The Constitutionality of an HPV Mandate and Its Implications for the Minor Patient

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The Human Papillomavirus ("HPV") vaccine can potentially prevent 11,000 cases of cervical cancer and approximately 3,900 related deaths a year. Since the prevalence of HPV is as high as 25 percent among men and women between the ages of 14 and 19, and 45 percent between ages 20 to 24,1 it is easy to see the potential impact of mandating the vaccine for pre-teens. Texas was the first state to mandate the vaccine for girls entering the sixth grade via an executive order signed by Governor Perry in 2007.2 Forty-one other states have since followed with proposed HPV legislation,3 including a vaccine mandate in the District of Columbia and Virginia.4 However, the political backlash that ensued was sufficient to prompt the Texas legislature to overturn the executive order in HB 1098,3 and the debate has spurred extensive discussion over the prudence of a mandate both in the media and healthcare literature.6 Thus far, discussion of the controversy has focused on such practicalities as its cost ($390 for the series of three shots),7 a fear that it will increase teenage promiscuity or create a false sense of protection from sexually transmitted infections ("STIs"), and concerns that mandating the shots undermines parental decision-making.8

In addition to the political and ethical objections to a mandate, there is also a legal argument that states lack the constitutional authority to mandate the vaccine. The argument is multifaceted, including issues of Equal Protection, the Establishment Clause,9 and parental privacy rights. However, this article will focus on how a mandate for the HPV vaccine would potentially violate the Fourteenth Amendment’s protection of sexual privacy rights and specifically the sexual privacy rights of minors. The discussion begins by examining the original vaccine mandate case and its application to HPV and other non-casually communicated viruses. Next, the article addresses the evolution of Constitutional law regarding Fourteenth Amendment privacy rights and how this affects modern vaccine mandates. The article then examines the question of whether framing the HPV

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Chair’s Corner

I place the Chair’s Corner columns of my predecessor David Johnson squarely in the “hard act to follow” category. David is not only an accomplished lawyer, he is a gifted writer. He is also a surfer, jazz aficionado, connoisseur of fine single-malt whiskeys and, need I say it, a Yale man. (As they say, “You can always tell a Yale man, you just can’t tell him much”). I have long admired David’s ability to draw on his diverse experiences to see relationships in a different light. Who else could lead off a column with the question, “So, what do Aretha Franklin, Herman Melville and a Nobel laureate in economics have in common?” David’s ability to reveal connections set a high bar for Chair’s columns. I have in mind specifically his columns on the wild fires in New Mexico, “Fire on the Mountain,” and his final column on the Council’s Spring Meeting, “Acoma,” in which he described the enlightening and moving presentations we received concerning the health and legal challenges faced by Native Americans living on tribal land and also of our tour of the Acoma Pueblo – the oldest continually inhabited community in North America, which sits atop a 367 foot high butte in New Mexico. David’s columns invariably caused me to take a break from the task at hand to reflect on relationships in different ways.

I have been thinking about relationships – context and connection – quite a bit recently. We are in the midst of a transformation in health law and policy that will affect every aspect of our practices. In the fraud enforcement context, my practice area, for example, over the past two decades government health law policy has focused on the threat that professional and financial relationships can pose to the cost-effective provision of healthcare goods and services. The Stark Law and the Anti-Kickback statute are intended to prohibit financial relationships that the government views as carrying the potential to corrupt the referral process. While the risk is inarguably real, the specific statutory remedy arguably sweeps too broadly, prohibiting beneficial relationships as well as detrimental ones. Referral relationships can reduce cost without compromising care. Similarly, privacy laws intended to protect the confidentiality of the physician-patient relationship can also be overbroad. Sometimes, a breach of strict patient confidentiality is just what the doctor ordered, for example disclosing information to a family member to ensure that a parent or relative is following the doctor’s orders. Statutes drafted in response to recognized harms that certain types of

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vaccine as implicating sexual health affects the constitutional analysis of a mandate in that it implicates case law allowing minors to make sexual health decisions without parental consent.

**The Original Vaccine Mandate Case: Are Smallpox and HPV Different?**

The first vaccine mandate was passed by the city of Boston in 1827 requiring the smallpox vaccination for school entry, but the U.S. Supreme Court did not address the issue until 1905 when Massachusetts resident Reverend Henning Jacobson challenged the state mandatory vaccination statute for smallpox, claiming that the law violated his Fourteenth Amendment rights. In *Jacobson v. Massachusetts*, the Supreme Court held that states have the authority to mandate vaccines based on their police powers to protect public health. The statute must have a "substantial relation" to the "necessity" of protecting the community and cannot be interpreted to lead to an "absurd consequence," such as mandating vaccination when it would lead to serious health risks. The Court noted that "[u]pon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members." Importantly, when Jacobson was heard, smallpox was imminently threatening the Massachusetts community.

Jacobson and its successor *Zucht v. King*, a case about school-based vaccine mandates, constitute the relevant Supreme Court case law for vaccine mandates. In the last century state courts have applied these cases to uphold a state's right to implement vaccine mandates as part of the police powers to protect public health even though the list of vaccines now includes easily communicated diseases like measles, polio and smallpox, as well as diseases that are not readily transmitted from person to person, like tetanus and Hepatitis B. In fact, HPV differs from most other vaccines for which there are mandatory vaccination laws because putting oneself at risk for transmission requires a behavioral choice – the choice to engage in sexual activity. The only comparable virus for which there is a vaccine mandate is Hepatitis B ("HBV"), which can be contracted through sexual intercourse, IV drug use, and rarely through more casual contact.

However, the *Jacobson* Court discussed at length how public health regulations should be of "paramount necessity" and not go "beyond what... [is] reasonably required for... safety." The Court was cautious because vaccine mandates interfere with the right to refuse medical treatment and the requirement of informed consent, both born out of the common law of battery. Also in *Jacobson*, the test is applied to a highly contagious, casually communicated and potentially fatal disease. If this test were applied more strictly to each individual vaccine that is required for public school attendance today, the argument could be made that some vaccines, such as HBV should not be mandated under *Jacobson* as it is neither readily communicable nor immediately fatal and debilitating. In other words, the legal test in *Jacobson* arguably does not go so far as to create a rubber stamp for any vaccination the Centers for Disease Control and Prevention ("CDC") recommends but instead espouses a necessity standard that should be applied to each vaccine individually.

For this reason many legal scholars have questioned the continued applicability and viability of *Jacobson* in the case of non-epidemic, casually communicable diseases that are not of paramount necessity to protect the community in the same way as a smallpox or polio vaccine. HPV is very different from smallpox in its effect on school attendance and imminence of disease in the community. The HPV vaccine is not of "paramount necessity" to protect the immediate safety or order in the same way a vaccine for an epidemic is. Additionally, there are alternative disease prevention methods for HPV – one can employ abstinence, condoms, and early detection and treatment of cervical lesions. The only alternative for preventing the spread of smallpox or measles is quarantine. Thus despite the traditional deference to state's rights in the regulation of public health and the historically broad application of *Jacobson* and *Zucht*, there is a strong argument that under the *Jacobson* framework, a mandate for the HPV vaccine may not be Constitutional.

**The Rise of Substantive Due Process: Vaccine Mandates and Fundamental Rights**

As illustrated in *Jacobson*, vaccine mandates may be legally objectionable because they infringe on rights of personal autonomy and bodily integrity protected by the Fourteenth Amendment. The Fourteenth Amendment specifically prohibits government interference with the life, liberty or property of citizens without due process of law, and part of that due process includes substantive rights elucidated by Supreme Court case law to set the boundaries of permissible state regulation of personal liberty. In these cases the Court examined state statutes restricting specific liberty interests to decide if a state's justification for a law is strong enough to overcome the curtailment of personal liberty. Originally
the Supreme Court applied this test with rigorous review of a state’s justification for a law, as illustrated in the Lochner Era of cases,\(^2\), of which Jacobson was one. In Lochner and its progeny, the Supreme Court employed a rigorous test requiring a state to have a “fair, reasonable and appropriate” explanation for state laws and require that the laws not be “unreasonable, unnecessary or arbitrary.”\(^2\) The Court used this test to invalidate many state laws regulating business and contracts as well as to protect more private issues such as parental rights in Pierce v. Society of Sisters\(^2\) and Meyers v. Nebraska.\(^2\) The lone rational basis test was the only standard of constitutional review until 1938 with U.S. vs. Carolene Products.\(^2\) In Carolene Products, the Court retreated from its rigorous analysis, worried that judicial politics would outweigh legislative intent in future interpretation of personal liberty cases, but insinuated in the famous footnote four that there could be multiple levels of judicial review.\(^2\)

Beginning in Griswold v. Connecticut,\(^2\) a case ensuring the right to contraception for married couples, the Court started employing a multi-tiered review system by requiring stringent review of state statutes infringing on specific types of Fourteenth Amendment liberty rights that could be defined as “privacy rights.”\(^2\) The Court designated these privacy rights as “fundamental”\(^2\) and Justice White’s concurrence explained these rights garner a heightened standard of judicial review called “strict scrutiny.”\(^2\)

The Court applied this test in subsequent cases including Roe v. Wade\(^2\) and Eisenstadt v. Baird,\(^2\) among others, but clearly combined and articulated the test in the 1997 case Glucksburg v. Washington.\(^2\) In Glucksburg the Court defined fundamental rights as rights “so deeply rooted in this Nation’s history and tradition...[and] implicit in the concept of ordered liberty, such that ‘neither liberty nor justice would exist if they were sacrificed,”\(^2\) including the right “to marry, to have children, to direct the education and upbringing of one’s children, to marital privacy, to use contraception, to bodily integrity...to abortion...and to refuse unwanted lifesaving medical treatment.”\(^2\) Based on this test, when the Supreme Court, or a state court applying constitutional law, addresses a substantive due process question it first attempts to decide if the right falls into one of the above categories and can thus be deemed fundamental. If the right is fundamental, the Court employs strict scrutiny review, which requires state regulation of the right be “narrowly tailored to serve a compelling state interest.”\(^2\)

This is significant because it requires very strong evidence on the part of the state to regulate the fundamental right and is usually used to invalidate statutes. Strict scrutiny review is more similar to the level of analysis the Supreme Court applied in the Lochner Era cases than it is to the modern rational basis test. If the right is not deemed fundamental, the regulation must only pass the modern rational basis test, meaning the state’s justification for a law is “rationally related to legitimate government interests,”\(^2\) a hurdle that can almost always be surmounted.

The arguments that an HPV vaccine mandate would be unconstitutional start with a comparison of the factual difference in HPV and smallpox and argue an HPV vaccine mandate would not pass the Jacobson necessity test due to the difference in contraction and the natural history of the diseases. Smallpox is casually communicable and causes immediate potentially fatal illness while HPV is contracted from sexual contact and causes disease 10 to 15 years post infection. However, other scholars have argued that Jacobson is no longer the controlling precedent because it has been superseded by the Supreme Court’s modern fundamental rights jurisprudence.\(^3\) Specifically, they refer to Cruzan by Cruzan v. Director, Missouri Dept. of Health\(^4\) and Glucksberg v. Washington.\(^5\) These two cases address end of life decision-making, but they are significant to the overall development of fundamental privacy rights because the Court specifically lists for the first time the “right to refuse medical treatment” alongside the other well established fundamental rights. These scholars argue that if the right to refuse medical treatment is fundamental, then vaccine mandates should be analyzed under the “strict scrutiny”\(^5\) test instead of the Jacobson necessity analysis. The significance in this classification is that few state regulations have sufficient justification to meet the requirements of strict scrutiny, and thus many modern vaccine mandates not regulating highly communicable diseases with epidemic potential would possibly be invalidated as a violation of the fundamental right to refuse medical treatment.

A Vaccine or a Sexual Health Issue: The Special Case of Sexual Privacy

Even if the Supreme Court did hold that the precedent for supporting state vaccine mandates should fall under the Glucksberg fundamental rights analysis instead of Jacobson, HPV is still a vaccine that prevents cancer. In fact, cervical cancer is a public health epidemic, and the vaccine is unaffordable for many Americans which could be remedied by mandating it for school attendance.\(^4\) Additionally there are socioeconomic and racial disparities in who gets cervical cancer because regular screening is often not affordable or is too onerous to obtain for lower income women. If they cannot
obtain adequate screening, the vaccine provides a simpler prevention alternative. Therefore, an HPV mandate could well pass strict scrutiny analysis if it is being weighed against only the right to refuse medical treatment. However, there is another alternative argument that singles out HPV from other viruses – HPV is an STI and is not contracted through casual contact. Hepatitis B is also sexually transmitted but can be contracted in a variety of ways not limited to sexual activity. HPV is exclusively an STI, making the decision to get the HPV vaccine a sexual health decision. Therefore, an HPV vaccine mandate could be analyzed as an issue of sexual privacy, a more specific type of fundamental privacy right, with additional implications for minors. This section will first examine the evolution of the Court’s sexual privacy case law and how it applies to the HPV vaccine. It will then look at the impact on constitutional analysis when the decision is defined as one of sexual health because it invites application of Supreme Court law regulating the sexual privacy rights of minors.

The Court began extending special protection to sexual privacy in Griswold v. Connecticut, where the Court held it unconstitutional to prohibit contraception for married persons. The Court extended the right to unmarried persons in Eisenstadt v. Baird, explaining that:

"[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."

The privacy rights surrounding procreation formed the legal basis for Roe v. Wade and its progeny. The Supreme Court continued to integrate the privacy rights dealing with marriage, family and contraception in a line of cases culminating in Lawrence v. Texas, the Court’s most recent statement on sexual privacy. In 2003 the Supreme Court overturned a Texas statute prohibiting "deviate sexual intercourse," including sodomy, which the state was attempting to enforce between two consenting adults. The Court stated that fundamental rights decisions:

involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. At the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.

The Court did not explicitly call "sexual privacy" a fundamental right and instead found there was not even a "legitimate state interest" in banning sodomy. Since the statute could not withstand even the lenient rational basis test, there was no reason for the Court to reach a decision about whether a fundamental right was at stake. Nonetheless, the amount of review given to the state’s arguments looked in substance, though not in formal language, like a strict scrutiny analysis. It can thus be argued that the Court was setting up sexual privacy to be a fundamental right, and in subsequent constitutional challenges, the Court may find sexual privacy to be a fundamental right. If issues of sexual privacy are afforded special protection, and procreation is definitively a fundamental right, then sexual health decisions about condom usage, STI testing and choice of partners are arguably fundamental rights, as well. At the very least they would be afforded the protection of Lawrence. The decision to get a vaccine preventing an STI could logically be included in this list of sexual privacy rights.

However, the Supreme Court has been hesitant to expand the fundamental rights category in the past, as seen in the effort to use the rational basis test in Lawrence and avoid calling sexual privacy a fundamental right. In Glucksberg the Court clearly stated “[w]e have always been reluctant to expand the concept of substantive due process because guideposts for responsible decision-making in this uncharted area are scarce and open-ended” and therefore “they must exercise the utmost care whenever...asked to break new ground in this field lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court.” Based on principles of judicial conservatism, while it is logical to include sexual health decisions in the concept of sexual privacy and to call sexual privacy a fundamental right, it is unlikely the Supreme Court would extend this most stringent protection to these issues, especially in the setting of a vaccine with alternative public health benefits.

The Significance of Sexual Health Decisions to the Minor Patient

The forgoing analysis argues that mandating the HPV vaccine would be potentially unconstitutional under the Fourteenth Amendment either under the original case law of Jacobson as failing the necessity test, as a right to refuse medical treatment or possibly as a sexual health decision. However, there are strong counter arguments presented for all of these arguments, including that the forgoing cases are about rights held by competent adults. Children by definition lack the capacity to give informed consent, and typically parents or guardians consent to their medical care. Therefore, applying Jacobson, Glucksberg, or Lawrence to
an HPV vaccine mandate that affects children includes a discussion of parental rights, as addressed previously. However, by reframing the question as one of sexual health, even if not an issue of highly protected sexual privacy, the age of the patient raises an additional constitutional question: Does the decision to vaccinate inhere to the minor and not the parent, meaning that states must allow minors to make the vaccination decision for themselves?

While parents or guardians make most medical decisions for minors, when it comes to decisions about sexual health, including contraceptive use, pregnancy, prenatal care and abortion, the decision-making frequently lies with the minor. These rights were established in two landmark cases following Roe v. Wade. In Carey v. Population Services Int’l, the court held that parental consent was not required for minors to obtain contraception. Carey drew on its pre-ceeding case, Bellotti v. Baird, which held that a state must allow minors seeking an abortion to opt-out of parental consent and appear in court to prove she is either a mature minor or that an abortion is in her best interest. If the court agrees with the minor, it must grant permission for the abortion, and judicial override of the minor’s choice is not permitted.

Bellotti went on to explain that the Bill of Rights does not apply identically to children and adults because children need the guidance of their parents, are vulnerable, and do not always have decision-making capacity. However, abortion is different. The Supreme Court compared marriage, which is restricted for minors, to abortion, citing four reasons these similarly protected rights are different. First, unlike the decision to marry, the need for an abortion is time sensitive. Marriage can be deferred; termination of pregnancy cannot. Secondly, the harm to the minor of unwanted pregnancy is not mitigated by her age, and at least in terms of her life prospects, the harm is probably increased. Third, parenthood itself brings adult responsibility to the minor, and fourth, there is a risk that denial of the abortion by a judge or parent could be arbitrary. The Bellotti framework is applicable to the HPV vaccine on at least three counts.

First and most importantly, the decision to get an HPV vaccine is time sensitive. The Advisory Committee on Immunization Practices (“ACIP”) recommends vaccination for girls and boys ages 11 to 12 with catch-up vaccination for 13-26 year olds. This recommendation is based on efficacy studies of the vaccine after the virus has already been contracted versus beforehand as well as the average age of sexual debut for the American teenager. As for efficacy, the HPV vaccine is greater than 90 percent effective in preventing cancer or a precancerous lesion in an HPV naïve patient. However, it is only 44 percent effective in patients with previous infection. Therefore, it is imperative to vaccinate before infection is established, and multiple studies have shown high rates of infection within the first few years after sexual debut. Studies have shown that as many as 30 percent of women contract the virus within a year of their first sexual encounter. This infection rate increases to 39 percent within the first 24 months after first intercourse and 54 percent at 48 months. Two additional studies have shown 44 percent of women contract the virus within 36 months after sexual debut. Other studies report that the prevalence of the virus for men and women between the ages of 14 and 19 is 25 percent, and 45 percent between the ages of 20 to 24, which implicates initial intercourse as early as 12 or 13 years old for some. The Department of Health and Human Services has reported on specific ages of first intercourse citing 29 percent of 9th graders, 39 percent of 10th graders, 50 percent of 11th graders, and 60 percent of 12th graders. Another source stated that 6.2 percent of girls have sex before age 13. It is also important to note that while these numbers reflect intercourse, the virus can also be contracted from homosexual activity between women and oral sex. Furthermore, the risk of persistent infections that lead to cancer or precancerous lesions increases with younger age of first intercourse and number of partners. Finally, in addition to the importance of vaccinating before sexual debut, the vaccine is more effective at a younger age given the greater immunogenic response shown in 10-15 year old girls as compared to 16-26 year olds. In sum, getting the HPV vaccine is a time sensitive issue that cannot wait if it is to be maximally effective.

Secondly, in Bellotti the Court noted that the harm of an abortion to the minor was not mitigated by her age. In the case of the HPV vaccine, being a minor does not change the potential safety risks involved, and based on the efficacy studies, not getting it in a timely manner could expose the minor to greater risk.

Finally, as for abortion, there is a risk that parents would refuse the vaccine for arbitrary reasons. For instance, some parents are concerned that vaccinated girls will be more promiscuous. However, there is little evidence to support this assertion. Additionally, the Court in Carey explicitly rejected the reasoning as valid for denying contraceptives to minors, stating “[i]t would be plainly unreasonable to assume that [the State] has prescribed pregnancy and the birth of an unwanted child [or the physical and psychological dangers of an abortion] as punishment for fornication.”

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The legislative branch has also spoken about a minor’s right to make his or her sexual health decisions in 1970 with the passage of Title X. Title X is part of the Public Health Service Act that is devoted to providing comprehensive resources for family planning and related preventative health services such as STI treatment and prevention. It specifically provides funding for STI treatment for minors without parental consent. Many states also permit teens to get treatment for STIs without parental permission.

If the HPV vaccine is considered a sexual health decision more similar to abortion and contraception than whether to take antibiotics for a cold, the minor’s decision to get the vaccine can be analyzed under Bellotti and Carey instead of the broader umbrella of sexual privacy. This alternative constitutional framework shifts the decision to choose to obtain the vaccine from the parents to the minor and provides an alternative and possibly stronger constitutional argument for protecting the right as it aligns with the decision with the minor’s right to make other decisions about his or her sexual health. This is significant to policy makers because not only would a mandate be potentially unconstitutional, but states may ultimately be required to provide a process for opting out of parental consent if the teenager wants the vaccine and the parents refuse.

The Significance of a Constitutional Challenge: Why Should Policy-Makers Care?

The foregoing analysis presents several paths for a constitutional challenge to an HPV vaccine mandate. First, the factual difference between smallpox and HPV argues the original vaccine mandate precedent in Jacobson would not apply to an HPV vaccine mandate. Secondly, the development of the Supreme Court’s substantive due process jurisprudence including the addition of the right to refuse medical treatment argues the decision to get the HPV vaccine can be framed as a fundamental right requiring states to have very compelling reasons for the mandate and pass the Court’s strict scrutiny standard. Third, the sexual privacy sphere outlined in Lawrence may offer further protection for the right to decide whether or not to be vaccinated because framing the vaccine decision as one of sexual health allows the issue to be analyzed under Bellotti. The Bellotti framework changes the question to a sexual health issue applicable to minors and in doing so raises a new question – not whether the state can mandate the HPV vaccine, but if minors are entitled to elect to get the vaccine without parental permission.

From a medical standpoint the HPV vaccine is highly recommended. It is more than 90 percent effective, and would hopefully reduce the incidence of cervical cancer in lower socioeconomic groups that currently do not regularly adhere to yearly screening recommendations for pap smears. However, while a mandated HPV vaccination program may be a beneficial public health policy, it would not make good law due to the potential constitutional infirmities presented in this article. Secondly, the precedent in Bellotti actually suggests that states may need a way to protect the minor’s ability to obtain the HPV vaccine without parental consent. Since all states currently allow minors to consent to treatment or screening for STIs without parental notification, a possible solution would be to specifically add the HPV vaccine as “treatment” for an STI along with treatment for diseases like gonorrhea or Chlamydia.

A mandate for the HPV vaccine does not facially seem to be about a choice that is so inherently private as to be protected by fundamental liberty rights. In fact, since it is a vaccine that prevents cancer, the decision can be framed as a preventative health choice more akin to getting a colonoscopy for colon cancer screening. Additionally, if states can allow local regulations of issues as minor as soda size to reduce obesity with minimal evidence of efficacy, why would a vaccine that has proven efficacy to prevent cancer be unconstitutional? The answer lies in the nature of the intervention and the type of disease at issue – vaccines are invasive and have to face the challenge of the right to refuse medical treatment preserved in Glucksberg, and HPV is an STI, making the decision to get vaccinated one about sexual health. Also, there are other methods of prevention for cervical cancer. Condoms and abstinence prevent contraction of the virus, and regular pap smears can prevent cancer by catching cervical lesions early.

Additionally, while the mature minor doctrine guides when minors can make general medical decisions, all states treat sexual health decisions differently, allowing minors to consent to STI treatment, and many states allow them to obtain contraceptives on their own. Decisions about sexual health are clearly treated differently from other healthcare decisions, so regulation of treatments for STIs should be regulated differently, as well. The decision to get the HPV vaccine is more similar to the decision to use a condom, have sex, be abstinent, or be tested for an STI than it is to getting a colonoscopy. It is about one’s sexual health, a type of decision so private that the Supreme Court has specifically held these decisions are afforded the most stringent constitutional protection, and ensured that even minors are allowed to make the more time sensitive decisions for themselves.

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Endnotes


5 Corrie MacLaggan, Peru lets HPV bill go into law, Austin American Statesman, May 9, 2007.


8 See, e.g., Lawrence Gotzin, Mandatory HPV Vaccination and Political Debate, 306 JAMA 1699 (2011) and Gillian Haber, et al., The HPV Mandate Controversy, 20 J. Pediatric & Adolescent Gynecology 325, 328 (2007) and Lane Wood, A Young Vaccine for Young Girls: Should the Human Papillomavirus Vaccination be Mandatory for Public School Attendance?, The Health Lawyer, Volume 20, Number 5 at 36, June, 2008 (noting that some scholars have argued that even highly contagious but less fatal viruses such as chicken pox should not have vaccine mandates given the risk of vaccinations and the lack of necessity to prevent epidemics).


See also, Lane Wood, A Young Vaccine for Young Girls: Should the Human Papillomavirus Vaccination be Mandatory for Public School Attendance?, The Health Lawyer, Volume 20, Number 5 at 36, June, 2008 (noting that some scholars have argued that even highly contagious but less fatal viruses such as chicken pox should not have vaccine mandates given the risk of vaccinations and the lack of necessity to prevent epidemics).


10 Locher v. NY, 198 U.S. 45 (1906).

11 Id. at 56.

12 268 U.S. 510 (1925) (holding laws requiring children to attend public school violated 14th Amendment substantive due process rights).

13 262 U.S. 390 (1923) (holding a law preventing the teaching of German to children under the 8th grade was an unconstitutional infringement on 14th Amendment substantive due process rights.)

14 304 U.S. 144, FN 4 (1938).

15 U.S. v. Caroleine Products Co., 304 U.S. 144, FN 4 (1938). In 1938 with FN 4 in Caroleine Products the Supreme Court marked a significant change in its substantive due process jurisprudence. Before this the Supreme Court used the language of the rational basis test to overturn state legislation they found in violation of the Due Process Clause, as in Lochner and Jacobson. However, after the switch, the rational basis test became effectively toothless unless the court sniffed a serious discrimination problem or corruption. The heightened standard of review became known as the “strict scrutiny” test as first put forth in Korematsu v. U.S., 323 U.S. 214 (1944).


17 Id. at 31.

18 Id. at 37.

19 Id. at 39.

20 Id. at 27.


22 McCarthy v. Boozman, 212 F. Supp. 2d 945 (D.C. AK 2002) (stating “[i]t has long been settled that individual rights must be subordinated to the compelling state interest of protecting society against the spread of disease. The Supreme Court long ago held that a state may adopt a program of compulsory immunization for school-age children.”).

23 See, Kimberly Garde, This will only hurt for... ever: Compulsory Vaccine Laws, Injured Children and no Redress, 3 Phoenix L. Rev. 809, 555 (2010) (Appendix A for concise up to date listing of text of state laws).


30 Id. at 728 (citing Heller v. Doe, 509 U.S. 312, 319-320 (1993) and Flores, 507 U.S. at 305 (internal quotations omitted).


interest even if she is not a mature minor. Opportunity to prove the abortion is in her best interest sets the standard of the state law on consent or notice, all states must have a procedure so the minor can appear in court and have the opportunity to prove she is mature and the abortion is in her best interests.

Bellotti, 443 U.S. at 633-34.

Id. at 642-44.

Advisory Committee on Immunization Practices, “ACIP Provisional Recommendations for HPV Vaccine,” October 25, 2011. The ACIP is a committee within the CDC comprised of medical and public health professionals to develop recommendations for the use of vaccines. It is relied on by physicians in making recommendations in their practice and by most states in deciding on vaccines mandated for school attendance. It was established under the Public Health Service Act, 42 U.S.C. § 271a. 60


Supra Kahn at note 1.


Supra Ho at FN 64.

S.L. Block, et al., Comparison of the immunogenicity and reactogenicity of a prophylactic quadrivalent human papillomavirus (Types 6, 11, 16, and 18) L1 virus-like particle vaccine in male and female adolescents and young adult women, 118 Pediatrics 2135 (2006).


Carey, 431 U.S. at 694-95.

42 U.S.C. ch. 6a.


Supra FUTURES II and Paavonen at FN 61.

Supra Guttmacher Institute at FN 77.

Under Caldwell v. Bechtol, 724 S.W.2d 739, 745 (Tenn, 1987), the seminal state case concerning the mature minor doctrine, there is a rebuttable presumption that minors between 14 and 18 can consent to their own medical care and between 7 and 14 a rebuttable presumption that the minor cannot consent. This case is applicable to decisions to get the HPV vaccine in that it would argue that teenagers over 14 could consent to get the vaccine themselves. However, the vaccine is recommended for children aged 9-10, suggesting they could not consent under the mature minor doctrine. On the other hand, the HPV vaccine is for prevention of an STI and STI treatments are different from other medical conditions. This is the case in Tennessee as well where T.C.A §56-10-104 (c) states that minors may be treated for STIs without parental consent.


Supra Guttmacher Institute at FN 77.
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relationships can cause fail to recognize the benefits that those very same relationships can yield.

Attacking relationships regardless of their purpose or effect can frustrate broader policy objectives. Looking at the record of exclusion, it certainly appears that the government has recognized that the theoretical benefit to the Medicare and Medicaid programs realized by exclusion, which essentially amounts to the government severing its relationship with the excluded entity, can be outweighed by the harm and disruption that would be inflicted on the programs’ beneficiaries.

The effort to reform healthcare is forcing the government to reevaluate its policies with respect to relationships in the healthcare goods and services industry. Whether through promotion of Accountable Care Organizations or the establishment of insurance exchanges, the government is encouraging policies and practices that create relationships, including referral inducements. This reevaluation not only promises to change fraud and abuse laws, the debate itself is already influencing how we assess violations of the law as it stands today.

My role as Chair of the Section affords me the luxury of experiencing the diversity of practices, issues and perspectives that our membership reflects beyond my own focused practice area. It is a joy and a privilege to work closely with leaders not only of our Section but of our profession. Not only do I learn from the breadth of their expertise but I am enriched by the quality of the relationships we have developed. I am grateful for each opportunity to pick up the phone to advance the mission of healthcare while lowering its cost. The chance to connect with leaders not only of our Section but of our profession are among the most valuable and lasting membership benefits.

As I draft this column, I am looking forward to seeing many of my Section colleagues at the Washington Health Law Summit, which has become the nation’s premier health law and policy conference. By the time the column is published, however, the Summit will be a fond memory. For many of my Section colleagues at the Washington Health Law Summit, which has become the nation’s premier health law and policy conference. By the time the column is published, however, the Summit will be a fond memory. For many of my Section colleagues at the Washington Health Law Summit, which has become the nation’s premier health law and policy conference. By the time the column is published, however, the Summit will be a fond memory. For many of my Section colleagues at the Washington Health Law Summit, which has become the nation’s premier health law and policy conference. By the time the column is published, however, the Summit will be a fond memory.

EMI 2013 will also offer ample opportunities to form and renew relationships, including our Welcome Reception, a diversity reception and, of course what has become EMI’s signature tradition; the Margarita Cup Golf Outing. For those of us who are non-duffers there will be a Taste of South Beach Culinary Experience and Boat Tour. (For more information and to register, simply go to ambar.org/emi2013)

As health lawyers in an age of reform, we will be challenged to see relationships in new and different ways. We will have the opportunity and responsibility to contribute our expertise to the national effort to improve the quality of healthcare while lowering its cost. The chance to contribute to that mission collaboratively with colleagues whose knowledge we respect and whose company we enjoy is a blessing to savor.

Endnotes
1 See The Health Lawyer, Vol. 24, No. 4 at 2, April, 2012.
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Generic Liability, or Lack Thereof, Under Duty-to-Warn: It’s All About the Labeling

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Introduction

Patients in the United States are taking more prescription drugs than ever before. A spring 2009 article in the Wall Street Journal reported that practitioners (e.g. physicians, advance practice nurses, dentists, etc.) prescribe nearly four billion prescriptions annually, at a cost of more than $230 billion to patient-consumers. Other reports indicate that more than $300 billion was spent on prescription drugs that year. Of those prescriptions issued in 2009, about 2.4 billion of them were written for generic drugs and about 1.4 billion were written for brand-name drugs. Not surprisingly, this shift from branded to generic products has been a noticeable trend in recent years, largely because the patents of several drugs used to treat chronic diseases like diabetes and high blood pressure have expired, making way for less expensive, generic versions of those drugs.

In addition to the expiration of patent protection, a variety of other factors contribute to patients’ increased use of generic drugs. Not surprisingly, many of these factors pertain to cost. For example, if a generic version of a drug is available, third-party payors generally will refuse to pay for the branded drug or charge substantially higher co-payments for the branded drug, thus effectively prohibiting patients from choosing the branded drug. Patients simply cannot afford to pay exorbitant amounts of money for a brand-name drug when a generic version is available at a fraction of the cost. Yet patients do not always make the decision to receive generic over brand (or vice versa for that matter). In fact, quite often it is the pharmacist who decides to dispense generic drugs to his or her patients, irrespective of costs. In the majority of states, pharmacists are legally permitted to dispense generic drugs, even if prescribers do not specifically instruct them to do so. And, in some of those states (as well as in others), pharmacists are not required to inform their patients that they have substituted brand-name drugs with generics. So patients often have absolutely no idea that they are taking generic drugs.

Until now, little attention has been paid to the fact that patients are effectively forced to use generic drugs (unless no generic version of a drug exists or there is a medical reason for taking the branded drug). Also, very little is mentioned about pharmacists being the ones who decide whether or not to substitute brand name drugs with their generic counterparts. The likely explanation for the lack of attention being paid to the generic substitution process is that the scientific literature supports the notion that generic drugs are essentially identical to their branded counterparts. A generic drug is expected to be as safe and as effective as its brand-name counterpart. Accordingly, there is very little reason to be concerned from a patient-health perspective that patients have little say in their use of generic drugs. Moreover, since the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (often referred to as the Hatch-Waxman Act, named after two of the Act’s primary Congressional sponsors), which streamlined the approval process for generic drugs, the routine substitution of brand-name drugs with their generic equivalents has been, and continues to be, the standard of practice in pharmacy. Yet, as a result of the United States Supreme Court’s June 2011 ruling in the case Pliva, Inc., et al. v. Mensing (“Pliva”), patients using generic versions of branded drugs now have good reason to be reluctant to use these drugs.

This article focuses on the impact that recent prescription drug case law is likely to have on the decisions of both patients and healthcare providers. Special emphasis will be given to the various avenues that plaintiffs have explored to hold pharmaceutical manufacturers liable for insufficient warnings with their products. In doing so, the article provides an overview of the Court’s decision in Pliva, including a brief discussion of potential means by which generic drug manufacturers can unilaterally change their products’ labeling, the Court’s explanation of preemption and the doctrine of impossibility, as well as the Court’s reasoning for distinguishing its holding in Pliva from its holding in Wyeth v. Levine – a case involving a state cause of action for failure to warn of the dangerous propensities of a brand-name drug. The article then discusses the regulatory foundation that permits the streamlined approval of generic drugs, including the requirements for labeling these drugs, and then explains the need for regulatory reform to provide guidance to generic drug manufacturers who want and need to change their products’ labeling when the brand-name counterpart is no longer on the market.

Pliva, Inc., et al. v. Mensing

This case involved the consolidation of two cases heard by the Fifth and Eighth Circuit Courts of Appeals.
The issue before the Supreme Court was whether federal drug regulations applicable to generic manufacturers directly conflict with (and thereby preempt) state tort law claims that allege generic makers of metoclopramide failed to provide adequate warnings in their products’ labeling. The Court in a 5-4 split held that the federal drug regulations applicable to generic manufacturers do indeed directly conflict with and thereby preempt patients’ state tort law claims.

The drug at issue in this case is metoclopramide, the generic version of Reglan®, which is indicated to relieve heartburn symptoms in gastroesophageal reflux disease (“GERD”), a.k.a. acid reflux) when certain other treatments do not work. It also relieves daytime heartburn, relieves heartburn after meals, and helps ulcers in the esophagus to heal. Metoclopramide is also approved for short-term use in patients with diabetic gastroparesis (delayed gastric emptying), as it speeds the movement of food through the digestive system; however, diabetic gastroparesis is a chronic condition that warrants the continuous use of metoclopramide for more than 12 weeks. Studies have demonstrated that long-term use (of more than 12 weeks) of metoclopramide has been associated with the development of tardive dyskinesia (“TD”).

TD is an abnormal movement disorder that is characterized by repetitive, involuntary, purposeless movements. Features of the disorder may include grimacing, tongue protrusion, lip smacking, puckering and pursing, and rapid eye blinking. Rapid movements of the arms, legs, and trunk may also occur, and involuntary movements of the fingers may be present. Patients taking metoclopramide long-term are at an increased risk of developing this disorder.

Both Mensing and Demahy, the patients in Pliva, took metoclopramide for several years. Mensing used the drug to treat diabetic gastroparesis and Demahy used the drug for GERD. Both contended that the generic manufacturers were liable under relevant state tort law (Minnesota and Louisiana, respectively) for failing to provide adequate warning labels (i.e. generics did not change their products’ labeling to reflect the increased risk of developing TD known by the generic makers). And, because the labeling had not been updated, it did not sufficiently communicate the risks of developing TD to consumers.

In both cases, the generic manufacturers argued that federal law preempted these patients’ state tort claims for failing to provide adequate warnings in the labeling. The manufacturers specifically asserted that their labeling mirrored that of the brand-name drug and argued that they could not take it upon themselves to change the labeling – only the brand-name manufacturer has the legal duty and authority under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to make such changes. As such, the manufacturers asserted that it was impossible for them to concurrently comply with both the federal law and the respective state tort laws at issue here.

The Courts of Appeals for the Fifth and Eighth Circuits rejected the generic manufacturers’ argument that these patients’ state tort law claims were preempted by federal law. The U.S. Supreme Court consolidated these two cases into one, and ruled that patients’ inadequate warning claims are indeed preempted by federal law – essentially overturning the rulings of the two Courts of Appeals. In reaching its decision, the Court first looked at the Minnesota and Louisiana laws in question. Under these state tort laws, a drug manufacturer that is or should be aware of dangers associated with its products must label the drug in such a fashion that renders it reasonably safe. Yet, reasonably safe does not imply that the product is free of dangers, which is an impossibility with prescription drugs because such drugs, by definition, are unavoidably unsafe. The only way in which a prescription drug can be made completely safe is to avoid using it altogether. Furthermore, because of the risks associated with prescription drug use, patients must only use them under practitioner supervision. In each of the states involved in this case, the duty to warn consumers of a drug’s dangers that are known, or should be known, falls squarely on the shoulders of the manufacturer.

The Court then turned to the federal law on point – the FDCA – which essentially states that before the federal Food and Drug Administration (“FDA”) will approve a brand-name drug manufacturer’s new drug application (“NDA”), the manufacturer must assure that the drug’s labeling accurately and adequately informs potential consumers about its safety and efficacy (which are based on the results of at least two randomized controlled trials). Furthermore, this law states that before the FDA will approve a generic drug manufacturer’s abbreviated NDA, the manufacturer must assure that the drug’s labeling (with regard to safety and efficacy) is identical to that of the brand-name drug. Thus, the Court concluded that brand-name and generic drug manufacturers have different preapproval responsibilities under the law with regard to the labeling of their products. Neither party disputed this conclusion. What was disputed, however, was to whether, and to what extent, generic manufacturers could change their drugs’ labeling after initial FDA approval.

The FDA provided the Court an amicus brief to help the Court understand some of the complicated issues at hand. The brief stated that the FDA interprets the law to require that the information about warnings in the labeling of a generic version or versions of a drug be identical to the warnings in

continued on page 14
the labeling of the brand-name drug because the brand-name drug is the basis for the approval of generic versions of it. Moreover, only the brand-name drug manufacturer can initiate a labeling change. The Court indicated that it will give FDA deference in its interpretation of its own law unless FDA’s interpretation is erroneous, inconsistent with the plain meaning of the law, or if there is some reason to doubt the agency’s interpretation.

The FDA asserted that the only way in which generic manufacturers can independently change the labeling of their products is to demonstrate to the agency that labeling changes are warranted in light of new evidence. The patients in Pliva disagreed with the FDA’s interpretation, and argued that there are two ways in which a generic manufacturer can unilaterally change the labeling of its generic products independent of the given brand-name product — either by way of the changes-being-effectuated (“CBE”) process or via the use of “Dear Doctor” letters. The generic manufacturers-defendants deferred to the FDA’s judgment that these processes are considered creating “labeling” and therefore are not available to generic manufacturers. Each of these proffered mechanisms is briefly discussed below.

Mechanisms by Which Generic Makers Can Independently Change Their Products’ Labeling

CBE Process

The patient-plaintiffs in this case explained that the CBE process permits generic manufacturers to add or strengthen a contraindication, warning, and/or precaution, as well as add or strengthen instructions on dosage and administration that is intended to increase the safe use of the drug product. The patients further explained that these changes can be made simply by filing a supplement to the product’s existing NDA, and without first receiving permission from the FDA. Generic manufacturers, however, referenced and supported FDA’s assertion that the CBE process only permits generic manufacturers to change their labeling either (1) to match newly updated brand-name labeling (which is indeed done without first sending FDA a proposal of the proposed changes to the labeling) or (2) to follow FDA instructions on specific changes that must be made in the generic product’s labeling. The FDA also asserted that a generic manufacturer using the CBE process to change its product’s labeling for any other reason would violate the laws that require the labeling of a generic product to match the labeling of its brand-name counterpart. The Court deferred to FDA’s interpretation of the CBE process.

The Use of “Dear Doctor” Letters

Here, the plaintiffs explained that “Dear Doctor” letters would inform healthcare professionals about risks associated with this and other medicinal drug products. In response, the generic manufacturers referenced and supported FDA’s assertion that these letters are considered part of a product’s labeling. Therefore, if a generic manufacturer were to send such a letter without the brand-name maker doing so as well, it would be effectively changing the labeling of the generic product, which would then no longer be identical to that of the brand-name product. In addition, receiving a letter from just one generic manufacturer of a product (and not from all generic manufacturers of that particular branded product) could mislead those health professionals who prescribe and dispense the drug by causing them to believe that the warning applies solely to that particular generic manufacturer’s product, and not to all generic versions of the branded drug. It is important to note that the FDA has the authority per the FDCA to withdraw the approval of a drug (brand or generic) whose labeling is false or misleading in any particular.

Again, the Court deferred to FDA’s explanation that the generic manufacturers were unable to send such “Dear Doctor” letters because such letters are considered part of a product’s “labeling.”

Proposal to FDA in Light of New Evidence

The FDA explained in its amicus brief that there is indeed a means by which generic manufacturers can change the labeling of their products. A generic maker, once it has reasonable evidence that its product has safety problems, must propose to the FDA that stronger warnings are needed in its product’s labeling. If the FDA agrees with this proposal, the agency then works with the brand-name manufacturer to create new labeling for both the brand and generic versions of the drug. The generic manufacturers argued that no such duty exists and that to date no generic manufacturer has acted pursuant to this duty. The Court stated that even if this duty exists, it still holds that the state tort law claims are preempted by federal law.

Discussion of the Court’s Analysis

Preemption and the Doctrine of Impossibility

The Court turned to the issue of preemption. According to the Supremacy Clause of the United States Constitution, federal law is the supreme law of the land; therefore, if a state law directly conflicts with a federal law, then the state law, if challenged, will be preempted and considered unconstitutional because the law violates the Supremacy...
The Supreme Court has ruled that state and federal law conflict in situations where it is impossible for a private party to comply with the requirements of both laws.\textsuperscript{24} The Court found impossibility in this case: If the generic manufacturers independently changed their labeling to strengthen the warnings about the side effect at hand (TD), then they would have violated federal law. If the manufacturers contacted the FDA about strengthening the warnings in the labeling (assuming that the duty to do so exists), manufacturers would not have satisfied their state tort law duty to provide adequate labeling (state law requires a safer label, and not simply contacting the FDA to request that it communicate with the brand-name maker about making the change).

Although the patients’ case was not based on the generic manufacturers’ failure to contact the FDA about changing the labeling, nonetheless the patients contended that if the generic manufacturers had indeed contacted the FDA about changing their products’ labeling, the generic manufacturers might have been able to accomplish, under federal law, what state law requires of them. The Court did not wholly disagree; however, it reasoned that federal law would permit the generic manufacturers to comply with state law, \textit{if and only if}, the FDA and the brand-name manufacturer changed the brand-name labeling to reflect the strengthened warnings. Nevertheless, the patients asserted that the generic manufacturers could not claim that it was impossible for them to concurrently comply with state and federal law because they did not even attempt to contact the FDA about strengthening the warnings about TD; had they done so, it may have resulted in a labeling change. The Court stated this argument was fair, but it rejected it due to the significant number of unknown variables that would have to take place to reach that endpoint.\textsuperscript{25}

The Court reasoned that the question of impossibility is whether a private party could independently do under federal law what state law requires of it. The Court believed there was just too much conjecture in the patients’ argument (i.e. complying with state law would have been possible if the brand maker and the FDA were able to negotiate a labeling change). The Court also explained that courts should not struggle to find ways to reconcile federal law with a seemingly conflicting state law. The Court explained that courts should look no further than the ordinary meaning of federal law and not distort it to accommodate a conflicting state law, and a preemption analysis should not involve speculation. The Court stated that when a party (such as the generic manufacturers here) cannot satisfy its state duties without the federal government’s special permission and assistance, which is dependent upon the exercise of judgment by a federal agency (the FDA here), that party cannot independently satisfy those state duties for preemption purposes.\textsuperscript{26}

\textbf{Distinguishing Wyeth v. Levine}

Next, the Court distinguished this case from \textit{Wyeth v. Levine}\textsuperscript{27} where patient Levine brought the same state tort law cause of action against Wyeth, albeit for a different product. Since Wyeth is a brand-name manufacturer, it could have changed its labeling via the CBE process or sent “Dear Doctor” letters, but it did not. Accordingly, Wyeth lost. The Court in \textit{Pliva} acknowledged that its ruling in favor of the generic manufacturers must make little sense to the injured patients, but the regulations that apply to brand-name manufacturers are meaningfully different from those that apply to generic manufacturers.\textsuperscript{28} Unfortunately for the patients in \textit{Pliva}, had they been given brand-name \textit{Reglan}\textsuperscript{®} rather than generic \textit{metoclopramide}, \textit{Wyeth v. Levine} would control, and their lawsuits would not have been preempted. In light of that critical factual distinction, the Court reversed the decisions of the Fifth and Eighth Circuits, and remanded for further proceedings consistent with its opinion in \textit{Pliva} that the state law cause of action is preempted via impossibility.

\textbf{Regulatory Framework for Generic Drug Approval and Labeling}

In order for a new prescription medication to be marketed in the United States, the medication must first be approved by the FDA for human use. In order to gain FDA approval, the manufacturer must submit an NDA to the FDA’s Center for Drug Evaluation and Research (“CDER”).\textsuperscript{29} Since the FDA does not conduct any of its own studies, an NDA is generally accompanied by the data from clinical and scientific trials (two or more) demonstrating that the drug is both “safe” and “effective” for its intended use. If the FDA determines a drug to be safe and effective, the manufacturer can then begin to market the drug for sale. Drugs undergoing the NDA process are colloquially referred to as “brand-name” drugs.

Prior to Hatch-Waxman’s enactment in 1984, all medications had to be approved using the same process. This was true even for medications that were virtually identical or chemical duplicates of other medications that were already approved and available on the market. A manufacturer wishing to market a chemical duplicate, or “generic” of an approved product was forced to undergo the same research and development processes, including conducting clinical and scientific trials, and submitting its findings to the FDA for a determination of safety and efficacy. Because it takes many years to bring a single drug to market and the cost for doing so is well over $800 million,\textsuperscript{30} only a handful of manufacturers were willing and able to devote the resources necessary to develop competitor products for entry in the market. Accordingly, continued on page 16
makers of brand-name drugs faced very little competition, resulting in a monopoly which allowed them to charge virtually whatever they wanted for their products. And, because of these high prices, millions of Americans simply could not afford needed medication.

In 1984, recognizing the lack of competition among pharmaceuticals, Congress passed the Hatch-Waxman Act. “Generic medications” were then able to be approved by the FDA without requiring manufacturers to conduct lengthy and expensive clinical trials. Rather, as a result of Hatch-Waxman, a generic drug can gain FDA approval by demonstrating generic equivalence to an already approved drug, known as a “Reference Listed Drug” (“RLD”) through an “Abbreviated New Drug Application” (“ANDA”). Generic equivalence requires a drug to be pharmaceutically equivalent and therapeutically equivalent to an RLD. Pharmaceutical equivalence refers to an identical amount of active drug ingredient(s) (i.e. same “strength” such as 500 mg), in the same dosage form (e.g. both are tablets or elixirs), and taken or administered via the same route (e.g. orally, intravenously, etc.). Two drugs that are pharmaceutical equivalents of one another that also have the same safety and efficacy profile are known as therapeutic equivalents. States, through their pharmacy practice acts, permit pharmacists to substitute a brand-name drug with its generically equivalent counterpart.

The labeling requirements for drug products – both brand and generic – are established under FDA regulations. Among other things, a drug’s labeling must provide adequate directions for use “...under which a layman can use a drug safely, and for the purposes for which it is intended.” An additional requirement of generic drugs is that a generic product’s labeling must exactly match the labeling of the RLD. Generally, the RLD for a generic drug is the NDA product or “innovator”, which is typically a brand-name medication. Thus, a generic medication’s labeling must match the labeling of the brand-name drug.

In order for a generic manufacturer to make a substantive change in its labeling (e.g. warning about the increased likelihood of an adverse effect), the brand-name manufacturer must first initiate and make that change. However, when a brand-name medication is removed from the market for reasons other than safety and efficacy (e.g. it is no longer profitable to produce the drug due to nearly-exclusive use of its generic), the discontinued brand-name medication no longer serves as the RLD. In these cases, the FDA unilaterally chooses a generic product, typically the one with the greatest U.S. market share, to serve as the new RLD. Should a manufacturer of a generic drug for which there is no NDA serving as the RLD request that FDA allow it to strengthen the warnings in the drug’s labeling, the agency has stated that it will work with that manufacturer and grant the request if warranted. Yet, according to the defendants in Pliva, there is no evidence that a generic manufacturer has ever requested that FDA allow it to unilaterally change its product’s labeling. If such a generic manufacturer ever requests a unilateral labeling change, and if the FDA, exercising its discretion, were to deny that request, it is highly unlikely that the agency will be held liable for any harm allegedly caused by its decision under the doctrine of Sovereign Immunity.

Generic Drugs Without a Brand RLD

As a result of the Court’s holding in Pliva, plaintiffs will be unsuccessful in their failure-to-warn claims against makers of generic drugs. The logic behind the ruling in this case is that brand-name manufacturers are the ones who will monitor risks associated with their products, and then strengthen their products’ warnings in light of new safety and efficacy data; the generic manufacturers – who simply do not have access to these data – will update their products’ labeling to include the those changes made by the brand makers. While this reasoning is of little comfort to those injured by using generic drugs, there is some sense to it. Unfortunately, however, the Court in Pliva did not consider the situation where the brand-name drug has permanently left the market, leaving only generic versions of the drug available to patients. Which generic manufacturer, if any, is responsible for reporting new safety and efficacy information in the labeling?

The Court in Pliva explained that generic drug manufacturers do not share the same level of responsibility as makers of brand-name equivalents to update warnings in their products’ labeling when important new risks materialize. So, what happens when the NDA serving as the RLD leaves the market? Which generic manufacturer, if any, is now responsible for ensuring that labels are updated to reflect these new risks? According to the FDA’s amicus brief in Pliva, generic manufacturers can request labeling changes from FDA; but, to date, no generic manufacturer has made such a request. This is really a nonissue when there is an NDA product on the market – its manufacturer is responsible for staying abreast of significant new risks and reporting them in its product’s labeling (and generic makers change their labeling to mirror that of the brand). Someone is minding the store, so to speak. This is not the case when the brand-name drug manufacturer – the holder of the NDA – permanently stops making its product.
Just how many widely used generic drugs in the United States do not have an NDA drug as the RLD? Currently, of the top 200 drugs dispensed in 2010 pursuant to written prescriptions, only two generic drugs do not have a brand name counterpart – hydrochlorothiazide (to treat high blood pressure) and isosorbide mononitrate (to treat/prevent chest pain).

Yet, when looking at the top 200 drugs of 2010 by sales, there are several generic medications without a branded drug on the market that are still commonly prescribed, including amitriptyline tablets (antidepressant), bacitracin ointment (antibiotic), baclofen tablet (muscle relaxant), bumetanide tablets (diuretic to treat heart failure), cefadroxil capsules and tablets (oral antibiotic), chlorpromazine tablets (antipsychotic), dexamethasone tablets (steroid), dicloxacillin capsules (oral antibiotic), flunisolide nasal spray (corticosteroid), haloperidol tablets (antipsychotic), isoniazid tablets (to treat/prevent tuberculosis), tamoxifen tablets (to treat breast cancer), and trazodone tablets (to treat depression and anxiety disorders). For all of these drugs, the RLD is a product with an ANDA (i.e. generic) and not an NDA. Several of these generic drugs without brand equivalents on the market have serious side effects requiring a boxed warning or a Medication Guide. A boxed warning is an alert prominently placed at the beginning of a drug's package insert and a Medication Guide is a paper handout, approved by the FDA, given to patients taking certain medications explaining, among other things, the risks associated with using the drug. Tables 1 and 2 below present several drug classes and individual (generic) drugs that no longer have a brand-name product as the RLD. All of these drugs have the potential for causing serious side effects in patients. Therefore, it is critical that makers of these drugs closely monitor their use and report new serious risks in the labeling.

### Failed Attempts to Hold Generic RLDs Liable

Since *Pliva*, plaintiffs' attorneys have been searching for alternative claims that would attach liability to generic drug manufacturers for the adequacy of warnings in their products' labeling. One such alternative, which has been repeatedly attempted, is to bring suit against the generic RLD under a duty-to-warn claim. As stated previously, when a brand-name version of a drug is no longer manufactured, a generic is selected by the FDA to become the RLD in place of a brand-name medication. Plaintiffs have argued that since the generic is now the “stand-in” for the brand-name medication, the FDA must have given its maker the authority and duty to alter its labeling in light of new scientific evidence, as if it was a brand-name medication. Accordingly, this would theoretically allow these FDA-appointed generic RLDs to unilaterally alter their products' labeling. Therefore, claims against a generic RLD should not be preempted under federal law.

Such claims, however, have been largely unsuccessful and repeatedly dismissed. Courts have refused to confer the responsibilities of a brand-name NDA-holder to the maker of a...
generic drug now serving as the RLD that has been categorized as such simply due to its dominance in the market. As one court noted in reaching this determination, “[a generic manufacturer] does not hold NDA status by virtue of becoming an RLD and thus does not bear the burden of its brand-name counterpart. It is the FDA that is responsible for mandating changes in labeling, and as [Pliva] recognized, NDA-approved drug makers alone retain duties above and beyond those of generic drug makers.”

In other words, serving as an RLD does not suddenly transform a generic medication into a brand-name medication. To date, no court has held that the maker of a newly-appointed generic RLD, or any other generic maker for that matter, is now suddenly legally responsible for reporting new risks in its labeling by virtue of the brand-name drug leaving the market.

### Conclusion

The *Pliva* case illustrates that the current regulatory scheme as it relates to the labeling of generic medications has largely left plaintiffs injured by insufficient or completely absent warnings without recourse against the manufacturers of these products. Until regulatory reform is enacted, patients will remain unable to recover for injuries sustained as a result of these inadequate warnings. This has created a serious public hazard, as many individuals who take generic medications are not even aware that they are doing so. They have also unknowingly given up significant legal rights. The United States Senate has responded to generic manufacturers’ inability to alter product labeling by proposing the Patient Safety and Generic Labeling Improvement Act; an amendment to the FDCA. Under this proposed amendment, the holder of an approved ANDA, including those not designated as RLDs in instances where no NDA is on the market, would be able to change the labeling of its approved product in a manner substantially similar to brand-name medications. Additionally, the Secretary of the Department of Health and Human Services would have the authority to order the change to all drugs that are approved and listed as equivalent to the product making the change.

Generic medications unquestionably fill a need in healthcare for millions of individuals. The existence of generics has greatly improved access to life-saving medications for individuals who otherwise may not be able to afford them. While the cost-savings associated with generic medications are significant, the trade-off as identified in *Pliva* may be equally significant. Namely, generics may come at a cost of sacrificing future legal remedies for individuals that are harmed by generic medications. Accordingly, patients should be provided with complete and accurate information about their drug therapy so that they are able to weigh the benefits of saving money on generic drug therapy against the potential risks of sacrificing a legal remedy should they become injured by using a particular generic drug product. In the meantime, let the buyer beware.

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**Table 2. Individual Drugs with Boxed Warnings**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Boxed Warning</th>
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<tbody>
<tr>
<td>Bumetanide</td>
<td>Potent diuretic requiring special supervision because it can cause severe electrolyte depletion</td>
</tr>
<tr>
<td>Etoposide</td>
<td>Severe myelosuppression</td>
</tr>
<tr>
<td>Flutamide</td>
<td>Hepatic injury</td>
</tr>
<tr>
<td>Ganciclovir</td>
<td>Clinical toxicity – granulocytopenia, anemia, thrombocytopenia</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>Severe and sometimes fatal hepatitis</td>
</tr>
<tr>
<td>Methyldopa &amp; Hydrochlorothiazide</td>
<td>Not for initial hypertension therapy</td>
</tr>
<tr>
<td>Nefazodone</td>
<td>Life-threatening hepatic failure</td>
</tr>
<tr>
<td>Propylthiouracil</td>
<td>• Hepatotoxicity&lt;br&gt;• Pregnancy</td>
</tr>
<tr>
<td>Tretinoin capsule</td>
<td>• Experienced healthcare provider and institution&lt;br&gt;• Retinoic acid-APL syndrome&lt;br&gt;• Leukocytosis&lt;br&gt;• Teratogenic effects</td>
</tr>
</tbody>
</table>
W. Thomas (Tommy) Smith, Jr., Pharm.D., J.D., graduated from the Saint Louis College of Pharmacy in 1994 with a Doctor of Pharmacy degree. Upon graduation, Dr. Smith served as the Director of Operations for Corum Health Services, Inc., a long-term care pharmacy in Saint Louis, Missouri. Dr. Smith earned his Juris Doctor degree in 2005, along with a Certificate in Health Law, from the Center for Health Law Studies at Saint Louis University School of Law.

Dr. Smith joined the faculty of the Saint Louis College of Pharmacy, and in 2008 joined the faculty of the University of Florida (“UF”) College of Pharmacy. At UF, he teaches “Pharmacy Law and Ethics” to doctor-of-pharmacy students in their third professional year of study, “Structure Process and Outcomes of Regulations” to students in their first semester of UF’s online Master of Science in Pharmacy program, as well as lectures on pharmacy law and ethics to first-year students and on the ethics of clinical research to residential Ph.D. and residential Master's students. He was promoted to the rank of clinical associate professor in July 2011, and was named University of Florida College of Pharmacy 2011-2012 Teacher of the Year. In April 2012, Dr. Smith was appointed as Director of the College's online Master of Science in Pharmacy Program (emphasis in pharmaceautical outcomes and policy).

Since joining the faculty at UF, Dr. Smith’s scholarly work has begun to focus primarily on disability education in pharmacy curricula and legal and ethical issues related to disability and healthcare. Dr. Smith has spoken on these issues at the 2010 American Pharmacists Association (“APhA”) Annual Meeting and Exposition, the 2010 American Bar Association (“ABA”) Annual Meeting, and the 2011 American Association of Colleges of Pharmacy (“AACP”) Institute. He has published articles in these areas in professional, peer-reviewed publications, including the Mississippi College Law Review, the American Journal of Pharmaceutical Education, and Academic Medicine.

Dr. Smith is also very involved in various professional organizations, including the American Society for Pharmacy Law (“ASPL”), the AACP, and the ABA. Since 2009, Dr. Smith has served on ASPL's Education and Scholarship Committee, as well as presented on behalf of ASPL at the 2010 and 2011 APhA Annual Meetings. In 2011, he was named Chair-elect to a newly-formed AACP Special Interest Group on cultural competency and health disparities. Within the ABA, he holds leadership positions in the Health Law Section and on the Special Committee on Bioethics and the Law. He also recently completed a three-year presidential appointment on the ABA’s Commission on Mental and Physical Disability Law. He may be reached at tsmith@cop.ufl.edu.

Eli G. Phillips, Jr., Pharm.D., J.D., serves as Special Counsel to the Dean and Assistant Professor of Pharmacy Practice at the University of the Incarnate Word, Feik School of Pharmacy in San Antonio, Texas. He also holds appointments as Adjunct Professor of Law at St. Mary’s University School of Law, San Antonio and Affiliate Clinical Assistant Professor at the University of Florida College of Pharmacy.

Dr. Phillips received his Doctorate in Pharmacy from Wilkes University in Wilkes-Barre, PA and his Juris Doctorate from Drexel University in Philadelphia, PA where he received certificates in Health Law and Intellectual Property Law. He has practiced pharmacy for a major national retailer, and has completed law internships with the Drug Enforcement Administration's Office of Chief Counsel in Arlington, VA and the Governor's Office of General Counsel for the Commonwealth of Pennsylvania in Harrisburg, PA.

He currently serves as a consultant to manufacturers, wholesalers, and pharmacies on a wide range of issues, including the licensing and regulation of healthcare professionals, professional negligence, and controlled substance diversion. He may be reached at 210-883-1000 or egphilli@uiwtx.edu.

Tina Christi Lopez, Pharm.D., M.S., serves as the Director of the Drug Information Center and an Assistant Professor of Pharmacy Practice at the University of the Incarnate Word Feik School of Pharmacy in San Antonio, Texas.

Dr. Lopez received her Doctorate in Pharmacy and Masters in Science in Pharmacy from The University of Texas at Austin. She practiced pharmacy at the University of Utah Drug Information Service and Anticoagulation Clinic before moving back to Texas to teach at the University of the Incarnate Word. She can be reached at 210-883-1000 or tmlopez@uiwtx.edu.

Endnotes
5 “Survey of Pharmacy Law”, National Association of Boards of Pharmacy (2012). Thirty-eight states and the District of Columbia are “permissive substitution states.”
In those states, the pharmacist decides whether or not to dispense a generic drug. In the remaining 12 states, however, pharmacists must dispense generic drugs, if available, unless the prescriber instructs them not to do so. The following states allow pharmacists to decide whether to substitute a brand name drug with its generic counterpart in the absence of a specific instruction by the prescriber: Alabama, Arizona, Idaho, Nebraska, South Carolina, South Dakota, and Utah.

6 Id. Pharmacists in Florida, for example, are required to substitute the branded drug with a generic drug if the prescriber does not write “MEDICALLY NECESSARY [to dispense the branded drug]” on the face of the prescription. See Florida statute 465.025 “Substitution of drugs.”

7 “Id. Patient consent to generic substitution is not required in the following states; Illinois, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Washington, and Wyoming.

8 See generally Kesselheim AS, et al., Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis, JAMA 2008;300(21):2514-2526.


13 Id.


16 Pliva at 2575, citing U.S. Brief 16.

17 Pliva, at 2576.

18 Pliva, at 2575.

19 Id.


21 Pliva, at 2576.

22 Pliva at 2577.

23 Id.

24 Id.

25 Pliva, at 2579.

26 Pliva, at 2581.

27 Wyeth v. Levine, 129 S.Crt. 1187 (2009). In this case, Levine was given brand-name Phenergan®, manufactured by Wyeth.

28 Id.


30 Healthcare Economist. Available at http://healthcare-economist.com/2006/04/29/802m/. Accessed July 4, 2012. Scholars have found that the time from the start of clinical testing to marketing approval was approximately 90.3 months. This figure is in addition to any development time which occurs before phase 1 clinical trial. The final estimate is that it costs – including the expense of failed drugs – $802 million to take a drug from phase I trials to approval. This price does not take into account the cost to develop the new chemical entity itself.

31 Public Law 98-417.


36 See supra note 9.

37 Pliva, at 2577.

38 Sovereign immunity refers to the legal doctrine that the government is unable to commit a legal wrong, and is therefore isolated from being sued for harms, unless it consents to being sued. See e.g., VA v. Stewart, 131 S.Ct. 1632 (2011), and FAA v. Cooper, 132 S.Ct. 1441 (2012). In a situation such as this hypothetical where the FDA rightfully exercises its discretion, it is immune from suit regardless of the harm(s) suffered.


41 Cooper v. Wyeth, Civ.A. 09-929-JJB, at 15 (M.D. La., 2012).

42 S. 2295, Patient Safety and Generic Labeling Improvement Act, (introduced and referred to committee April 18, 2012). No additional information is currently available regarding this proposal.

The articles published in The Health Lawyer reflect the opinions of the authors. We welcome articles with differing points of view.
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The full conference brochure will be available to all Health Law Section members. In the meantime, the schedule-at-a-glance is below to assist you in your planning. If you have any questions, please contact Amy Alder, Senior Meeting Planner, at amy.alder@americanbar.org. To register now, please visit www.americanbar.org/health.

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| 11:15am – 12:30pm | Conflict Resolution in the Hospital Board/Medical Staff Context |
| 11:15am – 12:30pm | Everything Your Clients Want You To Know About Tax Issues for ACOs and Clinical Integration Networks |
| 12:45 – 2:00pm | Interest Group Luncheons |
| 2:15 – 3:45pm | Emerging Trends in Enforcement Update |
| 3:45 – 4:45pm | Ethics Programs |
| 5:00 – 6:15pm | What’s for Dinner? Food Regulation and Public Health |
| 5:00 – 6:15pm | Current Topics and Emerging Trends in Managed Care Litigation |
| 5:00 – 6:15pm | Urgent Care Centers: The Legal and Practical Issues for Development |
| 6:30 – 9:00pm | Welcome Reception |

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Friday, February 22, 2013 (continued)

11:00am – 12:15pm Cells as Drugs: FDA Regulations of Your Drugs
12:30 – 1:45pm Interest Group Luncheons
2:00 – 3:30pm Emerging Trends in Physician Alignment Strategies: Consolidation, Joint Ventures and Payment Structures
2:15 – 3:30pm Law Student Meet and Greet
3:45 – 5:00pm Helping Employers With Compliance in a Post-PPACA World
3:45 – 5:00pm Observation Status: Caught Between a Rock and a Hard Place?
3:45 – 5:00pm Once More unto the Breach! Security Rule Compliance, Risk Assessments, Risk Mitigation Strategies, and What to Do When Things Go Wrong

Saturday, February 23, 2013

8:00 – 11:30am Open Council Meeting
12:15 – 5:30pm Margarita Cup Golf Outing
12:15 – 5:30pm Taste of South Beach Culinary Tour
6:00 – 9:00pm Chair’s Reception and Margarita Cup Awards Ceremony

Controlling Costs While Promoting Health: Implementation of the Affordable Care Act

Although federal healthcare reform has passed and survived a Supreme Court challenge, it is unclear how quickly states will be able to implement the new law, according to Mark McClellan, a former Centers for Medicare & Medicaid Services administrator.

“What we’re still seeing with how it plays out in the implementation of healthcare reform is the greater role states have in implementing reform as a result of the big role they are defined to play in the Affordable Care Act,” said McClellan, the keynote speaker at the American Bar Association’s Health Law Section’s 10th Annual Washington Health Law Summit. “What I think that is going to mean is that in ways we haven’t seen yet, the states are going to have more negotiating leverage.”

McClellan, who now serves as director of the Engelberg Center for Health Care Reform at the Brookings Institution, also said this scenario has started to evolve as states decide whether to accept the federal healthcare exchanges and how they choose to implement Medicaid reforms.

The Patient Protection and Affordable Care Act encourages each state to run its own exchange, which allows individuals and small businesses to purchase health insurance.

Timing will play a vital role in the months ahead now that the Obama administration has released new healthcare regulations, McClellan said.

“There isn’t much time between now and the fall of 2013, when the exchanges are supposed to be up and running,” he added. “It will be a fast march to the implementation of coverage.”

McClellan said lawyers can help in the process of creating a more productive health system by working to change policy that does not encourage more efficient and effective care.

“They should recognize that this is an incremental process that will lead to fundamental changes, so have the ultimate goal in mind: better care but lower costs,” he said. “However, recognize it will take time to get there.”

The Brookings Institution has issued a series of reports called “Bending the Curve: Effective Steps to Address Long-Term Health Care Spending Growth.”

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MEDICAID PAYMENT HOLDS DUE TO CREDIBLE ALLEGATIONS OF FRAUD

Larry Heyeck, Esq.
Deputy General Counsel
New Mexico Human Services
Department
Santa Fe, NM

Introduction

Section 6402(h) of the Patient Protection and Affordable Care Act ("PPACA") amended section 1903(i)(2) of the Social Security Act to provide that federal financial participation ("FFP") in the Medicaid program "shall not be made with respect to any amount expended for items or services (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished by an individual or entity to whom a State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against an individual or entity as determined by the State, unless the State determines in accordance with the federal regulations that good cause exists not to suspend such payments."

Federal law defines a "credible allegation of fraud" as an "allegation, which has been verified by the State, from any source." On February 2, 2011, the Centers for Medicare & Medicaid Services ("CMS") revised its regulations to comport with the new PPACA provisions. Under 42 C.F.R. §455.23 state Medicaid agencies “must suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud for which an investigation is pending under the Medicaid program against an individual or entity unless the agency has good cause to not suspend payments or to suspend payment only in part." Because the payment hold takes effect immediately, many providers will suffer cash-flow shortages and may ultimately be forced to close their doors. In such a situation, providers will first look to the state Medicaid Agency for relief as that was that agency that turned off the payments; however, under the revised rule once a payment hold is put in place, the agency may resume payments in whole or in part only if “good cause” exists.

Faced with this mandatory requirement to withhold payments to providers leaves state Medicaid agencies with limited discretion. This article provides suggestions to those agencies faced with complying with the statute's intent of ensuring the integrity of Medicaid funds and providing adequate access to services for Medicaid recipients.

The Suspension Process

CMS recognized that credible allegations of fraud “may stem from a variety of sources.” Once the state Medicaid Agency receives a credible allegation of fraud, it must conduct a preliminary investigation in accordance with 42 C.F.R. §455.14. Although there are no specific criteria on what should be included in a preliminary investigation, the state Medicaid agency should include the following:

- verification of professional credentials, enrollment and/or licensing;
- collection from the claims administrator of medical records relating to a provider;
- preliminary review and assessment of medical records and documentation by a medical expert reviewer and/or consultant;
- claims sampling/comparison to billing for services;
- interviews with patients and/or other providers or suppliers;
- consultation with medical experts and consultants, if necessary.

The threshold level of determining whether credible allegations of fraud exist under the revised rule is significantly lower than the requirement of “reliable evidence” under the old rule. CMS explained that it modified the terminology in “§455.23(a) that [under the prior language] refer[red] to ‘receipt of reliable evidence’ to . . . a ‘pending investigation of a credible allegation of fraud’” in an effort to create a “substantive difference between the threshold level of certainty or proof necessary to identify a ‘credible allegation’ versus the heightened requirement of ‘reliable evidence’ [under the prior language].” Consequently, state Medicaid agencies will be forced to withhold payments, in whole or in part, on more Medicaid providers than ever before.

Another requirement imposed upon a state Medicaid agency is the fraud referral to the Medicaid fraud control unit ("MFCU"). State MFCUs operate independently of the state Medicaid agency to investigate and prosecute violations of state laws pertaining to Medicaid fraud. This includes the ability of state MFCUs to refer any provider to the state Medicaid agency for imposition of a payment suspension when the state MFCU is conducting its own investigation into a credible allegation of fraud.

The revised rule makes clear that the state Medicaid Agency must immediately suspend payments before the provider is notified of the suspension. Once payment is suspended, albeit for a “temporary” period of time, the state Medicaid agency is required to provide written notice of the suspension and “[s]et forth the general allegations as to the nature of the suspension action, but need not disclose any specific information concerning an
been suspended in accordance with notice are told: (1) payments have lars. Thus, providers who receive such give a broad statement of the nature state Medicaid agencies should only litigation. agencies will act appropriately so as tion…” and expects “that State sensitive nature of a fraud investiga

global function of the health care system. The State Medicaid agency has any discretion – the “good cause” exceptions.

Application of the Revised Rule

Applying the revised rule puts State Medicaid agencies and their providers in a proverbial “Catch-22” scenario. The State Medicaid agency must suspend payments upon credible allegations of fraud and send written notice to the provider of “the general allegations.” The state agency cannot disclose the particulars of the investigation without possibly tampering with it, yet must give some indication to the provider of the nature of the claims. Even CMS recognized the “sensitive nature of a fraud investigation…” and expects “that State agencies will act appropriately so as not to jeopardize” the criminal investigation. This statement implies that state Medicaid agencies should only give a broad statement of the nature of the allegation without any particulars. Thus, providers who receive such notice are told: (1) payments have been suspended in accordance with 42 C.F.R. §455.23; (2) they are under investigation based upon credible allegations of fraud and the general nature of the allegations; and (3) they have a right to submit written evidence within 30 days of the date of the notice to support the removal of the withhold in whole or in part. Within 30 days of receipt of written arguments and documentation in response to the withhold, the state Medicaid agency will review the information and notify the provider of the results of that review. After the review, the determination to impose the payment withhold may be affirmed, reversed or modified, in whole or in part. This decision shall not be a determination on the results of any criminal investigation initiated by the MFCU.

For example, if the provider is an entity that is accused of submitting claims for services rendered by a non-licensed professional and/or double billing for a particular service, the state Medicaid agency should not disclose the non-licensed professional or identify the service in question, since doing so might impact what is now a criminal investigation. From the provider’s perspective, it is difficult to determine what “written evidence” should be presented if the provider does not know the substance of the investigation. And even if the provider is clairvoyant and “knows” the subject matter of the criminal investigation, submission of written evidence may be used against him at a criminal trial.

In some instances this becomes even more complex. For example, in New Mexico, approximately 80 percent of that state’s Medicaid population is enrolled in managed care. Since the final rule applies to Medicaid managed care, the state Medicaid agency receives referrals for possible fraud and/or abuse from the managed care organizations (“MCO’s”), reviews the information and can either conduct an in-depth audit itself on the identified providers or request that the MCO conduct further review. In both instances, the state Medicaid agency’s oversight committee will review the findings and, if verified, determine whether credible allegations of fraud exist. If credible allegations exist, the state Medicaid agency must: (1) suspend payments; (2) make a referral to the MFCU; and (3) provide notice to the affected provider.

Early on, when New Mexico instituted CMS’ revised rule, providers responded to the state Medicaid agency’s notice of payment suspensions with requests for more information regarding the allegations of fraud, including requesting administrative review under the revised rule. Although New Mexico does provide administrative review for provider recoupments and/or provider termination, such review is not available for accepted referrals by the MFCU for credible allegations of fraud. Accordingly, New Mexico revised its notice to impacted providers and now only permits submission of written evidence to support the provider’s assertion that good cause exists under the revised rule.

All state Medicaid agencies should consider this approach, as it limits the provider’s response to the good cause exceptions and avoids any discussion surrounding the fraud referral which is now out of the state Medicaid agency’s purview and is being investigated by the MFCU. This approach appears to be consistent with CMS’ response to the comments:

... Under the proposed rule [now final], providers have an opportunity to submit written evidence for consideration by the Medicaid agency regarding payment suspensions. Based upon this written evidence, a State may determine whether there is good cause to terminate a suspension of payment. Accordingly, we believe there are adequate due process protections in place pursuant to which a provider may establish good cause to terminate a payment suspension... Moreover,
we expressed in the proposed rule that suspensions, because of their significant impact upon providers, are only temporary. We provided in the rule several protections (such as quarterly law enforcement and State documentation requirements) and also various “good cause” exceptions… . We believe that significant built-in protections, in conjunction with the fact that we are not aware that the current Medicaid suspension process has caused significant undue hardship with providers having payments wrongly suspended, lend adequate safeguards to the process. CMS will also monitor States’ implementation of the Medicaid payment suspension rule through the various documentation requirements and State program integrity reviews, to ensure that there are no marked shortcomings with regard to States’ processes.21

Good Cause Exceptions

There are several circumstances that, under the final rule, could constitute “good cause” for a state Medicaid agency to determine not to suspend payments or to discontinue an existing payment suspension, in whole or in part, to an individual or entity despite a pending criminal investigation.22 As such, the state Medicaid agency has the discretion to determine good cause both at the pre-suspension (before notice is sent to the provider) and post-suspension stages (after the notice has been sent). As stated by CMS, good cause exceptions to terminate a whole payment suspension or impose a partial suspension generally include the following:

1. Specific requests by law enforcement that state officials not suspend (or continue to suspend) payment.

2. If a state determines that other available remedies implemented by the state could more effectively or quickly protect Medicaid funds than would implementing (or continuing) a payment suspension, such as requiring pre-approval of claims by a third-party billing agent before the state Medicaid agency pays the claim if improper billing practices have occurred.

3. If a provider furnishes written evidence that persuades the state that a payment suspension should be terminated or imposed only in part.

4. A determination by the state agency that certain specific criteria are satisfied by which recipient access to items or services would otherwise be jeopardized.

5. A state may, at its discretion, discontinue an existing suspension to the extent law enforcement declines to cooperate in certifying that a matter continues to be under investigation and therefore warrants continuing the suspension.

6. A determination by the state agency that payment suspension (in whole or in part) is not in the best interests of the Medicaid program.

7. The credible allegation focuses solely on a specific type of claim or arises from only a specific business unit of a provider and the state determines that a suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.23

CMS has stated that it will assess a state Medicaid agency’s implementation of the revised rule through its state program integrity reviews “to ensure that there are no marked shortcomings with regard to State’s processes.”24 This requires the state Medicaid agency to document the reasons for granting a good cause exception and conduct periodic reviews to ensure that the reasons remain valid. Otherwise, the state Medicaid agency jeopardizes its FFP on amounts paid to those providers who continue to serve Medicaid recipients during the pendency of an investigation for a credible allegation of fraud.25

Potential Ramifications

The imposition of a payment hold significantly impacts Medicaid providers and state Medicaid agencies. Generally, the allegation of fraud will include either: (1) the entire operation, including clinical staff; (2) supervisory and/or management responsibilities; or (3) billing. A provider with a substantial Medicaid patient base has several options. If the allegation is solely based on significant billing practices, such as upcoding or unbundling, the provider could request that the state Medicaid agency put in place an auditing agent who would be responsible for reviewing claims and certifying the accuracy of the claims prior to submission for payment.26 Upon submission, these claims would be paid by the state Medicaid agency. There would be a time-lag; however, at least there is the possibility of continued cash-flow to the provider. Another approach is to have the provider request that a management agency take over the operations and billings, using a “receiver” to operate the business until the criminal investigation can be completed. The provider would continue to operate using the same taxpayer identification and provider numbers. Last is the complete transition of the Medicaid recipients assigned to the provider. This could be accomplished by the provider notifying the state Medicaid agency of its intention to shut down or by filing bankruptcy and seeking protection of the federal bankruptcy court.
Once the payment withhold is in place, the state Medicaid agency has two primary responsibilities: (1) ensure that the Medicaid recipients receive care and treatment; and (2) protect the integrity of the Medicaid funds for prospective services. This can only be accomplished by working with the impacted provider, MFCU and CMS. In the first two instances, either having a billing agent come in and certify the claims prior to payment or using a management company that takes over the operations and billings, state Medicaid agencies will need to address this additional cost component. In most situations, the state Medicaid agency can require the impacted provider to pay this expense or deduct it from any prospective payment. If the provider intends to shut its doors, the state Medicaid agency will need to work with the provider to transition the Medicaid recipients so that they can continue to receive services. Under any approach, state Medicaid representatives will have to immediately address the situation, evaluate which approach is appropriate, and continue to be involved until the matter is resolved. This can be administratively burdensome but necessary to protect Medicaid recipients and Medicaid funds. The key is to minimize any disruption in services.

Conclusion

State Medicaid agencies are faced with imposing payment withhold whenever a credible allegation of fraud has been verified, a lower threshold than what was required under the former rule. Once payment has been suspended, impacted providers should submit to the state Medicaid agency written evidence and documentation to support its contention that good cause exists to remove the payment withhold, in whole or in part. This is the only discretion left with the state Medicaid agency, as the state’s MFCU has accepted the fraud referral and is now conducting a criminal investigation. If the decision to withhold is affirmed by the state Medicaid agency, the provider and the agency should work towards a viable solution until the MFCU can complete its investigation. This solution should include how Medicaid recipients can continue to receive services and how to protect the integrity of prospective payments.

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Endnotes

1 See 76 Fed.Reg. 5931 (February 2, 2011).
2 See 42 C.F.R. §455.2. The same definition for credible allegations of fraud is used for the Medicare program. See, 42 C.F.R. §405.370. Under Medicare, CMS, in consultation with the Health and Human Services Office of Inspector General and, as appropriate, the Department of Justice, must suspend payments based upon credible allegations of fraud. Similar to the revised Medicaid rule, the payment withhold can be suspended, in whole or in part, for good cause exceptions. See, 42 C.F.R. §§405.471 and 405.372.

3 See 42 C.F.R. §455.2. “A credible allegation of fraud may be an allegation, which has been verified by the State, from any source, including but not limited to the following: (1) fraud hotline complaint; (2) claims data mining; (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.” See id.


7 CMS stated that “[i]n the proposed rule, [we] acknowledge[] that the proposed threshold for triggering a payment suspension is lower than what is contemplated in current regulations, but [CMS] also indicated that [it] believed this result is dictated by the ACA.” See 76 Fed. Reg. 5935 (February 2, 2011).
9 See 42 C.F.R. §455.23(d). Although all states have a MFCU, the regulation permits referrals to an appropriate law enforcement agency which may include the Office of the Inspector General, state police or local district attorney’s offices.

10 See 42 C.F.R. Part 1007. MFCU organizations operate in all states and receive 90% of their funding from CMS. See National Association of Medicaid Fraud Control Units, http://namfcu.net.

11 See 42 C.F.R. §1007.9(e).
12 See 42 C.F.R. §455.23(a)(2). CMS did not agree “that providers should be given notice of a payment suspension prior to such action being taken.” CMS recognized “the sensitive nature of a fraud investigation which may be jeopardized by such notice, and expect that State agencies will act appropriately so as not to jeopardize any investigation.” See 76 Fed. Reg. 5737 (February 2, 2011).

13 See 42 C.F.R. §455.23(b)(2)(ii).
15 See 42 C.F.R. §455.23(a)(3).
18 See State of New Mexico, Human Services Department Medicaid eligibility reports by category or eligibility at: http://www.hsd.state.nm.us/mad/RMedicaidEligibility.html.


20 See NMAC 8.353.2.10(C)(1)(c).
22 See 42 C.F.R. §455.23(e) – (f).
23 See 42 C.F.R. §455.23(e) and See, CPI-B 11-04, March 25, 2011, regarding CMS Guidance to States on Section 6402(h) of PPACA.

26 CMS noted that the payment suspension would not apply to billing errors. See 76 Fed. Reg. 5926 (February 2, 2011).
Update to 2012 Emerging Issues Conference Presentation:
WHERE HAVE ALL THE DRUGS GONE? DEALING WITH DRUG SHORTAGES

Submitted by
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Drug shortages are not a new problem. The Government Accountability Office (“GAO”) reported 1,190 drugs have been in short supply between January 1, 2001 and June 20, 2011 with an average duration of 286 days.1 As of June 1, 2011, 11 percent of all Food and Drug Administration (“FDA”) approved and marketed drugs, vaccines and biologics were in short supply.2 In November 2011, the IMS Institute for Healthcare Informatics noted that half of the total generic injectable market was in short supply.3

The University of Utah Drug Information Service (“UUDIS”) tracks national drug shortages providing information on a public website at www.ashp.org/shortage.4 In 2001 UUDIS partnered with the American Society of Health-System Pharmacists (“ASHP”) and Novation to provide availability information and clinical management strategies to minimize the impact of drug shortages on patients. Their methods have been previously published.5 Briefly, the UUDIS receives voluntary reports via the public ASHP Drug Shortage Resource Center. The UUDIS also self-reports shortages experienced at the University of Utah Hospitals and Clinics. The UUDIS investigates the shortage and shares all information identified with ASHP, Novation and FDA’s Drug Shortages team. Manufacturers are contacted directly to determine if a shortage exists. If multiple suppliers are experiencing backorders or other supply problems, the shortage information is posted on the ASHP and Novation websites and updated until all suppliers have all products back in routine supply.

Data from the UUDIS show the rate of new drug shortages has rapidly decreased in 2012.6 As of October 19, 2012, a total of 154 new drug shortages have been identified. For comparison, a total of 180 new drug shortages occurred during just the first six months of 2011. This slowed rate of new drug shortages represents real progress. For the first time in five years, the dramatic increase in drug shortages is slowing (see Figure 1). However, while the rate of new shortages is decreasing, the number of active and ongoing shortages is at an all-time high (see Figure 2). New shortages are being prevented by the FDA, but the shortages that have occurred in the past are taking a long time to resolve.

Figure 1. National Drug Shortages. New Shortages by Year. January 2001 to October 19, 2012
Data Source: University of Utah Drug Information Service

Figure 2. National Drug Shortages. Active Drug Shortages by Quarter. January 2010 to September 2012.
Data Source: University of Utah Drug Information Service
Early notification by manufacturers is an effective tool in preventing drug shortages. Between November 2011 and June 2012, approximately 300 shortages were averted due to the early notification recommendations in President Obama's executive order on drug shortages and FDA's subsequent interim final rule. FDA received new authority to help prevent drug shortages in 2012 when the Food and Drug Administration Safety and Innovation Act ("FDASIA") was signed into law on July 9, 2012. Manufacturers are now required to notify FDA of supply disruptions or discontinuations of products. Previously this was voluntary and only required for permanent discontinuations of sole source products.

Drug shortages take a long time to resolve because there is very little resiliency in the supply chain. The United States has few manufacturers of injectable generic medications with just seven companies supplying the majority of the market. Fewer manufacturers may increase efficiency; however products available from just one or two sources are highly susceptible to drug shortages. Analysis from the IMS Institute reports that 50 percent of medications in short supply have just one or two suppliers. Further complicating the problem of drug shortages is the business practice of a “just in time” inventory. Manufacturers, wholesalers, and hospitals all use a “just in time inventory” to maximize efficiency and cost savings. Maintaining excess capacity or redundancies in manufacturing is expensive, and few manufacturers choose to maintain excesses for generic injectable products. However, with virtually no inventory on hand, even a short term glitch can result in profound drug shortages.

Drug shortages also take a long time to resolve when the cause of the shortage is a manufacturing problem. Manufacturers are not required to disclose the reasons for drug shortages and in many cases the reasons for shortages are unknown. However, according to the FDA, manufacturing problems are the primary reason for most recent shortages. Manufacturing sterile injectable products is a complex process. Manufacturers must comply with good manufacturing practices ("GMP"), a set of regulations that haven’t changed in over 40 years, that ensure high quality and safe medications. A June 2012 report from the Committee on Oversight and Government Reform suggests overzealous FDA inspections have created the drug shortage crisis by closing 30 percent of the manufacturing capacity of the four largest sterile injectable suppliers. However, missing from the report are the serious violations found during these FDA inspections, including fungal contamination, metal shavings, glass shards and precipitation of raw ingredients. While drug shortages can create safety problems on their own, no clinician wants to give patients unsafe products that are known to be contaminated. Little is known beyond published 483 forms and warning letters about the specific reasons manufacturers are having problems producing medications. Manufacturing lines are typically devoted to multiple products, resulting in multiple drug shortages if a single line is affected.

As in any business, economics play a role in the problem of drug shortages. Medications are unique products in that the typical rule of supply and demand doesn’t always apply. The Office of the Assistant Secretary for Planning and Evaluation ("ASPE") published an economic analysis of the causes of drug shortages, noting several reasons for this exception. In general, medications have few substitutions and demand for product rarely changes with prices as the clinical need for the product remains the same. For example, an anesthesiologist needs succinylcholine as a clinically necessary first line agent regardless of price. The ASPE analysis also noted that for 44 oncology products in short supply since 2008, prices for those products decreased by a mean of 26.5 percent between 2006 and 2008. Oncology products not impacted by drug shortages did not show the same price decreases during the same two year period. While products may be discontinued for profitability reasons or lack of return on investment to fix a manufacturing line, additional research is needed into the economic causes of drug shortages.

There is no question that patient care is impacted by these shortages. Survey data from the American Hospital Association ("AHA") University of Michigan and ASHP and the Institute for Safe Medication Practices ("ISMP") attempt to quantify the impact. The AHA reports virtually all responding hospitals experienced a drug shortage during 2011, and 82 percent of hospitals had to delay patient treatment as a result of drug shortages. Duke University recently published its process for rationing limited supplies of drugs using ethical principles. The University of Michigan and ASHP survey estimates the labor costs to manage drug shortages at $216 million. Most concerning is the direct patient impact reported in ISMP’s survey in 2010 noting multiple deaths and medication errors due to drug shortages.

The risk due to drug shortages is currently borne entirely by patients. Targeted solutions are difficult when many of the root causes for shortages are unknown. Increased communication alone cannot fix the problem of drug shortages. The key area of focus must be improving the ongoing manufacturing problems occurring at U.S. facilities that produce the majority of the sterile injectable drugs for the country. Manufacturing problems are complex and can take a long time to solve. Incentives are needed to encourage manufacturers to make quality and safety a priority. A potential future direction is in implementing quality by design, where the goal according to Janet Woodcock of the FDA is “a maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces

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high quality drug products without extensive regulatory oversight.\textsuperscript{20}

The important work required to solve the complex problem of drug shortages for patients, neighbors, and family members has begun and real progress can be seen in the decreased rate of new shortages. However, in order to resolve the large number of ongoing shortages impacting clinical care daily, the top priority must be improving the quality of drug manufacturing.

Endnotes
10. See supra note 7.
12. See supra note 3.
14. Id.
15. See supra note 13.
21. Id.
22. Id.
23. Id.
25. Id. AHA survey.
27. See Kaakeh et al supra note 24.
28. Supra note 18.
Update to 2012 Emerging Issues Conference Presentation:
MEDICAID FRAUD ENFORCEMENT: 
WHAT THE STATES ARE DOING 
AND HOW PROVIDERS ARE 
RESPONDING

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This article updates a presentation on developments in Medicaid fraud enforcement. One of the issues addressed in our presentation was whether a state Medicaid anti-kickback statute was preempted by the federal anti-kickback statute and thus unconstitutional. In People v. Guiamelon, a doctor was convicted of violating a state healthcare anti-kickback statute applicable to doctors and certain other licensed professionals, California Business and Professions Code Section 650. Dr. Guiamelon had paid independent contractors to market her preventative healthcare services to uninsured patients. She was found guilty notwithstanding the facts that she believed her payments were appropriate and legal and had acted in good faith.

In addition to contending that Section 650 is preempted by federal law, Dr. Guiamelon had also argued that under traditional criminal law principles Section 650 should be construed to include a mens rea requirement, not only because of the penalty imposed under the criminal law, but also because of the severe collateral consequences flowing from a criminal conviction under Section 650. The conviction triggered a variety of such consequences, including an indefinite suspension from all state healthcare programs under California Welfare and Institutions Code Section 14123 and a minimum five-year exclusion from all federal healthcare programs under 42 C.F.R. section 1001.101. The conviction also exposes her medical license to revocation under California law and triggers a series of potential “debarments” from hospital medical staffs and preferred provider organizations and other non-government payor arrangements.

Dr. Guiamelon appealed her conviction to the California Court of Appeal.


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