 2012).

[72] Stage 1 involves "data capture and sharing"; Stage 2 encompasses "advanced clinical processes"; and Stage 3 seeks "improved outcomes". *Meaningful Use Definition & Objectives*, *EHR Incentives & Certification*, HealthIT.gov, *available at* http://www.healthit.gov/providers-

professionals/meaningful-use-definition-objectives (last visited Oct. 15, 2012).

[73] *See Meaningful Use*, Centers for Medicare and Medicaid Services, *available at* http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Meaningful_Use.html.

[74] Patrick Ouellette, *Stage 2 Meaningful Use Checklist*, EHR Intelligence, Sept. 20, 2012, *available at* http://ehrintelligence.com/2012/09/20/stage-2-meaningful-use-checklist/.

[75] *Id.*

[76] American Recovery and Reinvestment Act of 2009 § 4101(a), 42 U.S.C. § 1395w-4(o)(5)(C) (2010).

[77] *Medicare Electronic Health Record Incentive Program for Eligible Professionals*, Centers for Medicare and Medicaid Services (Nov. 2010), *available at* http://www.documentcloud.org/documents/71331-tip-sheet-medicare-ehr-incentive-payments-for.html.

[78] American Recovery and Reinvestment Act of 2009 § 4201(a)(2), 42 U.S.C. 1396b(t)(3)(B) (2010).

[79] *Medicaid Electronic Health Record Incentive Payments for Eligible Professionals*, Centers for Medicare and Medicaid Services (Nov. 2010), *available at* http://www.documentcloud.org/documents/71332-tip-sheet-medicaid-electronic-health-records.html.

[80] Hazewinkel, *supra* note 9, at 34.

[81] *See* Bipartisan Policy Center, *supra* note 67, at 12 (noting that clinicians have cited financial incentives as one main reason for their adoption of EHR systems--in the Bipartisan Policy Center survey, 72% of respondents said that adoption of HIE technology would have a positive impact on their ability to participate in incentive programs).

[82] In the months following EHR adoption in a practice, doctors tend to see fewer patients and work longer hours. Many vendors suggest scheduling only 50% of patient capacity for the few weeks following EHR implementation to account for the learning curve. *See* Michael McBride, *Time check: Physicians see fewer patients as they implement EHRs*, Medical Economics, June 10, 2012, http://www.modernmedicine.com/modernmedicine/article/articleDetail.jsp?id=776741.

[83] *See* Olga Khazan, *For some doctors, electronic records aren't a miracle cure*, Wash. Post, Nov. 5, 2012, *available at* http://www.washingtonpost.com/national/health-science/for-some-doctors-electronic-records-arent-a-miracle-cure/2012/11/05/f12c3400-f1fb-11e1-a612-3cfc842a6d89_story.html ("Older physicians are less likely to use digital records, in part because . . . they've accumulated mounds of charts and aren't sure they'll be practicing long enough to make transitioning to a new system worthwhile.").

[84] The Center for Studying Health System Change found that, although doctors typically agree that EHRs will aid overall doctor-patient interaction (through the use of e-mails and the ability to pull up important patient information on the spot), many are concerned that interpersonal communication will suffer as a result of EHRs, particularly due to distractions in the software and because EHRs mean doctors, ironically, need to ask fewer questions of a patient during a visit. *See* Ann S. O'Malley, Genna R. Cohen & Joy M. Grossman, *Issue Brief: Electronic Medical Records and Communication with Patients and Other Clinicians: Are We Talking Less?*, Center for Studying Health System Change 2 (Apr. 2010), *available at* http://www.hschange.com/CONTENT/1125/1125.pdf.

[85] Anne Marie Valinoti, *Physician, Steel Thyself for Electronic Records*, Wall St. J., Oct. 22, 2012, http://online.wsj.com/article/SB10000872396390443675404578058480752741280.html.

[86] *Id.*

[87] Changes as small as a website's user interface refresh or as large as the switch to an entirely different operating system will often invoke the same type of rejection at first, though any well-planned transition will ultimately be accepted as its merits are understood and users spend more time interacting with the new system.

[88] *See* Fred Schulte, *Switch to electronic records getting mixed reviews at hospitals and clinics*, Center for Public Integrity (Nov. 24, 2009), http://www.publicintegrity.org/2009/11/24/7011/switch-electronic-records-getting-mixed-reviews-hospitals-and-clinics ("[M]ost doctors who have taken the plunge would never go back to pen and paper and [. . .] that those who are reluctant will come around.").

[89] Jaan Sidorov, *It Ain't Necessarily So: The Electronic Health Record And The Unlikely Prospect Of Reducing Health Care Costs*, 25 Health Affairs 1079, 1079 (2006) (citing *Office of the National Coordinator for Health Information Technology*, U.S. Dep't of Health & Human Servs. (May 23, 2005), http://www.hhs.gov/healthit/valueHIT.html).

[90] *Id.* at 1080.

[91] Reed Abelson, et al., *Medicare Bills Rise as Records Turn Electronic*, N.Y. Times, Sept. 22, 2012, at A1.

[92] *Id.*

[93] *Id.*

[94] *See* Reed Abelson & Julie Creswell, *U.S. Warning to Hospitals on Medicare Bill Abuses*, N.Y. Times, Sept. 25, 2012, at B1.

[95] *Id.*

[96] *See* Abelson, et al., *supra* note 91, at A1.

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] *Id.*

[101] *Id.*

[102] HHS has already announced it will step up audits of Medicare patients' hospital bills where EHRs are involved, looking out for instances of upcoding. *See* Schulte, *supra* note 35.

[103] Critics of the Medicare program's approach to EHRs say that not only did CMS fail to anticipate the rise in reimbursement rates, but that "meaningful use" incentive payments have also been improperly overseen, and that the program lacks appropriate safeguards. *See* Reed Abelson, *Medicare is Faulted on Shift to Electronic Records*, N.Y. Times, Nov. 29, 2012, http://www.nytimes.com/2012/11/29/business/medicare-is-faulted-in-electronic-medical-records-conversion.html?adxnnl=1&adxnnlx=1355253387-Kwwu6bNby4NDJqAIyr6Gng&_r=0.

[104] In the wake of the reimbursement rate controversy, the American Hospital Association wrote a letter to Secretary Sebelius and Attorney General Holder seeking the creation of guidelines on hospital coding. *See* Letter

from Rich Umbdenstock, AHA President and CEO, to Kathleen Sebelius, HHS Secretary, and Eric Holder, U.S. Attorney General (Nov. 12, 2012), *available at* http://www.ihealthbeat.org/articles/2012/11/15/aha-to-work-with-officials-to-curb-use-of-ehrs-for-upcoding.aspx.

[105] *Global Mobile Banking Customer Base to Reach 1.1 Billion by 2015, According to New Report by Global Industry Analysts, Inc.*, Global Industry Analysts (Feb. 16, 2010), http://www.prweb.com/releases/2010/02/prweb3553494.htm.

[106] Though there are no government-standard best practices in the Health IT realm, there are a number of private organizations that have identified key aspects of a secure EHR system. *See, e.g.*, Kathleen Roney, *5 Best Practices for Improving Data Security*, Becker's Hospital Review (May 9, 2012), http://www.beckershospitalreview.com/healthcare-information-technology/5-best-practices-for-improving-data-security.html (listing risk assessments, tailored data protection, employee training, upgraded data loss protection tools, and thinking outside the box as five key practices to reinforce records security).

[107] *See* McNickle, *supra* note 41.

[108] *See id.*

[109] Most recently, a Commonwealth Fund study found that 69% of PCPs in the U.S. reported using EHRs in 2012. *See* Cathy Schoen, et al., *A Survey Of Primary Care Doctors In Ten Countries Shows Progress In Use Of Health Information Technology, Less In Other Areas*, 10 Health Affairs 1377 (2012).

[110] Indeed, in response to a letter from House Republicans in October 2012, Secretary Sebelius said that "suspending the incentive program, arguing that it 'would be profoundly unfair to the hospitals and eligible professionals that have invested billions of dollars and devoted countless hours of work to purchase and install systems and educate staff,'" signaling that the Department is fully behind the move. *See* Abelson, *supra* note 91.

[111] Ken Terry, *EHR Adoption: U.S. Remains a Slowpoke*, Information Week, Nov. 15, 2012, http://www.informationweek.com/healthcare/electronic-medical-records/ehr-adoption-us-remains-the-slow-poke/240142152.

[112] "To measure EHR capabilities, the researchers asked physicians about electronic functions in four categories: The generation of patient information, such as lists of patients' medications; the generation of patient registry and panel information, such as a list of patients due for preventive care; order entry management, such as electronic prescribing; and decision support, such as alerts about potential adverse drug interactions. To be counted as a user of a multifunctional EHR, a practice had to report that its system had at least two functions in each of these four domains." *Id.*

[113] *See* Paul Cerrato, *5 Healthcare IT Resolutions for 2013*, Information Week, Dec. 10, 2012, http://www.informationweek.com/healthcare/cpoe/5-healthcare-it-resolutions-for-2013/240144068.

[114] Kenneth D. Mandl & Isaac S. Kohane, *Escaping the EHR Trap: The Future of Health IT*, 366 New England J. of Medicine 2240, 2241 (2012), *available at* http://www.nejm.org/doi/full/10.1056/NEJMp1203102.

[115] *Id.*

[116] *Id.*

[117] *See id.* at 2242 ("[T]he ONC-initiated Direct Project promotes a secure communications system for health care based on SMTP (Simple Mail Transfer Protocol), the decades-old store-and-forward email standard. The Direct Project exemplifies the way in which highly effective general technologies can be adapted to health care in an open, standard, integratable fashion.").

[118] *See* Milt Freudenheim, *The Ups and Downs of Electronic Medical Records*, N.Y. Times, Oct. 8, 2012, http://www.nytimes.com/2012/10/09/health/the-ups-and-downs-of-electronic-medical-records-the-digital-doctor.html.

[119] *See* Cerrato, *supra* note 113 ("[W]ith the push to do more big data analytics and get started in population health management, top-flight analysts are no longer a 'nice-to-have' but a must-have.").

[120] Anthony Vecchione, *9 Mobile EHRs Fight for Doctors' Attention*, Information Week, Dec. 12, 2012, http://www.informationweek.com/healthcare/electronic-medical-records/9-mobile-ehrs-fight-for-doctors-attentio/240144143.

[121] *Mobile EHRs-An Overview*, Excite Health Partners (Nov. 30, 2012), http://www.excitehealthpartners.com/news/mobile-ehrs-an-overview/.

[122] *Id.*

[123] *HIMSS Analytics Survey Demonstrates Widespread Use of Mobile Devices to Support Patient Care Activities*, HIMSS Analytics (Dec. 3, 2012), http://www.himssanalytics.org/about/NewsDetail.aspx?nid=81558 ("83 percent of IT professionals noted the devices used by their clinicians do not retain patient-specific information.").

[124] These activities, as noted in the HIMSS Analytics survey, include bedside data collection (45% of respondents); use of bar code reader on mobile devices (38%); monitoring data from medical devices (34%); and capturing visual representation of patient data (27%). *Id.*

[125] The HIMSS Analytics survey found that, while mobile EHR use is widespread for clinical activities, only 13% of respondents said their practice had created an app for patient use. *Id.*

[126] If anything, the ubiquitous nature of the internet means that we are more susceptible to identity theft, as normalcy breeds complacency and a greater number of theft-enticing services are accessed online now than ever before.

[127] *See* Freudenheim, *supra* note 118.

ACOs Through the Eyes of Evanston: Comparing Competitive Efficiencies and Harms of Hospital Mergers and ACO Formation

*Jacob Harper**

I. INTRODUCTION

The controversial Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act (collectively referred to as the Affordable Care Act ("ACA") and colloquially as "healthcare reform") are now infamous for the "individual mandate."[1] While much of the public focus rests on this hotly contested provision, the ACA also changes the nation's health care delivery systems[2] in a number of fundamental ways.[3] Foremost, this legislation strongly encourages the implementation of Accountable Care Organizations ("ACOs") through the Medicare Shared Savings Program.[4]

ACOs represent the newest iteration of the federal government's solution to the long-standing problem of increasing health care costs.[5] To incentivize the creation of these organizations, however, the government had to bend, and in some cases, break a number of laws affecting health care providers.[6] Among these laws are the Sherman, Clayton, and Federal Trade Commission ("FTC") Acts, collectively known as antitrust law, which seek to foster the healthy functioning of markets by protecting competition and deterring monopolization by a single firm.[7] To effectuate compliance with these laws, the FTC and the United States Department of Justice ("DOJ") jointly investigate and prosecute violations of antitrust law.[8]

When conducting such investigations, the FTC and DOJ are often required to weigh the pro-competitive benefits against the anti-competitive harms of the firm or merger they are analyzing.[9] This type of analysis generally requires an associated complex economic analysis and is intensely fact-driven.[10] In particular, because its members must often share information about their customers with rivals, the health care industry has faced long-standing antitrust scrutiny from the FTC and DOJ over concerns of coordinated economic activity.[11] Such scrutiny is only furthered by government mandates for health care entities to ensure continuity of care for their patients.[12] As rivals work ever more closely together, the opportunity for and likelihood of collusion rises.[13]

In evaluating pro-competitive efficiencies, the FTC may come to a sharp divide between the creation of ACOs and more traditional hospital mergers.[14] ACOs, in part because of their strictly regulated structure and less formal integration in business operations of their member organizations (i.e. each provider retains their separate legal identity in the ACO structure), will likely have striking pro-competitive benefits with only limited risks.[15] Conversely, hospital mergers, as the FTC has borne witness, often lead to higher prices with few lasting increases in efficiency.[16] As a result, mergers among hospitals have often been rejected or modified by the FTC to address these concerns.[17]

This comment will critically examine the various analyses used by the FTC and DOJ in assessing coordinated efforts by health care entities, and compare the pro-competitive efficiencies and anti-competitive harms of hospital mergers with those of ACOs. Part II discusses the history and structure of ACOs, as well as the laws, regulations, and guidelines that the FTC and DOJ may use in conducting antitrust analysis. Part III explores both the merit and the weight of harms and efficiencies present in hospital merger and ACO antitrust analysis. Part IV recommends possible solutions health care entities may consider to reduce exposure to antitrust suit while still maintaining a competitive business model.

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Finally, Part V finds that ACOs, while certainly not perfect, may be an effective organizational structure from an antitrust perspective.

II. HISTORY OF THE ACO PROGRAM AND RELEVANT LAWS AND GUIDANCE AFFECTING ACOS

A. Organizational Differences Between Hospitals and ACOs

Technically, an ACO is a "meta-organization" comprised of multiple hospitals and health care providers.[18] However, it could be set up without a hospital, but because of the massive upfront capital required, few providers have sufficient reserves to finance the start-up costs.[19] Some analysts predict that a single hospital or health system could create an ACO, and either contract with or directly employ the physicians and other providers needed to make the entity function.[20]

In terms of size, hospitals are for the most part unrestricted and can vary greatly.[21] ACOs, on the other hand, must agree to provide comprehensive health services to at least 5,000 beneficiaries for at least three years.[22] Thus, a small practice group or a small specialty hospital may be unable to meet the requirements for the provision of a full range of service, or may not be able to treat that number of individuals.[23] Therefore, physicians and hospitals are forced to work together to meet the ACO conditions of participation.[24]

As ACO health care providers begin to coordinate care and other practice operations, such as billing, administration and compliance, more fully, the ACO is anticipated to achieve an unheralded level of vertical integration.[25] In an ACO, primary care physicians, specialists, hospitalists, therapists, and home health providers would all function together to enhance continuity of care to beneficiaries.[26] Vertically integrated ACOs would likely have hospitals that could offer a full range of care — primary, secondary, and tertiary services.[27]

However, by themselves, hospitals only achieve modest vertical integration, because they are restricted through antitrust laws from achieving full integration.[28] Hospitals can contract with and employ physicians and practice groups, employ hospital staff, and purchase supplies and equipment.[29] There are limits on physician involvement, joint purchasing of supplies, and joint ventures on expensive equipment.[30] Moreover, the exchange of patient data, pricing, and cost report information among a hospital or hospitals and providers is challenging.[31] An ACO, conversely, must share cost, pricing, and patient information, among its member providers and hospitals.[32]

Hospitals generally obtain revenue from three sources: Medicare and Medicaid payments; private insurance payments; and, to a lesser degree, copayments and deductibles received from individual patients.[33] Hospitals cannot easily negotiate with Medicare and Medicaid for changes in payment rates, and any desired changes must be completed through roundabout lobbying efforts, not standard buyer-seller negotiations.[34] As such, a hospital's main buyer is private insurers, usually managed care organizations ("MCOs"), and hospitals negotiate with these private insurers.[35] Through negotiations with MCOs, hospitals receive either a per diem rate or a fee for each service performed ("fee-for-service" or "FFS"), which hospitals generally prefer.[36] Health care providers, as well, are almost always paid under an FFS system.[37]

As part of an ACO, hospitals and health care providers still receive FFS payments, but can also receive payments under the Medicare Shared Savings program.[38] While these entities are new, MCOs are also looking to contract with ACOs under terms similar to those set out under the Medicare program.[39]

Hospital mergers consist of identification of a potential acquisition, a series of negotiations with the target regarding price and other factors (i.e. religious directives, indemnities, medical staff relations) and due diligence reviews. of the risks and rewards a merger could bring.[40] In addition, any substantial mergers must be reviewed pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR") by the FTC and DOJ.[41] Even so, most mergers reported pursuant to HSR do not undergo serious investigation.[42] Overall, while a merger could cost millions depending on whether the government challenges, this process is generally less expensive than the formation of an ACO.[43]

Providers must consider several cost factors when forming an ACO, including administrative, actuarial, compliance and legal costs, and time spent interacting with and submitting an application to the government(which must be approved by the FTC).[44] Moreover, ACOs must also ensure participating providers perform their respective duties to the ACO and to the assigned beneficiaries, and consider the resultant risks, both financial and reputational, associated with the factors laid out above.[45] While the Centers for Medicare & Medicaid Services ("CMS") has estimated start-up costs for an ACO to be $1.8 million, the American Hospital Association, in an independent study, estimated that "the costs of the necessary elements to successfully manage the care of a defined population is considerably higher - $11.6 to $26.1 million . . . ."[46]

B. Relevant Laws Affecting ACOs

To understand the current antitrust issues surrounding ACOs, it is necessary to examine the intersection of health care and antitrust law in the United States.

1. Health Care Laws and Guidance

a. The Social Security Act

The period of heavy governmental regulation of the health care industry began in the mid-1960's with the passage of the Social Security Amendments of 1965 ("SSA") during the Lyndon Johnson administration.[47] In expanding programs for Social Security, the SSA created the Medicare and Medicaid programs.[48] These programs were intended to subsidize most, if not all, healthcare costs of the elderly (65 and older), disabled, and poor.[49]

Medicare was initially divided into two parts: Part A, which covered inpatient and hospital procedures and treatment; and Part B which covered outpatient and physician services, but required a premium and deductible.[50] While the Medicare program was considered a success in terms of its benefit to society, appropriations for the law quickly accelerated to meet increasing demand for government-subsidized health services.[51]

b. Health Maintenance Organization Act

By the mid-1970's, the federal government, recognizing the costs associated with federal health care programs, passed the Health Maintenance Organization Act of 1973 ("HMOA") as a cost-containment measure.[52] HMOA, in seeking to provide better integration of health care services and avoid duplication of effort by encouraging health care entities to provide most of a patient's care for a flat fee, paved the way for managed care organizations ("MCOs").[53] In return, insurers incentivized patients to remain in the care of one or a few predetermined providers through lower "in-network" costs.[54] Unfortunately, this legislation could not stem the tide of growth in health care spending.[55]

c. The Affordable Care Act

Witnessing these rising costs and other problems in the health care industry, legislators and the Obama administration passed health care reform in 2010, which set the stage for the rise of ACOs.[56] These laws represented the most sweeping changes to Medicare and Medicaid since the creation of these programs in 1965.[57]

ACA established the Medicare Shared Savings Program, which mandated the establishment of a methodology and controlling rules for the formation, payment, and regulation of ACOs.[58] Importantly, the Medicare Shared Savings Program called for the suspension of enforcement or limitation on enforcement of a number of laws affecting health care providers. These laws include the Stark law, Anti-Kickback Statute, and the Sherman and Clayton Acts. These laws generally prohibit improper financial relationships and coordination between health care providers, prohibitions which the federal government believes may limit over-utilization of services, medically unnecessary services and ultimately harm to patients.[59]

Designers of the program anticipate that ACOs will increase vertical integration in patient care, creating better coordination and efficiency among providers, while simultaneously disincentivizing over-utilization.[60] By forcing providers to reduce redundancy in medical tests and procedures, the government hopes to gain substantial savings in the Medicare program. As part of the ACO design,

participating providers will receive a portion of those savings (assuming they meet a host of quality benchmark requirements).[61]

2. Antitrust Laws and Guidance

a. The Sherman Act

In the late 19th century, several industries in the United States, such as oil and steel production, became heavily concentrated, allowing dominant operators to exercise considerable monopolistic powers, including decreasing output of goods and increasing prices to socially undesirable levels.[62] Moreover, industries were forming trusts, whereby executives of industry-leading firms would coordinate their activities and compel shareholders to put their shares in a large industry trust.[63] Once there, the leadership was able to coordinate all industry activity through operation of the trust, leading to significant anti-competitive effects.[64]

At this point, the federal government stepped in, enacting the Sherman Antitrust Act ("Sherman Act") in 1890.[65] Recognizing the negative impact that trusts and monopolies were having on consumers, the federal government, through the Sherman Act, outlawed "every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce . . . ."[66] Moreover, it declared that "every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of . . . the trade or commerce" would be guilty of a felony.[67] But because this language is overly broad and could be interpreted as restricting nearly every contract in existence, significant judicial interpretation of the law was required.[68]

b. Clayton Act

Despite the broad provisions of the Sherman Act,[69] it had difficulty rooting out anti-competitive activity of a single firm, since the law generally required an agreement or coordination of activity.[70] Moreover, sophisticated business executives could get around the laws through tacit agreements and other activities that the Sherman Act could not legally reach.[71] To overcome these situations, the federal legislature enacted the Clayton Antitrust Act in 1914.[72]

This Act made substantive additions to and revisions of the Sherman Act.[73] Not only did this Act seek to ban certain unilateral activities, it also extended the competition laws to potentially anti-competitive actions before they could influence price or output.[74] As the Act sets out, mergers may be illegal if "in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition [or merger] may be substantially to lessen competition, or to tend to create a monopoly."[75]

Importantly, the Clayton Act identified and made illegal activities such as price discrimination between different purchasers, tying arrangements, exclusive dealing arrangements, and mergers and acquisitions that may significantly reduce competition.[76] With the passage of the Clayton Act, anti-competitive outcomes did not need to be shown - instead, the federal government could point to factors such as market concentration to infer that anti-competitive effects existed or were likely to exist.[77] The Clayton Act significantly broadened the scope of antitrust enforcement authority.[78]

c. Federal Trade Commission Act

Simultaneous to the passage of the Clayton Act, the Wilson administration created the Federal Trade Commission Act ("FTC Act").[79] The FTC Act established the FTC as the authoritative body on assessing business and competition practices of corporations and other entities.[80] Tasked with enforcing the competition laws of the United States, the FTC was granted authority to investigate trade practices and act on its findings in order to preserve competition.[81]

d. FTC/DOJ Merger Guidelines

Recognizing that health care is a complex and unique area of commerce, the FTC and DOJ have jointly issued various statements and guidelines on their antitrust enforcement policies.[82] Moreover, these statements have been widely adopted and cited by the judiciary.[83]

For over forty-four years, DOJ has published a set of merger guidelines and enforcement policies.[84] First issued in 1968, these guidelines were significantly revised in 1982 and 1984.[85] Currently, however, only the 1984 amendments regarding vertical mergers

are still in effect. The FTC and DOJ jointly issued a comprehensive set of merger guidelines in 1992 ("Merger Guidelines") heavily focused on horizontal integration.[86] The Merger Guidelines outlined the FTC's enforcement policy and analytical techniques used when evaluating potentially anti-competitive mergers and acquisitions.[87] The Merger Guidelines were revised in 1997 and reworked again in 2010.[88]

e. Commentary to the Merger Guidelines

In addition to the guidance set out in the Merger Guidelines, commentary to the Merger Guidelines was issued in 2006.[89] This document was based on the ongoing experiential learning by the FTC and DOJ, as well as the changes occurring in the United States business climate throughout the past few decades.[90] While these Merger Guidelines do not apply to vertical mergers, an aspect of ACO integration which will not be explored in this comment, they do apply to horizontal agreements concerning rivals or potential rivals, which, in the case of ACOs, would be providers to providers or hospitals to hospitals.[91]

f. Statement on ACO Antitrust Enforcement

In 2011, the FTC and DOJ issued a Statement ("Statement") on the anticipated methodology for evaluating the propriety of a proposed or existing ACO, and whether the ACO could cause anti-competitive harms.[92] The Statement first sets out a safety zone in which the FTC and DOJ would likely not pursue enforcement against an ACO and a methodology for calculating such zone.[93] It further identified two exceptions for ACOs that fall outside of the safety zone, but may otherwise be sheltered from antitrust enforcement by the federal government.[94] Finally, the Statement details how ACOs that fall outside of the safety zone and do not qualify for an exception will be subject to a "rule of reason" analysis.[95]

C. In the Matter of Evanston Northwestern Healthcare Corp. – An Instructive Case in Hospital Merger Analysis

While the FTC and DOJ have long scrutinized mergers among hospitals, these organizations have expressly condoned the formation of ACOs and have issued specific guidance on how their antitrust analyses concerning these entities will be conducted.[96] To illustrate the potential benefits and harms that each type of entity could cause to competition, this comment examines the case of *In the Matter of Evanston Northwestern Healthcare Corp.*[97] This case was an administrative matter based on an FTC complaint against a Chicago-area hospital chain which had merged with a local rival.[98] The comment first analyzes the outcome of *Evanston* based on the five-part test set out by the FTC in the decision, noting elements and factors important to the Agency. Then, the comment uses these factors as a basis for analyzing ACOs under the FTC's rule of reason analysis.

1. Relevant Facts of Evanston

In *Evanston,* a small hospital chain merged with a local rival hospital and prices at these hospitals soon rose .[99] As a result of this and a recent additional acquisition, Evanston Northwestern Healthcare Corporation ("ENH") currently exists as a three-hospital chain in the suburbs of northern Chicago.[100] As of the *Evanston* case, the chain was composed of three hospitals: Evanston Hospital (400 beds), Glenbrook Hospital (125 beds) and Highland Park Hospital (200 beds).[101] These hospitals all provide varying levels of care, but all offer secondary care, and in some cases tertiary care.[102] In addition, there are at least one hundred hospitals serving the Chicago area, with nine hospitals located within fifteen miles of the ENH hospitals in question.[103] Nevertheless, the geographic triangle made up by these three hospitals did not contain any other hospitals.[104]

In 1999 and 2000, Highland Park executives agreed to merge Highland Park Hospital with ENH.[105] As a result of the merger, ENH was almost immediately able to leverage its regional market power to raise prices paid by private insurers, MCOs.[106]

When patients are treated by a health care entity that contracts with an MCO, the MCO generally pays the majority of the charges incurred.[107] The patient and other insured individuals in the patient's pool, through insurance policy premiums, fund the payor to make such payments.[108] In addition, a patient generally pays a deductible and copayment or coinsurance directly to the hospital.[109] Nevertheless, the majority of payment received by the hospital treating such a patient is determined through negotiated contracting

between the MCO and the hospital.[110] As a hospital's market share rises, an MCO servicing patients in that hospital's area may more likely need the hospital's services to meet its customer demands, and the payors are thus forced to agree to higher charges.[111]

In Evanston, Evanston and Glenbrook Hospitals had directly competed pre-merger against Highland Park Hospital for contracts with private , using separate negotiating teams and unaware of bids, discounts and pricing information that the other was offering.[112] Post-merger, the informational and negotiating objectives of the combined entity aligned, and ENH used this enhance leverage to command higher prices from MCOs.[113]

In 1998, Evanston and Glenbrook collectively brought in $441 million, fifty one percent of which was from private payors.[114] Similarly, Highland Park generated $101 million in 1998. Of this, forty five percent came from private MCOs.[115]

In 2004, the FTC brought a complaint against the merged entity, alleging that the merger had violated Section 7 of the Clayton Act, which prohibits mergers and acquisitions that tend to substantially lessen competition.[116] Both the FTC itself and an administrative law judge ("ALJ") considering the case found that this merger had indeed violated the law.[117]

While the ALJ mandated divestment of the Highland Park Hospital from ENH (in other words, that Highland Park return to its pre-merger position and all ownership and other functions be legally separated), the FTC tacitly recognized that efficiencies existed and held that total divestment was an undue burden on the entity, which had operated all three hospitals for seven years before divestment was mandated.[118] Considering this fact, the FTC ordered that ENH form two independent and uncoordinated MCO negotiating teams, one for Highland Park and the other for Evanston and Glenbrook, in order to restore the competition lost by this merger.[119]

III. A COMPARISON OF ACO FORMATION AND HOSPITAL MERGERS — ANTICIPATED EFFECTS AND HARMS

A. Mergers Under the Theory of Unilateral Adverse Effects

When assessing the propriety of a horizontal merger, the FTC uses a five part analytical framework as set out in the Horizontal Merger Guidelines.[120] These parts include:

1. defining a relevant market and evaluating market concentration;
2. identifying and weighing potentially adverse effects;
3. determining the ease of entry into the market and whether such possible entry would counteract the adverse effects identified;
4. determining and weighing any pro-competitive effects; and
5. determining whether one of the merging firms qualifies as failing.[121]

Due to provisions of HSR, proposed mergers of any substantial weight must be evaluated prospectively by the FTC or DOJ before consummation of the merger.[122] While Evanston was considered long after a merger had already taken place, the analysis involved is consistent with the framework outlined above, and in fact can be more elucidating, since the results of the merger are evident.[123]

1. Defining a Market

Perhaps the most critical step in conducting antitrust review of a merger is in defining the relevant market for which market power will then be calculated.[124] In turn, market definition is divided into a two-pronged analysis: identifying the relevant geographic market and determining the appropriate product market.[125]

To arrive at a legitimate geographic market, the FTC's Merger Guidelines analyze whether a hypothetical monopolist could "profitably impose at least a 'small but significant and nontransitory' increase in price ("SSNIP"), holding constant the terms of sale for all products produced elsewhere," in a given geographical region.[126]

This analytical framework, however, leaves much to be litigated, and reasonable experts can disagree on just how such an area may be defined.[127] In Evanston, the FTC asserted that the relevant market consisted of the triangle formed by the three hospitals in question.[128] Conversely, ENH stated that the market consisted of these three hospitals and several additional hospitals contained in a north-south axis of thirty-six miles.[129]

While the ALJ essentially split the parties' disagreement and defined the market as the ENH hospitals and several other hospitals within a close vicinity, the FTC rejected the ALJ's holding.[130] Instead, because this case was decided post-merger, the FTC had actual evidence of a price increase within the geographic area made up by the ENH hospitals.[131] Circularly, the relevant market was defined by where price increases occurred in that location.[132] Nevertheless, the FTC identified three factors that could be used to assist in defining a geographic market, to wit: population density, traffic patterns, and socio-economic factors.[133]

Product market definition is similarly based on the SSNIP of a hypothetical monopolist, but is chiefly concerned with what substitutes exist for a product that the merged firms are selling.[134] The FTC generally considers an SSNIP of five percent to demonstrate harm to competition, but is quick to acknowledge that this number may be higher or lower depending on the facts of each matter.[135]

In Evanston, the parties debated whether the product market should consist of only acute inpatient care or include outpatient procedures as well.[136] The FTC agreed with the ALJ that the relevant market was solely for inpatient care, and established a number of factors used to resolve the argument.[137] For instance, ENH executives testifying to the fact that the pricing for outpatient services was made independent of pricing for inpatient services, and without regard for whether consumers "would switch to outpatient services."[138] This lack of a corollary demand implied a low cross-elasticity.[139]

Other issues, too, were damning to ENH's position. The hospital's buyers, MCOs, testified that they could not substitute inpatient services and outpatient services.[140] Furthermore, multiple courts had long held that inpatient services constituted a definitive product market, such that the FTC would have had to severely upset precedent to include outpatient services.[141] Finally, the facts show that even the inclusion of outpatient services in the economic analysis "would not alter the outcome of this case."[142] With the relevant markets defined specifically along the lines the FTC had first envisioned, the analysis moved to the second step in the merger framework.[143]

2. Anti-competitive Effects

The step of identifying anti-competitive effects is perhaps the easiest, particularly when evaluating already-consummated mergers.[144] In Evanston, the FTC and the ALJ readily concluded that the price of inpatient services at ENH had gone up substantially.[145] The theory behind this price increase was one of unilateral effects.[146]

In a perfectly competitive scenario, two competing firms do not have access to the exact same resources or information necessary to leverage themselves in the marketplace, since each firm acts as a check on the monopolistic tendencies of the other.[147] Moreover, buyers can substitute the goods of these two firms based on need and preference if one is engaging in anti-competitive practices, assuming the other can sufficiently increase output to meet market demand.[148] As a result, the firms tend to remain at competitive levels of price and output.[149]

However, when these firms merge, buyers are left with no other option or, if there are other firms in the market, less attractive options in terms of the products they seek.[150] The merged firm has two methods to control price.[151] First, it may leverage its dominant position against buyers to create a "take-it-or-leave-it" situation, where consumers' only option is to pay higher prices for products.[152] While other firms may counteract this effect, they may not be a first or second preference for consumers because of higher costs or lower quality.[153] As a result, buyers are harmed.[154]

Second, through merger, the firms at issue align both their goals and their informational resources.[155] This coordinated alignment adds to their leverage against buyers because they now know the prices that each other's former buyers were previously willing to

pay.[156] Moreover, the goals of the prior firms were each to make profit for themselves to the detriment of the competing firm.[157] Now, these united firms seek to make profit for the same set of owners, and therefore coordinate their marketing and negotiating strategies to achieve this goal.[158]

Evanston defendants, likewise, coordinated their negotiation efforts with private payors, and actively forced higher prices to be paid by MCOs for the health services at issue.[159] As their representatives testified, the MCOs had no other available options than to provide coverage from one of these hospitals for their policyholders in the region.[160]

3. Ease of Entry

The Merger Guidelines call for an assessment of whether potential rivals could enter into a market if the merged firms engaged in anti-competitive practices.[161] Under the Merger Guidelines at the time of the case, entry by potential rivals must be likely enough in a two-year period to conclude that a merger's anti-competitive effects may be counteracted.[162]

In pre-merger analysis, the FTC examines the applicable barriers to entry, which may include: regulations and zoning, the possibility of predatory pricing, licensure and certification requirements, time, start-up capital, sophistication, intellectual property, and sunk costs.[163] Both the FTC and the ALJ in Evanston found that new entry would be unlikely to offset the harms caused by the ENH merger.[164] This determination was based primarily on the fact that no new hospitals had been built in the area, and that entry took a substantial amount of time and start-up capital, thereby making entry into this market substantially unlikely.[165]

4. Pro-competitive Efficiencies

Alternatively, pro-competitive effects may be used to balance out the anti-competitive harms of a merger.[166] These effects may consist of a variety of justifications, including enhanced administrative efficiencies, economies of scale, quality improvements, the ability to provide new product lines, other innovations, and increased financial strength in one or both of the merged firms.[167] Nevertheless, these efficiencies must be demonstrably strong in order to rebut the presumption of anti-competitive effects from an increase in price or showing of significant market power.[168]

Nearly every defendant argues that a merger will create significant administrative efficiencies and can cut costs.[169] Because the firms no longer need to duplicate their efforts in terms of administrative functions, human resources oversight and marketing efforts, the firms can function with essentially a single set of these professionals.[170] Still, it was difficult for ENH to tie the cost-cutting efficiencies to a restraint in price increases or other competitive benefit.[171] But in simply making itself stronger, ENH ignored that antitrust law is, at its heart, intended to protect competition, not the competitors.[172]

Economies of scale may demonstrate a rational basis for approving an otherwise anti-competitive merger.[173] These economies of scale efficiencies are achieved by stronger purchasing abilities, financial benefits, such as obtaining lower interest rates, and technological advantages of increasing returns to scale, whereby a firm's infrastructure and production investments lower the cost of each unit produced.[174] For instance, a hospital may invest, as ENH did here, in an electronic medical records system that seamlessly interacts with all departments of the hospital (or hospitals), allowing patients to be treated more thoroughly, precisely and quickly.[175] These economies of scale, however, have high upfront costs, and cannot usually be achieved by smaller firms with less capital.[176]

Economies of scale tend to be a compelling pro-competitive rationale, as they are typically related to quality improvements and innovation.[177] Although antitrust law views an increase in price with significant scrutiny, it is cognizant of the fact that many products are only developed through the efforts of major firms or through coordination among lesser firms.[178] Therefore, although dense market concentration is considered problematic, firms that can significantly increase the quality of an existing product or innovate to create new products may be able to point to these countervailing efficiencies when accused of a violation.[179]

Nevertheless, the "least restrictive alternative" rule tends to weaken the pro-competitive power of

innovation and quality improvements.[180] This theory holds that antitrust violations will only be excused when there is no less restrictive alternative available to achieve the efficiencies claimed.[181] In other words, if two entities could have formed a joint venture or other semi-coordinated entity to develop or enhance the goods offered instead of merging, the FTC and courts may still find a violation of antitrust law.[182]

In Evanston, for instance, ENH claimed that it significantly improved the quality of care at the Highland Park location, proffering a $120 million investment and expansion over sixteen service areas.[183] The FTC, conversely, set out a three-pronged test to determine whether such quality improvements should be considered.[184] This test requires that the efficiencies claimed be verifiable, merger-specific, and greater than the merger's anti-competitive effects.[185] Initially, the FTC noted that although ENH had invested funds towards quality improvements, there were no facts demonstrating that actual quality had been improved.[186]

Next, the FTC determined that the claimed benefits were not merger-specific, and could have been achieved by less restrictive means.[187] In fact, the agency found that Highland Park Hospital already had devoted $100 million to improve quality at the hospital before the merger, covering most of the same areas claimed by ENH, and had a plan in place to effectively finance these improvements.[188] While ENH argued that these improvements specifically required ENH management's skill, the FTC was unpersuaded that Highland Park could not have reasonably made the improvements on its own.[189] As a result, the merger efficiencies failed to meet the "least restrictive alternative" theory and failed to meet the second prong of the test set out above.[190] Notwithstanding the fact that these efficiencies were neither verified nor merger-specific, the FTC also held that ENH did not produce substantial evidence that these alleged benefits outweighed the concrete anti-competitive harms.[191]

5. Failing Firms

The Merger Guidelines do allow for an otherwise illegal merger to be approved if one firm is acquiring a firm that is imminently failing.[192] The Guidelines, nevertheless, require three specific criteria for this defense to be established.[193] These are:

1. the failing firm must be unable to meet its financial obligations in the short term;
2. this firm must not be able to reorganize and survive under Chapter 11 bankruptcy protection; and
3. the firm must have failed in making good-faith efforts to obtain an offer of acquisition that would allow its assets to remain in the relevant market.[194]

While Highland Park was considered a "weak" hospital in Evanston, it did not come close to meeting the applicable criteria, and such criteria can only be met in the most limited of instances.[195] As a result, the FTC flatly rejected this argument.[196]

B. ACO Antitrust Framework

The FTC has not yet demonstrated exactly how ACO antitrust analysis will commence, but has noted that any evaluations will be conducted under the rule of reason.[197] The rule of reason takes into consideration all of the relevant pro-competitive and anti-competitive effects when assessing the propriety of a proposed ACO formation.[198]

Considering the case of *Evanston* as if the hospitals had merely set up an ACO rather than engaged in a full merger, many aspects of the analysis remain the same. For instance, the product market and geographical market determination would be the same or similar.[199] The "failing firms" issue would be unlikely to arise, since the ACO does not necessarily have any "assets" other than skill of administrative personnel, which would not be lost to the market if the ACO exited.

Assessing the ease of entry does not yield a clear result. Although an ACO does not need to build an extensive physical plant and instead uses hospitals and providers already in a market, ACO formation requires time and significant capital investments.[200] Further, considering the limited supply of doctors and hospitals interested in joining an ACO, entry into the relevant market may be as difficult as creating another hospital.

Conversely, it may be harder for the FTC to establish a compelling theory of competitive harms when assessing a potential ACO.[201] Due to the lack of full integration among ACO member-hospitals, such as coordinated negotiating teams, ACOs will probably not be able to exert the same degree of competitive pressure as merged hospitals.[202] Nevertheless, the same anti-competitive risks exist, particularly with regard to price fixing, since all participants in the ACO will generally know the fees and costs of their rivals and can therefore more easily collude.[203] However, while informational effects could arise, the collusion of ACO member-hospitals in private payor negotiation is mitigated by their inability to fully leverage their position against MCOs, though such effect could exist if the ACO contracted universally with MCOs on behalf of its members.[204]

The most important differences in ACO formation analysis are in the pro-competitive efficiencies an ACO may realize. These include significant cost-cutting and the implementation of quality metrics.[205] Moreover, many believe that the ACO, if it functions correctly, serves as an innovative new product in and of itself. By providing an unprecedented continuum of care, increasingly positive health outcomes may be realized.[206] Patients are given preventative care, seen by hospitalists for emergencies and followed up by home health agencies that already know and understand each patient's unique medical history and care requirements.[207] Because of such coordination, fewer services, such as diagnostic tests or hospital readmissions, need to be performed, saving substantial amounts of federal Medicare money.

Furthermore, because of compliance and quality requirements, each ACO member will likely become a stronger, more viable competitor in its respective market.[208] Such positive effects will likely outweigh any associated rises in costs to private payors.

IV. WHAT SHOULD HOSPITAL ADMINISTRATORS DO TO AVOID OR LIMIT POSSIBLE ANTITRUST ALLEGATIONS

In general, antitrust analysis is a complex, fact-intensive undertaking and can have significant ramifications for hospitals and health care entities of any size.[209] Indeed, ENH, similarly sized to many nearby hospitals, unsuccessfully argued that these hospitals were competitors. As a result, hospital administrators should consider a variety of options when identifying potential growth and business opportunities. While ACOs may be arduous to set up, they represent a striking option from an antitrust perspective.[210]

Importantly, ACOs do not have the same type of integration as a traditional hospital merger. Unlike merged hospitals, one hospital under an ACO umbrella does not own or otherwise control the activities of another hospital in the ACO. Moreover, cost-containment measures such as reduction in administrative staff cannot be readily achieved. Finally, participation in the Shared Saving Program places a number of compliance burdens on ACO members they would not otherwise have to face.[211]

Nevertheless, ACOs tend to allow two important coordinated activities: first, knowledge and possible sharing of each member's private payor rates and negotiating postures, and second, the potential leverage of private payors through unilateral "take-it-or-leave-it" effects. In essence, ACOs may be able to achieve many of the same bargaining outcomes as member hospitals if they simply merged, particularly if the ACO negotiates with MCOs on behalf of all members. While the legality of these coordinated efforts may be debatable, the FTC and DOJ analysis is anticipated to be far more favorable to ACOs than to traditional hospital mergers. Moreover, ACOs have been expressly encouraged by lawmakers and administrative agencies alike, suggesting that the FTC and DOJ may be more receptive to arguments about efficiencies, cost-containment and other pro-competitive effects.

In addition, ACOs may also receive the benefit of involvement in the Medicare Shared Savings Program. For instance, Highland Park Hospital generated $101 million in 1998, of which forty three percent ($43.43 million) was derived from Medicare and Medicaid programs.[212] Assuming that an ACO participated in the two-sided risk-sharing model, the ACO would be eligible to receive up to sixty percent of the savings realized.[213] While actual revenue amounts would drop to achieve such savings, associated costs incurred to generate those additional revenues would also disappear. As a

result, it is likely that significant cost cutting could result in profits for the ACO. This, of course, is in addition to the possible rise in private payor rates as a result of greater information flows between ACO member entities.

ACO formation, however, may not be well-suited for every hospital wishing to expand its business operations. First and foremost, nothing truly takes the place of a traditional merger or acquisition in terms of an administrator's ability to operate multiple facilities and expand its practices.[214] Furthermore, ACOs as a health care delivery model are untested and represent significant upfront costs that many hospitals, particularly more rural hospitals, may be unable or unwilling to pay. Finally, participation in the ACO program requires a health care entity to meet significant quality benchmarks and reporting requirements. In other words, ACOs act as a guarantor of the health of the beneficiaries they are assigned, but their patients, conversely, are free to go elsewhere to receive treatment. Any negative health outcomes, however, may affect the ACO's payment or participation status.[215] For these reasons, a hospital administrator considering merger or ACO formation must think critically about the issues involved and weigh the corresponding risks and rewards for each option.

V. CONCLUSION

Antitrust analysis by the FTC, DOJ and federal courts will differ between hospital mergers and ACO formation.[216] While merging hospitals may be unable to offer substantial pro-competitive justifications for a rise in private payor costs, ACOs receive both a more favorable analytical framework and by their nature have significant efficiencies, effects which have been both recognized and developed by the federal government. This beneficial analysis, almost a "benefit-of-the-doubt", given to ACOs should serve as an additional incentive for hospital organizations to consider formation of this type of entity.

Admittedly, a host of criticism and functional difficulties still surround ACOs, but as improvements are made to the regulatory framework and experiential knowledge about ACO operation is gathered, these types of entities will become more viable. Hospital and health system executives should keep these entities in mind when determining business strategy and future organizational opportunities.

[1] *See* Patient Protection and Affordable Care Act of 2010 § 1501 (codified at 42 U.S.C.A. § 18091 and 26 U.S.C.A. § 5000A (2010)) [hereinafter ACA] (requiring that individuals who file tax returns after 2013 to continuously maintain health insurance coverage for themselves and their dependents); *see also* Florida ex. rel. Bondi v. United States Dep't of Health & Human Servs., 780 F. Supp. 2d 1256, 1298–99, 1304 (N.D. Fla. 2011) (holding section 18091 unconstitutional and the entire act void because this section was inseverable).

[2] *See* Delaware Healthcare Assoc. Glossary of Health Care Terms and Abbreviations, http://www.deha.org/Glossary/GlossaryH.htm (last visited Mar. 18, 2013) (defining health care delivery system as "that combination of insurance companies, employer groups, providers of care and government agencies that work together to provide health care to a population").

[3] *See* 42 U.S.C.A. § 1395jjj (2010); 42 C.F.R. pt. 425 (2011) (establishing a mechanism for the federal government to split realized cost savings in the Medicare program with private parties and ordering that HHS implement related regulations).

[4] *See* 42 U.S.C.A. § 1395jjj (2010).

[5] *See, e.g.*, Press Release, Dep't of Health & Human Servs., *Affordable Care Act Helps 32 Health Systems Improve Care for Patients, Saving up to $1.1 Billion* (Dec. 19, 2011), http://www.hhs.gov/news/press/2011pres/12/20111219a.html (noting that the Department of Health and Human Services ("HHS") seeks to reward providers for improving health while lowering health care costs).

[6] *See* Medicare Program: Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67992 (Nov. 2, 2011) [hereinafter Final Waivers Statement] (discussing the authority of the Secretary of HHS to waive certain laws "as necessary to carry out the provisions" of the Shared Savings Program); *see also* Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations, 76 Fed. Reg. 67026, 67026 (Oct. 28, 2011) [hereinafter ACO Antitrust Statement] (acknowledging that while the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") will "vigilantly monitor" competitive effects of ACOs, they "recognize that ACOS may generate opportunities" for innovation and achieving better health outcomes).

[7] *See, e.g*, John B. Kirkwood & Robert H. Lande, *The Fundamental Goal of Antitrust: Protecting Consumers, Not Increasing Efficiency*, 84 Notre Dame L. Rev. 191, 196 (2008) ("[T]he primary goal of antitrust is to protect consumers from paying higher prices to firms . . . .").

[8] Fed. Trade Comm'n, An FTC Guide to the Antitrust Laws: The Enforcers (last updated July 8, 2008), *available at* http://www.ftc.gov/bc/antitrust/enforcers.shtm (describing the joint role played by the FTC and the DOJ).

[9] Fed. Trade Comm'n, An FTC Guide to the Antitrust Laws: Mergers: Introduction (last updated May 26, 2011), *available at* http://www.ftc.gov/bc/antitrust/mergers.shtm (noting efficiencies which may include more efficient operation of a firm, but also harms such as higher consumer

prices, fewer goods, lower quality goods, and stunted innovation).

[10] *See* Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines, 1 (Aug. 19, 2010) *available at* www.ftc.gov/os/2010/08/100819hmg.pdf [hereinafter Horizontal Merger Guidelines].

[11] *See, e.g.*, Fed. Trade Comm'n, Bureau of Competition, Health Care Div., Overview of FTC Antitrust Actions in Health Care Services and Products, 1 (Mar. 2013) [hereinafter FTC Overview of Antitrust Actions] *available at* http://www.ftc.gov/bc/healthcare/antitrust/hcupdate.pdf (noting that since the mid 1970's, the FTC has had a division devoted solely to health care antitrust concerns).

[12] *See, e.g.*, Coordination and Continuity of Care, 42 C.F.R. § 438.208 (2012) (requiring entities that provide managed care to coordinate the delivery of health care services to enrollees).

[13] *See* Haley Paint Co. v. E.I. Dupont De Nemours and Co., 804 F. Supp. 2d 419, 426 (D. Md. 2011) (holding that defendant's attendance at trade association meetings followed by consistent and predictable industry-wide price increases was strong evidence of price fixing); *see also* In re Text Messaging Antitrust Litig., 630 F.3d 622, 627–28 (7th Cir. 2010) (finding that parallel pricing by rivals may be, but is not necessarily, proof of an antitrust violation).

[14] *See* Julie Brill, Comm'r, Fed. Trade Comm'n, Remarks before the North Carolina Bar Association's Antitrust and Trade Regulation Section (Feb. 9, 2012) (discussing the different approaches and attitudes the federal government has regarding hospital mergers and ACOs).

[15] *See, e.g.*, Press Release, Federal Trade Commission, Fed. Trade Comm'n and Dept. of Justice Issue Final Statement of Antitrust Policy Enforcement Regarding Accountable Care Orgs. (Oct. 20, 2011), *available at* http://www.justice.gov/atr/public/press_releases/2011/276482.pdf (identifying that "ACOs may allow health care providers to innovate and improve care for both Medicare and commercially insured patients," two important pro-competitive benefits).

[16] *See* Robert F. Leibenluft, Fed. Trade Comm'n, Statement Presented at the "First Friday Forum" of the Alliance for Health, Grand Rapids, Mich.: Antitrust Enforcement and Hospital Mergers: A Closer Look (June 25, 2007), *available at* http://www.ftc.gov/bc/hmerg1.shtm (deriding hospital mergers for "lead[ing] to higher prices, preclude[ing] future price reductions, reduc[ing] quality, and diminish[ing] the incentives for hospitals to operate more efficiently").

[17] Andrew I. Gavil, William E. Kovacic & Jonathan B. Baker, Antitrust Law in Perspective: Cases, Concepts and Problems In Competition Policy 477 (2nd ed. 2008) (explaining that most concerns over mergers are not resolved through litigation, but through firm restructuring of transactions or agreements or divestiture of certain assets).

[18] *See* Ctrs. for Medicare & Medicaid Servs., *Accountable Care Organizations*, CMS.gov, https://www.cms.gov/ACO/ (last visited Mar. 18, 2013) [hereinafter CMS ACO Overview] (explaining that ACOs may consist of "doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care").

[19] *But see* Cntr. for Medicare & Medicaid Innovation, *Advance Payment ACO Model*, CMS.gov, http://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/index.html (last visited Mar. 23, 2013) (identifying rural and physician-owned entities as those which may participate in this model).

[20] *See, e.g.*, Leigh Page, *HHS Releases Proposed Rules on ACOs; Antitrust Agencies Issue Enforcement Policy*, Becker's Hospital Review (Mar. 31, 2011), http://www.beckershospitalreview.com/hospital-physician-relationships/10-key-points-in-newly-released-proposed-rules-on-acos.html (explaining that so long as the proper number of primary care physicians was involved, a single hospital could become an ACO).

[21] *See* Jaimie Oh, *50 Largest Hospitals in America*, Becker's Hospital Review (Oct. 26, 2010), http://www.beckershospitalreview.com/lists/50-largest-hospitals-in-america.html (listing the largest U.S. facilities, such as the massive, 2,236-bed New York-Presbyterian Hospital in Manhattan).

[22] Ctrs. for Medicare & Medicaid Servs., Accountable Care Organizations: What Providers Need To Know 2 (Nov. 2012), *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Providers_Factsheet_ICN907406.pdf

[23] *See, e.g.*, Page, *supra* note 20, (detailing that, according to CMS officials, specialists would not be able to create an ACO).

[24] *See* CMS ACO Overview, *supra* note 18 (explaining that ACOs may consist of "doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care").

[25] *See* James J. Pizzo & Mark E. Grubs, *Getting to There from Here: Evolving to ACOs Through Clinical Integration Programs* Kaufman, Hall & Associates, Inc. 3 (2011), *available at* http://www.advocatehealth.com/documents/app/ci_to_aco.pdf (explaining that ACOs will have significant clinical integration and defining both horizontal integration and vertical integration).

[26] *See* David Dranove, *ACOs and the Looming Antitrust Crisis*, The Health Care Blog (Oct. 14, 2010), http://thehealthcareblog.com/blog/2010/10/14/acos-and-the-looming-antitrust-crisis/ (noting that ACOs will vertically integrate providers and hospitals, "achiev[ing] what previous incarnations of vertical integration could not.").

[27] *See, e.g.*, Sara Rosenbaum & Peter Shin, *Policy Research Brief No. 23: Medicare's Accountable Care Organization Regulations: How Will Medicare Beneficiaries who Reside in Medically Underserved Communities Fare?* Geo. Wash. U. Sch. Pub. Health & Health Servs., 3 (Apr. 20, 2011), *available at* http://www.gwumc.edu/sphhs/departments/healthpolicy/dhp_publications/pub_uploads/dhpPublication_6EFAAA15-5056-9D20-3DBE579D20C06F05.pdf (questioning whether the ACO program will be able to properly provide secondary and tertiary care in medically underserved areas short on primary care physicians).

[28] *See generally* FTC Overview of Antitrust Actions, *supra* note 11. (identifying a variety of concerns about hospital business interactions and relationships).

[29] *See generally* Robert Kocher & Mikhil Sahni, *Hospitals' Race to Employ Physicians — The Logic Behind a Money-Losing Proposition*, 364 New Eng. J. Med. 1790 (2011) (considering a full range of hospital-physician

relationships).

[30] *See* Dep't of Health & Human Servs., OEI-09-89-00330, Office of Inspector Gen., Financial Arrangements Between Hospitals and Hospital-Based Physicians 1 (1989), *available at* http://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf (describing the symbiotic relationship, as well as payment schemes, among hospitals and physicians). *See generally* Dep't of Health & Human Servs., Office of Inspector Gen., OEI-01-91-00770, State Prohibitions on Hospital Employment of Physicians (1991). *available at* http://oig.hhs.gov/oei/reports/oei-01-91-00770.pdf (describing various physician employment and ownership challenges involving hospitals).

[31] *See, e.g.*, Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, 110 Stat. 1936 (1996) (codified in scattered sections of 29 U.S.C., 42 U.S.C., and 45 U.S.C.); American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 13400–424, 123 Stat. 115 (2009) (also known as the Health Information Technology for Economic and Clinical Health Act ("HITECH")).

[32] *See* Jenny Gold, FAQ on ACOs: Accountable Care Organizations, Explained, Kaiser Health News (Oct. 21, 2011), http://www.kaiserhealthnews.org/stories/2011/january/13/aco-accountable-care-organization-faq.aspx ("[F]or ACOs to work they have to seamlessly share information.").

[33] *See* In the Matter of Evanston Northwestern Healthcare Corp., 2007 WL 2286195 at *5 (F.T.C. 2007) (finding that the hospitals in question received revenues from Medicare, Medicaid and private insurers).

[34] *See, e.g.*, Medicare Payment Advisory Comm'n, *Medicare Payment Advisory Committee, Hospital Acute Inpatient Services Payment System*, MedPac.gov, 1-2 (Oct. 2009), http://www.medpac.gov/documents/medpAc_payment_Basics_09_hospital.pdf (stating that hospitals must "agree to accept the [Medicare] program's predetermined payment rates as payment in full," and providers "fac[e] fixed payment rates").

[35] *See generally* Matthew S. Lewis & Kevin E. Pflum, Diagnosing Hospital System Bargaining Power in Managed Care Networks 1 (Sept. 30, 2011) (unpublished manuscript) (on file with author) (recognizing that MCOs are the "primary purchasers of hospital services").

[36] *See Evanston*, 2007 WL 2286195 at *6 (discussing fee-for-service arrangements and "per diem" payment systems).

[37] *See* Centers for Medicare & Medicaid Services, *Fee Schedule – General Information*, CMS.gov (Mar. 14, 2012 4:09 PM), https://www.cms.gov/FeeScheduleGenInfo/ (stating that CMS's list of fee maximums is used to reimburse providers on a fee-for-service basis).

[38] *See Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations*, 76 Fed. Reg. 67802, 67804 (Nov. 2, 2011) (codified at 42 C.F.R. pt. 425) [hereinafter Shared Savings Program] (explaining that because providers now have a financial benefit for not ordering excessive services, the program will reduce overall costs).

[39] *See* David Newman, Cong. Research Serv., R44174, Accountable Care Organizations and the Medicare Shared Savings Program 2 (2010), *available at* http://www.hospitalmedicine.org/AM/Template.cfm?Section=Advocacy_Policy&Template=/CM/ContentDisplay.cfm&ContentID=28506 (explaining that "ACOs may contract with any payer (Medicare, Medicaid, or private insurer) to provide services and share in any resulting savings").

[40] *See, e.g.*, Meritus Ventures, *Sample Due Diligence Checklist*, http://www.meritusventures.com/template_assets/pdf/diligence.pdf (last visited Mar.. 18, 2013) (describing important due diligence considerations, including information on competition and regulatory agency concerns).

[41] *See* Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. No. 94-435 (codified at 15 U.S.C. § 18a) (1976) (requiring merging or acquiring/acquired businesses to submit information to the FTC and DOJ in most instances at least 30 days before the transaction can be completed).

[42] *See* Dep't of Justice & Fed. Trade Comm'n, Commentary on the Horizontal Merger Guidelines 1 (Mar. 2006), *available at* http://www.justice.gov/atr/public/guidelines/215247.pdf [hereinafter Commentary on Merger Guidelines] ("[M]ost mergers between rivals do not create or enhance market power.").

[43] *See* Press Release, Am. Hosp. Assoc., New Study Finds the Start Up Costs of Establishing an ACO to be Significant, (Nov. 5, 2011), *available at* http://www.aha.org/presscenter/pressrel/2011/110513-pr-aco.shtml [hereinafter AHA Press Release] (estimating that formation and initial operation of an ACO costs between $11.6 and $26.1 million).

[44] *See generally* Shared Savings Program, *supra* note 38 (concerning the myriad technical and substantive requirements an ACO must meet, initially and on an on-going basis).

[45] *Id.* at 67802.

[46] *See* AHA Press Release, *supra* note 43.

[47] *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended in scattered sections of 42 U.S.C.).

[48] *See id.*

[49] *See id*.

[50] *See* Jennifer O'Sullivan, Cong. Research Serv., RL 32582, Medicare: Part B Premiums 3 (2004) (describing Parts A and B and explaining that Part B premiums originally financed 50% of that part of the program).

[51] *See, e.g.*, The Heritage Foundation, *Tax Revenues Devoured by Medicare, Medicaid, and Social Security in 2045*, Heritage.org, http://www.heritage.org/budgetchartbook/entitlements-historical-tax-levels (last visited Mar. 18, 2013) (graphing the growing expenditures of Medicare and Medicaid as a percentage of the federal budget).

[52] Health Maintenance Organization Act, Pub. L. 93-222 (1973) (codified at 42 U.S.C. § 300e).

[53] *See* Paul Saucier, et. al., *The Past, Present and Future of Managed Long-Term Care*, Off. of Disability, Aging & Long-Term Care Pol'y, Off. of the Assistant Sec. for Planning & Evaluation, Dep't of Health & Human Servs. 10 (2005), http://aspe.hhs.gov/daltcp/reports/mltc.pdf (explaining that HMOs and MCOs bear a financial risk in delivering health care services to their enrollees).

[54] Dep't of Health and Human Servs., Off. of Inspector Gen., OEI-02-99-00030, Medicare + Choice HMO Extra Benefits: Beneficiary Perspectives 6 (2000) (explaining how HMOs utilize a primary-care physician as a gatekeeper to higher-priced specialist services).
[55] *See* Christopher Chantrill, *US Health Care Spending History from 1900*, USGovernmentSpending.com http://usgovernmentspending.com/healthcare_spending (last visited Mar. 6, 2013) (graphically showing the increase in spending and stated that "Medicare and Medicaid have made health care into the biggest government program in the United States").
[56] *See, e.g.*, Kevin Sack & Marjorie Connelly, *In Poll, Wide Support for Government-Run Health*, N.Y. Times, June 20, 2009, at A1, *available at* http://www.nytimes.com/2009/06/21/health/policy/21poll.html (noting that 85 percent of poll respondents thought the United States health care system needed to be fundamentally reformed); *see also* ACA § 3022 (codified in 42 C.F.R. pt. 425 (2011)) (expressly titled to signify the goal of reducing U.S. health care costs).
[57] *See* 42 C.F.R. § 425.10(a)(2011) (signaling a change in health care by establishing the individual mandate, insurance exchanges and the Shared Savings Program).
[58] *See id*. at § 425.10(b) (noting such rules as quality metrics and compliance plans).
[59] Final Waivers Statement, *supra* note 6, at 67993.
[60] *See* Shared Savings Program, *supra* note 38, at 67822 (explaining that because providers now have a financial benefit for not ordering excessive services, the program will reduce overall costs).
[61] *Id.* at 67814–15. (setting out both the quality metrics and compliance activities ACOs must meet to receive such savings).
[62] *See, e.g.*, Standard Oil Co. of New Jersey v. United States, 221 U.S. 1, 77 (1911) (holding that a firm's price fixing and limitation on production were anti-competitive and violated the law).
[63] *See* Federal Trade Commission, *FTC Fact Sheet: Antitrust Laws: A Brief History*, 1 *available at* http://www.ftc.gov/bcp/edu/microsites/youarehere/pages/pdf/FTC-Competition_Antitrust-Laws.pdf (last visited Mar. 18, 2013) [hereinafter FTC Fact Sheet] (describing the history and development of antitrust law in the United States).
[64] *See id*. (describing the anti-competitive schemes of trusts in the late 19th century).
[65] *See* Sherman Antitrust Act, 26 Stat. 209 (1890) (codified at 15 U.S.C. §§ 1–7).
[66] *See* Sherman Antitrust Act as amended, 15 U.S.C. § 1 (2004).
[67] *See id*. at § 2.
[68] *See* L.A. Scot Powe, The Supreme Court and the American Elite, 1789-2008 164 (2009) (acknowledging that "the Sherman Act's overly broad language mandated a judicial construction").
[69] *Id.*
[70] *See* FTC Fact Sheet *supra* note 63, at 1 (noting that the Clayton Act was necessary to preempt anti-competitive actions).
[71] *See id.* (describing the ways in which businesses avoided Sherman Act violations).
[72] Clayton Antitrust Act, Pub. L. No. 63-212, 38 Stat. 730 (codified at 15 U.S.C. §§ 12–27 and 29 U.S.C. §§ 52–53) (1914).
[73] *See id.* (imposing new penalties in areas where the Sherman Act had failed to correct identified problems).
[74] *See* FTC Fact Sheet, *supra* note 63, at 1.
[75] Clayton Antitrust Act, 15 U.S.C. § 18 (1996).
[76] *See Antitrust: An Overview*, Cornell University Law School Legal Information Institute, http://www.law.cornell.edu/wex/antitrust (last visited Mar. 18, 2013) (explaining that the Sherman Act could not reach certain anticompetitive activities).
[77] Horizontal Merger Guidelines *supra* note 10, at 25.
[78] *See* Michael J. Trebilcock, *The Evolution of Competition Policy: Lessons from Comparative Experience*, *in* Business, Markets and Government in the Asia Pacific 86, 91 (Rong-I Wu & Yun-Peng Chu eds., 1998).
[79] *See* Federal Trade Commission Act, 38 Stat. 717 (codified at 15 U.S.C. §§ 41–58).
[80] *See id.*
[81] Federal Trade Commission Act, 15 U.S.C. § 46 (2006) (authorizing the FTC to "gather and compile information concerning, and to investigate from time to time," business entities).
[82] *See Statements of Antitrust Enforcement Policy in Health Care*, Dep't of Justice & Federal Trade Comm'n (Aug. 1996), http://www.justice.gov/atr/public/guidelines/0000.htm (noting the unique nature of the health care industry).
[83] *See* William J. Kolasky & Andrew R. Dick, *The Merger Guidelines and the Integration of Efficiencies into Antitrust Review of Horizontal Mergers*, Dep't of Justice, 33 (2002), *available at* http://www.justice.gov/atr/hmerger/11254.pdf.
[84] *See* William J. Kolasky & Andrew R. Dick, *The Merger Guidelines and the Integration of Efficiencies into Antitrust Review of Horizontal Mergers*, Dep't of Justice, 7–14 (n.d.). 2002) *available at* http://www.justice.gov/atr/hmerger/11254.pdf.
[85] *Id*. at 14, 17.
[86] *Id*. at 24.
[87] *See* Horizontal Merger Guidelines, *supra* note 10, at 1, n. 1. (setting forth the notion that the publication of such information would allow courts, legal practitioners and businesses to gain a better understanding of the Agencies' enforcement decisions).
[88] Kolasky, *supra* note 84, at 25; Horizontal Merger Guidelines, *supra* note 10.
[89] *See generally* Commentary on Merger Guidelines, *supra* note 42, at 2 (setting out the five-part analytical framework for mergers).
[90] *Id*. at 5.
[91] *Id*. at v (explaining that horizontal mergers are "a significant dynamic force" and that the "vast majority" of these mergers are harmless and in fact beneficial).
[92] *See generally* ACO Antitrust Statement, *supra* note 6.
[93] *Id.* at 67028 (laying out a calculus for determining market share and determining that a market share greater than thirty percent would disqualify an ACO participant from the safety zone).
[94] *Id*. at 67029 (such as an ACO set up in a rural area).
[95] *Id.* at 67027 ("A rule of reason analysis evaluates whether the collaboration is likely to have anticompetitive

effects and, if so, whether the collaboration's potential pro-competitive efficiencies are likely to outweigh those effects.").

[96] *Id*. at 67028-29 (establishing a "safety zone" for ACOs in more competitive areas and stating that ACOs falling out of this zone would still undergo review under the "rule of reason").

[97] 2007 WL 2286195 at *1 (F.T.C. 2007).

[98] *See* Erica L. Rice, *Evanston's Legacy: A Prescription for Addressing Two-Stage Competition in Hospital Merger Antitrust Analysis*, 90 B.U. L. Rev. 431, 443–52 (2010) (describing the background of the Evanston case).

[99] In the Matter of Evanston Northwestern Healthcare Corp., 2007 WL 2286195 at *2 (F.T.C. 2007) (stating, "there is no dispute that ENH substantially raised its prices shortly after the merg[er]").

[100] *Id.* at *9 (identifying the triangle these three hospitals currently form); *see also* Rush North Shore Medical Center Merger Into NorthShore University HealthSystem Final, NorthShore University HealthSystem, (Jan. 1, 2009), http://www.northshore.org/about-us/press/press-releases/rush-north-shore-medical-center-merger-into-northshore-university-healthsystem-final/ (discussing the completed acquisition of Rush, now known as Skokie hospital, by ENH).

[101] *Evanston*, 2007 WL 2286195 at *8-10.

[102] *Id*. at *9 (discussing the Kellogg Cancer Care Center, various trauma centers, psychiatric care, neurosurgery and other secondary and tertiary services).

[103] *Id.* at *9-10

[104] *Id.*

[105] *Id.* at *10 (discussing the goals of management, particularly the goal of reducing competition among Evanston and Highland Park); *see also* Rice, *supra* note 98, at 449 (listing the two goals of the merger as reducing competition and increasing negotiating clout with private payors).

[106] *Evanston*, 2007 WL 2286195 at *12 (detailing the price increase and subsequent negotiating tactics of ENH).

[107] *Id*. at *5-6 (discussing payment mechanisms for managed care organizations such as HMOs and PPOs).

[108] *Id.* at *5.

[109] *Id.* (describing the practical functioning of copays and their purpose); *see also What is Copay, Coinsurance and Deductible?,* Medical-Billing-Coding.org, http://www.medical-billing-coding.org/Content246.htm (last visited Mar. 18, 2013) (defining copay as "a flat dollar amount paid for a medical service by an insured").

[110] *Evanston*, 2007 WL 2286195 at *6-7 (describing competition among hospitals for managed care contracts).

[111] *Id.* at *14 (assessing the testimony of Jane Ballengee and noting that the insurer was forced into accepting greatly increased prices because without the hospital chain there would be insufficient coverage).

[112] *See id*. at *14 (noting that the MCOs could work each entity against the other to reduce prices); *see also* Rice, *supra* note 98, at 455–56 (commenting that courts should recognize the MCO as the true buyer of hospital services because of the significant role it plays in commanding prices).

[113] *But see* Rice, *supra* note 98, at 449 (noting that while rising prices were "clearly established and undisputed," the activity "was only illegally if [the increase] was a direct result of [ENH's] increased market power.").

[114] *Evanston*, 2007 WL 2286195 at *8.

[115] *Id.* at *9.

[116] *Id.* at *3 (referencing the FTC's three-count complaint alleging violations of the Clayton Act through price-fixing, attempting to monopolize and raising prices above competitive levels).

[117] *Id.* at *4 (reporting that while the administrative law judge had dismissed the second count, he still found that ENH had violated the Clayton Act).

[118] *Id.* at *3 (ruling that divestiture of Highland Park Hospital was not appropriate given the substantial costs involved and the long history of existing as a merged entity).

[119] *Id.* at *79 (rejecting divestiture and requiring establishment of two negotiating teams).

[120] *See* Commentary on Merger Guidelines, *supra* note 42, at 2 (discussing the framework used by the FTC and DOJ in analyzing both pre- and post-merger antitrust investigations).

[121] *Id.* at 2.

[122] Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. No. 94-435 (codified at 15 U.S.C. §18a) (requiring merging or acquiring/acquired businesses to submit information to the FTC and DOJ in most instances at least thirty days before the transaction can be completed).

[123] Commentary on Merger Guidelines, *supra* note 42, at 2; *see also* Rice, supra note 98, at 432 ("[T]he [post-acquisition FTC complaint] is notable because although not unheard of, post-merger challenges are generally rare, particularly with regard to hospital mergers.").

[124] *See Evanston*, 2007 WL 2286195 at *49–50 ("There are substantial factual and analytical overlaps between the market definition process and competitive effects analysis in unilateral effects cases.").

[125] *See id*. at *45-49 (analyzing the FTC's specific tests in defining the relevant markets, that of the "hypothetical monopolist"); *see also* In the Matter of DaVita Inc., F.T.C. Docket No. C-4152 (F.T.C. 2005) (ordering divestiture for a dialysis corporation after an extensive review of the geographic product markets of the company and its acquired competitor).

[126] *Evanston*, 2007 WL 2286195 at *48; *see also* Horizontal Merger Guidelines, *supra* note 10, at 13 (further discussing and revising this test).

[127] *See, e.g.*, *Evanston*, 2007 WL 2286195 at *45–49 (weighing valid points made by each party's economic experts).

[128] *Id*. at *48 (circularly positing that, because of actual evidence obtained, the FTC could specifically delineate these three hospitals as a relevant market).

[129] *Id.* (arguing that MCOs and other payers had a bevy of contracting options throughout northern Chicago).

[130] *See* Rice, *supra* note 98, at 446 (analyzing the ALJ's "payor problem" and "silent majority" problem as well as the ALJ's unique calculus for determining the geographic market).

[131] *See Evanston*, 2007 WL 2286195 at *53 ("Higher-than-

predicted post-merger price increases resulted from market power gained through the merger".).

[132] *Id.* at *49 (identifying that both parties' experts saw price increases greater than the FTC's SSNIP test). *But see* Rice, *supra* note 98, at 444 (positing that because most merger challenges are prospective, such evidence will be "highly speculative").

[133] *See Evanston*, 2007 WL 2286195 at *48.

[134] *See* Horizontal Merger Guidelines, *supra* note 10, at 8–9 ("the Agencies use the hypothetical monopolist test to identify a set of products that are reasonably interchangeable with a product sold by one of the merging firms.").

[135] *See id.* at 10 (explaining "the Agencies may accordingly use a price increase that is larger or smaller than five percent").

[136] *See* Rice, *supra* note 98, at 445 (describing the fight between the FTC's narrow product market definition and the broader definition, including all services purchased by MCOs, cited by ENH).

[137] *Evanston*, 2007 WL 2286195 at *46.

[138] *Id*. at *46-47.

[139] *See* United States v. Archer-Daniels-Midland Co., 866 F.2d 242, 248 (8th Cir. 1988) (requiring that two products not be included in the same market absent a high cross-elasticity of demand between the goods).

[140] *See Evanston*, 2007 WL 2286195 at *47 (contending that if a patient needs inpatient services, which are usually more critical and intensive, the MCO cannot appropriately substitute less intensive outpatient services to meet the patient's needs).

[141] *See, e.g.*, Fed. Trade Comm'n v. Freeman Hosp., 69 F.3d 260, 268 (8th Cir. 1995); United States v. Rockford Mem'l Corp., 898 F.2d 1278, 1284 (7th Cir. 1990); United States v. Long Island Jewish Med. Ctr., 983 F. Supp. 121, 138-140 (E.D.N.Y. 1997) (all identifying inpatient hospital services as a single cluster of products constituting a valid product market).

[142] *Evanston*, 2007 WL 2286195 at *47 (acknowledging that ENH's expert had calculated the price increases both with and without outpatient services, and both sets of calculations had led to extraordinary increases).

[143] *Id.* at *49 (introducing the theory of unilateral anticompetitive effects).

[144] *See* Horizontal Merger Guidelines, *supra* note 10, at 3 ("Evidence of observed post-merger price increases or other changes adverse to customers is given substantial weight.").

[145] *See Evanston*, 2007 WL 2286195 at *2.

[146] *Id*. at *49 (identifying unilateral effects as those that "result when a merger leads to higher prices due to the loss of competition between the two merging firms"); *see also* Horizontal Merger Guidelines, *supra* note 10, at 20 (explaining the FTC's enforcement approach to unilateral effects); Gavil et. al., *supra* note 17, at 535–54 (further summarizing the unilateral effects theory).

[147] *See* Tasneem Chipty, *Competitor Collaborations in Health Care: Understanding the Proposed ACO Antitrust Review Process*, CPI Antitrust Chronicle2 (May 2011), *available at* http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/Chipty_CPI_Antitrust_Chronicle_May2011.pdf (noting that misaligned incentives and insufficient flow of information may break down the competitive process).

[148] *See* Horizontal Merger Guidelines, *supra* note 10, at 20-22 (observing that the "extent of direct competition" between two products is important to the unilateral effects theory).

[149] *See id.* at 22 (commenting that buyers may negotiate with several sellers to reduce price, but when these sellers merge, the buyer is prevented from engaging in this practice).

[150] *See* Jonathan Baker, *Unilateral Competitive Effects Theories in Merger Analysis*, 11 Antitrust 21, 22 (1997) (discussing the economics behind buyer substitution).

[151] *See id*. (introducing how unilateral effects actually result in anti-competitive harms).

[152] *Id.* (explaining the effect of a merger of the most attractive firms on market prices).

[153] *See id.* (stating that all sellers can price equivalent products to a buyer at the cost of the most expensive producer the buyer must buy from).

[154] *See id.* (suggesting either through paying higher prices to the merged firms, paying higher prices to less efficient firms, or by receiving lower quality products altogether).

[155] *See, e.g.*, In the Matter of Evanston Northwestern Healthcare Corp., 2007 WL 2286195 at *11 (F.T.C. 2007) (describing similar negotiating goals of two executives, Ronald Spaeth and Mark Newton).

[156] *See id.* at *31 (discussing "Learning-About-Demand" whereby the merged firms increase their knowledge of the market through review of each other's closely-kept bidding data).

[157] *See, e.g.*, J. Scott Armstrong, *The "Myth of Market Share": Can Focusing Too Much on the Competition Harm Profitability?*, Knowledge@Wharton (Jan. 24, 2007), http://knowledge.wharton.upenn.edu/article.cfm?articleid=1645 ("[I]t is a common practice of many companies to focus their attention on grabbing market share from their competitors.").

[158] *Id.* (describing a study testing cooperation to achieve profit maximization).

[159] *See Evanston*, 2007 WL 2286195 at *10–11, *13 (describing the various ways by which Evanston coordinated their efforts and secured substantially better contracts from MCOs).

[160] *See id*. at *14 (noting that an MCO's clientele had stated that it could not effectively market without ENH in its network).

[161] *See, e.g., id*. at *63 (describing ENH's argument about possible influx of new competitors into the relevant market).

[162] *See* Commentary on Merger Guidelines, *supra* note 42, at 46–47 (acknowledging a two year limit but further noting that the FTC would readily challenge whether additional entrants were likely to establish themselves during that window).

[163] *See* Horizontal Merger Guidelines, *supra* note 10, at 15–16 (describing who is and is not considered a market participant for purposes of antitrust review).

[164] *See Evanston*, 2007 WL 2286195 at *63 (identifying elements that made it unlikely for new market participants to enter within two years, such as actual construction times and regulatory delays).

[165] *See id.* (noting that there was no reason ENH could not exercise market power in this defined region).
[166] *See, e.g.*, *id.* at *67 (considering ENH's arguments that the competitive efficiencies of the merger outweighed the corresponding harms).
[167] *See* Commentary on Merger Guidelines, *supra* note 42, at 49 (setting forth these and other efficiencies, such as the ability to provide new product lines and other innovations and increased financial strength in one or both of the merged firms).
[168] *See id.* at 49 (requiring that any claimed efficiencies be "cognizable" and "merger-specific").
[169] *See, e.g.*, *Evanston*, 2007 WL 2286195 at *67-73 (finding that, while ENH put forth a variety of precompetitive benefits, these claims were not sufficiently substantiated or merger-specific).
[170] *Id.* at *12 (discussing a consultant's estimation that, through the merger, Evanston could cut costs through economies of scale and elimination of duplicative functions).
[171] *Id.* at *70 (stating that, regardless of the claimed improvements and cost-savings, these factors had no verifiable effect of counteracting the anti-competitive harms).
[172] *See* Brunswick Corp. v. Pueblo Bowl-o-mat, Inc., 429 U.S. 477, 488 (1977) (citing Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962)) ("The antitrust laws, however, were enacted for 'the protection of competition not competitors.'").
[173] *See, e.g.*, Staffan Canbäck, *Diseconomies of Scale in Large Corporations* 8 (Henley Management College, Working Paper) (Feb. 2004), available at http://canback.com/archive/disec.pdf (defining economies of scale as the ability of firms to decrease their average cost per unit as production expands).
[174] *See* Arthur Sullivan & Steven M. Sheffrin, Economics: Principles in Action 157 (3rd ed. 2003) (further clarifying economies of scale).
[175] *See Evanston*, 2007 WL 2286195 at *71 (identifying that installation of an electronic medical records system and integration of the teaching hospital were the only two merger-specific efficiencies ENH could justify).
[176] *See* Henry Chesbrough, Open Innovation: A Key to Achieving Socioeconomic Evolution, Japan Economic Foundation (2010), *available at* http://openinnovation.berkeley.edu/papers/How_Smaller_Companies_Can_Benefit.pdf (explaining that small and medium enterprises usually do not have enough resources to dedicate personnel specifically for technological and knowledge improvement).
[177] *See Evanston*, 2007 WL 2286195 at *44.
[178] *See generally* Joseph Farrell, Dep. Assist. Atty. Gen., Dep't of Justice, *Thoughts on Antitrust and Innovation* Remarks at the National Economists' Club (Jan. 25, 2001), *available at* http://www.justice.gov/atr/public/speeches/7402.htm (discussing the important role of innovation and product quality in antitrust analysis).
[179] *See* Commentary on Merger Guidelines, *supra* note 42, at v (clarifying that many mergers produce efficiencies that pose no harm to consumers).
[180] *See generally* Gabriel Feldman, *Misuse of the Less Restrictive Alternative Inquiry in Rule of Reason Analysis*, 58 Am. U. L. Rev. 561 (Feb. 2009) (reviewing the applicability of the "least restrictive alternative" rule).
[181] *See id* at 564.
[182] *See id*. at 566–70.
[183] *See* In the Matter of Evanston Nw. Healthcare Corp., 2007 WL 2286195 at *69 (F.T.C. 2007).
[184] *See id*. at *70 (citing the FTC Merger Guidelines § 4, which sets out specific elements of the test which must be met before the Commission or a court should consider claimed quality improvements).
[185] *See* Horizontal Merger Guidelines, *supra* note 10, at 30–31 (listing merger-specific, verified efficiencies of a "character and magnitude" sufficient to overturn any potential harms).
[186] *See* Evanston, 2007 WL 2286195 at *71 (stating that although ENH may have invested considerable funds in quality improvements, it provided no evidence showing any positive effects of those improvements); *see also* Rice, *supra* note 98, at 450–51.
[187] *See Evanston*, 2007 WL 2286195 at *71 (holding that the "vast majority of the claimed improvements at Highland Park were not merger-specific").
[188] *See id*. (noting that the ALJ reviewed Highland Park's improvement plans and held that few of them actually required the merger to be realized).
[189] *See id*. at *72. (observing that leadership, management and other roles can be changed without a merger).
[190] *See id.* (holding that the quality improvements at Highland Park were not appropriately "credited" as merger benefits).
[191] *See id.* at *73 (explaining that the "dearth of verifiable evidence" from ENH demonstrated that the claimed benefits did not outweigh the competitive harms, and possibly did not exist).
[192] *See* Horizontal Merger Guidelines, *supra* note 10, at 32 (but cautioning that this efficiency defense is only available when failing firm assets are close to exiting the relevant market).
[193] *See id*. *But see Evanston*, 2007 WL 2286195 at *78–80 (setting out prior iteration of Merger Guidelines, which also required that the failing firm prove that without the proposed merger, its assets would be lost and unavailable to the relevant market).
[194] *See* Horizontal Merger Guidelines, *supra* note 10, at 32 (explaining that use of this defense is "an extreme instance" where it is better for customers to suffer anti-competitive harms than lose the assets at issue completely); *see also Evanston*, 2007 WL 2286195 at *67–69 (discussing the "weakened company" justification); United States v. Gen. Dynamic Corp., 415 U.S. 486, 492 (1974) (expanding the failing firm doctrine to consider firms with "severely limited" resources as potentially failing). *But see* Kaiser Aluminum & Chem. Corp. v. Fed. Trade Comm'n, 652 F.2d 1324, 1336–41 (7th Cir. 1981) (observing that evidence of a weakened firm may be one of many factors to overcome anticompetitive concern, but "is probably the weakest ground for justifying a merger.").
[195] *See Evanston*, 2007 WL 2286195 at *68 (noting that the "vast majority of the operating loss reported by Highland Park in 1999 was for merger-related costs").
[196] *See id*. at *69.

[197] *See* ACO Antitrust Statement, *supra* note 6, at 67030.
[198] *Id.*
[199] *See Evanston*, 2007 WL 2286195 at *45–49 (outlining the specific considerations the FTC gives to market definition).
[200] *See* AHA Press Release, *supra* note 43 (describing the unforeseen costs in CMS' initial estimate).
[201] *See generally* ACO Antitrust Statement, *supra* note 6 (describing the proposed enforcement scheme).
[202] *See* Evanston, 2007 WL 2286195 at *74 (demonstrating that the FTC recognizes the serious upward pricing effects of collusive negotiations).
[203] *See* Ken Terry, *ACOs Forging the Links*, Hospitals & Health Networks http://www.hhnmag.com/hhnmag_app/jsp/articledisplay.jsp?dcrpath=HHNMAG/Article/data/01JAN2011/0111HHN_Coverstory&domain=HHNMAG (last visited Mar. 24, 2013).
[204] *Id*. (describing the current confusion regarding how private payors will interact with ACOs, but noting that a number of MCOs are engaging with hospitals and health systems about ACO strategy).
[205] *See generally* Shared Savings Program, *supra* note 38, at 67870 (laying out the number quality reporting requirements an ACO must meet to receive a portion of savings).
[206] *See, e.g.*, American Academy of Professional Coders, *CMS: ACO Prototype Succeeds* (Aug. 11, 2011), http://news.aapc.com/index.php/2011/08/cms-aco-prototype-succeeds/ (discussing a CMS press release that notes considerable quality success in an ACO demonstration project).
[207] *See, e.g.*, Center for Medicare & Medicaid Innovation, *Accountable Care Organizations (ACOs): General Information*, CMS.gov http://innovation.cms.gov/initiatives/aco/ (last visited Mar. 24, 2013) (explaining how ACOs will lead to better coordination of care).
[208] *See* Shared Savings Program, *supra* note 38, at 67952 (setting out the final rule regarding mandatory compliance plans in ACOs; in requiring such reporting of quality, providers are forced to become more efficient in their provision of services while maintaining a high quality of care).
[209] *See* Horizontal Merger Guidelines, *supra* note 10, at 1 (describing the investigative processes of the FTC and DOJ).
[210] *See* ACO Antitrust Statement, *supra* note 6, at 67030 (noting the use of rule of reason analysis for this review).
[211] *See* Shared Savings Program, *supra* note 38, at 67952 (discussing mandatory compliance initiatives); *cf*. ACA §§ 6102, 6401 (mandating that all health care providers have a compliance plan).
[212] *Evanston*, 2007 WL 2286195 at *9.
[213] *See* Shared Savings Program, *supra* note 38, at 67930 (discussing the proposed and final sharing methodology).
[214] *See, e.g.*, Rice, *supra* note 98, at 445 (explaining that while ENH maintained separate facilities for its post-merger chain, all corporate functions were combined, and an integrated billing system was established. Furthermore, the three hospitals all used a single Medicare identification number and granted medical privileges to physicians on a universal basis).
[215] *See* Shared Savings Program, *supra* note 38, at 67871 (setting out that if the federal government determines the ACO had too many negative health outcomes, it may withhold the shared savings, and that such decision is not appealable).
[216] *See generally* Horizontal Merger Guidelines, *supra* note 10; *cf.* ACO Antitrust Statement, *supra* note 6 (because of the unique nature and structure of ACOs, the FTC cannot approach them the same way).

An Uncommon Examination of a Generic Problem: Pliva Inc. v. Mensing and Its Effect on the Liability of Generic Drug Manufacturers

*Heather Dorsey**

I. INTRODUCTION

Imagine there was a generic version of a brand–name car. Now imagine that the makers of the generic car were allowed, by federal statute, to make the generic car because it was identical to the brand–name car in every way except its name and lower price. Additionally, federal regulation, interpreted by case law, allowed for the maker of the brand–name car to be held liable under a failure to warn theory, but disallowed the same for the generic car. Moreover, the maker of the generic car could not, by law, amend its user manual to warn about hazards of the usage of the car unless the makers of the brand–name did so first. This is a simplified illustration of the differences in liability and ability to warn consumers between brand–name and generic drugs.

The Food, Drug, and Cosmetic Act ("FDCA") regulates all drugs, which necessarily includes generic and brand–name drugs.[1] However, as the regulatory scheme currently stands, generic manufacturers cannot unilaterally alter their warning labels, as they must be identical to the brand–name warning labels.[2] The Hatch-Waxman Act created this regulatory scheme.[3] It was intended to, and has, accomplished the goal of increasing access to new drugs by allowing a generic drug company to enter the market by simply showing its drug to be identical to an already approved brand–name drug.[4] However, as seen in recent cases, a plaintiff who is injured by a generic drug may have no recourse in a failure to warn tort claim because federal preemption prevents the generic manufacturer from complying with both state and federal law.[5] Generic manufacturers have prevailed on the theory of impossibility preemption, arguing they are precluded from complying with federal and state law, because under federal law they cannot unilaterally strengthen their warning label, regardless of whether they are informed of adverse events.[6] Recently, however, the possibility of a plaintiff prevailing on a theory of design defect has been raised as an alternative to hold generic manufacturers liable when a consumer is injured by their product.[7] This Comment will discuss the controversy and possible solutions.

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II. REGULATORY STRUCTURE

A. Background

The FDCA gives the FDA the power to regulate drugs.[8] For the purposes of the FDCA, a "drug" is defined as, "intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."[9] All drugs must be approved by the FDA prior to being distributed or marketed under the "new drug application" ("NDA") procedure.[10] The Drug Amendments of 1962 were the most important change in the FDCA's drug regulatory framework, as they created a shift from premarket notification to premarket approval for safety and effectiveness.[11] Prior to 1962, a drug manufacturer was required to submit a premarket notification NDA that would become effective after 60 days if the FDA did not oppose it.[12] However, the 1962 FDCA Amendments fundamentally changed the NDA process to one of premarket approval, requiring multiple steps of clinical testing to demonstrate the drug's safety and effectiveness prior to FDA approval.[13] After

the passage of these Amendments, the regulation of drugs became one of the most contentious and vital functions of the FDCA.[14]

A pioneer drug manufacturer is required to perform considerable clinical testing showing the drug is safe and effective.[15] The NDA processes usually last between five to ten years, and for every 5,000 new chemical entities that begin, approximately only one will survive to be approved as a drug under an NDA.[16] The cost of this process is borne exclusively by the brand–name manufacturer and averages almost $1 billion per drug.[17]

Prior to any human clinical testing, the brand–name manufacturer must show anticipated risks associated with the drug, based on pharmacological and toxicological data obtained from animal studies.[18] The brand–name manufacturer is then required to conduct multiple stages of heavily regulated clinical testing investigations in human subjects that show whether the drug is effective and safe for use.[19] While the NDA must show that the new drug is safe and effective, no drug has ever been shown to be completely safe.[20] The broad safe and effective requirement has been interpreted by the FDA to mean that the benefits of the drug outweigh the risks.[21]

The new drug must conform to the labeling requirements of the FDCA.[22] The FDA completely controls the drug label, which must contain adequate approved directions for use, warnings, side effects, contraindications, and effectiveness.[23] Once the NDA has been approved, the drug is "listed" as an approved drug.[24] After the NDA has been listed as an approved new drug, the manufacturer must maintain records of research on the drug and report any adverse effects.[25] This includes annual reports detailing new information about the drug or unexpected complications that affect the safety or effectiveness of the drug.[26]

A notable process associated with the change in warning label is the "changes being effected" ("CBE") process.[27] Under certain conditions, the CBE process requires a brand–name manufacturer to unilaterally change the warning label without prior FDA approval.[28] When a brand–name manufacturer becomes aware of the need for an additional warning label, it is required to add the new information to the labeling "as soon as there is reasonable evidence of a causal association" between the adverse event and the drug.[29] Further, brand–name manufacturers must delete content from the warning label if it contains "false, misleading, or unsupported indications."[30] Additionally, under CBE, a brand–name manufacturer may strengthen the warning label regarding "a contraindication, warning, precaution, or adverse reaction," which can include changes to dosage or administration of the drug.[31]

B. The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act ("Act"), established a new FDA procedure for generic drugs to be approved based on the authorization of an equivalent pioneer drug, or brand–name drug, known as the abbreviated new drug application ("ANDA").[32] This Act was a compromise: manufacturers of generic drugs would no longer have to conduct and report the expensive clinical testing required of a pioneer drug, and in return pioneer drugs received extended patent exclusivity.[33] ANDAs piggyback on a brand–name manufacturer's NDA.[34] An ANDA is required to show that the generic drug is the bioequivalent of the approved brand–name drug, also known as the "listed" drug.[35] Additionally, an ANDA must provide a copy of the labeling for the "listed" brand–name drug, a copy of the proposed labeling for the ANDA, and a side-by-side comparison of the generic and brand–name drug.[36] The "side by side" comparison between the generic and the brand–name drug emphasizes the fact that the generic and the brand–name drug must be identical in every way, including the formula and warning.[37] Unlike a brand–name manufacturer, a generic manufacturer does not have to demonstrate the results of preclinical and clinical testing of safety and effectiveness.[38] Notably, the labeling requirement for an ANDA requires the generic manufacturer to demonstrate that its labeling is identical to that of the brand–name manufacturer.[39]

The Act was enacted to advance two important public policies. First, Congress wanted to provide explicit patent protection and a period of market exclusivity for brand–name drug manufacturers.[40]

As brand–name manufacturers invest significant time and resources in the IND and NDA processes, Congress wished to provide an incentive for drug innovation.[41] Second, Congress sought to encourage lower prices and availability of generic drugs after the brand–name patent protection and market exclusivity expired.[42] Overall, this framework has successfully provided greater access to generics through lower prices and greater availability, but it is questionable whether it has provided a benefit to brand–name drug manufacturers.[43]

C. Implications

The Hatch-Waxman Act is a friend of patients who wish to obtain reasonably priced drugs, however, the preemptive effects of the Act, as interpreted by caselaw, are a terrible foe. The Act allows a generic drug company to file an ANDA to obtain expedited approval of a generic drug that is identical to a brand–name drug.[44] As an incentive for generic drug manufacturers to create more affordable alternatives to brand–name drugs, the Act also provides the first successful ANDA filer with a 180 day period in which that generic manufacturer is the exclusive manufacturer of the particular generic drug sold.[45] During the exclusive marketing period, generic manufacturers typically price their drugs only slightly less — about five percent — than the brand–name counterpart.[46] However, when a second generic company enters the market, the price drops an average of fifty percent.[47] This achieves one of the goals of the Hatch-Waxman Act because when multiple generic drug companies enter the market drug prices are lowered and a wider array of drugs are available to more patients.[48]

However, this lower price may come with the cost of unintended consequences due to the Supreme Court's recent holding in PLIVA Inc. v. Mensing. A patient who is injured after receiving a generic substitute for a brand–name drug dispensed by the pharmacist, even though the patient may be unaware the pharmacist dispensed a generic drug, will unlikely be able to recover damages for a failure to warn cause of action against a generic drug manufacturer.[49] The Act has been criticized for creating this statutory dilemma due to federal preemption in state failure to warn cases.[50] Therefore, while the Hatch-Waxman Act improves accessibility to otherwise high priced drugs it does so with the consequence of precluding injured patients from recovering damages if they are harmed by a generic drug.

III. CASE LAW: FAILURE TO WARN, FEDERAL PREEMPTION, AND DESIGN DEFECT LIABILITY

A. Wyeth v. Levine: Brand–name manufacturers may be held liable under failure to warn.

Wyeth v. Levine involved a state cause of action for failure to warn and federal preemption.[51] Diana Levine was administered Phenergan through the now notorious "IV–push" method.[52] The drug entered her artery, caused gangrene, and as a result, her arm was amputated.[53] Levine filed suit against the maker of the brand–name drug Phenergan on the theory of common law failure to warn negligence and strict liability.[54] She alleged that Phenergan was not reasonably safe for the "IV–push" method and that its labeling failed to reasonably warn physicians of the foreseeable risks of gangrene and amputation when this method is used.[55] Finally, Levine alleged that the risks of losing a limb outweighed the therapeutic benefits of Phenergan when administered through the "IV–push" method.[56] Wyeth alleged that Levine's claim was federally preempted, arguing that the FDCA establishes "both a floor and a ceiling" for a drug's label.[57] Wyeth pointed to the preamble of a 2006 federal regulation governing the prescription drug labels as evidence that FDA approval of labeling explicitly preempts conflicting or contrary state law.[58]

The Supreme Court held that Phenergan's label did not contain an adequate warning for its administration through the "IV–push" method and that the federal regulation did not preempt the state law tort claim.[59] The Court stated that Wyeth had a duty to provide a warning of the risk associated with the "IV–push" method, and could have done so through the CBE process.[60] The Court emphasized that a central premise of the FDCA is that the drug manufacturer retains liability for its label at all times.[61] Moreover, the Court pointed to the CBE regulations as proof that the manufacturer is ultimately responsible for its label as a safety precaution.[62]

The Supreme Court rejected Wyeth's argument that FDA regulations explicitly preempt state law.[63] It stated that Congress has not authorized the FDA to directly preempt state law and that the Supreme Court has never deferred to an agency's conclusion that its regulations preempt state law.[64] The Court stated that the 2006 preamble to the regulation was insufficient to prove that the FDA and Congress intended all FDA regulations to preempt state law.[65] Moreover, the Court refused to accord the preamble any deference, and criticized it as a procedural failure, stating that the FDA finalized the rule without input from the states, "articulat[ing] a sweeping position on the FDCA's pre-emptive effect in the regulatory preamble."[66]

The Supreme Court emphasized that Congress did not intend for the FDCA to preempt state tort suits.[67] The Court further noted that the FDA has limited resources to monitor the 11,000 approved drugs, and therefore, state tort suits are an important means of discovering drug defects and motivating people to come forward for compensation.[68] Also, state tort suits support the assertion that the manufacturer bears the ultimate responsibility for a drug's label.[69] Finally, although Wyeth was a brand–name manufacturer, the Court did not make a distinction between brand–name and generic manufacturers, stating that a drug manufacturer bears responsibility for its labeling "at all times."[70]

B. PLIVA Inc. v. Mensing: Federal law preempts state tort claims against generic manufacturers, who cannot unilaterally change a warning label.

In *PLIVA Inc. v. Mensing,*[71] patients alleged that PLIVA Inc., the generic manufacturer of metoclopramide (brand–name Reglan), a drug used for stomach disorders, knew or should have known that the drug had a high risk of causing tardive dyskinesia, a permanent neurological disorder.[72] Gladys Mensing and Julie Demahy were prescribed the brand–name Reglan, but were given the generic metoclopramide by their pharmacists as a less expensive generic alternative.[73] The generic version of metoclopramide was approved pursuant to the Hatch-Waxman Act[74] that allows the FDA to approve generic drugs that are identical to a brand–name version.[75] Both women took the drug as directed for a period of years, and both developed tardive dyskinesia.[76]

The Supreme Court deferred to the FDA's interpretation of the Hatch-Waxman Act and held that a generic drug label may only display warnings contained in the equivalent brand–name drug label.[77] The Court concluded that because PLIVA Inc. was a generic drug manufacturer, the CBE process was not available to make the type of change required by state law.[78] Thus, the state tort claim based on a failure to warn was preempted because federal statutes do not allow a generic manufacturer to independently change its label.[79] The Court distinguished Wyeth, stating that in Wyeth the manufacturer was a brand–name manufacturer who had the power to unilaterally change its label without FDA approval.[80] The Court acknowledged that the difference between Wyeth and this case seemed trivial as the only difference was that the manufacturer in Wyeth was a brand–name, while the manufacturer in this case was a generic.[81] Nevertheless, the Court stated that the way the statute was written caused a preemption issue that must give way to federal law under the Supremacy Clause.[82]

C. Bartlett v. Mutual Pharmaceutical Co.: Generic manufacturers may be held liable under a theory of design defect.

While a plaintiff may not be able to recover from a generic drug manufacturer under a failure to warn theory of liability, Bartlett v. Mutual Pharmaceutical Co. provides hope for a plaintiff to prevail under a design defect theory of liability.[83] This requires a paradigm shift however, as the CBE process is irrelevant in the design defect context.[84] In the design defect context, whether the manufacturer is brand–name or generic is unimportant.[85] Nevertheless, the design defect theory of liability as applied to generic drug manufacturers is important because it provides a potential alternative theory of liability when a plaintiff cannot otherwise prevail under a failure to warn theory of liability.[86]

In Bartlett v. Mutual Pharmaceutical Co.,[87] the First Circuit rejected a preemption claim in response to a state tort claim similar to that in PLIVA Inc. v. Mensing, holding that federal law does not preempt state law design-defect claims.[88] Karen Bartlett brought a strict products liability state tort claim for

failure to warn against a generic drug manufacturer of sulindac.[89] Sulindac is a generic non-steroidal anti-inflammatory drug ("NSAID"), manufactured by Mutual Pharmaceutical Company ("Mutual").[90] In rare cases, sulindac can cause Stevens–Johnson Syndrome[91] or toxic epidermal necrolysis ("SJS/TEN").[92] Bartlett's doctor prescribed Bartlett the brand–name Clinoril for shoulder pain, and her pharmacist dispensed the generic sulindac.[93] Bartlett's reaction to sulindac was severe.[94] Sixty to sixty–five percent of her body was covered in open–wound skin lesions.[95] She spent over 50 days in the burn unit and her reaction resulted in permanent near–blindness and severe disfigurement.[96]

Bartlett argued that sulindac's risks outweighed its benefits, which made the product unreasonably dangerous even though the FDA approved the "safety and effectiveness" of the brand–name version, Clinoril.[97] The court held that it was proper for Bartlett to show that sulindac was "in a defective condition" and it was "unreasonably dangerous," even though it was approved by the FDA.[98] The court noted that Mutual could have avoided liability had it shown that sulindac was unavoidably unsafe but nonetheless very useful.[99]

The design defect theory of liability presents an alternative to the indirect process suggested in PLIVA, of placing the burden on the generic manufacturer and the FDA to convince the brand–name manufacturer to strengthen the warning label. The court in Bartlett stated that "although Mutual cannot legally make sulindac in another composition, . . . it certainly can choose not to make the drug at all; and the [FDCA] might permit states to tell [a manufacturer] it ought not be doing so if risk-benefit analysis weights against the drug, despite what the Supreme Court made of similar arguments in the labeling context."[100] Instead, under a design defect theory of liability, perhaps the FDCA could be interpreted to reserve to the states the power to tell a drug manufacturer that it should not be selling a drug if the risk benefit calculus is unacceptable.[101]

The analysis in Wyeth v. Levine lends support to using a design defect theory of liability.[102] Because state tort suits motivate manufacturers to strengthen their label, and the FDA does not have adequate resources to monitor the thousands of drugs on the market, state tort suits are an important enforcement mechanism.[103] Strict liability in a state tort action for design defect could add another layer of enforcement.[104] Additionally, this mechanism could provide a patient who is injured by a generic drug an alternative course of action: strict liability for a design defect without regard to the fact that the FDA approved the drug as "safe and effective."[105]

The Supreme Court granted certiorari to Bartlett, to resolve the issue of whether federal law preempts state law design-defect claims.[106] Petitioner Mutual argues that Bartlett is an outlier case, and regardless of what a state tort claim is called, courts have recognized that state law must yield.[107] The Generic Pharmaceutical Association, in its amicus curiae brief in support of Mutual, argues that if the mere ability of a manufacturer to withdraw a product from the market was sufficient to defeat preemption, it is unclear when the Supremacy Clause would have any force.[108] Conversely, Respondent Bartlett argues that nothing in federal law precludes Mutual from complying with state law as federal law does not require manufacturers to sell sulindac and Mutual's decision to manufacture it is entirely its own.[109] Bartlett further states there is no conflict of law under PLIVA, Inc., because this case involves design defect, while PLIVA, Inc., involved failure to warn, an entirely different cause of action.[110] In their amicus curiae brief in support of Bartlett, American Association for Justice, and Public Justice argue that Congress did not intend to deprive compensation to individuals who are injured by drugs, and design defect claims compliment the objectives of the FDCA of approving only safe and effective drugs.[111]

IV. RECOMMENDATIONS

Different suggestions have been made for how to fix the paradox of the Hatch-Waxman Act's unintended consequence of denying any liability to patients injured by generic drugs.[112] However, as stated in *Bartlett,*[113] a better alternative may be to empower states, through the judicial means of state torts suits, to disallow any company from selling a drug with questionable safety and effectiveness "if risk–benefit analysis weights against the drug."[114] This could provide a plaintiff with a strict liability design defect case theory against a generic manufacturer.[115]

Alternatively, the Hatch-Waxman Act could be amended to explicitly state that the burden is placed on manufacturers of equivalent drugs to monitor the labels and safety of both the generic version of the brand–name version through a modified market share liability scheme.[116]

A. Allow risk-benefit analysis in a design defect case against a generic manufacturer.

In Wyeth v. Levine, the Court rejected the idea that the FDA retains the burden of proper labeling for a drug at all times.[117] In fact, the Court stated that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."[118] The Court provided evidence for this statement by referring to the CBE changes established in 2007 that allow the FDA to order manufacturers to revise their labels.[119] The Court stated that under the CBE process, Congress granted the FDA the authority to allow brand–name drug manufacturers to unilaterally strengthen their warning labels.[120] In doing so, Congress reaffirmed the manufacturer's obligation to increase label warnings when necessary.[121] This reflects the manufacturer's ultimate responsibility for its label by providing a mechanism for adding safety information to the label prior to FDA approval.[122] Therefore, in Wyeth, the Court held that Wyeth had a duty to provide a warning that "adequately described the risk" of Phenergan.[123]

Interestingly, the Court in Wyeth did not make a distinction between generic and brand–name manufacturer's responsibilities with regard to the content of a warning label.[124] The Court in PLIVA Inc. v. Mensing distinguished Wyeth, stating that in Wyeth, the manufacturer was a brand–name manufacturer who had the power to unilaterally change its label without FDA approval.[125] In fact, the Court in Wyeth emphasized the reasons why it is almost exclusively the manufacturer's responsibility for post-market surveillance of a drug.[126] The Court stated that the FDA has limited resources with which to monitor the 11,000 drugs currently on the market.[127] Second, manufacturers have a large advantage over the FDA regarding access to information and awareness of new adverse effects.[128] Finally, it is more likely that consumers will contact the manufacturer of the drug rather than the FDA in order to obtain financial compensation.[129] It is clear that the burden of retaining responsibility for monitoring the drug even after it is on the market applies equally to brand–name and generic manufacturers.[130]

When the Court in PLIVA distinguished Wyeth as a case about a generic drug manufacturer, it could not have meant that these requirements for post-market surveillance do not apply to generic manufacturers.[131] In fact, the Court in Wyeth stated that "the FDA's views are 'controlling unless plainly erroneous or inconsistent with the regulation[s]' or there is any other reason to doubt that they reflect the FDA's fair and considered judgment."[132] Thus, as the FDA has determined that it is almost exclusively the manufacturer's responsibility to conduct post-market surveillance, surely this must apply to generic drug companies, as they are also drug manufacturers.[133] The entry of many new generic drugs on the market due to the Hatch-Waxman Act, and the small amount of resources available for the FDA to monitor the more than ten thousand drugs on the market remain controlling factors even when the plaintiff happens to be a generic manufacturer.[134]

As in Bartlett, it therefore seems that a plaintiff in a state tort suit against a generic drug manufacturer may be able to prevail on a design defect theory of liability.[135] This is because the generic manufacturer has a duty to weigh the risks and benefits of producing the drug, and it can be held liable for choosing to make an unreasonably dangerous product.[136] Even though the FDA had never withdrawn its "safe and effective" approval of the drug, the manufacturer could nonetheless be held liable for making a product with risks of harm that outweigh the benefits.[137] Under this scheme, state juries would be allowed to second guess the FDA's approval as an additional layer of oversight for manufacturers.[138] Accordingly, manufacturers would have to give careful thought as to whether they ought to be making the drug at all.[139]

The Supreme Court has not yet ruled on the applicability of design defect claims in cases such as the federal preemption claims in *PLIVA*.[140] However, the Supreme Court noted that the result in *PLIVA was "unfortunate," "bizarre" and "unusual."*[141] Therefore, the Supreme Court may be likely to uphold

a tort claim against a generic drug manufacturer under the design defect theory of liability.[142]

B. Require manufacturers of equivalent drugs to monitor the generic and brand–name version under a modified shared market liability theory.

The Court in PLIVA noted the bizarre outcome of Mensing's state tort claim due to FDA regulations.[143] Had Mensing been given the brand–name Reglan instead of the generic version metoclopramide, she would have prevailed in her case against the brand–name manufacturer.[144] Mensing was given metoclopramide at the discretion of her pharmacist.[145] It is unlikely that most consumers of generic drugs would know the minutiae of FDCA regulations well enough to ask for the brand–name version as an assurance they would succeed in a failure to warn claim. Further, many insurance plans require that prescriptions be filled by generic drugs. Therefore, as the current system provides incentives for making generic drugs more available and less expensive to increase accessibility to important medicines, it also follows that the drug companies responsible for creating increased access should be held responsible if their products cause harm.[146]

As the regulations currently stand, generic manufacturers cannot independently change the label warnings as a brand–name manufacturer is able to do.[147] To remedy this, Congress could amend 21 C.F.R. §§ 314.70 and 314.97 to allow generic drug manufacturers to be able to unilaterally strengthen their warning labels.[148] However, this could possibly lead to consumer confusion as the same drug could contain different warnings.[149]

Alternatively, Congress could amend the FDCA to explicitly place the burden on the manufacturers of equivalent brand–name and generic drugs to monitor their version of the listed drug and assess damages under a modified version of the shared market liability theory.[150] The concept of market share liability was first introduced in *Sindell v. Abbott Laboratories*.[151] Judith Sindell brought a state tort action, on behalf of herself and others, against Abbott Laboratories and other companies who manufactured the drug diethylstilbesterol ("DES").[152] DES was a synthetic version of estrogen, taken by pregnant women to prevent miscarriages between 1941 and 1971.[153] DES posed a high risk, and indeed caused cancerous vaginal and cervical growths in thousands of daughters whose mothers took the drug during pregnancy.[154] The cancer and growths spread quickly and required painful and frequent surgeries and medical procedures.[155] During the period in which DES was marketed, the makers of the drug knew, or should have known of the risk of cancer, as well as the drug's ineffectiveness at preventing miscarriages.[156] Despite evidence showing that DES was not safe or effective, its makers continued to produce it and market it as a miscarriage preventative.[157] Sindell's mother took DES as a miscarriage preventative, and as a result, Sindell developed a malignant bladder and adenosis.[158]

Sindell argued, and the Supreme Court of California agreed, that each of the defendants were jointly liable as they acted in concert, on the basis of express and implied agreements, and in reliance upon the FDA's approval and each other's testing and marketing methods.[159] The court emphasized that it was of great importance that the drugs each company produced were fungible, meaning the drugs are identical as to be freely exchangeable.[160] Thus, the court held that each manufacturer's liability would be equivalent to the share of the market it held at the time the drug was taken.[161] However, if a manufacturer could prove that it did not, or could not have manufactured the drug at issue in the case, it would not be liable for damages.[162] Therefore, if a plaintiff knew which manufacturer produced the drug that caused the harm, market share liability was precluded.[163]

To apply the market share liability theory to a failure to warn case against a generic drug manufacturer, the theory would need to be modified. The requirement that the plaintiff be unaware of exactly what manufacturer caused the harm would need to be eliminated, as the person who is injured by a generic drug is aware of what company manufactured the drug.[164] This way, a patient who is injured by a generic drug would have a course of action against all of the drug companies who make the drug, regardless of whether they are generic or brand–name manufacturers.[165] Under this framework, the drug company would have to pay the percentage of damages equal to its percentage of the market it occupies for the drug it is selling.[166] The policy

behind this is that all manufacturers of a drug that is potentially very dangerous should be responsible for the effects thereof.[167] In this manner, drug companies would have an incentive for working together with and sharing improved technology and knowledge of adverse events.[168] It would likely create cooperation between drug companies that manufacture bioequivalent drugs, brand–name or generic, as each would have an incentive to account for all risks, as all would be responsible if a person is injured due to a failure to warn.

V. CONCLUSION

It is inherently unfair that a patient who receives a drug from a pharmacist who made a decision to substitute a generic version of a drug for a brand–name version will be unable to prevail in a failure to warn tort case, despite how horrific their damages are. The Hatch-Waxman Act provides incentives for generic drug companies to enter the market for the laudable goal of increasing access to new drugs. However, the federal regulations that implement the Act require that the labeling of the generic drug be identical to that of the brand–name drug. This creates the unintended consequence of prohibiting a generic drug manufacturer from strengthening its warning label, regardless of how many documented cases it receives of adverse effects. Further, due to federal preemption, the Supreme Court has held that generic manufacturers cannot warn against adverse effects without the brand–name manufacturer doing so first.

Moreover, as federal regulations currently stand, a brand–name manufacturer has no duty to change its label even in response to pleas from a generic drug manufacturer. This leads to the real world consequence of severely injured patients being left with no form of recourse against a company whose product injured them. To remedy this problem, the FDCA could be amended to allow courts to conduct risk–benefit analysis of the reasonable safety of the drug itself, and expressly state that failure to warn and design defects claims are not federally preempted. In this way, a generic manufacturer could be held liable under a theory of design defect in products liability, rather than under a theory of failure to warn. This would force generic manufacturers to consider whether they ought to be making a drug with severe adverse effects. However, it would be preferable to amend FDCA to allow generic manufacturers to change their warnings, as this would allow some drugs that would potentially be taken off the market under the design defect theory would to remain on the market.

Alternatively, Congress could amend the FDCA to explicitly place the burden on manufacturers who manufacture equivalently identical drugs to monitor each other through a modified market share liability scheme. Under this scheme, all manufacturers of a bioequivalent drug would be held liable for damages caused by that drug in proportion to their share of the market of the drug. This would cause the market to police itself, independently checking the warning label, and creating a sense of urgency in the brand–name drug to change its label in response to reporting of adverse events. In either case, Congress must act to provide individuals who are injured by generic drugs with an avenue of recourse.

[1] *See generally* 21 U.S.C. § 355 (2006); P.L. 75-717 (1938) (as amended by P.L. 112-144 (July 9, 2012)).
[2] *See* 21 U.S.C § 355(j); P.L. 98-417 (1984).
[3] *See id*.
[4] *See* Drug Price Competition and Patent Term Restoration Act of 1984: Hearing Before the S. Comm. on the Judiciary, 108th Cong. (2003) [hereinafter *Hearings*] (statement of Daniel E. Troy, Chief Counsel, United States Food & Drug Admin.), *available at* http://www.fda.gov/NewsEvents/Testimony/ucm115033.htm.
[5] *See* PLIVA Inc. v. Mensing, 131 S. Ct. 2567, 2581 (2011) (holding state tort law is preempted by federal law under the Supremacy Clause, thus precluding a failure to warn claim against a generic manufacturer); *Bartlett v. Mut. Pharm. Co*., 678 F.3d 30, 37-38 (1st Cir. 2012) (ruling for the patient under a products liability theory, realizing that a failure to warn theory is likely to fail).
[6] *See PLIVA Inc.*, 131 S. Ct. at 2581; *Bartlett*, 678 F.23 at 37.
[7] *See Bartlett*, 678 F.3d at 35, 37.
[8] 21 U.S.C. §§ 301–99.
[9] Food, Drug, and Cosmetic Act § 201(g)(1)(B).
[10] *See* 21 U.S.C. § 355(a). While federal law only applies to drugs within interstate commerce, the FDCA has been interpreted broadly to include all drugs marketed or manufactured in the United States; *see* Food & Drug Admin., Compliance Policy Guide § 440.100, Marketed New Drugs Without Approved NDAs and ANDAs (2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm.
[11] Peter Barton Hutt, Richard A. Merrill, & Lewis Grossman, Food & Drug Law: Cases & Materials 14 (3d ed. 2007). *See generally* 21 U.S.C. § 355 (a)–(e), (h) (as amended by P.L. 112-144 (July 9, 2012)); Weinberger v.

Hynson, Westcott, & Dunning Inc., 412 U.S. 609, 612–14 (1973) (affirming the constitutionality of the shift to premarket approval).

[12] Hutt Et Al., *supra* note 11, at 577.

[13] *See id.*

[14] *See id.* (stating it takes 10 to 15 years to develop the chemical that will become the drug, about five out of every 5,000 chemicals reach the clinical testing stage, and the average cost of the NDA process is about $1 billion).

[15] 21 U.S.C. §§ 355(b)(1), 355(d).

[16] Hutt Et Al., *supra* note 11, at 677.

[17] *See* Christopher Lea Lockwood, Comment, Biotechnology Industry Organization v. District of Columbia: *A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals,* 19 Alb. L.J. Sci. & Tech. 143, 148 (2009).

[18] *See* 21 C.F.R § 312.23(a)(8).

[19] *See* 21 U.S.C. § 355(d).

[20] *See* Peter Barton Hutt, *The Regulation of Drug Products by the United States Food and Drug Administration*, in Food & Drug Law: Cases And Materials 677 (3d ed. 2007) (noting the FDA has exercised discretion in assessing the requirements to show safety and effectiveness).

[21] *See id.*

[22] *See* 21 U.S.C. § 352.

[23] *See* 21 U.S.C. §§ 352(f),(n); 21 C.F.R. § 201.25.

[24] *See* 21 U.S.C. § 355(b)(1), (j)(7)(A)(iii). When the FDA approves an NDA it publishes a listing of the drug in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

[25] *See* 21 U.S.C. § 355(k); 21 C.F.R. §§ 314.80–81.

[26] *See* 21 C.F.R. §§ 314.80, 314.81, 314.98.

[27] *See* 21 C.F.R. § 314.70(c)(6)(iii).

[28] *See id.*

[29] *See* 21 C.F.R. § 201.57(c)(6).

[30] *See* 21 C.F.R. § 314.70(c)(6)(iii)(D).

[31] *See* 21 C.F.R. § 314.70(c)(6)(iii)(A), (C)–(D); Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 686 (E.D. Pa. 2006) (stating letters to doctors are not labeling changes and are not prohibited by labeling regulations). *But see* 21 C.F.R. § 202.1(1)(2) (according to FDA labeling regulations, letters to doctors can be considered as labeling for a drug).

[32] *See* 21 U.S.C § 355(j); P.L. 98-417 (1984); Peter Barton Hutt, *Landmark Pharmaceutical Law Enacted*, 1 Health Scan, No. 3, p. 11 (1984).

[33] *See* 21 U.S.C § 355(j); 27 U.S.C. § 271(e)(1).

[34] *See* 21 U.S.C § 355(j); 27 U.S.C. § 271(e)(1).

[35] *See* 21 U.S.C § 355(j); 27 U.S.C. § 271(e)(1); 21 C.F.R. § 320.1(e) (defining bioequivalence as the absence of a significant difference in the rate and extent of the active ingredient's effects when administered at the same dose under similar conditions).

[36] *See* 21 C.F.R. § 314.94.

[37] *See* 21 U.S.C § 355(j); C.F.R. § 314.94(a)(8)(i), (iv) (except in the case of inert ingredients, which are not required to be identical to the listed drug).

[38] *See* 21 U.S.C § 355(j).

[39] *See* 21 U.S.C. § 355(j)(2)(v) (except for changes required because of differences approved under petition or because the new drug and the listed drug are produced or distributed by different manufacturers).

[40] *See Hearings*, *supra* note 4.

[41] *See e.g.*, *id.*

[42] *See id.*

[43] *See id.* ("Since 1984, over 10,000 generic drugs have entered the market, and generics now account for close to fifty percent of prescriptions filled."); Hutt Et Al., *supra* note 11, at 764 (raising the concern that pioneer drugs are being displaced by generic drugs and fewer pioneer drugs are being approved by the FDA).

[44] 21 U.S.C. § 355(j)(2)(A); *see* Fed. Trade Comm'n, Authorized Generic Drugs: Short-term Effects and Long-term Impacts 2 (2011) *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf.

[45] 21 U.S.C. § 355(j)(5)(B)(iv); *see* Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 Alb. L.J. Sci. & Tech. 441, 449 (2008).

[46] *See* United States Food & Drug Admin., *Generic Competition and Drug Prices*, (last updated Mar. 1, 2010), [hereinafter *FDA Study*] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm. *See generally* Erika King Lietzan, *A Brief History of 180–Day Exclusivity Under the Hatch Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 Food & Drug L.J. 287 (2004).

[47] *See FDA Study*, *supra* note 46.

[48] *See* Hutt, *supra* note 32, at 11.

[49] *See* 131 S. Ct. 2567, 2574–75 (2011).

[50] *See* Eli Lily & Co. v. Medtronic Inc., 496 U.S. 661, 679 (emphasizing that the Act is not an "elegant piece of statutory draftsmanship," and it creates a "good deal of legal imprecision"); *cf. PLIVA Inc.*, 131 S. Ct. 2567, 2581 (describing the effects of the Act on state tort liability as unfortunate, unusual and bizarre); *see also* 21 U.S.C. § 355(j)(2)(v) (Congress based the framework on the generic–brand and name–brand being identical in all meaningful aspects, thus federal law preempts state law that requires the generic manufacturer to unilaterally change the label by adding a warning).

[51] 555 U.S. 555 (2009).

[52] *See Wyeth*, 555 U.S. at 559 (the "IV–push" method involves directly injecting the drug into the patient's vein, as opposed to the "IV–drip" method which involves the drug slowly entering through an intravenous hanging bag with saline solution).

[53] *See id.*

[54] *See id.* at 560.

[55] *See id.* (advocating that the label should have instructed providers to prefer the "IV–drip" method over the "IV–push" method).

[56] *See id.* (asserting a cost-benefit analysis also used in a products liability theory of recovery).

[57] *See id*. at 560, 573 (asserting that once FDA has approved a label, a state may not deem that it is inadequate, even if there is evidence the FDA considered the strengthened warning at issue).

[58] *See id.* at 575 (citing Requirements on Content and

Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3992, 3935 (Jan. 24, 2006) (codified at 21 C.F.R. pt. 201, 314, and 601).

[59] *See id.* at 571-72, 581.

[60] *See id.* at 571.

[61] *See id.* at 570–71 (rejecting Wyeth's argument that the FDA has primary responsibility for a drug's labeling); 21 C.F.R. §§ 201.80(e), 314.80(b); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49605 (Aug. 22, 2008) (codified at 21 C.F.R. pt. 314, 601, 814) (reiterating that manufacturers retain their responsibility to maintain and update drug labels).

[62] *See Wyeth*, 555 U.S. at 571.

[63] *See id.* at 576–78.

[64] *See id.*

[65] *See id.* (citing Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81103 (codified at 21 C.F.R. pt. 201) ("this proposed law does not preempt state law.")).

[66] *See id.* at 577 (citing Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)) ("the weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness.).

[67] *See id.* at 578.

[68] *See id.*

[69] *See id.* at 578–79.

[70] *Id.* at 570–71 ("It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug remains on the market."); *see e.g.,* 21 C.F.R. § 201.80(e) (stating a manufacturer must revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); § 314.80(b) (requiring manufacturers to continue to monitor a drug even after it is approved for the market).

[71] 131 S. Ct. 2567 (2011).

[72] *Id.* at 2569.

[73] *Id.* at 2572.

[74] The Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355(j)(2)(A)(2006).

[75] *PLIVA Inc.*, 131 S. Ct. at 2572.

[76] *See id.*

[77] *See id.* at 2574–75; *see also* Erwin Chemerinsky, *A Devastating Decision*, 47 Trial, 54, 54 (Sept. 2011).

[78] *See PLIVA, Inc.*, 131 S. Ct. at 2576.

[79] *See id.* at 2577–78.

[80] *See id.* at 2581.

[81] *See id.* (lamenting the "unfortunate hand" dealt to Mensing by federal drug regulations).

[82] *See id.* (observing the "bizarre" result of the FDA regulations but concluding: "We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme.").

[83] *See generally* 678 F. 3d 30, 35 (1st Cir. 2012). Notably, the Supreme Court left the door open for alternative interpretations when it stated that it did not resolve the issue of whether federal law placed a burden on the generic manufacturers to ask for the FDA's assistance in convincing the brand–name manufacturer to adopt a stronger warning label. *See PLIVA, Inc.*, 131 S. Ct. at 2577.

[84] *See* 21 C.F.R. § 314.70(c)(6)(iii); *PLIVA, Inc.*, 131 S. Ct. at 2576.

[85] *See* Transcript of Oral Argument at 3–5, Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012)(No. 12-142). *But see* Brief for Petitioner at 48 Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No. 12-142) (arguing that the purposes of the Hatch-Waxman Act would be frustrated if the design defect theory of liability were to stand).

[86] *Compare* Bartlett v. Mutual Pharmaceutical Co., 678 F. 3d 30 (1st Cir. 2012), *with PLIVA, Inc.*, 131 S. Ct. at 2577–78.

[87] 678 F.3d 30 (1st Cir. 2012).

[88] *Id.* at 38; *See First Circuit Rejects Preemption Argument in Generic Drug Design Defect Case*, 21 FDA Enforcement Manual Newsl. (June 2012).

[89] *Bartlett*, 678 F.3d at 34. The brand name of sulindac is Clinoril. *Sulindac*, PubMedHealth (last updated Sept. 1, 2010), http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000529/.

[90] *Bartlett*, 678 F.3d at 34.

[91] A skin disorder that is thought to occur in response to medications, infections, or illness. It is also known as Erythema Multiforme. The symptoms include painful symmetrical skin lesions that cause complete deterioration of the affected skin. SJS/TEN has high death rates and lesions cover a significant portion of the body. *Erythema Multiforme*, MedLinePlus (last updated Oct. 10, 2010), http://www.nlm.nih.gov/medlineplus/ency/article/000851.htm.

[92] *See Bartlett*, 678 F.3d at 34.

[93] *Id.*; Transcript of Oral Argument at 10–11, Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No. 12-142); *cf.* 21 C.F.R. § 320.1(e) (as the drugs are required to be bioequivalent, the generic drug sulindac would have posed the same risk as the brand–name version, Clinoril).

[94] *See Bartlett*, 678 F.3d at 34.

[95] *Id.*

[96] *See id.* at 43 (describing Bartlett's injuries including esophageal, vaginal, eye, and lung burns as "truly horrific" and "hell on earth").

[97] *See id.* at 34–35.; 21 U.S.C. §§ 355(b)(1), (d), (j)(2)(a) (allowing a generic drug manufacturer to gain approval of a generic drug as "safe and effective" if it is virtually identical to a previously approved brand–name drug).

[98] *Bartlett*, 678 F.3d at 35.

[99] *Id.* at 36.

[100] *See id.* at 37.

[101] *See id.*

[102] *See* Wyeth v. Levine, 555 U.S. 555, 575 (2009) (announcing that Congress did not intend FDA oversight to be the only way to ensure compliance with drug safety and effectiveness); Transcript of Oral Argument at 18, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No. 12-142) (stating the analysis implies the manufacturer could simply stop selling the dangerous product).

[103] *See Wyeth*, 555 U.S. at 575.

[104] *Cf. id.* at 575.

[105] *Bartlett*, 678 F.3d at 37–38.
[106] *See* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012). *Compare PLIVA, Inc.*, 131 S. Ct. at 2576, *and* Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (holding the Medical Device Amendments preemption clause bars a challenge to the safety and effectiveness of an FDA approved medical device), *and* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 524 (1992) (holding the Federal Cigarette Labeling and Advertising Act preempts a state failure to warn claim), *with* Bartlett v. Mut. Pharm. Co., 678 F. 3d 30, 35 (1st Cir. 2012).
[107] *See* Brief for Petitioner at 1 Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No-12-142).
[108] Brief for Generic Pharm. Assoc. as Amici Curiae Supporting Petitioner at 9, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No-12-142) (citing *PLIVA, Inc.*, 131 S. Ct. at 2579).
[109] Brief for Respondent at 23–24, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No-12-142).
[110] Brief for Respondent at 24, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No-12-142); *see PLIVA, Inc.*, 131 S. Ct. at 2573.
[111] Brief for The American Assoc. for Justice & Public Justice as Amici Curiae Supporting Respondent at 6, 9, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No-12-142).
[112] *See* Sara C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 Vand. J. Ent. & Tech. L. 185, 210 (Fall 2010) (suggesting compensatory scheme similar to the Vaccine Injury Compensation Trust Fund); Allen Rostron *Beyond Market Share Liability: A Theory of Proportional Share Liability for Nonfungible Products*, 52 Ucla L. Rev. 151, 152 (2004) (suggesting the use of market share liability without the requirement of fungibility).
[113] 678 F.3d 30, 37 (1st. Cir. 2012).
[114] *Id.*
[115] *See e.g.*, *id.* at 36–37. (stating it was proper for the plaintiff to show the generic drug was unreasonably dangerous and perhaps it should not be manufactured at all).
[116] *Cf.* PLIVA Inc. v. Mensing, 131 S. Ct. 2567, 2577 (2011) (leaving the door open as to whether it is the generic manufacturer's responsibility to persuade the brand–name manufacturer to strengthen its label).
[117] *See* Wyeth v. Levine, 555 U.S. 555, 570-71 (2009).
[118] *Id.* at 571.
[119] *See id.*
[120] *See id.* at 571; 21 C.F.R. §§ 314.70, 601.12.
[121] *See Wyeth*, 555 U.S. at 571; 21 C.F.R. §§ 314.70, 601.12.
[122] *Wyeth*, 555 U.S. at 571; *see* 21 C.F.R. §§ 314.70, 601.12.
[123] *Wyeth*, 555 U.S. at 571.
[124] *See id.*
[125] *See* PLIVA Inc. v. Mensing, 131 S. Ct. 2567, 2581 (2011).
[126] *Id.* at 578–79.
[127] *Id.*
[128] *See id.*
[129] *See id.*
[130] *See id*. at 571; PLIVA Inc. v. Mensing, 131 S. Ct. 2567, 2576 (2011); U.S. Dept. of Health & Human Servs., Food & Drug Admin, *Drug Applications and Current Good Manufacturing Regulations*, (last updated Sept, 7, 2012), http://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm090016.htm (stating that FDA may not approve NDAs from companies who have been cited for failing to adhere to current good manufacturing practices).
[131] *Cf. PLIVA Inc*., 131 S. Ct. at 2576 (citing *Wyeth*, 555 U.S. at 570–571) (a generic–brand drug manufacturer retains responsibility for its drug labeling at all times precisely because it is a drug manufacturer).
[132] *Id.*; Auer v. Robbins, 519 U.S. 452, 461 (1997).
[133] *See e.g.*, *PLIVA Inc*., 131 S. Ct. at 2576; *Auer*, 519 U.S. at 461–462.
[134] *See Wyeth*, 555 U.S. at 571; 21 C.F.R. §§ 314.70, 601.12.
[135] *See* Bartlett v. Mutual Pharm. Co. 678 F.3d 30, 36 (1st Cir. 2012).
[136] *See id.* at 36–37.
[137] *See id.* at 34–35.
[138] *E.g. id.* at 37 (citing *Wyeth*, 555 U.S. at 575 ("state law serves as a 'complementary form of drug regulation'")).
[139] *See id.* at 37–38 (suggesting the generic manufacturer perform additional risk–benefit analysis).
[140] *See id.* at 36. *See generally* PLIVA Inc. v. Mensing, 131 S. Ct. 2567, 2581 (2011).
[141] *See PLIVA Inc.*, 131 S. Ct. at 2581.
[142] *See id.* at 4 (stating the Supreme Court would be less likely to deprive Bartlett of her only "remaining avenue of relief.").
[143] *See id.* at 2581.
[144] *See id.*
[145] *See PLIVA Inc.*, at 2574–75.
[146] *See Hearings*, *supra* note 4 (noting the multiple objectives of the Hatch-Waxman Act of encouraging innovation while maintaining FDA's high standards of safety and effectiveness); *PLIVA Inc.*, 131 S. Ct. at 2576 (citing *Wyeth*, 555 U.S. at 570–571) (asserting a drug manufacturer, without regard to whether it is brand–name or generic, retains responsibility for its drug labeling at all times).
[147] *See* 21 U.S.C. § 355(j)(2)(v) (stating that the generic label must be identical to the brand-name label).
[148] *See* Duncan, *supra* note 112, at 209 (suggesting the amendment of federal regulations to allow generic manufacturers to be able to change their labels); Transcript of Oral Argument at 11–12, Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 694 (2012) (No. 12-142) (discussing the possibility of a strict liability regime similar to the vaccine compensation program). *But see* 21 U.S.C § 355(j) (requiring the generic label to be identical to the brand–name label).
[149] *See* Duncan, *supra* note 112, at 209 (noting that any remotely dangerous condition associated with the drug could be listed as a warning, and could cause confusion even between different generic–brand drugs); 21 U.S.C. § 355(j)(2)(A)(2006).
[150] *See generally* Sindell v. Abbott Labs., 607 P.2d 924 (Cal. 1980).
[151] *See id.*
[152] *See id.* at 925.

[153] *See id.* (the procedures included cauterization, surgery, cryosurgery, biopsy or colposcopic examination).
[154] *See id.*
[155] *See id.*
[156] *See id.* at 926.
[157] *See id.* at 925–36.
[158] *See id.* at 926 (adenosis is a condition that causes precancerous vaginal and cervical growths which may spread to other areas of the body).
[159] *See id.*
[160] *See id*. ("DES was produced from a common and mutually agreed upon formula as a fungible drug interchangeable with other brands of the same product"). Market share liability does not apply to nonfungible products. *See* Setliff v. E. I. Du Pont de Nemours & Co., 38 Cal. Rptr. 2d 763, 769 (Dist. Ct. App. 1995); Edwards v. A.L. Lease & Co., 54 Cal. Rptr. 2d 259, 262 (1st Dist. 1996).
[161] *Sindell*, 607 P.2d at 938.
[162] *See id.*
[163] *See id.*; Edwards v. A.L. Lease & Co., 54 Cal. Rptr. 2d 259, 263 (1st Dist. 1996) (dismissing the case because plaintiffs could identify those who caused the harm). Since *Sindell*, courts have generally only applied the market share liability theory to fungible products. *See* Smith v. Cutter Biological, Inc., 823 P.2d 717, 724 (Haw. 1991); Hymowitz v. Eli Lilly & Co., 539 N.E.2d 1069, 1081 (N.Y. 1989); Martin v. Abbott Labs., 689 P.2d 368, 381 (Wash. 1984); Collins v. Eli Lilly & Co., 342 N.W.2d 37, 44 (Wis. 1984). *But see* Skipworth v. Lead Indus. Ass'n, 690 A.2d 169, 172-73 (Pa. 1997) (rejecting market share liability for lead paint as different colors contain varying amounts of lead rendering them nonfungible); Rostron, *supra* note 112, at 154 (arguing market share liability should be applied to nonfungible products). Some states have refused to apply market share liability regardless of whether the product is fungible. *See* Smith v. Eli Lilly & Co., 560 N.E.2d 324, 337 (Ill. 1990) (Illinois); Mulcahy v. Eli Lilly & Co., 386 N.W.2d 67, 76 (Iowa 1986) (Iowa); Zafft v. Eli Lilly & Co., 676 S.W.2d 241, 247 (Mo. 1984) (en banc) (Missouri); Sutowski v. Eli Lilly & Co., 696 N.E.2d 187, 192 (Ohio 1998) (Ohio); Gorman v. Abbott Labs., 599 A.2d 1364, 1364 (R.I. 1991) (Rhode Island). However, other states have chosen not to explicitly accept market share liability, but indicate that if they were to, it would only be applicable to fungible products. *See, e.g.*, Black v. Abex Corp., 603 N.W.2d 182, 189 (N.D. 1999) (declining to adopt market share liability but nonetheless stating that plaintiff would have had to prove fungibility); Case v. Fibreboard Corp., 743 P.2d 1062, 1065, 1067 (Okla. 1987) (declining to adopt market share ability but stating it is of importance that the drugs in *Sindell* were fungible as it was produced from a single formula and used for a singular purpose). Market share liability provides a meaningful way to hold manufacturers who produce harmful products liable for injuries the product causes. *See Sindell*, 607 P.2d at 926; Rostron, *supra* note 112, at 158 (citing Symposium, *The Problem of the Indeterminate Defendant: Market Share Liability Theory:* Hymowitz v. Eli Lilly & Co., 55 Brook. L. Rev. 863 (1989).
[164] *E.g.*, Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 34 (1st Cir. 2012) (plaintiffs could identify the drug they took as sulindac and the manufacturer as Mutual Pharmaceutical Company); PLIVA Inc. v. Mensing, 131 S. Ct. 2567, 2581 (2011) (plaintiffs could identify the drug they took as metoclopramide and the manufacturer as PLIVA Inc.); Edwards v. A.L. Lease & Co., 54 Cal. Rptr. 2d 259, 262 (1st Dist. 1996) (case dismissed because the plaintiffs could identify those who caused the harm). *But see Sindell*, 607 P.2d at 927-28 (plaintiffs were unable to identify the manufacturer of the DES their mother took); Abel v. Eli Lilly & Co., 343 N.W.2d 164, 168 (Mich. 1984) (plaintiffs were unable to identify the manufacturer, and thus could use the market share liability theory).
[165] *Compare PLIVA Inc.*, 131 S. Ct. at 2575–77 (finding impossibility preemption and thus no generic manufacturer liability), *with Sindell*, 607 P.2d at 936–37 (allowing a shared market share liability scheme).
[166] *See Sindell*, 607 P.2d at 611–12.
[167] *See* Rostron, *supra* note 112, at 158.
[168] *See id.*

There's a Coupon for that: How Coupons for Medical Services on Daily Deal Websites Violate the Federal Anti-kickback Statute

*Claudia Ahiabor**

I. INTRODUCTION

"Flaunt your beaming beauty with today's Groupon: for $150, you get an in-office Zoom! teeth-whitening treatment (an $800 value), x-rays (a $187 value), and a new-patient exam (a $99 value) . . . (a $1,086 total value)."[1] Groupon, a portmanteau derived from group and coupon, is a daily deal website where customers can purchase coupons for goods and services at local businesses.[2] The Groupon business model is relatively simple: a local business displays a coupon on its website with a pre-determined amount of coupons that must sell before the deal is applicable to any buyer.[3] Groupon gets a share of all coupons sold and the local business gains new customers, greater exposure, and increased market share.[4] The success of Groupon has led to the proliferation of daily deal websites on the Internet, targeting customers in specific cities or demographic groups.[5] Moreover, these sites are attracting providers of medical services, like general practitioners and health testing centers, hoping to reap such benefits.[6] Many coupons for medical services advertised on daily deal websites do not raise anti-kickback concerns since the advertised services are not covered by Federal health care programs. However, not all medical coupons advertised on daily deal websites are lawful under the anti-kickback statute.

The Department of Health and Human Services, Office of Inspector General ("OIG") — a government agency charged with combating fraud, waste and abuse in Federal health care programs — approved a proposed business arrangement akin to the daily deal website model.[7] In advisory opinion 12-02, the OIG favorably opined on a website that displayed coupons and advertisements from health care providers and suppliers, exclusively, for items and services billable to Federal health care programs.[8] However, the OIG was careful to distinguish the proposed arrangement from arrangements currently in effect that do raise kickback concerns.[9] The proposed arrangement stated, among other things, that customers would be able to print coupons that are only redeemable after services are rendered.[10] Customers would not pre-pay for the services they seek and the website would fully comply with the discount regulatory safe harbor, which excludes certain transactions from being considered "prohibited remuneration" under the anti-kickback statute.[11] The OIG found this arrangement posed a low risk of fraud and abuse under the anti-kickback statute because the marketer is not a health care provider, payments to the marketer did not depend on the volume or value of business, advertising on the site would be comparable to advertising in print media, and providers would not be unduly influenced to provide medically unnecessary services since customers would not pre-pay for coupons.[12] Under a similar analysis, the current arrangement between daily deal websites and providers of services billable to Federal health care programs presents an unacceptable risk of fraud and abuse because several important factors intrinsic in advisory opinion 12-02 do not exist.[13]

This article argues business arrangements between daily deal websites and providers of medical services nonetheless violate the anti-kickback statute because they arrange for the use of services billable to Federal health care programs through targeted advertising activity.[14] Furthermore, parties to this arrangement, as currently structured, are unlikely

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to evade prosecution under the criminal and civil penalties of the statute since these arrangements follow a percentage compensation structure and do not fall within applicable regulatory safe harbors.[15] Part II examines the federal anti-kickback statute jurisprudence and rules applicable to arrangements between daily deal websites and health care providers.[16] Part III argues that while daily deal websites do not actively market to beneficiaries of Federal health care programs, the peculiarities of this arrangement, such as the financial incentive to increase the number of customers purchasing coupons, support an inference of illegality under the anti-kickback statute.[17] Part III also posits that regulatory safe harbors for personal services and management contracts and for discounts do not shield parties under this arrangement from criminal prosecution because compensation under this arrangement takes into account the volume of generated business.[18] Part IV argues the discount regulatory safe harbor should be amended to encompass these arrangements because Congress intended the safe harbors to evolve to reflect current business practices.[19] Lastly, this article concludes that unless the regulatory safe harbors are amended to encompass the daily deal website structure, participants in these arrangements are at an increased risk of liability under the anti-kickback statute.

II. BACKGROUND

A. Judicial Enforcement of the Anti-kickback Statute and the Government's Burden of Proof

Congress enacted the anti-kickback statute to deter the practice of providing remuneration as an inducement to refer services reimbursable by Federal health care programs.[20] The anti-kickback provision of the Social Security Act of 1972 prohibits kickbacks, bribes, or rebates offered directly or indirectly, overtly or covertly, in return for referring individuals for items or services payable by Federal health care programs.[21] Furthermore, referrals under the statute include arranging for or recommending purchasing, leasing, or ordering goods and services for which payment may be made, in whole or in part, by the federal government.[22] Such broad language implicates even mundane business transactions in the healthcare industry, and it applies to all federally funded healthcare programs.[23] The impetus behind the enactment of the anti-kickback statute is the prevention of program abuse and fraudulent claims and the protection of program beneficiaries.[24]

In 1985, the Third Circuit held in *United States v. Greber* that the federal anti-kickback statute is violated so long as one purpose of a business arrangement is to induce future referrals.[25] The "one-purpose" doctrine judiciously broadened the scope of the anti-kickback provision and is the standard by which courts and the OIG analyze possible violations.[26] In addition, for a successful criminal conviction under the statute the federal government must prove that the defendant knowingly and willfully intended to transfer prohibited remuneration.[27] Unlike the "one-purpose" doctrine - the majority rule - courts were split on how the government must prove the requisite intent.[28] However, the Patient Protection and Affordable Care Act in 2010 clarified the *mens rea* requirement by expressly stating that the defendant need not have actual knowledge or specific intent to violate the statute.[29]

In the same way, anti-kickback statute violations ultimately depend on the totality of the circumstances.[30] The government need not find specific instances of fraud and abuse of Federal health care programs to prosecute under the statute.[31] The potential for abuse, coupled with inadequate safeguards, makes practitioners and daily deal websites vulnerable to prosecution.[32] Entities involved in arrangements that do not adequately satisfy the requirements of a regulatory safe harbor are especially vulnerable.[33]

B. Regulatory Safe Harbor Exceptions to the Anti-kickback Statute

The practice of discounting is statutorily exempt from the anti-kickback statute only if discounts are properly disclosed and reflected in reimbursement claims submitted to Federal health care programs.[34] In addition, Congress authorized the OIG to issue regulations specifying payment practices that are protected from criminal and civil liability.[35] Accordingly, several legally sanctioned activities, written in the Code of Federal Regulations, shield an entity from both civil and criminal prosecution.[36] However, failure to fall within one of the regulatory

safe harbor exceptions does not automatically make an arrangement unlawful; rather, the arrangement is assessed under the statute for legality.[37] The OIG often issues advisory opinions on the applicability of a particular safe harbor provision to a hypothetical arrangement in cases where the legality of an arrangement may be unclear.[38]

Of the twenty-five safe harbor exceptions, one of the most important provisions to the daily deal business arrangement is the discounts safe harbor provision.[39] For daily deal websites to fall within the discount safe harbor, a claim submitted by a seller on behalf of a buyer must show the discount was provided at the time of service.[40] Furthermore, the seller must be able to show, upon request, that the offeror, which is an entity that promotes the purchase of an item or service, notified the seller of its obligations to report such a discount.[41] A medical provider who submits a claim on behalf of a patient who bought a coupon from a daily deal website must show that the discount was made at the time of service and that the daily deal website notified the seller of its obligation to report the discount; otherwise, the safe harbor provision does not apply.[42]

Furthermore, the safe harbor for personal services and management contracts is relevant to daily deal website arrangements.[43] This safe harbor exempts service contracts from anti-kickback scrutiny if they fully comply with the seven requirements outlined in the provision.[44] These requirements include that a business arrangement must serve a reasonable commercial purpose and it must not be based on the volume of business generated by the principal and the agent.[45] An agent for purposes of the safe harbor is any person other than a bona fide employee of the principal.[46]

Like other provisions of the statute, the intent behind a payment arrangement is controlling in the determination of compliance with the discount safe harbor.[47] Thus, a profit motive alone may be insufficient to prove intent to transfer illegal remuneration.[48] Yet there may be cases where a jury can infer intent to induce referrals of beneficiaries of Federal health care programs where the profit motive is overwhelming.[49]

C. Business Arrangements that are Highly Disfavored by the OIG Because of Their Susceptibility to Abuse

The parties in *Zimmer, Inc. v. Nu Tech Medical, Inc.* agreed to a percentage-based compensation agreement where a manufacturer of orthopedic products, Zimmer, consigned products to a supplier of medical items, Nu Tech.[50] Nu Tech would then distribute to physician offices and bill Medicare.[51] Nu Tech would retain a percentage of all reimbursements depending on the volume of billable products.[52] Zimmer sought an advisory opinion when the parties began to differ on the proper execution of the contract.[53] Zimmer also filed suit seeking a declaratory judgment that the contract was unenforceable since it violated the anti-kickback statute.[54] This advisory opinion was fully considered and incorporated by the District Court for the Northern District of Indiana in its opinion.[55] It is not unusual for a court to defer to the conclusions of an advisory opinion in judicial proceedings when analyzing possible violations of the anti-kickback statute.[56] Advisory opinion 98-01 was an analysis of the proposed arrangement between Zimmer and Nu Tech.[57] The *Zimmer* court adopted this opinion to conclude that the proposed arrangement presented significant financial incentives to increase marketing and billing practices, that Nu Tech would unduly influence referral sources and patients, and that the arrangement contained insufficient safeguards against fraud and abuse.[58]

Nursing Home Consultants v. Quantum Health Services exemplifies another case where percentage compensation agreements have been found illegal under the anti-kickback statute.[59] In *Quantum Health Services*, Quantum, a medical equipment supplier, and NHC, a marketer of medical supplies, entered into a contract that obligated NHC to identify Medicare recipients who needed medical supplies and arrange for the recipients to purchase supplies from Quantum.[60] NHC's compensation was tied to the number of units of medical supplies Quantum sold, so the more Medicare business NHC sent to Quantum, the greater NHC's compensation.[61] The United States District Court for the Eastern District of Arkansas found the underlying marketing agreement illegal and unenforceable under the anti-

kickback statute when NHC filed a breach of contract claim.[62] The court further held that the marketing agreement was not shielded by the safe harbor for personal services since compensation was based on the number of sales NHC generated.[63]

Lastly, the anti-kickback statute does not distinguish between physicians and lay persons because either party can refer, arrange for, or recommend federal health care business.[64] The court in *United States v. Polin*, for instance, found this distinction a distortion of the Act.[65] In *Polin*, the medical director and registered nurse of a cardiac monitoring facility were charged with violating the anti-kickback statute when they paid a pacemaker salesman to recommend their services to beneficiaries of Medicare.[66] The court found this to be a classic kickback scheme explicitly prohibited by the statute.[67]

III. ANALYSIS

A. Arrangements Between Daily Deal Websites and Providers of Medical Services Violates the Anti-Kickback Statute Because They Present an Increased Risk of Fraud and Abuse.

The potential for business arrangements between daily deal websites and health care providers to encourage overutilization of Federal health care programs, and provision of medically unnecessary care, poses an unacceptable risk of program abuse.[68] Moreover, certain aspects of the current arrangement between these parties are not only potentially abusive, but also violative of the anti-kickback statute according to judicial and administrative interpretations.

1. Percentage Compensation Arrangements Have Been Disfavored by the Courts and the OIG Because of the Potential for Overutilization and the Financial Incentive to Increase Federal Health Care Business.

Business arrangements that encourage overutilization of services covered under Federal health care programs, or that otherwise increase program costs, pose an unacceptable risk of fraud and abuse.[69] In particular, the OIG has found percentage compensation arrangements potentially abusive because of the financial incentive to increase services billable to Federal health care programs.[70] Percentage compensation arrangements are susceptible to abusive practices because of the lack of safeguards against fraud and abuse, the financial incentives to increase abusive marketing practices, and the opportunity to unduly influence referral sources and patients.[71] Through specialized marketing, the hallmark of daily deal websites, these sites ensure a minimum threshold of customers for the practitioner utilizing its services.[72] In addition, daily deal websites necessarily have an incentive to exceed this threshold of customers to increase their financial gain.[73] This business arrangement encourages overutilization of Federal health care programs by incentivizing procurement of the maximum number of customers, of which the federal government is certain to pay for services rendered to beneficiaries of the programs.[74]

A pre-determined fee arrangement between these parties would help refute the notion that daily deal websites function as referral organizations or arrange for the purchase of reimbursable services because the underlying financial incentive to increase the supply of patients would be mitigated.[75] The OIG reached a favorable decision in advisory opinion 12-02 partly because the proposed arrangement established a set fee that would be paid in advance, irrespective of the volume of referrals.[76] The requestor would charge a flat monthly fee based on the level of a provider's membership.[77] In contrast, since compensation is tied to the volume of business in the case of daily deal websites, these arrangements pose an increased risk of fraud and abuse.[78] The OIG has maintained, in discussions of other proposed arrangements, that "per click," "per patient," and similar compensation arrangements are highly disfavored under the anti-kickback statute.[79]

Nevertheless, whether a profitable business arrangement was entered into with the intent to induce referrals of federally funded business is usually a question for a jury.[80] So long as the benefits of a profitable business scheme passes to the federal government, incentives to generate business may not be particularly troublesome.[81] Yet, in daily deal arrangements it is not always the case that the federal government reaps the benefits of a profitable business scheme. For example, where a customer buys a coupon for year-long membership in a

medical group, not every service billable to Federal health care programs will be discounted because the discount applies to membership fees and not health services.[82]

2. Daily Deal Websites Violate the Anti-Kickback Statute by Referring Patients to Practitioners and Arranging for or Recommending Services Reimbursable by Federal Health Care Programs.

Although it is left to a jury to decide whether the parties to an arrangement had the requisite intent to commit fraud, the substantive agreement between daily deal websites and providers of medical services alone is indicative of an intent to induce referrals of federally funded business.[83] As the court held in *Zimmer*, the four corners of the contract, when unambiguous, are an expression of the intent of the parties to the contract.[84] Since providers enter arrangements with daily deal websites to promote their business and to ultimately retain customers for the long term, a provider's retention of new customers using daily deal websites supports an inference of illegal conduct.[85]

The anti-kickback statute prohibits knowingly and willfully paying, offering, soliciting or receiving remuneration in return for referring an individual or arranging for any service for which payment may be made in part under a Federal health care program.[86] Daily deal websites receive as compensation a percentage of all medical service coupons customers purchase, and in turn practitioners gain new patients.[87] Alternatively, practitioners are also offering remuneration for arranging for service for which payment may be made in whole or in part under a Federal health care program.[88] This qualifies as illegal remuneration as defined in the anti-kickback statute because where a practitioner shares profits amassed from advertising discounted medical services in exchange for new patients who will likely stay long term, a valuable exchange takes place. Daily deal websites essentially operate as referral organizations under such arrangements; thus, a reasonable interpretation of the agreement between these parties will support an inference of illegal conduct or the potential for an exchange of prohibited remuneration.[89]

As in *Quantum*, daily deal websites arrange for or recommend the purchase of services reimbursable by Federal health care programs.[90] For example, in a deal for discounted membership in a medical group offering primary care and lab services covered by Medicare, one could easily conclude that the daily deal website is arranging for or recommending the purchase of services billable to Federal health care programs.[91] The court in *Quantum* found that a marketing company violated the anti-kickback statute by recommending to Medicare recipients that they purchase their supplies from a supplier that paid the marketing company a percentage of all products sold.[92] In the aforementioned example, the daily deal website essentially recommended the purchase of services from a medical group when it marketed the discounted membership to thousands of its members in exchange for a percentage of all coupons sold.[93]

3. Daily Deal Websites Do Not Actively Market to Beneficiaries of Federal Health Care Programs; However, These Sites Exert Influence over Referral Sources by Way of Their Popularity in the Market.

The opportunity for a marketer to unduly influence referral sources and patients is a significant factor in evaluating whether a particular arrangement is in violation of the anti-kickback statute.[94] While daily deal websites do *receive* remuneration and practitioners *offer* remuneration for services billable to Federal health care programs, daily deal websites arguably influence beneficiaries and practitioners to purchase and post coupons for medical services.[95] In *Polin*, the unfettered recommendations of a pacemaker sales representative to use the appellees' cardiac monitoring service were held sufficient to substantiate a kickback charge against the appellee.[96] Unlike the sales representative in *Polin*, however, daily deal websites do not market directly or solely to beneficiaries of Federal health care programs.[97] Active marketing and direct contact with beneficiaries present opportunities to improperly influence referral sources.[98]

Daily deal websites do not engage in what the OIG refers to as "white coat marketing."[99] White coat marketing, or marketing activities engaged in by health care professionals, is subject to closer scrutiny because health care professionals are in a special

position of trust.[100] Like the requestor of advisory opinion 12-02, daily deal websites are non-health care entities that market coupons. Moreover, in this case it is more favorable that daily deal websites offer coupons for a variety of goods and services, not just those from health care entities.[101] This further shows that daily deal websites are not health care entities or affiliated solely with the health care industry. Additionally, daily deal websites market coupons to the general population irrespective of whether or not a customer has a particular health insurance.[102] Their marketing practices do not raise the usual red flags found in marketing schemes discussed in OIG advisory opinions.[103]

However, this arrangement steers patients to particular providers because advertising on daily deal websites is not akin to advertising on other public websites or print media.[104] While customers are the ultimate decision makers on whether or not to purchase coupons for a medical service, daily deal websites control the prominence of the deal on its website and the frequency of targeted emails it sends to thousands on its listserve.[105] As discussed in advisory opinion 12-02, advertising activity that is simply displayed on a website and not targeted to the customer using the site presents a low risk of fraud and abuse because it is not meant to induce the purchase of a practitioner's coupon.[106] In that opinion, the OIG noted that patients would not perceive coupons to be an endorsement of any particular health care provider other than the provider advertising its business.[107] However, in the case of daily deal websites, targeted advertising activity to frequent users of its website presents an increased risk of program abuse.[108]

The risk of program abuse when daily deal websites influence beneficiaries' choice in medical services is further compounded when beneficiaries receive unnecessary medical service.[109] Pre-paid coupons for medical services may improperly influence a provider's medical judgment to render medically unnecessary or inappropriate services.[110] The proposed arrangement in advisory opinion 12-02 presented a decreased risk of abuse because customers would not pre-pay for coupons, thus alleviating the pressure on practitioners to provide medically unnecessary services.[111] This is not the case in current arrangements with daily deal websites because customers pay up front for the coupon, and consequently have an expectation to receive applicable services, regardless of the necessity of such services.[112] Practitioners, well aware of this expectation, will likely feel pressured to provide a service even when it is not appropriate to do so. To the extent this is directed toward Federal health care program beneficiaries, this may be an abusive practice, encouraging overutilization of these programs.[113]

B. Regulatory Safe Harbors Are Inapplicable to Daily Deal Websites as Currently Structured Because These Arrangements Do Not Meet All the Requirements of Relevant Safe Harbors.

Business arrangements between daily deal websites and practitioners have the potential to violate the anti-kickback statute; however, participants in this arrangement can shield themselves from liability by structuring the arrangement to fully comply with a regulatory safe harbor.[114] Of course, since non-compliance with a safe harbor is not a requisite element of establishing an AKS violation, it is important to note that the inquiry into whether a defendant's conduct falls within a regulatory safe harbor is reserved for trial.[115] Instead, the government must also prove that the defendant knowingly and willfully intended wrongful conduct.[116] The safe harbor for personal services and management contracts and the safe harbor for discounts are the most applicable to this arrangement.[117] Yet the parties in these arrangements, as currently structured, will not be shielded from criminal penalties and civil sanctions under the anti-kickback statute.[118]

1. The Safe Harbor for Personal Services and Management Contracts Is Inapplicable to the Daily Deal Website Arrangement Since This Arrangement Takes into Account the Volume of Business Generated.

Under the personal services and management contract safe harbor, a practitioner functions as the principle within the meaning of the regulation.[119] Accordingly, daily deal websites function as the agent of the principle since it is not a *bona fide* employee of the health organization.[120] Five of the seven requirements set out in this safe harbor

are dispositive upon a cursory assessment of the arrangement. Presumably, the arrangement between daily deal websites and practitioners are set out in writing and signed by the parties.[121] The written instrument likely details the specific services daily deal websites will provide to practitioners, and the agreement also specifies the duration of the arrangement.[122] Lastly, services under the contract can be deemed reasonably necessary to accomplish commercially reasonable business purposes.[123]

However, the arrangement fails to meet two of the seven standards outlined in the regulation.[124] The first failure concerns part five of the regulation; daily deal websites do not receive compensation in advance of the launch of the coupon.[125] As the *Zimmer* court held, it is unreasonable to interpret a percentage compensation agreement as payment for services rendered.[126] Here, daily deal websites are paid a percentage of all coupons sold; therefore, the aggregate compensation is not set out in advance as required by the regulation.[127] In advisory opinion 99-12, where company A would print and distribute coupons from retailers involved in the delivery of health care items or services, the OIG found it central to its analysis that compensation was not conditioned on the actual use of the coupon on a reimbursable item or service.[128] Also, in the case of daily deal websites, compensation is not dependent on customers actually obtaining services billable to the federal government. But unlike the proposed arrangement in advisory opinion 99-12, daily deal websites are not paid a set fee prior to displaying the coupons, a favorable factor contributing to the sanction of the proposed arrangement.[129]

This arrangement also fails to meet another prong of part five of the safe harbor, which requires that compensation should not take into account the volume of business generated between the parties.[130] Compensation of daily deal websites is tied to the volume of business generated by coupons displayed on behalf of practitioners, and Federal health care programs pay (in whole or in part) for a portion of business generated from these coupons.[131] *Zimmer* held that by virtue of including a percentage compensation scheme in the contract, the court was justified in concluding that the parties intended to increase the sale of products billable to Medicare.[132] The agreement between the parties in this instance can similarly be held illegal and unenforceable because it could evince intention to increase services billable to Federal health care programs.[133]

2. The Discount Safe Harbor Provision Is Inapplicable to the Daily Deal Website Arrangement Because Proper Disclosures and Notifications Are Not Made.

Practitioners and daily deal websites must meet the requirements for "seller" and "offeror," as outlined in the discount safe harbor in order to shield themselves from criminal and civil sanctions.[134] Under the discount safe harbor, practitioners that submit a claim on behalf of a customer must provide, upon request, information that shows that the daily deal website gave notice, "in manner reasonably calculated to give notice," to the practitioner of its duty to report the discount.[135] For daily deal websites to meet the requirements of the discount safe harbor, it must simply give notice to practitioners, "in a manner reasonably calculated to give notice," of its obligation to report discounts.[136] Although these requirements are straightforward, it is unclear whether they are included in the current practices of daily deal websites.[137] The requestor of advisory opinion 12-02 received a favorable opinion because the requestor certified that it would satisfy its obligation to notify sellers and buyers of their duty to report discounts through the Terms of Use on its website.[138] Daily deal websites must notify customers purchasing coupons for medical services as well as practitioners using its service of this duty to report; otherwise, a discount safe harbor defense is precluded.[139]

Daily deal websites do not have sufficient safeguards to ensure that discounts pass to the federal government since. For example, a patient enrolled in a medical group under discounted membership fees from a daily deal website promotion will not receive perpetually discounted health care services.[140] Rather, the discount will only apply to the patient's cost-sharing obligations, not the entire service.[141] Sufficient safeguards to mitigate the risk of overutilization of Federal health care programs are partly why the proposed arrangement reached a favorable result in advisory opinion 12-02.[142] In this

proposed arrangement, the requestor also certified that through its Terms of Use it would inform practitioners and customers utilizing its services that discounts must apply to the entire item or service, not just the customer's cost-sharing obligation.[143] In other words, the requestor certified it would comply with the discount safe harbor, which daily deal websites fail to do since discounts apply to the customer's cost-sharing obligation.[144]

Moreover, there is potential for providers to engage in abusive billing practices because there are inadequate safeguards in place to prevent these practices.[145] Although customers first have to purchase coupons for medical services and then redeem those coupons before any potentially fraudulent or abusive billing practices can take place, it is irrelevant to the anti-kickback inquiry whether increased cost to the federal government is actually realized.[146]

IV. POLICY RECOMMENDATION

Although the business arrangement between practitioners and daily deal websites is illegal under the anti-kickback statute and unprotected by a statutory or regulatory safe harbor, the discount safe harbor should be amended to offer protection to this kind of arrangement.[147] As is, the safe harbor for discounts is not intended to protect arrangements between practitioners and daily deal websites because daily deal websites are not an offeror within the meaning of the safe harbor.[148] An offeror must be the entity that provides a discount on an item or service to a buyer.[149] Since daily deal websites do not provide the discounts but instead market them to their customers, they are technically not within the purview of the safe harbor.[150]

However, Congress intended the regulatory safe harbors to evolve to reflect current business practices.[151] Evolving safe harbors ensure that the health care industry can take advantage of innovative discount practices so that savings may be passed on to the federal government.[152] Certain deals currently on the market fail to have the necessary safeguards in place to ensure discounts pass to the federal government.[153] Specifically, deals only applying to the customer's cost sharing obligation under Federal health care programs and not to the entire item or service billable to the federal government raise significant concern.[154] Amending the discount safe harbor can provide some guidance to practitioners and daily deal websites on how to structure a deal to meet this end.[155]

V. CONCLUSION

Medical services coupons advertised on daily deal websites violate the anti-kickback statute because practitioners essentially offer remuneration for referrals from these websites.[156] The favorable opinion issued by the OIG on a similar arrangement presented a low risk of fraud and abuse because it did not encompass a percentage compensation structure and did not create financial incentives to over-utilize Federal health care programs.[157] In contrast, through targeted advertising activity, daily deal websites may arrange for the purchase of services billable to Federal health care programs.[158] Furthermore, this business arrangement encourages overutilization of Federal health care programs because daily deal websites have an incentive to increase the amount of customers purchasing coupons for medical services, since it will receive a percentage of all coupons sold.[159] Because the safe harbor provisions for personal services and management contracts and for discounts do not apply to these arrangements, practitioners and these websites are vulnerable to prosecution under the anti-kickback statute.[160] To enable compliance with the statute by practitioners and daily deal proprietors, the discount safe harbor should be amended to reflect current business practices so discounted health care items and services may be passed to the federal government.[161] Amending the statute is consistent with what Congress intended when it enacted the discount exception to the anti-kickback statute.[162]

[1] *See Valerie Barba DDS Deal of the Day*, Groupon, http://www.groupon.com/deals/valerie-barba-dds-central-jersey (last visited Feb. 27, 2013) (advertising dental services from a practitioner in New Jersey).

[2] *See FAQ*, Groupon, http://www.groupon.com/faq#3 (last visited Feb. 27, 2013) (stating if not enough persons purchase a deal, it is cancelled and customer will not be charged).

[3] *See id.* (claiming the customers are not required to sign up groups of people for the deal to take effect since Groupon consists of millions of members).

[4] *See Why Groupon Works for Business*, Groupon Works, http://www.grouponworks.com/why-groupon (last visited Feb. 27, 2013) (citing a survey that found ninety–one

percent of customers have returned or plan to return to the merchant).

[5] *See, e.g.*, Living Social, http://livingsocial.com/cities/1-washington-d-c (last visited Feb. 27, 2013) (daily deal website based in Washington, D.C.); Man Deals, http://mandeals.com/index.php (last visited Feb. 27, 2013) (daily deal website catering to men).

[6] *See, e.g.*, *The Best Deals in Georgetown/Foggy Bottom-One Medical Group-Annual Membership*, Living Social, http://www.livingsocial.com/cities/1171-georgetown-foggy-bottom/deals/391530-annual-membership?show_missed=true (last visited Feb. 27, 2013) [hereinafter Living Social] (advertising discounted membership to a medical group offering primary care services).

[7] *See* Office of Inspector General | U.S. Department of Health and Human Services, https://oig.hhs.gov/about-oig/about-us/index.asp (last visited Feb. 27, 2013) (comprising of six departments, including the Office of Counsel to the Inspector General—which renders advisory opinions on issues that may implicate the Anti-kickback statute).

[8] *See* Op. Dep't Health & Human Servs. Office of Insp. Gen. 12-02 at 1 (Mar. 27, 2012) [hereinafter Advisory Opinion 12-02], *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions /2012/AdvOpn12-02.pdf (analyzing whether the proposed arrangement would result in exclusion from federal health care programs or imposition of civil monetary penalties for violating the anti-kickback statute).

[9] *See id.* at 2 (stating the proprietor of the website would contract with physicians and other health care providers who wish to participate in one of five membership levels offering varying degrees of promotion and coupon display).

[10] *See id.* at 5 (stating customers would not be required to create an account to access the coupons).

[11] *See id.* (proposing that customers submitting their own claims to federal health care programs will be advised to report any discounts from use of a coupon).

[12] *See id.* at 10-11 (concluding the proposed arrangement could potentially generate prohibited remuneration if the parties had the requisite intent to induce or reward federal health care business; however, the OIG would not impose administrative sanctions because of the low risk of abuse).

[13] *See generally* Social Security Act of 1972 §§ 1128A(a)(7), 1128B(b), 42 U.S.C. §§ 1320a-7a(a)(7), 1320a-7b(b) (2006) (enacting criminal and civil monetary penalties for prohibited acts involving federal health care programs).

[14] *Contra* Advisory Opinion 12-02, *supra* note 9 at 8 (finding proposed arrangement low risk under the anti-kickback statute because coupons are equivalent to print advertisements and are not targeted to particular customers).

[15] *See* OIG Anti-Kickback Provisions Response to Comments and Summary of Revisions, 56 Fed. Reg. 35,952, 35,954 (July 29, 1991) (codified at 42 C.F.R. pt. 1001) (stating participation in an arrangement structured in compliance with a regulatory safe harbor provision shields a person from criminal or civil prosecution).

[16] *See infra* Part II (discussing the nuances of anti-kickback case law and interpretation of regulatory safe harbors).

[17] *See infra* Part III(A) (arguing percentage compensation agreements inherently incentivize overutilization of federal health care programs).

[18] *See infra* Part III(B) (analyzing the arrangement between daily deal websites and practitioners under the personal services and management contracts safe harbor, and the discount safe harbor).

[19] *See infra* Part IV (proposing safe harbors should be amended so the health care industry can take advantage of innovative discount practices which would pass saving to the federal government).

[20] See generally John A. Bourdeau, Annotation, *Illegal Remuneration Under Medicare Anti–kickback Statute (Social Security Act § 1128B) (42 U.S.C.A. §§ 1320a-7b)*, 132 A.L.R. Fed. 601 (1996).

[21] *See* 42 U.S.C. §§ 1320a-7b(b) (2006) (prohibiting acts that increase the likelihood of fraud and abuse of federal health care programs).

[22] *See, e.g.*, Dep't Health & Human Servs. Office of Insp. Gen. Op. 98-01 at 8 (Mar. 19, 1998) [hereinafter Advisory Opinion 98-01], *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_1.pdf (declining to give a favorable opinion where a company would market and bill Medicare on behalf of a medical supply company).

[23] *See* David E. Matyas & Carrie Valiant, Legal Issues in Healthcare Fraud and Abuse: Navigating the Uncertainties 17 (3d ed. 2006) (opining that the Anti-kickback statute will remain a focus of the health care industry because its reach is expanding).

[24] *See* United States v. Bay State Ambulance Serv., Inc., 874 F.2d 20, 29 (1st Cir. 1998) (stating inducement of Medicare business is the essence of the Medicare fraud); *see also* United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1985) (recognizing the purpose of the Anti-kickback statute is to combat financial incentives for physicians to order medically unnecessary services).

[25] *See Greber*, 760 F.2d at 69 (affirming jury instructions stating defendant is guilty if *a* purpose of the arrangement was to induce further orders of services).

[26] *E.g.*, United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000) (adopting the "one-purpose" test as the correct interpretation of the statute); United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989) (finding *Greber* court's interpretation of the Anti-kickback statute consistent with legislative history).

[27] *See* 42 U.S.C. § 1320a-7b(b) (2006) (prohibiting remunerations to induce referrals of beneficiaries of Federal health care programs); Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) (outlining standard of proof as an intent to exert undue influence over the reason or judgment of another to produce referrals).

[28] *Compare* United States v. Neufeld, 908 F. Supp. 491, 495-96 (S.D. Ohio 1995) (finding the knowingly and willfully standard does not require knowledge of illegality of defendant's conduct), *with Hanlester Network*, 51 F.3d at 1400 (reasoning violation of the anti-kickback statute requires specific intent to violate the statute).

[29] *See* 42 U.S.C. § 1320a-7b(h) (2011) (imposing a maximum fine of $25,000, imprisonment up to five years, or both, and automatic exclusion from Federal health care programs under a general intent standard).

[30] *See* United States v. Shaw, 106 F. Supp. 2d 103, 115 (D. Mass. 2000) (explaining the statute penalizes conduct that crosses the line from permitted price competition to

impermissible discounting especially where savings do not pass to Federal health care programs).

[31] *See* United States v. Ruttenberg, 625 F.2d 173, 177 (7th Cir. 1980) (holding a determination of direct and immediate costs to the Medicare-Medicaid system irrelevant to conviction under the statute because the government punishes the potential for increased costs).

[32] *See* Issuance of Advisory Opinions by OIG, 62 Fed. Reg. 7,350, 7,351 (Feb. 19, 1997) (codified at 42 C.F.R. Part 1008) (stating application of safe harbor is appropriate where an arrangement contains limitations, requirements, or controls that adequately ensure that Federal health care programs cannot be abused).

[33] *See* OIG Anti-kickback Provisions Response to Comments and Summary of Revisions, 56 Fed. Reg. 35,952, 35,954 (July, 29 1991) (codified at 42 C.F.R. Part 1001) (rejecting suggestions to protect arrangements that substantially comply with safe harbors, or *de minimis* violations of the statute).

[34] *See Shaw*, 106 F. Supp. 2d at 111 (explaining discount provision of anti-kickback statute was Congress's way of ensuring normal discounting in business would remain legal).

[35] *See id.* at 112 (discussing the enactment of paragraph (e) of the anti-kickback statute, which authorizes the Secretary of the Department of Health and Human Services to promulgate regulations exempting payment practices from prosecution).

[36] *See* 42 C.F.R § 1001.952 (2011) (codifying twenty-five exceptions to anti-kickback statute).

[37] *See* Response to Comments and Summary Revisions, 61 Fed. Reg. 2,122, 2,124 (Jan. 25, 1996) (codified at 42 C.F.R. Part 1001) (advising commenters not to infer illegality of an arrangement when safe harbor provisions are inapplicable to an arrangement).

[38] *See, e.g.*, Dep't Health & Human Servs. Office of Insp. Gen. Op. 08-19 (Nov. 5, 2008) [hereinafter Advisory Opinion 08-19], *available at* http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-19.pdf (analyzing a proposal to extend an internet pay per lead advertising service to the chiropractic industry); Dep't Health & Human Servs. Office of Insp. Gen. Op. 99-12 (Dec. 6, 1999) [hereinafter Advisory Opinion 99-12] *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_12.htm (analyzing a coupon distribution program utilizing physician practices and clinics to distribute non-health care coupons).

[39] *See* 42 C.F.R § 1001.952(h) (2011) (dividing parties to a discount arrangement into buyers, sellers, and offerors of discounts). *See generally* Michael K. Loucks & Carol C. Lam, Prosecuting and Defending Health Care Fraud Cases 269 (2d ed. 2010) (explaining proper interpretation of the regulatory safe harbors should be informed by the statutory safe harbor).

[40] *See* Clarification of Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions, 64 Fed. Reg. 63,518, 63,527 (Nov. 19, 1999) (codified at 42 C.F.R. part 1001) (requiring the seller to fully and accurately report discounted claims to the appropriate federal health care program).

[41] *See id.* at 63,527 (stating that the offeror is protected irrespective of the buyer or seller's failure to report the discount if the offeror has done everything that it reasonably could under the circumstances).

[42] *See* United States v. Shaw, 106 F. Supp. 2d 103, 119 (D. Mass. 2000) (holding that the jury must determine whether disclosures are proper and appropriate to satisfy the discount provision).

[43] *See* 42 C.F.R § 1001.952(d) (2011) (exempting from the illegal remuneration provision of the anti-kickback statute payments made as compensation for services).

[44] *See id.* (requiring a written agreement for not less than one year, signed by the parties to the agreement).

[45] *See* 64 Fed. Reg. at 63,525 (clarifying that the test is not lawfulness under the statute but rather whether the arrangement is reasonably calculated to further the business of the purchaser).

[46] *See* OIG Anti-Kickback Provisions Response to Comments and Summary of Revisions, 56 Fed. Reg. 35,952, 35,974 (Jul. 29, 1991) (agreeing that advertising activities fall under the safe harbor when such activities do not involve direct contact with program beneficiaries or the entities are not involved in health care delivery).

[47] *See Shaw*, 106 F. Supp. 2d at 114 (declaring that a trier of fact must determine an intent to commit a violation from the substance of the transaction rather than the form or label attached to the transaction).

[48] *See id.* at 119 (stating that providers are encouraged to seek discounts as good business practices so long as federal or state health care programs share in the benefit of the discount).

[49] *See id.* at 121 (cautioning that while a jury can infer that the purpose behind a particular business arrangement was to induce federally funded business, the jury should also understand that good business practices that increase profits should not preclude immunity under the discount exception); *see also* Zimmer v. Nu Tech Med., 54 F. Supp. 2d 850, 862 (N.D. Ind. 1999) (holding that a percentage-based compensation scheme was sufficient to conclude the parties were motivated to increase the sale of products reimbursable by federal or state health care programs).

[50] *See Zimmer,* 54 F. Supp. 2d at 851–52 (noting that the parties intended their business relationship to be that of a supplier and an independent contractor responsible for distribution and billing).

[51] *Id.*

[52] *See id.* at 852 (explaining that Nu Tech would retain twenty to twenty-five percent of the dollar volume receivable per year).

[53] *See id.* (seeking an advisory opinion pursuant to 42 U.S.C. § 1320a-7d(b)).

[54] *See id.* at 853 (arguing that the agreement was void and unenforceable under Indiana law since it was illegal under federal law).

[55] *See id.* at 856 (stating that although an advisory opinion is not mandatory authority, considerable weight should be given to its conclusions).

[56] *See, e.g.*, United States v. Shaw, 106 F. Supp. 2d 103, 113 (D. Mass. 2000) (rejecting the notion that OIG statements regarding its regulations are controlling but also expressing the wisdom in considering the OIG's interpretation

of key terms since it is the agency charged with its implementation).

[57] Advisory Opinion 98-01, *supra* note 22.

[58] *See Zimmer,* 54 F. Supp. 2d at 861 (finding that the parties intended to enter into a percentage compensation agreement, thereby violating the anti-kickback statute); *see also* United States v. Miles, 360 F.3d 472, 480 (5th Cir. 2004) (finding a PR agency did not violate the anti-kickback statutebecause the agency had no influence on a physician's decision to use a particular home health care service).

[59] *See* Nursing Home Consultants v. Quantum Health Servs., 926 F. Supp. 835, 841 (E.D. Ark. 1996) (analyzing a marketing agreement for legality under the anti-kickback statute).

[60] *See id.* at 839 (noting that NHC was not involved in the actual sale of medical supplies).

[61] *See id.* (stating that the marketing agreement was for one year and would automatically renew for an additional one-year period unless either party was notified of cancellation).

[62] *See id*. at 842 (reasoning that by virtue of its compensation scheme, the marketing agreement is the sort of business arrangement prohibited by the anti-kickback statute).

[63] See *id.* at 844 (declining to extend protection to the marketing agreement since the safe harbor specifically prohibits compensation schemes which take into account the volume of referrals or business).

[64] *See, e.g.*, United States v. Polin, 194 F.3d 863, 866-67 (7th Cir. 1999) (ruling that providing payment in return for directing Medicare patients to a cardiac monitoring service violates the anti-kickback statute regardless of whether or not payments were paid to a physician).

[65] *See id*. at 867 (rejecting the assertion that the different subsections of the anti-kickback statute address different and non-overlapping schemes).

[66] *See id.* at 865 (explaining that the defendants offered a cardiac salesman $50 for each Medicare patient he referred).

[67] *See id.* at 866 (rejecting defendants' argument that they did not violate the anti-kickback statute since their agent was not a physician and only physicians could refer a patient under the statute).

[68] *See* Advisory Opinion 98-01, *supra* note 22 (discussing the potential for abuse leading to increased program costs where compensation incentivizes overutilization of services).

[69] *Id.*

[70] *See id.* (analyzing an arrangement where, under contract, Company B would market services and goods to physicians, submit claims of purchases to insurance carriers distributing Medicare and Medicaid funds, and forward reimbursements (less Company B's fee of twenty to twenty-five percent of collected revenues) to Company A).

[71] *Id.* at 6.

[72] *See* Bari Weiss, *Groupon's $6 Billion Gambler*, The Wall Street Journal, Dec. 20, 2010, *available at* online.wsj.com/article/SB10001424052748704828104576021481410635432.html (stating that Groupon markets in over 375 American cities and thirty-five countries).

[73] *See, e.g.*, Zimmer v. Nu Tech Med., 54 F. Supp. 2d 850, 857–58 (N.D. Ind. 1999) (discussing examples of percentage compensation schemes struck down by courts because one party was in a position to control the supply of persons or services to its benefit).

[74] *See id.* at 862 (holding that the parties' agreement involved prohibited remuneration because products might be paid for in full or in part by Federal health care programs).

[75] *See* Nursing Home Consultants v. Quantum Health Servs., 926 F. Supp. 835, 841 (E.D. Ark. 1996) (finding that a marketing agreement where compensation is tied to a pre-determined annual fee would be legal and distinct from the agreement in question, which tied compensation to the number of sales made by the defendant).

[76] *See* Advisory Opinion 12-02, *supra* note 8, at 4.

[77] *See id.*

[78] *See* Advisory Opinion 99-12, *supra* note 38.

[79] *Id.*

[80] *See* United States v. Shaw, 106 F. Supp. 2d 103, 121 (D. Mass. 2000) (stating that whether the discount or other reduction in price was passed to the federal government can suggest the requisite intent of the parties).

[81] *See id.* at 111 (discussing Congress's intention to encourage good business practices which may result in savings to Federal health care programs).

[82] *See* Living Social, *supra* note 6 (limiting a coupon for discounted membership in a medical group to one per person per visit).

[83] *See id.* (establishing that the reason behind a transaction and the requisite state of mind are more substantial than the form of the transaction).

[84] *See* Zimmer v. Nu Tech Med., 54 F. Supp. 2d. 850, 859 (N.D. Ind. 1999) (applying fundamental contract principles to determine intent to engage in prohibited conduct under the anti-kickback statute).

[85] *See Shaw*, 106 F. Supp. 2d. at 121 (permitting a jury to use a strong profit motive to infer willfully and knowingly acting to induce referrals of federal health care business). *But see* United States v. McClatchy, 217 F.3d 823, 834 (10th Cir. 2000) (explaining that an expectation or hope that referrals may ensue from legitimate services is not a violation of the AKS).

[86] *See* 42 U.S.C. § 1320a-7b(b) (2006) (stating that prohibited remuneration includes kickbacks, bribes, or rebates).

[87] *See* Weiss, *supra* note 71 (explaining that Groupon obtains roughly fifty percent of the coupon revenue).

[88] *See* 42 U.S.C. § 1320a-7b(b) (2006) (including remuneration offered directly or indirectly, overtly or covertly).

[89] *See Zimmer*, 54 F. Supp. 2d at 853-54 (N.D. Ind. 1999) (rejecting defendant's alternate interpretation of a percentage-based supplier-distributer agreement as an unreasonable interpretation); *see also* United States v. Ruttenberg, 625 F.2d 173, 177 (7th Cir. 1980) (concluding that the potential for increased costs is the evil Congress sought to avoid).

[90] *See* Nursing Home Consultants v. Quantum Health Servs., 926 F. Supp. 835, 843 (E.D. Ark. 1996) (finding the arrangement in violation of subparagraph B of the anti-kickback statute because the medical equipment supplier

was paid for recommending to Medicare recipients that they purchase supplies from its business partner).

[91] *See* Living Social, *supra* note 6 (advertising One Medical Group, a medical office offering primary care services and on-site lab services in the District of Columbia).

[92] *See Quantum Health Servs.*, 926 F. Supp. at 839 (noting that the compensation scheme in the marketing agreement fell within the class of transactional relationships prohibited by the anti-kickback statute).

[93] *See* Living Social, *supra* note 6 (advertising annual membership for $99, a fifty percent savings).

[94] *See Zimmer*, 54 F. Supp. 2d at 855 (deferring to OIG advisory opinion 98-01 which found that the percentage compensation arrangement between the parties presented opportunities for both parties to unduly influence referral sources by marketing actively, and directly to Medicare patients).

[95] *See* United States v. Miles, 360 F.3d 472, 480 (5th Cir. 2004) (finding that the company, by engaging in promotional activities on behalf of the appellants, did not unduly influence physicians who were the subject of the promotional activities).

[96] *See* United States v. Polin, 194 F.3d 863, 866 (7th Cir. 1999) (rebutting appellee's argument that because physician approval was ultimately needed before a patient could use its services, only a physician was capable of making a referral).

[97] *See Partner with Living Social*, Living Social, https://getfeatured.livingsocial.com/getfeatured/us (last visited Aug. 20, 2012) (suggesting targeted marketing to trendsetters, families and food lovers to reach valuable new customers).

[98] *See* Advisory Opinion 98-01, *supra* note 22 (analyzing proposed arrangement to find Company B would have opportunities to influence referral sources because Company B markets, consults and bills in connection with home medical equipment).

[99] *See* Advisory Opinion 08-19, *supra* note 38.

[100] *Id.*

[101] *Id.*

[102] *See* Advisory Opinion 99-12, *supra* note 38 (evaluating the totality of the circumstances, including distribution to all patients regardless of health insurance coverage, to conclude proposed arrangement does not implicate the anti-kickback statute).

[103] *See, e.g.*, *id.* (sanctioning a proposed arrangement because, among other things, coupons were distributed to all patients, irrespective of their insurance coverage); Advisory Opinion 08-19, *supra* note 38 (finding significant that all potential customers will receive the same automated service in an arrangement where advertising activity would extend to the chiropractic industry).

[104] *See* Advisory Opinion 12-02, *supra* note 8 at 8 (stating that accurate and non-deceptive print advertising does not raise anti-kickback concerns).

[105] *See* Roadmap and Timeline for Merchants Groupon Works, Groupon Works, http://www.grouponworks.com/merchant-services/groupon-roadmap (last visited Aug. 20, 2012) (touting emails to thousands of subscribers while targeting likely new customers of the advertiser).

[106] *See* Advisory Opinion 12-02, *supra* note at 9.

[107] *Id.*

[108] *See Partner with Living Social*, Living Social, https://getfeatured.livingsocial.com/getfeatured/us (last visited Aug. 20, 2012) (claiming its members are looking for a reason to try new things).

[109] *See* Advisory Opinion 12-02, *supra* note 8, at 8.

[110] *Id.*

[111] *See id.* (likening coupons in the proposed arrangement to those mailed to consumers since there is no up-front investment by consumers).

[112] *See Terms and Condition*, Living Social, http://livingsocial.com/terms#certain_conditions_placed_on_your_use_of_the_site_and_services (last visited Aug. 07, 2012) (requiring customers to redeem coupons in its entirety in one visit since promotional value of the deal is time sensitive).

[113] *See* Advisory Opinion 98-01, *supra* note 22, at 6 (finding that the potential for overutilization of items and services poses an unacceptable risk of fraud and abuse).

[114] *See, e.g.*, 42 C.F.R. § 1001.952(h) (2011) (outlining requisite elements in an arrangement to shield entities from criminal and civil prosecution under the anti-kickback statute).

[115] *See* United States v. Shaw, 106 F. Supp. 2d 103, 122 (D. Mass. 2000) (rejecting defendant's argument that his motion to dismiss should prevail because the alleged wrongdoing is protected under the discount exception).

[116] *See* Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) (holding specific intent is not the requisite *mens rea* under the anti-kickback statute).

[117] *See generally* 42 C.F.R. § 1001.952 (promulgating permissive exclusions based on anti-kickback statute violations).

[118] *See* OIG Anti-Kickback Provisions Response to Comments and Summary of Revisions, 56 Fed. Reg. 35,952, 35,954 (July, 29 1991) (codified at 42 C.F.R. Part 1001) (stating that arrangements which do not fully comply with a regulatory safe harbor are not protected from criminal and civil sanctions).

[119] *See* 42 C.F.R. § 1001.952(d) (defining the principle as the individual making payments as compensation for services performed).

[120] *See id.* (explaining that the agent is shielded from liability so long as all the seven standards are met).

[121] *See* 42 C.F.R. § 1001.952(d)(1) (requiring a written instrument signed by both parties).

[122] *See* 42 C.F.R. § 1001.952(d)(2)-(4) (declaring that the agreement must specify an exact schedule of intervals, precise length, and exact charge for periodic or sporadic services provided by the agent but that the term of the agreement must not be less than a year).

[123] *See* 42 C.F.R. § 1001.952(d)(7) (requiring that the aggregate services be commercially reasonable).

[124] *See* Nursing Home Consultants v. Quantum Health Servs., 926 F. Supp. 835, 842 (E.D. Ark. 1996) (declaring a marketing agreement unenforceable because the parties failed to set payment in a manner that did not take into account the volume of business).

[125] *See Partner with LivingSocial*, Living Social, https://getfeatured.livingsocial.com/getfeatured/us (last visited

Aug. 20, 2012) (noting no upfront cost to practitioners when running a promotion).

[126] *See* Zimmer v. Nu Tech Medical, 54 F. Supp. 2d 850, 861 (N.D. Ind. 1999) (using defendant's fee schedule, which outlined the percentage of billable services due per year, to conclude that the defendant's fee was not for goods sold).

[127] *See Quantum*, 926 F. Supp. at 844 (noting that failure to satisfy this provision of the safe harbor makes the agreement illegal, regardless of whether it was a technical violation of the statute).

[128] *See* Advisory Opinion 99-12, *supra* note 38 (indicating it may have reached a different conclusion had coupons tied directly or indirectly to a service reimbursable by Federal health care programs).

[129] *See id.* (specifying that the clinics in the proposed arrangement would be compensated before coupon distribution).

[130] *See* 42 C.F.R. § 1001.952(d)(5) (2011) (requiring aggregate compensation to be consistent with fair market value in arms-length transactions).

[131] *See* Advisory Opinion 98-01, *supra* note 22 (discussing the potential for abuse leading to increased program costs where compensation incentivizes overutilization of services).

[132] *See Zimmer*, 54 F. Supp. at 861 (N.D. Ind. 1999) (finding irrelevant to the analysis of legality whether a particular party was responsible for the actual marketing of products).

[133] *See id.* at 863 (declining to sever Federal health care programs from the agreement because it would re-write the contract).

[134] *See generally* 42 C.F.R. § 1001.952(h)(5) (2011) (defining discount as a "reduction in the amount charged for an item or service based on an arms-length transaction").

[135] *See id.* at § 1001.952(h)(2) (stating that discounts must be reflected in the claims customers submit on their own behalf).

[136] *See id.* at § 1001.952(h) (outlining standards to shield entities from criminal and civil prosecution under the anti-kickback statute).

[137] *See, e.g.*, Living Social, *supra* note 6 (neglecting to state disclosures in fine print or terms of use).

[138] *See* Advisory Opinion 12-02, *supra* note 8, at 9 (stating that the term "offeror" was not intended to encompass daily deal websites; however, arrangements can be tailored to comply with the safe harbor).

[139] S*ee* OIG Anti-Kickback Provisions Response to Comments and Summary of Revisions, 56 Fed. Reg. 35,952, 35,956 (July 29, 1991) (declining to shield an entity from criminal or civil prosecution for technical or *de minimis* violations of the regulatory safe harbors).

[140] *See Shaw*, 106 F. Supp. 2d at 115 (stating that discounting must be based on the understanding that the discount can only pass to the federal government if it is made aware of the discounts).

[141] *See* Advisory Opinion 12-02, *supra* note 8 at 3, 9-10 (finding it significant that the coupons themselves applied to the entire item or service, not just the customer's cost).

[142] *See id.* at 10 (declining to offer safe harbor protection to potential parties involved in the proposed management since parties were not joined in the request of the opinion and did not provide certifications of compliance with the discount safe harbor).

[143] *See Shaw*, 106 F. Supp. 2d at 119 (concluding that the question of whether disclosures are proper and appropriate depends on the details of the transaction and other evidence proffered at trial under the scrutiny of a jury).

[144] *See, e.g.*, *Terms and Conditions*, Living Social, http://livingsocial.com/terms#certain_conditions_placed_on_your_use_of_the_site_and_services (last visited Aug. 20, 2012) (failing to make the proper disclosures to comply with the discount safe harbor in its terms of use).

[145] *See* United States v. Ruttenberg, 625 F.2d 173, 177 (7th Cir. 1980) (finding that paying for the opportunity to provide services billable to Federal health care programs constitutes an illegal use of federal funds).

[146] *See id.* at 177 (stating that the potential for increased costs to the federal government is evident where payments are made to influence the judgment of the relevant decision maker); *cf.* United States v. Miles, 360 F.3d 472, 480 (5th Cir. 2004) (finding it significant that alleged illegal remuneration occurred after a physician already decided to use defendant's home health care services for which the defendant would pay a fee to a PR agency who advertised to physicians on its behalf).

[147] *See* Clarification of Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions, 64 Fed. Reg. 63,518, 63,528 (Nov. 19, 1999) (codified at 42 C.F.R. Part 1001) (noting that Congress intended the regulatory safe harbors to both incorporate and enlarge upon the statutory discount exception found in the anti-kickback statute).

[148] *See id.* (explaining that an offeror is not the seller of the item or the service but provides a discount on an item or service to a buyer).

[149] *See id.*

[150] *See, e.g.*, Advisory Opinion 12-02, *supra* note 8, at 9 (permitting the requestor to structure its daily deal website to fall within the discount safe harbor although the daily deal website was not an offeror within the meaning of the safe harbor).

[151] *See* United States v. Shaw, 106 F. Supp. 2d 103, 112 (D. Mass. 2000) (stating that it was Congress's intent to have the regulations updated periodically when it granted the OIG authority to protect certain arrangements).

[152] *See id.* at 115 (explaining that the discount exception to the anti-kickback statute was passed to encourage a free health care market system so that the federal government could reap cost-saving benefits).

[153] *See, e.g.*, Living Social, *supra* note 6 (failing to specify whether discounted membership in a medical group will translate to discounted services billable to Federal health care programs).

[154] *See* Advisory Opinion 12-02, *supra* note 8 (blessing a proposed daily deal website partly because third party payors, including the federal government, would benefit from the reduction in cost of the item or service).

[155] *See* Clarification of Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions, 64 Fed. Reg. 63,518, 63,528 (Nov. 19, 1999) (codified at 42 C.F.R. Part 1001) (allowing certain coupons and discounts to qualify for safe harbor protection as long as the

arrangement meets the requirements of the discount safe harbor provision).

[156] *See* 42 U.S.C § 1320a-7b(b) (2006) (prohibiting remuneration offered directly, indirectly, overtly or covertly).

[157] *See* Advisory Opinion 12-02, *supra* note 8, at 11 (narrowly tailoring a favorable opinion to the proposed arrangement and explicitly disclaiming reliance on the opinion by any other individual or entity).

[158] *See id.* at 8-9 (stating that advertising which is only displayed on a website and not targeted toward customers using the website does not raise significant anti-kickback concerns).

[159] *See* Zimmer v. Nu Tech Med., 54 F. Supp. 2d 850, 855 (N.D. Ind. 1999) (rendering a percentage compensation agreement unenforceable under the anti-kickback statute because both parties had significant financial incentives to engage in abusive marketing and billing practices).

[160] See Issuance of Advisory Opinions by OIG, 62 Fed. Reg. 7,350, 7,351 (Feb. 19, 1997) (codified in 42 C.F.R. Part 1008) (stating application of safe harbor is appropriate where an arrangement contains limitations, requirements or controls that adequately assure federal health care programs cannot be abused).

[161] *See* 64 Fed. Reg. at 63,528 (explaining that the safe harbor provisions protect all discounts protected by Congress in the statutory discount exception found in the anti-kickback statute).

[162] *See* United States. v. Shaw, 106 F. Supp. 2d 103, 112 (D. Mass. 2000) (outlining the expansion of the regulatory safe harbor provisions to encompass innovative payment practices).

Individual Liability For Medicare Overpayment Claims

*By David P. Parker and James Hennelly**

I. SCOPE OF THIS ARTICLE

This article addresses the case where an individual or "natural person" owns an interest in a Medicare health care provider that is incorporated[1] under state law as a corporation, limited liability company ("LLC"), limited partnership ("LP"), or another type of legal person. The individual may be a shareholder, member, limited partner, or some corresponding term for an owner of the company, but in all these cases the common factor is limitation of liability of owners.

Owners of providers facing Zone Program Integrity Contractors ("ZPIC")[2] or other Medicare contractor audits or appealing an overpayment demand often ask what risk they face of being held personally liable for the overpayment claims, or otherwise punished personally, if their appeals are unsuccessful. This article uses a hypothetical to explain the extent of such owners' personal liability as a result of a Medicare overpayment claim.*

II. DEFINITION OF OUR CASE

Consider a common scenario in which a provider organized as a corporation or LLC (the "Company") with one or more individual owners (i.e. individual "shareholders" or "members") is enrolled with Medicare, has provided services to Medicare beneficiaries over a substantial period of time, and has received payments from the Medicare contractor. A ZPIC or other contractor, such as a Medicare Recovery Audit Contractor ("RAC")[3] or a Comprehensive Error Rate Testing ("CERT") contractor,[4] then selects the Company for post-payment audit. After reviewing a sample of records, the contractor determines that overpayments have occurred and issues an audit results letter assessing an amount it claims Medicare overpaid in the sample. The contractor also assesses a much larger extrapolated amount it deems Medicare overpaid in all of the Company's Medicare receipts during the period under review. The Medicare Administrative Contractor ("MAC") then makes a written formal demand for refund by the Company of the extrapolated amount.

Assume further that the Company either fails to appeal this overpayment determination, referred to as an "Initial Determination," or appeals and loses. Either way, the Company owes the full extrapolated amount to the Centers for Medicare & Medicaid Services ("CMS"), plus interest that begins to accrue thirty days from the date of the formal demand by the MAC. Also assume that this sum amounts to several years of gross revenues for the Company, and it has no means to repay it. The MAC begins to recoup payments of new Medicare billings by the Company, and the Company shuts down as it exhausts its funds available to cover payroll and operating expenses. Finally, assume, as is commonly the case, that the Company has no significant assets that CMS can seize and liquidate to satisfy the overpayment. Thus, the primary issue is whether the Company's individual owner or owners are on the hook for the unpaid amount of the CMS overpayment claim. A related issue is the potential for liability of other provider entities owned by the same individuals. In other words, under what circumstances can CMS or its contractors lawfully collect the overpayment from the individual owners or their other provider companies? What other sanctions can the government apply against the individuals and affiliates in such a case?

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III. CONCEPT OF LIMITED LIABILITY

In the United States and most Western legal systems the concept of incorporation of a business is available to shield its owners from claims for the business's debts. This is the concept of "limited liability," meaning the owners' personal liability for the debts of the business is usually limited to the amount of the capital they have invested in it. If the business owes money to a creditor, the creditor will have recourse to the business, meaning the money and other assets the business itself owns. In this way, the creditor can collect the capital the owner has bound up in the business, but the creditor has no right to make the owner pay from his own assets.

IV. THRESHOLD RULE OF LIMITED LIABILITY; EXCEPTIONS AND "PIERCING THE CORPORATE VEIL"

The general rule of limited liability applies to CMS and its contractors when dealing with shareholders of incorporated health care providers, just as it does to other creditors. No statute or case law makes owners of incorporated health care providers personally liable for their companies' debts to CMS, except in certain very narrow circumstances that apply to all debtors and creditors. These circumstances are no more likely to arise in the health care industry than elsewhere.

The principal exceptions to the rule of limited liability of shareholders are collectively known as "piercing the corporate veil." Under certain circumstances, courts will allow creditors of an insolvent corporation, LLC, or other legal entity to reach through the corporate structure and collect their debts from shareholders or similar owners.[5] Notably, however, CMS and its contractors rarely seek to pierce the corporate veil, as courts tend to disfavor the practice and narrowly interpret common law governing the area. While an exhaustive discussion of this topic is beyond the scope of this article, courts have cited numerous factors to justify imposing liability on shareholders for corporate debts, including the following:

A. Defective Incorporation

Failure to meet legal statutory requirements for organizing the corporation or LLC can and will result in shareholders being liable for corporate debts. Without compliance with the requirements for incorporation, no corporation ever exists in the first place to shield the shareholders from liability.

B. Ignoring the Separateness of the Corporation

Entering into contracts and otherwise transacting business variously in a corporate name and an individual name can justify piercing the corporate veil. Likewise, commingling corporate and individual assets, or transferring assets without formalities between company and owner, or company and a sister company, can yield the same result.

C. Significant Undercapitalization

A corporation must have a reasonably sufficient amount of capital to pay its expected debts. Failure to do so is grounds to impose liability on the shareholders. Undercapitalization is normally difficult to prove, as courts determine the adequacy of capital at the time it is injected, not when the liability arises. Further, courts tend to defer to any good-faith estimate of how much capital will be needed.

D. Excessive Dividends or Other Payments to Shareholders

When owners are actually working for a corporation they can in most cases pay themselves whatever compensation is even remotely fair, as long as it is clearly characterized as salary or wages. Dividends and other non-compensation distributions, however, are judged very differently, and can safely be taken out by shareholders only to the extent of profits. When shareholders take non-compensation distributions in excess of profits, these distributions constitute a return of capital and can give rise to an undercapitalization claim by any corporate creditor who is subsequently not paid.[6] If such distributions are made when the corporation is actually insolvent, the creditors' claims against the shareholders will be almost impossible to defend.

E. Misrepresentation and other Unfair Dealings with Creditors

Dishonesty and false statements to corporate creditors, asset concealment, and other deceptive

practices can make shareholders liable for corporate debts.

F. Absence or Inaccuracy of Records

If corporate records go missing or prove to be inaccurate, they can form a basis to pierce the corporate veil, especially if they hinder a creditor's collection efforts against the corporation.

G. Failure to Maintain Ongoing Legal Requirements

Each state's statutes impose annual franchise fees and various report-filing requirements on corporations and similar entities. Although these have generous grace periods and cure provisions, if they are neglected long enough, the corporation or LLC will legally cease to exist and shareholder liability will result.[7]

Given any of the above factors, CMS and its Medicare contractors can seek to pierce the Company's corporate veil and collect the overpayment from the Company's owners. These circumstances, however, are not typical for health care providers and are easily avoided. Veil piercing depends on facts that by their nature are difficult to prove in a court of law, often involve subjective judgments, and in most cases are subject to dispute. The burden of proving the facts is always on the creditor. Correspondingly, courts tend to disfavor veil piercing claims and narrowly construe the applicable law, so veil piercing has a reputation as a difficult remedy to invoke successfully.

V. RULES IN BANKRUPTCY

While CMS enjoys certain advantages and unique rights under U.S. bankruptcy laws, it does not have any advantage over other creditors in reaching the pockets of shareholders of a bankrupt company.

A basic rule in bankruptcy is that filing a petition automatically halts or "stays" all acts by creditors to collect debts which pre-date the petition.[8] Since 2005, this "automatic stay" has been ruled not to impair CMS's right to exclude providers from its programs.[9] Additionally, federal case law appears to hold that the automatic stay does not prevent CMS and its contractors from recoupment against new Medicare billings by a provider in bankruptcy.[10] But no bankruptcy law gives Federal health care programs special debt collection rights against shareholders of providers, so CMS and its contractors, like other creditors, can collect Medicare overpayments from shareholders and other owners of a bankrupt entity only in the veil piercing circumstances described above, which are narrowly-drawn and strictly interpreted against the creditor.

VI. FEDERAL AGENCY PRACTICE ON PURSUING INDIVIDUAL LIABILITY

Federal agencies are not as a rule aggressive in collection of their debt claims, and CMS is no exception. For example, in government loan programs where shareholders are required personally to guarantee the debt, once corporate assets are exhausted in default cases, federal agencies rarely pursue the guarantors' personal credit and discourage their contractors and even private holders of government-guaranteed loans from doing so.[11] With this in mind, it should be no surprise that most federal agencies seldom if ever seek to pierce any corporate veil.[12] As noted, veil piercing is difficult because it involves many ambiguities and is dependent on individual facts and circumstances; government agencies are reluctant to risk the time and resources required. Government agencies also fear the adverse publicity that regularly arises from collection efforts against individuals. While federal authorities might pursue such remedies in an extreme case or under the glare of unusual publicity, they are otherwise unlikely to do so.[13]

VII. SUCCESSOR LIABILITY

The individual owners in the hypothetical will not be able to continue in the health care industry using the Company itself as a practice vehicle. They may wish to organize and capitalize another entity to provide the same or a similar type of services. In what circumstances can new entities organized by the owners after the Company's demise be held liable for the Company's overpayment obligation? This area of the law is referred to as "successor liability," and it provides remedies that allow creditors to pursue the new entity in some cases. Like veil piercing, this remedy is an exception to the general rule of limited liability of corporate owners, is available to creditors in certain narrow circumstances, and is not specific

to government creditors or health care provider debtors.

Successor liability flows from state statutes and state court case rulings that allow the creditors of a debtor company to collect their debt claims from another company to which one or more assets of the debtor have been transferred, if it is a successor to the original debtor. The exact circumstances that make the other company a successor vary from state to state. In most states the law gives a list of elements that can establish successor status, but uses a balancing test, meaning there is no concrete rule of which or how many elements must be satisfied to prove a claim. The creditor sues the transferee company to initiate such a claim, and the court hearing the case decides not only which elements are present, but also whether they are enough to make the defendant a successor.[14] But if a creditor can prove enough of them, it can obligate the transferee to pay the debt.

Elements commonly listed to impose liability on the transferee of a debtor's assets include (i) common ownership (whole or part) between the original debtor and the separate company; (ii) the transferee was established to hinder the creditors of the debtor; (iii) the original debtor and the transferee company provide the same goods or services; (iv) the same or recognizably similar company name or DBA; (v) same business location; (vi) same customers or customer sources; (vii) same officers or managers; (viii) same employees; and (ix) the transferee pays other debts of the original debtor, or states that it will do so. In most cases, one or two elements alone will usually be insufficient to establish liability.[15]

Successor liability is not as uniformly disfavored in courts as veil piercing but remains uncommon in practice. Like veil piercing, it is rarely used by federal agencies and contractors. Whether any specific circumstances will make a transferee company liable as a successor to another is beyond the scope of this article; nonetheless, asset transfers between commonly-owned companies occur frequently yet may not easily be identifiable as such to a non-lawyer. In the hypothetical, the Company's owners may be sorely tempted to use the same business location or same employees or managers in the new provider as in the Company, and may wish to have the new entity collect unpaid receiveables. Any of these steps could subject the new entity to the overpayment, or to any other creditor claim. Successor liability can be invoked against pre-existing entities under common ownership with the Company as well. Owners of health care providers having other companies subject to any Medicare contractor collection action need to avoid any such transfers scrupulously. They can make their other provider liable in common for an overpayment claim.

VIII. OTHER GOVERNMENT SANCTIONS AGAINST OWNERS AND AFFILIATES FOR NON-PAYMENT BY AN INCORPORATED PROVIDER

Pursuing owners personally for repayment of a provider's overpayment liability isn't the only sanction CMS and its contractors might logically seek to apply to punish non-payment. Excluding related persons and companies from health care program participation comes to mind. This could take at least three forms, each of which we will examine in turn.

A. Exclusion of Individual Owners

The authority for HHS to exclude both companies and individuals from involvement in its health care programs has been established at the statute, regulation, and policy manual levels.

The basic authority for exclusion is granted to the Secretary of HHS under Sections 1128 and 1156 of the Social Security Act.[16] These sections list all the grounds for which a party may be excluded.[17] Most of these sections are written so that if an entity commits acts that are grounds for exclusion, the owners are likewise at risk.[18] Most of the grounds for exclusion are not relevant here, such as conviction for felonies, or health care related misdemeanors. Three grounds for exclusion, however, relate to providers' services, namely submitting charges to any Federal health care program in excess of the provider's usual charges, furnishing services in excess of the needs of patients, and furnishing services of a quality not meeting recognized professional standards.[19] The lack of medical necessity grounds for denial that

appear in most overpayment cases corresponds to the "furnishing services in excess of the needs of patients" grounds for exclusion. So the question is whether lack of medical necessity of our Company's services is, in and of itself, valid grounds to exclude it, and therefore also exclude its owners?

These service-related grounds for exclusion are addressed in the *Medicare Program Integrity Manual* (the "PIM") in Chapter 4, Sec. 4.19. This section states, "In order to prove such cases, the PSC and the ZPIC BI unit shall document a long-standing pattern of care where educational contacts have failed to change the abusive pattern. Isolated instances and statistical samples are not actionable. Medical doctors must be willing to testify.[20]

Only these service-related grounds for exclusion could plausibly be applied to the facts of our overpayment hypothetical, without serious wrongdoing beyond simple failure to repay. The contractor documentation in a typical post-payment audit would not appear to satisfy the PIM requirement of "document[ing] a long-standing pattern of care where educational contacts have failed to change the abusive pattern."[21] Accordingly, exclusion of the provider and its individual owner does not appear to be a substantial risk in the hypothetical.

B. Bars to Subsequent Applications

In the hypothetical, the individual owners will not be able to continue in the health care industry using the Company itself as a practice vehicle. They may wish to organize and capitalize another entity to provide the same or a similar type of services. What are the risks that CMS and its contractors might punish the Company's failure to satisfy its proven overpayment demand, by barring the enrollment application of the owner's new provider entity?

In order to bar a new provider owned or controlled by owners of the hypothetical defaulting provider, however, CMS and its contractors must be aware of the relationship between the two companies. So the initial inquiry must be whether the new-provider enrollment process will itself call the attention of CMS or its contractors to the relationship between the non-paying Company and the new applicant. This process is largely embodied in the enrollment application document. The current form of Medicare enrollment application for most incorporated providers, CMS-855A requires disclosure of any "Adverse Legal Actions/ Convictions" of individuals with ownership or control of the entity.[22] The Company's owners from the hypothetical would therefore be required to disclose any such as part of the enrollment application. The listing of adverse adjudications that constitute Adverse Legal Actions/Convictions includes most criminal convictions, state license and government program revocations, suspensions, exclusions and debarments, as well as "[a]ny current Medicare payment suspension under any Medicare billing number."[23]

This form does not require the new applicant's owner to disclose the problems of the Company in the hypothetical, or even mention its existence, for two reasons. First, "payment suspension" is a very specific Medicare sanction, and usually not present in an overpayment demand case. Second, the disclosure is explicitly directed at the individual owner, and its wording does not extend it to other entities under the owner's ownership or control. Section 6 of the PIM provides the following:

> 1. Has the individual in Section 6A, under any current or former name or business identity, ever had a final adverse legal action listed on page 16 of this application imposed against him/her?[24]

New program developments in Medicare, however, may change the above situation and extend required disclosures to entities under common ownership or control with new applicants. In its 2013 Work Plan, the HHS OIG proposed the following concerning oversight of "currently not collectible debt":

> [The OIG] will also determine whether [currently not collectible] debtors are closely associated with other businesses that continue to receive Medicare payment. CMS defines a [currently not collectible] debt as a Medicare overpayment that remains uncollected 210 days after the

provider or supplier is notified of the debt and for which recovery attempts by CMS contractors have failed.[25]

No mention is made in the Work Plan of what, if any, sanctions HHS is considering against businesses "closely associated" with defaulting debtors, but affiliates of debtors defaulting on overpayments are clearly a topic of concern to the agency. Program changes on this subject may be forthcoming, and would logically be brought to bear in the new provider enrollment process.

Means already exist – such as simple data mining – for CMS and its contractors to identify other providers under common ownership with a defaulting provider.[26] With or without changes coming from the Work Plan, there is a substantial risk that in our hypothetical, CMS or its contractors would become aware of the connection between the new application and the Company's unsatisfied overpayment.

Grounds for denial of enrollment are similar to grounds for exclusion.[27] They include felony convictions and program debarments, as well as exclusions of "[a] provider, supplier, an owner, managing employee, an authorized or delegated official, medical director, supervising official, or other health care personnel furnishing reimburseable Medicare services who is required to be reported on the enrollment application."[28] Further, denial of enrollment based on an existing overpayment is expressly mentioned in this regulation: "(6) Overpayment. The current owner (as defined in § 424.502), physician or nonphysician practitioner has an existing overpayment at the time of filing of an enrollment application."[29] This provision does not include the Company's overpayment in our hypothetical as grounds for denial of the new provider's enrollment, and no other part of the regulation appears to do so either. So it appears that even if CMS or its contractor is aware of the affiliation of the Company and the new entity, it could not deny the new enrollment. In practice, however, it is highly likely the agency would strive to find other grounds for denial in such a case, and the affiliation with the Company would make enrollment extremely difficult for the new provider entity. Additionally, changes to the Medicare enrollment process resulting from the OIG Work Plan discussed above could include an expansion of the grounds for denial of enrollment to include overpayments by entities under common control with the applicant.

C. Sanctions Against Companies Under Common Ownership or Control

If we add to the hypothetical another existing health care provider business that is incorporated as an entity separate from the Company but under common ownership or control, another question arises: what are the risks that CMS and its contractors might punish a failure to satisfy a proven overpayment demand with sanctions against the other existing Medicare provider entity? In the veil piercing and successor liability topics above, we noted that such acts as ignoring the formalities of legal separateness between the Company and the other provider entity, and transferring assets between them, can allow creditors such as CMS and its contractors to pursue their debt claims against both entities. But as also noted in that topic, such remedies are hard to invoke, disfavored by courts in practice, and seldom used by government agencies. So our inquiry turns to exclusion of the other entity from government programs and revocation of its Medicare enrollment.

Section 1320a-7(b)(8) of the Social Security Act allows incorporated entities to be excluded if a five percent or more owner or control person has been excluded. The Company's owners will own the other entity in our hypothetical, so if the conduct of the Company were grounds to exclude the owners, § 1320a-7(b)(8) would allow the other entity to be excluded likewise. But as discussed in (a), above, the PIM exclusion requirements make it unlikely that the exclusion sanction could be applied in a normal overpayment case. Likewise, the regulations governing revocation of enrollment do not identify an overpayment by a provider under common control as grounds for revocation.[30] Accordingly, no clear avenue exists under current Medicare law and policy to exclude or revoke the enrollment of the commonly owned provider in our hypothetical.

IX. CONCLUSION

In sum, the established legal rule of limited liability of owners of incorporated businesses appears to be alive and well in the Medicare service provider area,

and federal agencies and their contractors by and large respect it. The separateness of legally distinct incorporated businesses under common ownership also remains in effect. However, these rules have significant exceptions.

Owners of incorporated health care provider entities, absent some written agreement to the contrary, are insulated from personal liability for overpayment obligations owed by their companies to Federal health care program authorities by the same state laws which insulate them from their companies' other debts. Generally, federal health care laws do not change these rules. If your company's assets are insufficient to satisfy its debts, procedures exist for federal claimants (like other creditors) to try to reach through your company and pursue your personal credit to satisfy their claims. But this requires a lawsuit to be filed against you personally; the laws of the states specify only certain narrow circumstances where they can be successful. Accordingly, creditors rarely try to "pierce the corporate veil," and this is probably more true of federal creditors than private ones.

The most likely situation where an insolvent provider's creditor can successfully reach the personal credit of the owner is when the owner has taken dividends and other sums from the company which cannot be characterized as salary or compensation for employment, at times when the debtor company was already insolvent. Likewise, the most likely way a new provider company being organized by an existing provider's owner can become liable to its creditors is for assets to be transferred from the old provider to the new. Owners of multiple providers should consult legal counsel to examine all dealings between them for successor liability and similar issues whenever one provider becomes liable for overpayments, because many risk-creating activities will not be recognizable as such without legal training.

In addition to debt collection risks, HHS can exclude owners of providers from Federal health care programs, which operates to exclude other provider entities under common ownership. The available grounds for exclusion, however, do not normally arise in an overpayment case. Similarly, HHS regulations provide for the revocation of the enrollment of health care providers in certain cases. The grounds for revocation do not include a defaulted overpayment by a separate provider under common control.

The main area of risk for the affiliates of a defaulting provider subject to an overpayment is the enrollment application by a new provider entity under common ownership. While the strict wording of the current enrollment application form does not require disclosure of the overpayment situation in our hypothetical, and overpayment by a commonly-owned provider is not currently a listed basis for denial of the new enrollment, in practice the existence of a defaulted overpayment obligation poses a substantial risk to any related party's enrollment. Initiatives are under way inside HHS that could change these risks to certainties.

[1] The term "incorporated" will be used here to refer to the legal process of creating any form of legal entity providing limited liability to its owners (e.g. limited partnerships and LLCs) not just to the creation of a corporation.

[2] ZPICs are contractors dedicated to program integrity by handling functions such as audits, medical reviews, and potential fraud and abuse investigations consolidated into a single contract. Medicare Program Integrity Manual, Centers for Medicare & Medicaid Services, Ex. 1 (Dec. 28, 2012), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83exhibits.pdf.

[3] RACs focus on identifying and recovering improper Medicare payments through the efficient detection and collection of Medicare overpayments. *See* Ctrs. for Medicare & Medicaid Servs., *Recovery Audit Program*, CMS.gov (last updated Mar. 13, 2013), http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/index.html?redirect=/rac/. Unlike ZPICs, RACs are paid on a contingency basis and focus more on fraud.

[4] CERT contractors measure improper Medicare payments. The CERT program uses random samples to select claims and is therefore often unable to label a claim fraudulent. *See* Ctrs. for Medicare & Medicaid Servs., *Comprehensive Error Rate Testing (CERT)*, CMS.gov (last updated Mar. 13, 2013), *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/index.html?redirect=/CERT/.

[5] *See* Walkovszky v. Carlton, 18 N.Y.2d 414, 418-19 (1966) (refusing to pierce the corporate veil on account of undercapitalization alone); Sea-Land Servs., Inc. v. Pepper Source, 941 F.2d 519 (7th Cir. 1991) (finding that the corporate veil will be pierced when there is no separation between the corporation and its owner and when a fraud or injustice would result if the veil were not pierced).

[6] This practice is harder to defend than a claim for initial undercapitalization, because in this case there is evidence that at the time of organization, the owners believed the capital later taken out was needed in the business.

[7] Failure to hold annual meetings or keep corporate minutes has seldom been the basis for shareholder liability.
[8] 11 U.S.C. § 362.
[9] 11 USC § 362(b)(28)
[10] *See* In re Slater Health Center, Inc., 398 F.3d 98, 104-05 (1st Cir. 2005) (allowing CMS to recoup money as an adjustment for a Medicare overpayment, even though the provider was in bankruptcy). The US Bankruptcy Code does not explicitly address recoupment, and the *Slater* ruling may not apply in all circumstances. Among other things, its application turns on the overpayment and the new billing being part of the "same transaction." Otherwise, the contractor's claim against the new billing is a setoff that is specifically addressed in the Code and is generally halted in bankruptcy by the automatic stay. *See, e.g.*, In re University Medical Center, 973 F.2d 1065, 1073 (3rd Cir. 1992) (holding that a debtor hospital's claim that HHS violated the automatic stay by withholding payments for Medicare services rendered after debtor hospital filed for bankruptcy arose under the Bankruptcy Code).
[11] Gerri Detweiler, *What to Do if You Can't Make Your SBA Loan Payments*, Credit.com (May 30, 2011), http://blog.credit.com/2011/05/what-to-do-if-you-cant-make-your-sba-loan-payments/ (explaining that while the Small Business Administration can seize debtors personal collateral in the event of a default, in practice it encourages the lending bank to work out a reasonable settlement).
[12] The notable exception to this rule is the Internal Revenue Service's pursuit of shareholders to collect corporate tax liability. The IRS has in recent years successfully pierced the corporate veil in a number of well-publicized cases.
[13] In over thirty years of representing participants in Federal programs, I have never been involved in any case where such a remedy was sought against a client or any other individual.
[14] *See, e.g.*, Cab-Tek v. E.B.M. Inc., 153 Vt. 432 (Vt. 1990).
[15] Typical statements of state successor liability rules can be found in Marks v. Minn Mining & Mfg. Co., 187 Cal. App. 3d 1429 (Cal. Ct. App. 1986) and Sweatland v. Park Corp., 587 NYS 2d 54 (App. Div. 1992).
[16] 42 USC §§ 1320a-7 and 1320c-5.
[17] For a helpful chart from HHS OIG that lists all of the bases for exclusion, see *Exclusion Authorities*, Dep't of Health & Human Servs. (last visited April 8, 2013), https://oig.hhs.gov/exclusions/authorities.asp.
[18] The recurring text appears, for example, in 42 USC § 1320a-7(b)(6). That section provides that the Secretary of HHS may exclude "Any individual or entity that the Secretary determines… has furnished or *caused to be furnished* … items or services to patients substantially in excess of the needs of such patients…." Since owners of a provider entity are normally in control of it, if the entity has done the described act, the owner can be said to have *caused* the act, and is therefore subject to the same grounds for exclusion [emphasis added].
[19] 42 USC § 1320a-7(b)6).
[20] Ctrs. for Medicare & Medicaid Servs., *Medicare Program Integrity Manual*, CMS.gov, Ch. 4, § 4.19.2 (Dec. 28, 2012), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c04.pdf.
[21] Notably, no practitioner at this health care law firm has seen exclusion attempted or threatened against the provider or its owners in a simple overpayment case.
[22] *See Medicare Enrollment Application: Institutional Providers, CMS-855A*, Centers for Medicare & Medicaid Services § 6, *available at* http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855a.pdf.
[23] *See id.* at § 15 (extending the required disclosure to all subsequent periods, effectively making it an Evergreen requirement).
[24] *Id.* at § 6.
[25] *Office of Inspector General Work Plan: Fiscal Year 2013*, Dep't of Health & Human Servs. at 38 (2013), *available at* https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf. The OIG's FY 2012 Work Plan contained an identical provision. *See Office of Inspector General Work Plan: Fiscal Year 2012*, Dep't of Health & Human Servs. at I-32 (2012), *available at* https://oig.hhs.gov/reports-and-publications/archives/workplan/2012/Work-Plan-2012.pdf.
[26] For example, CMS-855 program application forms have long required owners of all applicants to be identified by name and Social Security Number. Cross-checking these identifiers against identifiers of owners from the CMS-855 of defaulting debtors could easily be implemented.
[27] *See* 42 C.F.R. § 424.530(a); *see also* Medicare Program Integrity Manual, Centers for Medicare & Medicaid Services, Ch. 15.8 (Dec. 28, 2012), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf.
[28] 42 CFR § 424.530(2).
[29] *Id.* at § 424.530(6). The regulation defining the term "owner" includes holders of five percent greater ownership interests. Grounds for denial of enrollment based on payment suspension are set forth in nearly identical language in § 424.530(7).
[30] *See* 42 CFR § 424.535. Note that this revocation regulation includes a grounds for revocation corresponding to § 424.530(a)(2) (felony conviction, debarment or suspension by the provider, its owner or key personnel) but no grounds for revocation corresponding to § 424.530(a)(6) (existing overpayment by the provider or its owner).

In The News

Drug Shortages: FDASIA and Incentives for Compliance Through the Tax Code

*Robert Alinsky**

I. INTRODUCTION

The Food and Drug Administration Safety and Innovation Act (FDASIA) became law in July 2012 and authorizes the Federal Drug Administration (FDA) to take more aggressive action in combating drug shortages in the U.S.[1] FDASIA provides the FDA with new tools to better prepare for impending shortages such as more strict reporting requirements for pharmaceutical companies engaged in the manufacture of certain covered drugs.[2] However, while an alert system is important, the new law does not directly address the underlying issue of how to prevent drug shortages by ensuring an adequate supply.[3] As many public, private, and governmental organizations stress, drug shortages is a pressing issue affecting many people who rely on critical medications. This issue needs immediate aggressive legislative attention.[4] The FDA is seeking solutions to this problem and is open to working with pharmaceutical companies to increase production of certain drugs.[5] In addition to the existing early warning system, one possible solution would be to use the tax code to create positive incentives for drug manufacturers to prevent and relieve drug shortages. This article argues to broaden the scope of the Increasing Research Activities Credit to cover pharmaceutical company expenses targeted at drug shortages, and that the calculation of the credit could be based on the formula employed in the Renewable Energy Production Credit.[6]

II. BACKGROUND

Under FDASIA's broad-stroke policy objectives aimed at reducing drug shortages, the FDA is required to establish a Drug Shortages Task Force (Task Force) whose responsibility is to develop and implement a drug shortages plan.[7] The Task Force has since opened its plan development to public comments and has articulated a number of areas in which they seek specific suggestions.[8] One such item the Task Force seeks comments on are "incentives that FDA can provide to encourage manufacturers to establish and maintain high-quality manufacturing practices, to develop redundancy in manufacturing operations, to expand capacity, and/or to create other conditions to prevent or mitigate shortages."[9] The tax system can be utilized for such incentive behavior.[10] One available avenue is to employ the current Increased Research Activities credit and incorporate into that credit the formula used in the highly successful Energy Production Credit for renewable fuels.

A. FDASIA

Congress updated The Federal Food, Drug & Cosmetic Act (FD&C Act) through FDASIA by amending certain provisions which now require pharmaceutical companies to notify the FDA of impending shortages and to keep records of drug levels.[11] The FDA was further instructed to facilitate better inter- and intra-agency communication about drug shortages and use a Task Force to form a strategic plan to thwart shortages.[12] The Task Force seeks solutions to attack the underlying problems of drug shortages including encouraging increased manufacturing, exploring better metrics for monitoring drug levels, and incentivizing pharmaceutical companies to "establish and maintain high-quality manufacturing practices, to develop redundancy in manufacturing operations, to expand capacity, and/or to create other conditions to prevent or mitigate shortages."[13]

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B. Increased Research Credit

Under 26 U.S.C. § 41, the tax code provides corporations with a non-refundable incremental tax credit for increased qualified research expenses and activities.[14] The credit is limited to certain activities outlined in a four-part test, requiring: expenses that qualify as research under 26 USC § 174; technological in nature; involves a business component; and involves a process of experimentation related to a qualified purpose.[15] To satisfy the business component element, expenses must be related to research regarding products, process, formulas, or software, which are to be held for sale, lease, or used in the organization's trade or business.[16] The purposes for which the credit is to be applied are limited to those related to a new or improved function, performance, or reliability and quality.[17] Permitted purposes do not include, among other things, research after commercial production has begun, adapting a business component to a particular customer's needs, or duplication of an existing business component.[18] Seemingly narrow, the code could be broadened by interpreting what the permitted purposes apply to and should be read to mean.[19]

C. Renewable Energy Production Credit

Intended to incentivize production of alterative energy sources to fossil fuels, the Renewable Energy Production Credit permits a tax credit to production facilities that produce electricity from renewable sources.[20] The credit is calculated by a simple mathematical formula based on the amount of electricity actually produced by the qualified facility.[21] This tax credit has successfully incentivized the use of alternative fuels to produce electricity, and the production-dependent formula used to calculate the credit is directly related to increased production of electricity by renewable energy.[22]

III. ANALYSIS

The Task Force's recent comment period sought suggestions from the public to help relieve drug shortages. Notably, the Task Force announced that it is looking for ways to work with other federal government agencies to accomplish its mission.[23] The Treasury Department can provide a resource to the FDA in this regard by promulgating regulations or pressuring congress for a bill that would incentivize pharmaceutical companies to maintain sufficient quantities, more effectively monitor drug levels, and/or resume manufacturing of drugs that the FDA determines are in shortage.[24] Sections 41 and 45 of the tax code could be used together to promote synergy between pharmaceutical companies and the FDA to improve manufacturing mechanisms, processes, and supply monitoring systems of the critical drugs needed by many Americans.

A. Reinterpret § 41 to Accommodate FDASIA Objectives

Faster and more efficient then asking Congress to pass a bill granting new authority to Treasury or the FDA, the Task Force should work with Treasury to draft new interpretive, legislative, or procedural regulations to expand the scope of the Increasing Research Credit to include stop-gap drug shortage efforts by drug companies. The new regulation should interpret the qualified research language in § 41 to include such measures that allow a company to easily and quickly produce more of an essential drug.[25] Moreover, the regulation's authority is linked to the policy objectives of Congress, which support incentivizing the pharmaceutical industry through tax credits.[26] The statute is intended to incentivize research activities, and such activities will benefit society if they include pharmaceutical efforts to increase production of drugs that are facing a critical level of supply as prescribed by the FDA.[27]

Although the credit is limited to certain purposes, the current language of the credit encompasses the type of costs associated with activities outlined in FDASIA objectives.[28] Funds spent towards meeting FDASIA's goal of research and implementation of new processes to prevent shortages and maintain adequate drug supplies meet the requirements of § 41: expenditures made in discovering new technological information relating to a new or improved function, performance, or reliability or quality of a business component.[29] The language of the statute is broad enough to encompass the intent of FDASIA by allowing a credit for pharmaceutical

companies who invest funds in better tools and new methods in order to improve their ability to prevent shortages and continue or restart manufacturing when the FDA alerts that supplies are low.[30] However, Treasury should work with the Task Force to develop language that reinterprets the scope of the credit to cover broader costs associated with developing systems to better monitor drug stockpiles for the enumerated drugs listed by FDA. Additionally, a Treasury regulation could better explain the "reliability" function of permitted purposes of § 41(d)(3)(iii) to account for expenses used to increase reliability of drug manufacturing practices. This would encourage production of better quality products, which would increase overall drug stock and reduce costs associated with defective drug units.[31] A regulation could also interpret § 41 and associated treasury regulations to limit the disallowed purposes of products already manufactured or duplication of business competent by outright excluding such research activities pertaining to drug shortages.[32]

B. Incorporate the Renewable Energy Production Credit Formula

To further achieve the goals of the FDASIA Task Force, a treasury regulation should further interpret and adjust procedurally how the credit will be calculated based on the methodology used in calculating the Energy Production Credit.[33] As discussed, this credit amount is based upon the amount of energy produced by alternative fuel facilities. Renewable Energy Production Credit could be applied in such a way that pharmaceutical producers would receive a tax credit to offset the costs incurred by efforts to improve production processes to prevent or alleviate a shortage. The formula will provide credits proportional to the additional drug units produced due to improved processes. By integrating the Renewable Energy Production Credit formula, pharmaceutical companies will only get the credit if their research and productive activities directly contribute to increased levels of critical pharmaceuticals. This measure will help to reduce over-production for the sole benefit of receiving the credit. Moreover, the regulation should specify that only expenses related to drugs named on FDA shortage lists could qualify for the credit; allocation of mixed-use research expenses would be permitted.[34] Therefore, the credit benefit will be allowed based on the costs actually spent for investment in solving or preventing a drug shortage.

IV. CONCLUSION

Drug Shortages present a serious problem and there is an ever-increasing need for more regulatory adjustments to better combat the issue.[35] In an effort to encourage the pharmaceutical industry to work with the FDA to prevent and alleviate drug shortages under the newly invigorated FDASIA, joint solutions should be sought with the Treasury Department. The Treasury Department could leverage the Increased Research Credit to provide tax incentives to pharmaceutical companies to increase research related to solving drug shortages by using the same credit-calculation method as the Renewable Energy Credit.

[1] *See Regulatory Information: FDASIA*, U.S. Food and Drug Administration (Nov. 27, 2012), http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA (providing an overview of the law which amended the Federal Food, Drug, and Cosmetic Act).

[2] *See* Food And Drug Administration Safety And Innovation Act (FDASIA), PL 112-144, sec. 1001-1008, § 356 c and d, 126 Stat. 993 (2012) (defining covered drugs as those which are "life-supporting, life-sustaining; or intended for use in the prevention or treatment of a debilitating disease or condition").

[3] *See* Valerie Jensen, *FDA Is Asking The Public To Send In Ideas For Combating Drug Shortages*, FDA Voice (Feb. 13, 2013), http://blogs.fda.gov/fdavoice/index.php/2013/02/fda-is-asking-the-public-to-send-in-ideas-for-combating-drug-shortages (noting the FDA itself can do more with help from the public).

[4] *See, e.g.*, *American Academy of Pediatrics – Comment*, FDA Drug Shortages Task Force Strategic Plan; Request for Comments (April 2, 2013), *available at* http://www.regulations.gov#!documentDetail;D=FDA-2013-N-0124-0125 (noting the serious impacts of drug shortages on the care of children).

[5] Food and Drug Administration Drug Shortages Task Force and Strategic Plan Notice, 78 Fed. Reg. 9928-29 (Feb. 12, 2013) [hereinafter *Task Force Notice*] (calling on the public for methods to incentivize drug companies).

[6] *See* 26 U.S.C. §§ 41, 45 (2010) (respectively: Increasing Research Activities Credit; Renewable Energy Production Credit).

[7] *See* § 356d.

[8] *Task Force Notice*, *supra* note 5.

[9] *Id.*

[10] *See* Eric Friske, Note, *Addressing Looming Prescription Drug Shortages Through Legislative and Regulatory Approaches*, 14 Minn. J.L. Sci. & Tech. 521, 539 (2013) (arguing generally that perhaps tax incentives can be used to encourage firms to maintain adequate drug levels).
[11] § 356c.
[12] *Id*. § 356d.
[13] *Task Force Notice*, *supra* note 5.
[14] 26 U.S.C § 41 (2010).
[15] *Id.* § 41(d).
[16] *Id.* § 41(d)(2).
[17] *Id*. § 41(d)(3).
[18] *Id*. § 41(d)(4).
[19] *See generally Tax Research: Understanding Sources of Tax Law*, CCH, http://www.cchgroup.com/opencms/opencms/web/TAA/LP/all/federaltaxlaw/DOC_Treasury-Regulations.pdf (last visited April 13, 2013) (explaining the powers of Treasury to promulgate regulations and the department's scope of authority).
[20] American Taxpayer Relief Act of 2012, PL 112-240, 126 Stat 2313 (2013) (extending the credit and revising portions of 26 U.S.C. § 45 (2010)).
[21] 26 U.S.C. § 45(a) (2010).
[22] *See generally* Mona Hymel, *The United States' Experience with Energy-Based Tax Incentives: The Evidence Supporting Tax Incentives for Renewable Energy*, 38 Loy. U. Chi. L.J. 43 (2006) (arguing how the tax credit has been an successful incentive and helped overcome the costs of complying with Congressional policy objectives by correlating the benefit with investment).
[23] *Task Force Notice*, *supra* note 5.
[24] *See also* Food And Drug Administration Safety And Innovation Act, PL 112-144, sec. 1004, § 356c, 126 Stat. 993 (2012) (mandating that the "Secretary shall maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States").
[25] *Cf.* 21 U.S.C. § 41(d) (2010) (defining qualified research as relating to new or improved business components which could include processes designed to better manage drug supply levels).
[26] *See generally* Sheila Campbell, Congressional Budget Office, Pub No. 2927, Federal Support for Research and Development (2007) (indicting that research credits result in many benefits); David H. Austin, Congressional Budget Office, Pub No. 2589, Research and Development in the Pharmaceutical Industry (2006) (discussing, in part, advancements in the drug industry due to congressional policy).
[27] *See also* Kreig Mitchell, *Section 41 Research and Experimentation Tax Credit Audit Considerations*, 37 Colo. Law, Mar. 2008, at 49 (noting the legislative history; articulating incentives and importance of the credit to encourage research activities).
[28] *But see* § 41(d)(4) (listing excluded expenses, those for businesses components that are already commercially manufactured, or for duplication of such existing components).
[29] *See* § 41(d).
[30] *See id*. (excluding certain purposes for which potentially include actual costs for unit production does not explicitly prohibit expenses for improvement of such manufacturing processes, monitoring, or other costs of restarting production at the request of the FDA).
[31] *See* Staff of H. Comm. on Oversight and Government Reform, 112th Cong., FDA's Contribution to the Drug Shortage Crisis 14 (2012) (pointing to a study about the impacts of poorer quality manufacturing on drug supplies).
[32] *Cf.* 26 C.F.R. § 1.41–4(c)(2)(ii) (2013) (explaining the credit in a treasury regulation that activities conducted after the components are ready for commercial sale are not permitted as qualified research purposes).
[33] *See also* Campbell, *supra* note 26, at 27 (finding that the current method of calculation for the research credit has been criticized, noting how different formulas could encourage more research).
[34] *See* Food And Drug Administration Safety And Innovation Act, PL 112-144, sec. 1004, § 356c, 126 Stat. 993 (2012) (calling for the FDA to publish which drugs are at risk).
[35] *See* Exec. Order No. 1358876, 76 Fed. Reg. 68295 (2011) (calling on the FDA to use new approaches including examining ways to encourage improvements to manufacturing and other tools to prevent shortages by President Obama though executive order).

In The News

Science over Politics: Why the FDA Must Allow Plan B as a Nonprescription Drug

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On April 5, 2013, the United States District Court for the Eastern District of New York held that the Food and Drug Administration (FDA) had 30 days to allow the sale of Plan B[1] without a prescription and without age or point-of-sale restrictions.[2] The court had previously given the agency a chance to allow Plan B to have nonprescription status regardless of age without a mandate from the court,[3] but the FDA not only refused to revise its decision on the drug's status, but also failed to provide sufficient evidence to support its decision. The fight over the approval of Plan B for over-the-counter sale seems to be the result of politics rather than scientific evidence, as evidence suggests that Plan B is safe for use by all women of childbearing age yet the FDA has continuously imposed age-based and point-of-sale restrictions.

Plan B is an emergency contraceptive pill that can be taken by a woman up to 72 hours after unprotected sex or birth control failure.[4] The side effects of Plan B are mild and similar to the side effects associated with regular birth control pills, including menstrual cycle changes and nausea.[5] These mild side effects make Plan B safer than other drugs that are currently approved for over-the-counter sale that rely labeling for safe use of the drug, without any point of sale or age restrictions.[6] Before a drug is approved for sale to consumers, the manufacturer submits a new drug application (NDA) to the FDA.[7] After a NDA is approved, if a drug manufacturer wants to make the drug available for additional indications, thus making the drug available to more individuals, the manufacturer must submit a supplemental new drug application (SNDA).[8] When considering whether to approve an NDA or SNDA, the FDA looks at evidence of the drug's safety and effectiveness in light the indicated use(s) of the drug.[9] When the FDA initially approved Plan B as an emergency contraceptive, it was approved for women eighteen years of age and older without a prescription but a prescription was required for women under eighteen years of age. The practical effect of this decision was that point-of-sale restrictions were necessary, as women were required to show identification to prove their age before purchasing Plan B and point of sale restrictions were enacted by selling Plan B behind the pharmacy counter.[10]

After receiving the initial approval of Plan B, the manufacture was unable to obtain a change in the status of the drug until the court intervened. The manufacturer of Plan B submitted three different SNDAs in an attempt to change the status of Plan B. First, the manufacture attempted to expand access to all ages without requiring a prescription or imposing point of sale restrictions, but the FDA rejected the SNDA. Second, the manufacture attempted to expand access to all women sixteen years of age and older without prescription but this SNDA was also rejected by the FDA. Third, the manufacturer attempted to expand access to all women seventeen years of age and older without a prescription yet again the FDA rejected the SNDA.[11] In 2009, however, the court forced the FDA to expand access to Plan B without a prescription to all women seventeen years of age and older. The court also remanded the issue back to the FDA so that the agency could determine whether available information on the safety of Plan B warranted making additional changes to the drug's status.[12] Specifically, the court indicated that the FDA should consider the status of Plan B, utilizing the agency's general policies for approving drugs for over-the-counter sale rather than political considerations.[13]

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The FDA denied the SNDA and citizen petition, a petition to change a drug's status made by the public, requesting to change the status of Plan B making available to women of all ages without a prescription, based on Secretary of Health and Human Services Kathleen Sebelius's Order. A December 2011 memorandum to the Commissioner of the FDA, Dr. Margaret Hamburg, detailed Secretary Sebelius's justification for declining to switch Plan B to over-the-counter status.[14] Secretary Sebelius's involvement and disagreement with the FDA Commissioner was unprecedented, Secretary Sibelius effectively overruled a decision by the FDA despite strong scientific evidence supporting the FDA's position. The FDA analyzed Secretary Sebelius's memorandum attempting to justify the denial of over-the-counter status to Plan B without age restrictions and found little evidence in support of her position, which lead the court to conclude that her position was focused on the political consequences of allowing unrestricted access to Plan B rather than scientific evidence.

There are number of issues with Secretary Sebelius's justifications for declining to make Plan B available to all women over-the-counter. First, as she argued that the data related to label comprehension and actual use did not account for women of all age ranges to which Plan B would be available if the drug were available over-the-counter without point of sale or age restrictions.[15] However, the FDA had previously waived the requirement that the studies include participants between the ages of eleven and thirteen because the use of Plan B by girls in this age range is rare and the number of participants in this age range included in the studies would have been so small as to be unrepresentative.[16] Second, Secretary Sebelius pointed to cognitive and behavioral differences between older and younger adolescents as a relevant factor in denying access to Plan B as an over-the-counter drug to women of all ages.[17] The Director of the Office of New Drugs at the FDA, however, determined that cognitive and behavioral differences between older and younger adolescents did not address whether the younger girls of reproductive age can safely understand and use Plan B but rather whether the younger girls of reproductive age should be engaging in the types of sexual behavior that necessitate the use of Plan B;[18] the latter issue is not an issue that the FDA is designed to regulate as the role of the FDA is to determine whether a drug is safe and effective for its intended use. Furthermore, if the issue is that younger reproductive age girls may not be able to comprehend the labeling and usage of Plan B, in the past, data establishing such claims has never been required as part of a drug's approval for over-the-counter status..[19] Finally, Secretary Sebelius failed to identify the harm associated with making Plan B available to all women of reproductive age given that the FDA typically approves drugs for over-the-counter sale without requiring the manufacture to show that the drug is safe for the youngest populations.[20] The likelihood of unsafe use, abuse, or misuse of Plan B is extremely low, especially when compared to the risks associated with other more dangerous drugs[21] that are currently sold over-the-counter without any restrictions.

The same day that Secretary Sebelius sent the memorandum justifying the denial of the SNDA for Plan B, Commissioner Hamburg released her own statement[22] explaining that the scientific data used by the Center for Drug Evaluation and Research (CDER) supported the finding that Plan B could be safely used by all women of childbearing age and that the role of the FDA was to approve drugs based scientific evidence regarding the drug's safety and efficacy for its intended use.[23] Commissioner Hamburg went on to note that, "following Secretary Sebelius's direction"[24] the FDA had to deny the SNDA for non-prescription access to Plan B for women under seventeen years of age, despite the FDA's typical approval process and evidence of Plan B's safety that she acknowledged in the rest of her statement.

In reviewing the FDA's actions in denying the citizen petition[25] to remove point-of-sale and age restrictions on Plan B, the court looked to whether the agency's actions were "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law."[26] This standard is deferential to the agency,[27] but the court determined that the unprecedented nature of Secretary Sebelius's involvement,[28] particularly its disregard of the FDA's standards and typical practices for switching a drug's status and the secretary's lack of technical expertise, made the FDA's decision denying the SNDA arbitrary, capricious, and unreasonable.[29]

It seemed clear to the court that there was no scientific justification for the age or point-of-sale restrictions and, therefore, the denial of the citizen petition was reversed; the FDA was given thirty days to allow access to Plan B as a nonprescription drug and the issue was remanded to the FDA to make any necessary labeling changes or changes based on the different available doses of Plan B.[30] The court's decision looked past the potential political consequences of allowing women of all ages to access a contraceptive designed for use after sex and upheld the FDA's role as a regulator of the safety and efficacy of drugs based on science. The court was appropriately deferential to the FDA and provided the FDA with an opportunity to use scientific evidence to justify its age and point-of-sales based restrictions on Plan B, but as seen through the analysis of Secretary Sebelius's justification for the restrictions on the sale of Plan B, the science simply did not support the restrictions that the FDA placed on the sale of Plan B. By maintaining the FDA's standards and typical procedures for decisions to allow drugs to be available over-the-counter, the court has reinforced the idea that an agency's technical determinations should be based on scientific evidence, insulated from political influence, to prevent inconsistent or unjustifiable results.

[1] Plan B, also known as the "morning-after pill", is used to refer to Plan B One-Step, the specific one-pill dosage type at issue in this case; however, there is no meaningful difference between this type of Plan B and other forms aside from the number of pills that need to be taken for the drug to work effectively.

[2] *Tummino v. Hamburg*, No. 12 CV 763 (ERK)(VVP), 2013 U.S. Dist. WL 1348656, at *31 (E.D.N.Y. 2013).

[3] Tummino v. Torti, 603 F. Supp. 2d 519, 550 (E.D.N.Y. 2009).

[4] Plan B One-Step (levonorgestrel): About. http://www.planbonestep.com/about-plan-b-one-step.aspx (last accessed Apr. 12, 2013) (explaining that Plan B is not to be used as a regular form of birth control but rather it is to be used as a back-up form of contraceptives when another form contraception fails).

[5] Plan B One-Step (levonorgestrel): FAQs. http://www.planbonestep.com/faqs.aspx (last accessed Apr. 12, 2013).

[6] *Tummino*, WL 1348656 at *15 (examining other drugs that are approved for over-the-counter sale that pose a more significant risks to users under the age of 18 than Plan B, including cough syrup that contains dextromethorphan that poses high risk of abuse by teens, and acetaminophen, which is frequently ingested in high doses by individuals attempting to commit suicide).

[7] 21 U.S.C § 355(b)(1) (2010).

[8] 21 U.S.C. §§ 355(b)(4)(A)-(B) (2010).

[9] U.S. Food and Drug Admin., Comm'r Statement, *Statement from FDA Comm'r Margaret Hamburg, M.D. on Plan B One-Step* (Dec. 7, 2011) [hereinafter Hamburg Statement] http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm (last accessed Apr. 12, 2013).

[10] Alastair J.J. Wood, M.D et al., *The Politics of Emergency Contraception*, 366 New Eng. J. Med. 101, 101-02 (2012) www.nejm.org/doi/full/10.1056/NEJMp1114439 (last accessed Apr. 12, 2013).

[11] Tummino v. Torti, 603 F. Supp. 2d 519, 523 (E.D.N.Y. 2009).

[12] *Id.* at 550.

[13] *Id.* at 548 (concluding that the FDA has not presented any evidence to rebut the assertion that it was acting in bad faith and in response to political pressure in its review of the status of Plan B).

[14] Memorandum from Kathleen Sebelius to Margaret Hamburg, M.D. Comm'r of Food and Drugs (Dec. 7, 2011) [hereinafter Sebelius Memo] http://www.hhs.gov/news/press/2011pres /12/20111207a.pdf (last accessed Apr. 12, 2013).

[15] *Id.*

[16] Tummino v. Hamburg, 2013 U.S. Dist. WL 1348656, at *7-*8 (E.D.N.Y. 2013) (noting that Secretary Sebelius' disagreement over granting an age waiver for the study was not a valid reason to effectively overrule the FDA's decision).

[17] Sebelius Memo, *supra* note 14.

[18] *Tummino*, WL 1348656 at *8.

[19] *Id.* (noting that the FDA has never precluded the over-the-counter sale of drugs based on this reasoning).

[20] *Id.* at *9 (noting that the FDA approves drugs for over-the-counter status without such data, relying on labeling to effectively indicate age-based restrictions).

[21] *Id.* (explaining that the reasoning offered would require removal of over-the-counter status for drugs containing dextromethorphan, laxatives, analgesics, and acetaminophen).

[22] U.S. Food and Drug Admin., Comm'r Statement, *Statement from FDA Comm'r Margaret Hamburg, M.D. on Plan B One-Step* (Dec. 7, 2011). http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm (last accessed Apr. 12, 2013).

[23] *Id.* (discussing the review of scientific evidence and risk/benefit assessment conducted to reach the conclusion that Plan B One-Step met the regulatory standard for a nonprescription drug).

[24] *Id.*

[25] *Tummino*, WL 1348656 at *19 (noting that the Court had jurisdiction over the citizen petition and not the SNDA; however, the two are related because once Secretary Sebelius directed the FDA to deny the SNDA, there was no basis to approve the citizen petition as the same data was relied on for both applications).

[26] *Id.* (citing the Administrative Procedure Act 5 U.S.C. § 706(2)(A)).

[27] *Id.* at *20.

[28] Alastair J.J. Wood, M.D et al., *The Politics of Emergency Contraception*, 366 New Eng. J. Med. 101, 101-02 (2012) www.nejm.org/doi/full/10.1056/NEJMp1114439 (last accessed Apr. 12, 2013) (discussing Secretary Sebelius's decision to overrule the FDA on Plan B and indicating

that it was the first time the Secretary of the United States Department of Health and Human Services had ever overruled a regulatory decision on drug approval that was made by the FDA).

[28] Alastair J.J. Wood, M.D et al., *The Politics of Emergency Contraception*, 366 New Eng. J. Med. 101, 101-02 (2012) www.nejm.org/doi/full/10.1056/NEJMp1114439 (last accessed Apr. 12, 2013) (discussing Secretary Sebelius's decision to overrule the FDA on Plan B and indicating that it was the first time the Secretary of the United States Department of Health and Human Services had ever overruled a regulatory decision on drug approval that was made by the FDA).

[29] *Tummino*, WL 13648656 at *22.

[30] *Id.* at *31.

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