

# Health Law Litigation

Committee on  
Health Law Litigation  
American Bar Association  
Section of Litigation

## HEALTH LAW LITIGATION NEWSLETTER<sup>1</sup>

Andrew B. Williams II, Co-Chair  
Senior Litigation Counsel  
HCA, Inc.  
One Park Plaza  
Nashville, Tennessee 37203  
Phone: (615) 344-1491  
Fax: (615) 344-1189  
E-Mail: [andrewb.williams2@hcahealthcare.com](mailto:andrewb.williams2@hcahealthcare.com)

Grant C. Killoran, Co-Chair  
Michael Best & Friedrich LLP  
100 East Wisconsin Avenue  
Suite 3300  
Milwaukee, WI 53202  
Phone: (414) 225-2745  
Fax: (414) 277-0656  
E-Mail: [gkilloran@michaelbest.com](mailto:gkilloran@michaelbest.com)

### CONTENTS

1. Will The Shift to Medicaid Managed Care and the Accompanying Shift in Power to the States Create A Second Tier System For Medicaid Beneficiaries?, By Terese A. Mosher Beluris and Benjamin A. Durie; pages 4-10.
2. Texas Supreme Court Rules that Hospitals May Pursue Their Lawsuit Against A Medicare Advantage Organization Without First Exhausting Medicare Administrative Remedies, By Michael L. Hood; pages 12-13.
3. American Bar Association House of Delegates Update, By Grant C. Killoran; pages 14-15.
4. Wisconsin Court Alert: Anti-Trust and Statute of Limitations Decisions, By Paul E. Benson and Steven P. Means; pages 16-17.
5. Physician Criminal and Civil Liability for Off-Label Marketing of FDA Approved Drugs: An Emerging Trend? By Kevin E. Raphael and Alexander C. Gaugler; pages 19-22.

---

<sup>1</sup>Issue: 8th Edition – Volume 2. Copyright © 2007 American Bar Association. All rights reserved.

The Health Law Litigation Newsletter is published at irregular intervals by the Health Law Litigation Committee of the Section of Litigation, American Bar Association, 321 N. Clark Street, Chicago, IL 60610; website: [www.abanet.org/litigation](http://www.abanet.org/litigation). For permission to reprint, contact ABA Copyrights & Contracts, 321 N. Clark Street, Chicago, IL 60610; fax: (312) 988-6030; email: [copyright@abanet.org](mailto:copyright@abanet.org). Address corrections should be sent to the American Bar Association c/o ABA Service Center, 321 N. Clark Street, Chicago, IL 60610.

The views contained herein do not necessarily reflect the views of the American Bar Association, the Section of Litigation or the Health Law Litigation Committee.

**MESSAGE FROM THE CO-CHAIRS**

We would like to extend a warm welcome to you, the members of the Health Law Litigation Committee.

The Committee has members active in all areas of healthcare litigation, and has a number of substantive Subcommittees focused on the following areas:

Antitrust and Consumer Protection  
Fraud and Abuse  
Licensing and Peer Review  
Managed Care

Medical Ethics  
Medical Malpractice  
Nursing Home  
*Qui Tam*

We also have Subcommittees and an Editorial Board dedicated to the development and publication of this Newsletter, e-communications and our website. We encourage you to visit our website, which we have designed to provide substantive content and links to other helpful sites. Our goal is to make this Committee a strong resource for use in your practice.

One of our goals for the coming year is to expand our resource base to provide you even more useful and timely information. To that end, we plan to send out periodic e-alerts to help keep our members on the cutting edge of the changing Health Law landscape. We welcome your ideas for Newsletter articles and e-alerts to our members.

We are looking forward to an exciting year. The ABA Mid-year Meeting will be held in Los Angeles on February 2-12, 2008. The Section of Litigation Annual Meeting will be held in Washington, D.C. on April 14-16, 2008. We encourage you to attend these meetings and welcome your participation in the Committee. We ask that you contact the Newsletter Editors, any of the Subcommittee Chairs or either of us if you would like to become involved. We are always grateful for volunteers.

We look forward to seeing more of you.

Andy and Grant

### EDITORS' COLUMN

This issue of the Health Law Litigation Newsletter contains informative articles on subjects ranging from the effect of mandatory managed care on the ability of Medicaid participants to obtain top-tier healthcare services to the risks associated with marketing off-label uses for FDA approved drugs. We hope you will find each of these articles to be beneficial to your practice.

Please consider contributing an article for an upcoming Newsletter. The article can be long or short and can address nearly any topic related to the healthcare field that might be of interest to your fellow litigators. More information about the Committee can be found at [www.abanet.org](http://www.abanet.org) and at [www.abanet.org/litigation/committee/health/home.html](http://www.abanet.org/litigation/committee/health/home.html).

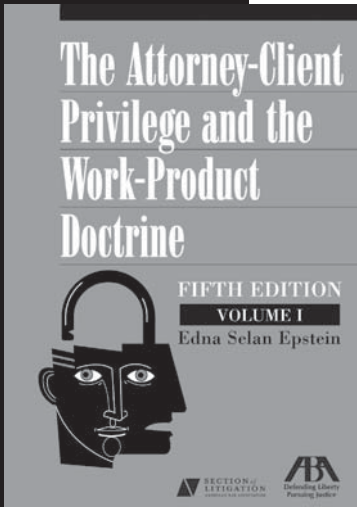
Please pass this invitation along to anyone else you think might be interested in contributing to the Newsletter and call or e-mail us with your ideas (or to volunteer). Thanks.

Erin K. Dickinson  
Michael Best & Friedrich LLP  
100 East Wisconsin Avenue, Suite 3300  
Milwaukee, Wisconsin 53202-4108  
Phone 414-271-6560  
E-Mail: [edickinson@michaelbest.com](mailto:edickinson@michaelbest.com)

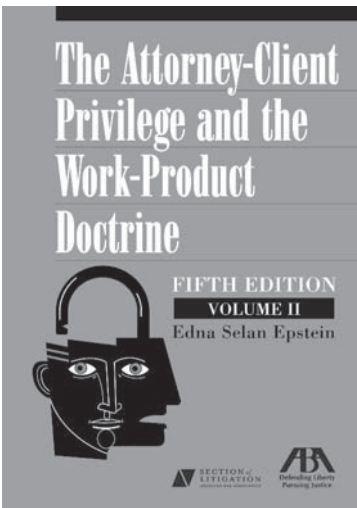
Jonathan C. Wertz  
Michael Best & Friedrich LLP  
100 East Wisconsin Avenue, Suite 3300  
Milwaukee, Wisconsin 53202-4108  
Phone 414-271-6560  
E-Mail: [jcwertz@michaelbest.com](mailto:jcwertz@michaelbest.com)

NEW EDITION

UPDATED...EXPANDED...AN ABA BEST SELLER



**The Attorney-Client  
Privilege and the  
Work-Product  
Doctrine**  
FIFTH EDITION  
VOLUME I  
Edna Selan Epstein



**The Attorney-Client  
Privilege and the  
Work-Product  
Doctrine**  
FIFTH EDITION  
VOLUME II  
Edna Selan Epstein

**THE ATTORNEY-CLIENT PRIVILEGE  
AND THE WORK-PRODUCT DOCTRINE**  
FIFTH EDITION  
EDNA SELAN EPSTEIN

*The Attorney-Client Privilege and the Work-Product Doctrine* has helped thousands of lawyers through this increasingly complex area. In addition to providing a comprehensive overview of the current law of the attorney-client and work-product immunities, this perennial ABA best-seller includes case illustrations and contextual examples, as well as numerous tips and guidance. Practical, accurate, reliable and clear, this book is the ideal guide for a practicing litigator: intellectually rigorous, but without the theoretical and academic baggage that can make writing on this subject cumbersome and leaden. The Fifth Edition maintains the style and emphasis of the previous editions, but now is divided into **two volumes**. Volume One examines the attorney-client privilege and Volume Two covers work-product protection and factors common to both the attorney-client privilege and the work-product protection.

**2007, 2 VOLUMES (1,474 PAGES), 6 X 9, PAPER**  
ISBN: 978-1-59031-804-1  
PC: 5310363  
\$195.00 REGULAR PRICE  
\$165.00 LITIGATION MEMBER PRICE

1-800-285-2221      WWW.ABABOOKS.ORG

*Editors' Note: This article explains state-imposed mandatory managed care programs in the context of Medicaid and addresses the possibility that such programs might prevent Medicaid participants from obtaining the high quality healthcare services they need.*

## **WILL THE SHIFT TO MEDICAID MANAGED CARE AND THE ACCOMPANYING SHIFT IN POWER TO THE STATES CREATE A SECOND TIER HEALTHCARE SYSTEM FOR MEDICAID BENEFICIARIES?**

By Terese A. Mosher Beluris and Benjamin A. Durie<sup>1</sup>

Medicaid is a state-run health care program, funded jointly by the federal government and the states, designed to provide medical care to low-income individuals. When the program was enacted in 1965, Congress intended to create a program offering the same access and quality of health care services as was available to individuals with private insurance, rather than merely a “safety net” health care program offering less than high quality care. It enacted statutes that include a series of guarantees, conditions and safeguards. Chief among these requirements is the provision that ensures “freedom of choice” of providers.<sup>2</sup> This and related provisions require that states administering the Medicaid program ensure that Medicaid enrollees can access medical care in the same manner as other individuals residing in the same geographic area.

Since the early 1980s, as Medicaid expenses began to grow, the states have been implementing varying cost-saving mechanisms. One of the most powerful cost-control methods in use today is state-imposed mandatory managed care, which can be authorized by a waiver granted by the

Centers for Medicare and Medicaid Services (“CMS”). These waivers allow states to operate programs that mandate some or all of the individuals eligible for Medicaid enroll in primary care case management programs or managed care organizations (“MCOs”), which may be operated on a fee-for-service or prepaid capitation basis, either for all health care services or merely certain categories, such as behavioral health care. To implement these programs, CMS may waive certain Medicaid requirements that otherwise ensure beneficiary access to any health care facility or practitioner, provided (i) the waiver is not projected to have a negative impact on beneficiary access and quality of care and (ii) the proposed managed care program will not cost more than what the Medicaid program would have cost in the absence of the waiver.

Through the enactment of the Balanced Budget Act of 1997 and a series of judicial decisions, Medicaid beneficiaries and providers have been virtually excluded from seeking enforcement of these statutory safeguard provisions. As discussed below, recent federal and state decisions have made enforcement of the safeguard provisions particularly difficult in suits brought under 42 U.S.C. § 1983, proceedings in mandamus, and state administrative procedures acts, which had been the mainstay for similar challenges in the past.

### **I. THE SHIFT TO MEDICAID MANAGED CARE**

#### **A. Motivation for the Shift**

The most important administrative change to the structure of the Medicaid program over the past 25 years has been the increasing use of federal waivers and the accompanying development of state-administered managed care programs. Under the Social Security Act, the federal government offers funding

to any state that submits a detailed plan to CMS, and represents that it will comply with all the conditions outlined in the Act, including the safeguard provisions.<sup>3</sup> Although this waiver program was created with lofty expectations, over the intervening decades the realities of skyrocketing health care costs, questionable quality of care and shrinking state budgets have caused states across the country to lobby aggressively for relief from these conditions.

Meanwhile, through the use of these federal waivers, states have sought to implement the same tools that have been used in the commercial insurance market to reduce costs. Some states have also sought to expand access to a larger pool of beneficiaries and to improve quality of care. The resulting shift to managed care that has occurred over the last 15 years has been dramatic. As of June 2006, over 65% of Medicaid beneficiaries were enrolled in some form of managed care plan, an increase from only about 9% in 1991.<sup>4</sup>

### **B. Operational Characteristics of Medicaid MCOs**

Although the term “managed care” encompasses a wide variety of organizational structures, there are several general characteristics that are typical of most entities operating in the Medicaid arena. Most Medicaid MCOs will have strong utilization controls such as prior authorization, heavily restricted provider networks, and intensive case management. In many instances, these cost containment mechanisms are used much more aggressively in the Medicaid setting than by mainstream employer-sponsored insurance, largely because states appear to be more willing to accept the trade-offs associated with such mechanisms than are private consumers. States have been highly motivated to use MCOs to achieve

predictable budgetary cost increases and guaranteed access for expanded categories of beneficiaries. However, many of the mechanisms used in the commercial insurance market, such as large rate increases and consumer cost-sharing through the use of co-payments, are not feasible in the Medicaid setting because of the structural characteristics of the program.

### **C. Types of MCOs Present in the Medicaid Program**

Medicaid beneficiaries generally face significantly greater barriers to accessing health care than other segments population, and therefore their health issues can often be more advanced and more complex. Health plans participating in Medicaid face a more daunting administrative cost structure than do commercial plans. Consequently, the mix of plans in Medicaid is quite different from what is available in the larger employer-sponsored insurance market.

By 2005, roughly 19 million beneficiaries or 42% of the total Medicaid population were enrolled with HMOs.<sup>5</sup> This is a much higher percentage than in the general commercial market, which had dropped to a low of 21% by 2005.<sup>6</sup> Almost all plans participating in Medicaid are “Medicaid-only,” meaning they have specialized in providing care to Medicaid beneficiaries to reduce high administrative costs associated with providing care to various types of enrollees simultaneously.<sup>7</sup>

### **D. The Impact of the Shift for Beneficiaries and Providers in Medicaid MCOs**

The shift to managed care that was intended to reduce costs and improve access for Medicaid beneficiaries has actually increased costs in many cases<sup>8</sup> and in some cases resulted in reduction in overall

quality.<sup>9</sup> The higher cost structure faced by Medicaid MCOs has meant a smaller number of companies are participating in the program and the beneficiaries now have fewer plan choices and reduced access to providers.<sup>10</sup> The same factors creating problems for beneficiaries are also causing difficulties for providers who are constantly moving between various plans, which often leads to significant prompt payment and network deselection issues.

During this period when Medicaid participants are faced with new and ever-increasing challenges as they struggle to access medical care, legal remedies to serve as a check on the system are increasingly essential. However, during this same period, the remedies available to challenge the administration of the Medicaid program have essentially faded away.

## **II. THE STATUTORY SCHEME FOR MEDICAID MCO WAIVERS**

States historically have been allowed to apply for waivers of Medicaid program requirements from the Health Care Financing Agency (under the HHS), but over the last 20 years the waiver process has been streamlined and states granted more flexibility in the administration of their individual programs.<sup>11</sup>

There are four main waiver provisions regularly invoked today: (a) the § 1915(b) waiver giving states permission to omit the freedom of choice provision and allowing them to managed care programs; (b) the § 1915(c) waiver allowing states to create home and community based programs; (c) the concurrent § 1915(b)/(c) waiver allowing states to offer community based services in a managed care setting; and (d) the § 1115 waiver allowing a more

fundamental departure from the Medicaid statute for research and demonstration projects, Pharmacy Plus and HIFA. Since the passage of the Balanced Budget Act (“BBA”) in 1997, states wishing to create mandatory managed care enrollment for Medicaid beneficiaries have been allowed to bypass the waiver process by filing an amendment to their existing Medicaid state plans.<sup>12</sup> The BBA also gives states the power to set conditions for managed care contracts, including more flexibility over the rate setting process.

The reforms of the BBA are emblematic of a much larger trend granting states much more power over the administration of their Medicaid programs. There is a deep-rooted belief that the only way to reduce costs is to give states continued flexibility to experiment with their programs, especially with various forms of managed care. Regardless of whether this strategy is ultimately successful, the practical effect for participants in the Medicaid program – including beneficiaries, health plans and institutional providers – is that, unlike traditional Medicaid benefits, there may be no legally enforceable right to benefits provided under waiver programs.

## **III. THE FALLIBILITY OF MECHANISMS TO CHALLENGE STATE ADMINISTRATION OF MEDICAID MCOs**

### **A. Potential Remedies**

There are four main enforcement mechanisms available for Medicaid participants who want to challenge a state’s administration of the program: (1) defer to the Secretary of the HHS to enforce the state plan, which could ultimately result in the withholding of federal funds; (2) seek enforcement of the state laws governing the

administration of the program, including state procurement procedures; (3) file an action in federal court under 42 U.S.C. § 1983 seeking direct enforcement of the provisions in the Medicaid statute; and (4) file an action in federal court under § 1983 seeking indirect enforcement of the Medicaid statute through enforcement of the actual waiver provision in a state plan.<sup>13</sup>

The success of any of these mechanisms depends on who brings the action, which specific provision in the Medicaid statute is challenged and the jurisdiction in which the action is filed. However, as a general matter, the only mechanism with a real chance of success is an action brought by a Medicaid beneficiary – not a provider or MCO – under § 1983 seeking to enforce the freedom of choice provision.

#### **B. Enforcement by the HHS**

The Secretary of the HHS has the authority to reduce or suspend the funding of any state participating in Medicaid after demonstrating that it has failed to comply with the terms of its plan.<sup>14</sup> Although there is a detailed administrative review process available for the HHS, the federal government rarely exercises this power. From the perspective of a Medicaid participant, the suspension of federal funds would be counterproductive because it would make it even more difficult for a state to provide services.

#### **C. Direct Enforcement in State Court**

For institutional providers or health plans, direct enforcement of state law could also be an option depending where the claimant was already a party to a state contract. Where, however, a provider or plan seeks to prevent a state from constructing barriers to health

care providers or services or restricting choice in health care services, the obstacles may be insurmountable.

For example, in July 2006 Indiana sought to contract with MCOs that would assume full financial risk for developing and managing a health care network to administer and deliver Medicaid benefits, including behavioral health care and long-term inpatient services in state-operated facilities. Harmony Health Plan of Indiana, Inc. (“Harmony”) was one of seven health plans vying for a state-awarded contract to administer the Indiana Medicaid Program known as Hoosier Healthwise, with contracts estimated to be worth \$ 4.4 billion over a four-year period. After Indiana failed to award it a contract, Harmony filed a petition for judicial review and alternative action for mandate and request for declaratory relief against various state agencies and the other bidders (both successful and unsuccessful) alleging that the state agencies had failed to apply their own criteria and state law in determining who should be awarded contracts.

Specifically, Harmony claimed scoring errors were made in determining how well Harmony met the State’s criteria for women’s and minority business enterprise participation, as well as in determining Harmony’s Indiana economic impact score, as a result of mathematical errors and substitute criteria among the bidders (e.g., Harmony alleged that its economic impact was determined based on the number of full-time equivalent Indiana residents it utilized in its then-current contract, while it scored all other bidders on the basis of the projected number of full-time equivalent Indiana residents that they would utilize if awarded a contract). In essence, Harmony’s action under state law sought to direct the State agencies to correct these scoring errors. The

Indiana Court of Appeals affirmed the trial court's decision that Harmony, as a prospective contracting party, did not have standing to complain that the State failed to comply with the State's own criteria for a successful Medicaid MCO bidder.<sup>15</sup>

It is very likely that similar claims brought in other states would suffer from the same standing problems. In most cases an unsuccessful bidder must either show they have some property interest that has been infringed upon by a government agency or demonstrate that the decision by the state agency was fraudulent or arbitrary and capricious.<sup>16</sup>

It is also possible to claim, as Harmony did unsuccessfully in Indiana, that the procurement policies used by a state violates the state's Administrative Procedures Act ("APA"). However, the APA may present its own hurdles. First, it may not apply to contracts for services and the state may endeavor to characterize an MCO contract as such. Second, judicial review is typically dependent upon a prior exhaustion of all other administrative remedies or a demonstration of the futility of exhausting administrative remedies.<sup>17</sup>

#### **D. Direct Enforcement Under § 1983**

The central enforcement mechanism available to challenge state administration of Medicaid managed care programs has been an action under § 1983.<sup>18</sup> Although historically the success of 1983 actions seeking enforcement of the Medicaid statute have been heavily dependent on the particular provision in question, the Supreme Court decisions in *Blessing v. Freestone*<sup>19</sup> and *Gonzaga University v. Doe*<sup>20</sup> have made enforcement almost impossible. Together these decisions have

created strict standing requirements, known as the *Blessing* test, for any claim brought under § 1983. First, the plaintiff must demonstrate that the statute in question actually creates an enforceable right of private action. This requires a showing that: (1) Congress intended that the provision in question benefit the plaintiff; (2) the right assertedly protected by the statute is not so vague and amorphous that its enforcement would strain judicial competence; and (3) the statute unambiguously imposes a binding obligation on the states.<sup>21</sup> Second, the plaintiff must survive any rebuttal by the defendant demonstrating an alternative comprehensive enforcement scheme.<sup>22</sup>

The most challenging requirement of this test is derived from the Supreme Court's interpretation of the Congressional intent prong of the *Blessing* test. In *Gonzaga*, the Court stated that the right of private action must be "unambiguously conferred" by the use of "rights-creating language" in order to be considered enforceable.<sup>23</sup> The practical effect of this requirement is that very few courts are willing to find any private right of action for either beneficiaries individually or for institutional providers and health plans seeking to enforce the beneficiaries rights as third parties. There are exceptions to this overall trend<sup>24</sup> but generally courts have denied standing to beneficiaries, institutional providers and health plans seeking to enforce provisions of the Medicaid statute relevant in the managed care setting.<sup>25</sup>

The second major hurdle for those seeking to enforce the Medicaid statute is that even if the plaintiff can convince a court that a private right of action exists for the particular provision underlying the claim, the state will often have been granted a waiver by the HHS for the provision in question. This issue is most likely to arise in actions seeking to enforce the freedom of

choice provision because this is the provision most likely to contain a right of private action and is also the provision that must be waived pursuant to § 1915(b) in order for states to contract with MCOs. So even for beneficiaries, freedom of choice claims will rarely be successful when the state has received a § 1915(b) waiver.

#### **E. Indirect Enforcement of Benefits Through the State Waiver Provision**

One way to avoid these problems involved with attempts to enforce provisions of the Medicaid statute that have been the subject of HHS waivers may be to seek direct enforcement of the waiver provision itself. Section 1396n(b) of the Medicaid statute permits states to limit beneficiaries' access to providers – normally guaranteed by the freedom of choice provision – as long as the restrictions are based on standards “consistent with access, quality, and efficient and economic provision of the covered care and services.” In addition the waiver will only be granted by the HHS if the restriction “does not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing” services.<sup>26</sup> A Medicaid participant could challenge a state's compliance with these two conditions as long as a court finds that the waiver provision itself creates a private right of action for the type of participant seeking enforcement (i.e., beneficiary, institutional provider or health plan). In a post-*Gonzaga* environment persuading a court that the right is “unambiguously conferred” may be difficult but the issue has not yet been the subject of much litigation.

In a 2006 case, however, plaintiff Medicaid beneficiaries, health plans and providers were held to have no standing to complain

under § 1983 that the Indiana had violated the “freedom of choice” and “methods and procedures” requirements of 42 U.S.C. § 1396(a)(23) and (30) by failing to adhere to the terms of a waiver in utilizing a flawed or biased MCO selection process for its Medicaid program. The court condemned the effort, stating that this was “nothing more than a backhanded effort to secure the Plaintiffs a right to enforce each and every provision of the State plan” and “[i]f there is any redress for the injuries that Plaintiffs assert in their (a)(23) and (a)(30) claims, the cause of action will have to be found not in the rights secured by those waived statutes, but in the rights, if any, conferred by Congress in the waiver statute itself.”<sup>27</sup>

#### **IV. CONCLUSION**

The trend of recent decisions is cause for concern that Medicaid's statutory safeguards are largely unenforceable, and that the primary effect of Medicaid MCO waivers will ultimately be the permanent establishment of a second-tier health care system for Medicaid beneficiaries.

---

<sup>1</sup>Terese A. Mosher Beluris is a partner in the Los Angeles office of McDermott Will & Emery LLP. She is Co-Chair of the Managed Care Subcommittee of ABA Section of Litigation Health Law Litigation Committee. She can be reached at 310-551-9344 or [tmosherbeluris@mwe.com](mailto:tmosherbeluris@mwe.com). Benjamin A. Durie is a third year law student at the University of Arizona James E. Rogers College of Law.

<sup>2</sup> 42 U.S.C. §1396a(a)(23)(2007).

<sup>3</sup>*Id.*

<sup>4</sup> Centers for Medicare and Medicaid Services, *Medicaid Managed Care Enrollment Report* (2006).

<sup>5</sup> Kaiser Commission on Medicaid and the Uninsured, *Medicaid Budgets, Spending and Policy Initiatives in State Fiscal Years 2005 and 2006* (2006).

<sup>6</sup> Kaiser Family Foundation and Health Research and Education Trust, *Annual Employer Health Benefits Survey* (2005).

<sup>7</sup> In 1998, there were 283 commercial plans HMOs and only 136 Medicaid-only HMOs participating in Medicaid. CMS, *Medicaid Managed Care Enrollment Report* (1998). By 2005 the number of

commercial plans participating in the program had dropped to 157. CMS, *Medicaid Managed Care Enrollment Report* (2005).

<sup>8</sup> Holahan & Suzuki, *Medicaid Managed Care Payment Methods And Capitation Rates In 2001*, 22 HEALTH AFFAIRS 204 (1-2/03).

<sup>9</sup> Thompson, et al., *Quality of Care for Children in Commercial and Medicaid Managed Care*, 290 JAMA 1486 (2003).

<sup>10</sup> Felt-Lisk, Dodge & McHugh, *Trends in Health Plans Servicing Medicaid – 2000 Update*, Kaiser Commission on Medicaid and the Uninsured (2001).

<sup>11</sup> For example, the Omnibus Budget Reconciliation Act of 1981 created the § 1915(b) freedom of choice waivers and the § 1915(c) community based care waivers. Pub. L. No. 97-35, § 2173, 95 Stat. 808.

<sup>12</sup> This option is pursuant to §1932(a) and is only available when states want to implement comprehensive managed care and primary case care management plans.

<sup>13</sup> 42 U.S.C. § 1396n(b)(4) (2007).

<sup>14</sup> 42 C.F.R. § 430.35 (2007) (power to cut of funds for failure to comply).

<sup>15</sup> *Harmony Health Plan of Ind., Inc. v. Ind. Dep't of Admin.*, 864 N.E.2d 1083, 1087-91 (Ind. Ct. App. 2007).

<sup>16</sup> For example, under Rhode Islands Purchasing Act an unsuccessful bidder must demonstrate has shown that a state official “acted so corruptly or in bad faith, or so unreasonably or so arbitrarily as to be guilty of a palpable abuse of discretion.”

<sup>17</sup> *Harmony Health*, *supra*, at 1089 (finding that seeking agency review would have been a futile gesture and holding that the trial court should not have required Harmony to exhaust its administrative remedies before seeking judicial review).

<sup>18</sup> *Arkansas Med. Soc’y, Inc. v. Reynolds*, 6 F.3d 519 (8th Cir. 1993) (Medicaid providers sued under 42 U.S.C. § 1983 alleging that Arkansas agency had deprived them of federal rights by violated the “equal access” provision of 42 U.S.C. § 1396a(a)(3)(A)); *Evergreen Presbyterian Ministries Inc. v. Hood*, 235 F.3d 908, 927-28 (5th Cir. 2000) (plaintiff providers and Medicaid recipients claimed Louisiana agency violated the “public process” and “equal access” provisions at §§ 1396a(a)(13)(A) and (a)(30)(A); *Harris v. Olszewski*, 442 F.3d 456 (6th Cir. 2006) (putative class of Medicaid beneficiaries exercised their private right of action to sue Michigan agency to enforce the “freedom-of-choice” provisions of § 1396a(a)(23)); *Methodist Hosps., Inc. v. Sullivan*, 91 F.3d 1026 (7th Cir. 1996) (providers challenged state’s payment rules violated § 1396a(a)(30)(A); (*Visiting Nurse Ass’n v. Bullen*, 93 F.3d 997 (1st Cir. 1996) (court held that health care workers have standing to enforce § 1396a(a)(30)’s requirement that the state adopt methods and procedures which will afford equal access to medical care); *see also Antrican v. Buell*, 158 F. Supp. 2d 663 (E.D.N.C. 2001), *aff’d* 290 F.3d 178 (4th Cir. 2002); *Boulet v. Cellucci*, 107 F. Supp. 2d 61 (D. Mass. 2000); *Cramer v. Chiles*, 33 F. Supp. 2d 1342 (S.D. Fla. 1999); *Lewis v. New Mexico Dep’t of Health*, 94 F. Supp. 2d 1217 (D.N.M. 2000), *aff’d* 261 F.3d 970 (10th Cir. 2001); *Rodriguez v. City of New York*, 197 F.3d 611 (2d Cir. 1999); *Rolland v.*

*Cellucci*, 52 F. Supp. 2d 231 (D. Mass. 1999); *Wood v. Tompkins*, 33 F.3d 600 (6th Cir. 1994).

<sup>19</sup> 520 U.S. 329 (1997).

<sup>20</sup> 536 U.S. 273 (2002).

<sup>21</sup> *Blessing*, *supra*, at 340-41.

<sup>22</sup> *City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113 (2005); *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 106 (1989); *Wilder v. Virginia Hosp. Ass’n*, 496 U.S. 498, 508 (1990).

<sup>23</sup> *Gonzaga*, *supra*, at 287.

<sup>24</sup> *See e.g. Harris v. Olszewski*, 442 F.3d 456 (6th Cir. 2006) (holding Medicaid beneficiaries possessed private right of action to enforce the freedom-of-choice provision); *Martin v. Taft*, 222 F. Supp. 2d 940, 977-78 (S.D. Ohio 2002) (finding that the comparability of services, reasonable promptness, and freedom of choice provisions all created a federal right enforceable under § 1983); *Bryson v. Shumway*, 308 F.3d 79 (1st Cir. 2002) (holding that Medicaid patients suing on behalf of a class had a § 1983 cause of action arising from the “reasonable promptness” provision of 42 U.S.C. § 1396a(a)(8)); *Ball v. Rodgers*, 492 F.3d 1094 (9th Cir.2007) (deciding that Medicaid recipients enjoy rights under the “free choice” provisions of §§ 1396n(c)(2)(C) and (d)(2)(C) that can be enforced in a § 1983 action).

<sup>25</sup> *See e.g.* cases where court found there was no private right of action for beneficiaries under §1396a(a)(30)(a): *Westside Mothers v. Olszewski*, 454 F.3d 532, 542 (6th Cir. 2006); *Sanchez v. Johnson*, 416 F.3d 1051, 1059 (9th Cir. 2005); *Mandy R. v. Owens*, 464 F.3d 1139, 1148 (10th Cir. 2006). *See e.g.* cases where court found there was no private right of actions for third parties: *New York Ass’n of Homes & Servs. v. Debuono*, 444 F.3d 147 (2d Cir. 2006); *Pennsylvania Pharmacists Ass’n v. Houstoun*, 283 F.3d 531 (3d Cir. 2002).

<sup>26</sup> 42 U.S.C. § 1396n(b)(4).

<sup>27</sup> *Molina Healthcare of Ind., Inc. v. Henderson*, 2006 U.S. Dist. LEXIS 87729, at \*43-44 n.12 (S.D. Ind. 12/4/06).

*Editors' Note: A party seeking to obtain payment for denied Medicare benefits normally must exhaust its administrative remedies before pursuing litigation. This article describes one scenario where such exhaustion is not necessary.*

**TEXAS SUPREME COURT RULES THAT HOSPITALS MAY PURSUE THEIR LAWSUIT AGAINST A MEDICARE ADVANTAGE ORGANIZATION WITHOUT FIRST EXHAUSTING MEDICARE ADMINISTRATIVE REMEDIES.**

By Michael L. Hood<sup>1</sup>

In *Christus Health Gulf Coast et al v. Aetna Inc. et al.*, No. 05-0710 (Tex. Sup. Ct. 8/31/07), the Texas Supreme Court addressed an issue involving a payment dispute over Medicare reimbursements to hospitals. More specifically, the issue was whether the Medicare Act requires healthcare providers, like hospitals, that do not have a contract with a managed-care insurer, like Aetna, to exhaust the Medicare administrative appeals process on coverage questions before suing to recover from the insurer.

Aetna refused to pay five area Houston hospitals as much as \$13 million for Medicare patients' treatment after Aetna's contract management company, North American Medical Management of Texas (NAMM), became insolvent. NAMM had contracts with the hospitals to pay claims for Medicare patients enrolled in Aetna's HMO. The hospitals sued NAMM, alleging that it mismanaged its accounting and ceased payment for services. The hospitals also sued Aetna, arguing that Aetna remained obligated to pay the hospitals for the services they rendered to Aetna enrollees. The trial court dismissed the case on Aetna's

argument that the hospitals must first exhaust Medicare administrative remedies. The court of appeals affirmed.

The Texas Supreme Court reversed and held that the administrative process was not required. Although the parties did not contract directly with each other, each had agreements with NAMM (Aetna contracted with NAMM, and NAMM contracted with the hospital providers). Their dispute concerned not whether the services were covered under Medicare, but rather who should bear the loss associated with NAMM's failure to pay, due to its insolvency. The court wrote:

Aetna's contention that the Hospitals must first seek an administrative determination of some 6,000 claims misconstrues a claim seeking payment for services provided to Medicare patients as a claim for Medicare benefits. That is, failing to pay due to insolvency or a dispute about who is contractually obligated to pay is different from failing to pay due to lack of coverage . . . The federal administrative scheme exists, first and foremost, to protect enrollees' rights to health care, not to act as a de facto claims administrator for Medicare organizations and their delegates.

Important considerations that led to the court's ruling were:

- (1) the Medicare enrollees were not denied services or reimbursement for services;
- (2) pursuant to their contracts, the hospitals waived right to seek payment from enrollees;
- (3) Medicare, having tendered its capitation payments, no longer had a financial interest in the case; and

(4) the dispute regarding the hospitals' interest in receiving payment from Aetna was an issue solely between the providers and the insurer.

The Texas Supreme Court concluded that it "appears that the administrative review process attendant to [Medicare] Part C does not extend to claims in which the enrollee has no interest." The court remanded the case to the trial court to determine Aetna's contractual obligations to the hospitals.

Aetna contends that the decision does not address the merits of the hospitals' claims, but rather allows the trial court to determine whether Aetna can be held responsible, if at all, for the alleged claims. Aetna strongly maintains that it cannot be held liable for NAMM's obligations, and that it will ultimately prevail on the merits.

---

<sup>1</sup>Michael Hood is a partner in the Dallas office of the law firm Haynes & Boone, L.L.P. He is the Co-Chair of the Managed Care Subcommittee of the ABA Section of Litigation Health Law Litigation Committee and practices business litigation, with a focus on managed care litigation. He can be reached at 214-651-5000, or at [michael.hood@haynesboone.com](mailto:michael.hood@haynesboone.com). The author would like to thank Janet Ayaad, a third-year law student at Baylor University Law School, for her contributions to this article.

THE BENEFITS OF MEMBERSHIP

*Seeing Both Sides with the Section of Litigation*

## Information in Your Inbox

If the ABA does not have your email address on file, you could be missing out on important Section of Litigation committee news and announcements. By registering your email address, you'll be eligible to receive case notes, event invitations, and more from the Section and the ABA.

Log on to myABA today and be sure your address is up to date at [www.abanet.org/abanet/common/MyABA/](http://www.abanet.org/abanet/common/MyABA/)

 SECTION of LITIGATION  
AMERICAN BAR ASSOCIATION

*Editors' Note: This article describes two public policy initiatives proposed by the ABA's Health Law section to the American Bar Association's House of Delegates during the ABA's 2007 annual meeting in San Francisco.*

## **AMERICAN BAR ASSOCIATION HOUSE OF DELEGATES UPDATE**

By Grant C. Killoran<sup>1</sup>

At the American Bar Association's Mid-Year and Annual Meetings each year, the American Bar Association's House of Delegates meets to consider policy initiatives proposed by the various Sections of the ABA. The House is the policy making body for the ABA. Many of these proposals come from the Section of Litigation and the Health Care Section.

The House again convened at the ABA Annual Meeting in San Francisco in August, 2007 and considered a large number of Recommendations, two of which are of potential interest to health care litigators.

### **I. REPORT 120A: LEGAL-MEDICAL COMMUNITY PARTNERSHIPS**

The ABA Health Law Section submitted a Recommendation that lawyers work to develop partnerships with health care organizations to provide helpful legal information to patients:

“RESOLVED, That the American Bar Association encourages lawyers, law firms, legal services agencies, law schools and bar associations to develop medical-legal partnerships with hospitals, community-based health care providers, and social service organizations to help identify and resolve diverse legal issues that affect patients' health and well-being.”

This Recommendation seeks to improve the health care services available to the elderly, children, people living with chronic diseases and low-income individuals and families by focusing not only on access to medical treatment, but also on access to legal and social services impacting same. The first medical-legal partnership in a hospital setting was established in 1993 at the Boston Medical Center by doctors serving low-income patients and such partnerships since have been adopted at more than 60 sites nationwide.

This Recommendation was adopted by the House.

### **II. REPORT 120B: DISASTER PREPAREDNESS**

The ABA Health Law Section also submitted a Recommendation that the ABA support nationwide disaster preparedness rules for the health care system:

“RESOLVED, That the American Bar Association support the study of the regionalization of the nations' Emergency Care System and Emergency Departments and the enactment of legislation and promulgation of rules, specifically as it relates to disaster preparedness, as an effective and efficient means of improving patient safety, health care quality, cost reduction, coordination of care, and increased accountability of the system.”

This Recommendation seeks to improve the national Emergency Care System and the readiness of Emergency Departments in hospitals around the country to respond to terrorism, bioterrorism and disaster by “regionalizing” emergency care to improve the availability of care. As noted in the Recommendation, the “overarching theme is having the right person at the right place at

the right time” to provide medical care during a crisis.

This Recommendation also was adopted by the House.

For more information regarding these two Resolutions, or prior Resolutions, please visit the ABA website at [www.abanet.org/leadership/2007/annual/](http://www.abanet.org/leadership/2007/annual/).

---

<sup>1</sup> Grant Killoran is the Co-Chair of the ABA Section of Litigation Health Law Litigation Committee and is one of the State Bar of Wisconsin’s Delegates to the ABA House of Delegates. He is a partner in Litigation Practice Group and the Health Care Practice Group in the Milwaukee, Wisconsin office of Michael Best & Friedrich LLP. He can be reached at 414-271-6560, or at [gckilloran@michaelbest.com](mailto:gckilloran@michaelbest.com).



## Take David Berg to Court with You

Acclaimed trial lawyer David Berg has spent more than 30 years refining his litigation techniques. Learn his winning methods in *The Trial Lawyer: What It Takes To Win*, now available on DVD.

“I THINK OF DAVID AS A PEOPLE’S LAWYER IN THE CLARENCE DARROW TRADITION. HE HAS AN ABILITY TO PERSUADE JURORS THAT IS THE EQUAL OF ANY PRACTITIONER I KNOW. *THE TRIAL LAWYER* SHOWS HOW IT CAN BE DONE.” —MORRIS DEES

In this 6-hour program, Berg shares his strategies for telling your client’s story during every phase of trial. Whether you are new to the practice of law or are seeking fresh ways to persuade at trial, turn to *The Trial Lawyer*. The DVD package includes the softcover edition of the book.

 SECTION of LITIGATION  
AMERICAN BAR ASSOCIATION

Learn more at [www.abanet.org/litigation/triallawyer/](http://www.abanet.org/litigation/triallawyer/)

*Editors' Note:* The following article summarizes two recent Wisconsin decisions addressing (1) the ability to bring a price-fixing claim in the pharmaceuticals area and (2) when patients can sue their healthcare providers.

### **WISCONSIN COURT ALERT: ANTI-TRUST AND STATUTE OF LIMITATIONS DECISIONS**

By Paul E. Benson and Steven P. Means<sup>1</sup>

#### **I. WISCONSIN SUPREME COURT ALLOWS PHARMACEUTICAL PRICE-FIXING LAWSUIT TO PROCEED.**

On July 13, 2007, the Wisconsin Supreme Court upheld an appellate decision allowing a plaintiff to assert claims for price-fixing and market division under Wisconsin antitrust law. *Meyers v. Bayer AG*, 2007 WI 99, -- Wis. 2d --, 735 N.W.2d 448.

The decision turned on the intended scope of Wis. Stat. § 133.03, which prohibits combinations and conspiracies in restraint of trade. In seeking dismissal at the trial court level, the defendants had argued that Wisconsin's antitrust statute should only reach in-state conduct and should not be construed to overlap federal antitrust law which regulates interstate commerce. The Supreme Court rejected this view, holding that a state-law antitrust claim may be brought when the challenged conduct either occurred within the state or "substantially affected the people of Wisconsin and had impacts in this state." *Id.*, ¶ 57.

#### **II. WISCONSIN COURT OF APPEALS CLARIFIES TIME LIMIT FOR SUING HEALTH CARE PROVIDERS.**

On May 9, 2007, the Wisconsin Court of Appeals issued its Decision in *Forbes v. Stoeckl*, 2007 WI App. 151, -- Wis. 2d --, 735 N.W. 2d 536 (publication recommended). There, the Court held that when a health care provider engages in a "continuum of negligent treatment," the statute of limitations for bringing legal action against the health care provider starts to run when the course of treatment ends. In so holding, the Court reversed a circuit court ruling which had dismissed claims against a dentist as time-barred.

In ruling on the legal issue, the Court accepted the plaintiff's allegations that she had been a patient of the defendant, Dr. Stoeckl, from 1985 through 2001. In 1989, plaintiff was diagnosed with temporomandibular joint disorder, commonly known as "TMJ." The diagnosis was followed by various treatments and procedures, including treatments and procedures to address adverse effects of the TMJ treatments. Treatment ended on September 18, 2001 and suit was filed on July 7, 2004. Plaintiff alleged misdiagnosis and various acts of negligence throughout the course of treatment for TMJ.

By statute, malpractice actions against health care providers generally must be brought within three years of the date of injury. Wis. Stat. § 893.55(1m)(a). However, there are two exceptions. The first exception is a statutory "discovery rule" which allows an action to be commenced within one year after an injury is discovered, even though the three-year statute of limitations has run. The "discovery rule," applies if the injury was not discovered earlier, and could not have been discovered

earlier in the exercise of reasonable diligence. Wis. Stat. § 893.55(1m)(b). In addition, even if the "discovery rule" extends the normal three-year statute of limitations, an action is barred if the negligent act or omission occurred more than five years before legal action is commenced.

The second exception is known as the "doctrine of continuous negligent treatment." This doctrine was first recognized by the Wisconsin Supreme Court in *Tamminen v. Aetna Casualty and Surety Co.*, 109 Wis. 2d 536, 327 N.W.2d 55 (1982). Under *Tamminen*, if negligent acts or omissions are continuous, a cause of action is not complete until the last act or omission occurs. Therefore, if an action is timely with respect to the last act or omission, it is timely with respect to the entire course of treatment.

In *Forbes*, the Court of Appeals clarified the interaction between the two exceptions by holding that the five-year statute of repose in Wis. Stat. § 893.55(1m)(b) will not bar

actions based on acts or omissions that occurred more than five years before, if there was a continuous course of negligence and the last act was within the generally applicable three-year statute of limitations.

Because the rules applied to Dr. Stoeckl also apply to other health care providers, the *Forbes* decision also has implications for hospitals, nursing homes, physicians and other providers. In particular, if there is a continuous course of treatment, there is no assurance that a provider cannot be sued for acts or omissions that occurred three or even five years earlier. For providers who purchase liability coverage on a "claims made" basis, the *Forbes* rule makes it even more important to consider "tail coverage" or "extended reporting coverage."

<sup>1</sup>Paul Benson is a partner in the Milwaukee, Wisconsin office of Michael Best & Friedrich LLP and is the Chair of its Litigation Practice Group. He can be reached at 414-271-6560, or at [pebenson@michaelbest.com](mailto:pebenson@michaelbest.com). Steven Means is the Deputy Administrator of the Division of Legal Services for the State of Wisconsin Department of Justice. Steve also is a former partner in the Madison, Wisconsin office of Michael Best & Friedrich LLP. He can be reached at [spmeans@charter.net](mailto:spmeans@charter.net).

## Business and Commercial Litigation in Federal Courts

EDITED BY ROBERT L. HAIG



Covering the most common commercial litigation subjects, the new edition of *Business and Commercial Litigation in Federal Courts* takes readers through a step-by-step analysis of the entire litigation process. With 16 new chapters and more than 500 pages of forms and jury charges on CD-ROM, the set is an indispensable resource for the commercial litigator.

### SPECIAL SAVINGS FOR LITIGATION MEMBERS

The eight-volume set is now available at a 40% discount to Section of Litigation members.

[www.abanet.org/litigation/books](http://www.abanet.org/litigation/books)

 SECTION of LITIGATION  
AMERICAN BAR ASSOCIATION

*Editors' Note: Our Fall, 2007 newsletter contained an article that addressed the risks associated with the prescribing of non-FDA approved drugs. This article addresses the risks associated with a different, but temporally related activity: the marketing of FDA approved drugs for off-label uses.*

### **PHYSICIAN CRIMINAL AND CIVIL LIABILITY FOR OFF-LABEL MARKETING OF FDA APPROVED DRUGS: AN EMERGING TREND?**

By Kevin E. Raphael and  
Alexandra C. Gaugler<sup>1</sup>

Most healthcare providers cannot help but notice the federal government's stepped up scrutiny of pharmaceutical companies regarding off-label promotion of FDA-approved drugs and devices. According to a recent front page article in the *New York Times*, "nearly every [pharmaceutical] company is under either civil or criminal investigation for alleged efforts to expand the use of its drugs beyond the specific illness or condition for which they are approved."<sup>2</sup> Department of Justice ("DOJ") attorneys have recently estimated that there are approximately 150 pending civil pharmaceutical cases in 35 districts across the United States.<sup>3</sup> While not all of these pending cases deal exclusively with off-label promotion, this area is unquestionably a continuing source of interest for the federal government.<sup>4</sup>

Pharmaceutical companies engaging in off-label marketing have paid a heavy price. They have been the target of criminal investigations, attendant negative publicity and uncertainty, and multi-million dollar settlements. In addition, the False Claims Act has been used against them, resulting in the payment of vast sums of money to the

federal government and the "whistleblowers" who initiated the lawsuits.

All of this attention on pharmaceutical companies may lead the unwary healthcare provider to believe that he or she is not at risk in this current environment. To the contrary, now more than ever, Healthcare professionals must conduct themselves and their practices with the utmost care to avoid becoming next month's headline. An emerging risk area for physicians concerns off-label promotional activities.

### **THE FINE LINE BETWEEN OFF-LABEL USE AND OFF-LABEL PROMOTION**

The FDA does not have the power to regulate the practice of medicine.<sup>5</sup> As a consequence, once the FDA approves a drug for a particular use, physicians are free to prescribe the drug for any purpose.<sup>6</sup> The practice is routine among physicians. A study released in May 2006 reported that for 2001, roughly two-thirds of prescriptions written for six common drugs were for off-label uses.<sup>7</sup> As long as individual physicians are using drugs or devices off-label based on their professional judgment that such uses are in the best interest of their patients, the federal government should have no right to interfere.<sup>8</sup>

While a physician's right to use a device or prescribe a drug off-label is relatively clear-cut, a physician's right to promote the off-label use of a drug is not without limits. At first glance, the issue appears as simple as the right to prescribe off-label. Doctors can, and indeed frequently do, confer with colleagues about their successes with the off-label use of a particular device or drug. Yet, what if the physician is conferring with his or her colleagues during a conference paid for by the drugmaker? This and similar

situations may indeed expose the individual physician to criminal and civil liabilities.<sup>9</sup>

### **PROSECUTION OF A PHYSICIAN FOR OFF-LABEL MARKETING: THE GLEASON INDICTMENT**

Dr. Peter Gleason did what thousands of doctors do every day: he prescribed to patients of his private practice in Maryland a drug for off-label use. The drug at issue was Xyrem, approved by the FDA to treat patients suffering from narcolepsy. Dr. Gleason believed that Xyrem also was an effective treatment for patients suffering from insomnia and severe depression, conditions not approved by the FDA. However, Dr. Gleason's off-label prescribing caught the attention of Xyrem's manufacturer, Orphan Medical, Inc.<sup>10</sup> At the request of Orphan, Dr. Gleason soon was speaking to other physicians about his experiences with Xyrem, specifically its off-label uses. Orphan paid Dr. Gleason for his time. So far, this scenario sounds fairly commonplace.

Yet, in April 2006, the United States Attorney's Office for the Eastern District of New York filed a criminal indictment against Dr. Gleason. The government alleges that Dr. Gleason conspired with Orphan sales representatives to promote off-label uses of Xyrem in violation of the Food Drug and Cosmetic Act ("FDCA").<sup>11</sup>

This criminal case is alarming because an individual physician now faces criminal charges relating to off-label promotion. The case illustrates the government's willingness to prosecute physicians for their off-label promotional activities.

Dr. Gleason told the *New York Times* that he thought his arrest was a gag. He stated that he believes he merely expressed his true

opinion about the drug to other doctors, based upon his experience with his patients.<sup>12</sup> How can this common practice be criminal conduct?

In its indictment, the government paints the picture of a physician who crossed the line that separates a physician's right to practice medicine and express his views from that of a greedy puppet for the drug company. The government asserts, and Dr. Gleason does not deny, that he received tens of thousands of dollars from Orphan. The *New York Times* reports that the Xyrem talks became Dr. Gleason's primary source of income.<sup>13</sup>

Besides being paid handsomely for promoting off-label uses of Xyrem during his speeches, Dr. Gleason also allegedly told physicians to provide an incorrect diagnosis to insurance companies to insure payment for the off-label use.<sup>14</sup> This has given rise to a health care fraud count in the indictment.

In July 2007, Jazz Pharmaceuticals, successor to Orphan, agreed to pay \$20 million to settle civil and criminal proceedings concerning its off-label marketing of Xyrem. United States Attorney for the Eastern District of New York, Roslynn R. Mouskopf, in announcing the settlement commented:

"The illegal marketing of prescription medications for unauthorized medical uses is a serious crime that poses significant public health risks."

Ms. Mouskopf added that the investigation is "continuing."<sup>15</sup> Indeed, shortly after reaching a settlement with Jazz Pharmaceuticals, the government filed a superseding indictment in the *Gleason* case, adding a former Orphan sales representative as a co-defendant.

The *Gleason* prosecution serves as a warning to all physicians that they are not exempt from the government's close scrutiny of off-label activity. While off-label prescribing remains a perfectly legitimate practice, health care professionals should be extremely cautious in their advocacy of off-label uses of drugs. Caution is especially warranted when the physician engages in a financial relationship with a drug company whose drug the physician advocates for off-label use. Further, in discussions concerning off-label uses, physicians should insure that all statements they make concerning a drug with off-label uses are accurate and supported by data.

#### **THE CIVIL RISKS TO PHYSICIANS WHO PROMOTE DRUGS OFF-LABEL**

Insurance companies are increasingly aggressive in their attempts to recover monies paid to providers, and increasingly are willing to pursue civil actions against providers to do so. Off-label marketing allegations provide an avenue by which insurers can pursue healthcare providers, and there has been at least one action commenced under this theory.

Dr. David Longmire, an Alabama neurologist, discovered that his use of Neurontin for the FDA-approved use of treating seizures had the non-indicated effect of reducing pain. He told his colleagues about his finding and soon Parke-Davis, the division of Warner-Lambert responsible for Neurontin, was paying him to tell others.

Warner-Lambert (now owned by Pfizer) pled guilty to violating the Food Drug and Cosmetic Act by, among other things, paying physicians to do what it could not: promote non-FDA approved uses of Neurontin and eventually paid more than \$430 million to settle criminal and civil

liabilities. After the settlement, private insurers began suing Warner-Lambert. In 2006, Dr. Longmire was named as a defendant in various suits, including a suit filed by Blue Cross and Blue Shield of Alabama against Pfizer alleging that Dr. Longmire conspired with Warner-Lambert to encourage physicians to prescribe Neurontin more frequently than they otherwise would have, thereby causing insurers to pay millions of dollars in improper reimbursements. Dr. Longmire's attorney is optimistic that his client will prevail. However, Dr. Longmire must expend significant time mounting a defense, and risks being found liable and having to pay substantial civil penalties.

As a result of recent legislation in a handful of states and the District of Columbia, we predict more criminal and civil activity against physicians as payments become more transparent.<sup>16</sup> One need only look to a recent *New York Times* front-page article exposing several physicians who received large payments from drug makers for promotional activities to see that both the government and the public are questioning the propriety of these arrangements.<sup>17</sup>

#### **CONCLUSION**

The *Gleason* matter has not yet concluded, and it remains to be seen whether the government will succeed in its prosecution over alleged "off-label" marketing by a physician. Yet, *Gleason* may signal an emerging trend by the government to pursue individual physicians and the pharmaceutical companies who pay them for off-label marketing. Physicians who are not cautious in their off-label promotional activities risk being perceived as putting their own greed ahead of what matters most: the welfare of their patients.

<sup>1</sup>Kevin E. Raphael is a shareholder at the Philadelphia law firm of Miller, Alfano & Raspanti, P.C. He is a former prosecutor in Philadelphia and can be reached at 215-972-6400 or [www.mar-law.com](http://www.mar-law.com). Alexandra C. Gaugler is a senior associate at Miller, Alfano & Raspanti, P.C. and practices in the areas of Civil and Criminal Health Care Fraud Defense and complex civil litigation. She can be reached at 215-972-6400 or [www.mar-law.com](http://www.mar-law.com).

<sup>2</sup>*N.Y. Times* (12/18/06) at A1.

<sup>3</sup>See e.g. Comments of First U.S. Attorney Michael Loucks, as reported in 1-12 *Rx Compliance Report*, (10/11/06).

<sup>4</sup>See e.g. Comments of OIG Chief Counsel Lewis Morris, as reported in 10-23 *BNA's Health Care Fraud Report* (11/22/06).

<sup>5</sup>The power to regulate the practice of medicine vests with the individual states.

<sup>6</sup>The FDA determines what goes on a drug's label. Each drug label states the FDA-indicated use and serves as a certification by the FDA that there is substantial evidence to support the safety and efficacy of the drug if used as indicated on the label. "Off-label", therefore, refers to a drug that is used, prescribed, or marketed for a use other than that contained on its label.

There are two key "off-label" distinctions: off-label prescribing and off-label marketing. Once a drug is approved by the FDA for one use, physicians can prescribe the drug for whatever use he or she wishes. Yet, drug manufacturers cannot market the drug for any other (i.e. "off-label") uses.

<sup>7</sup>Radley, Finkelstein & Stafford, *Off-label Prescribing Among Office-Based Physicians*, *Archives of Internal Medicine* (5/8/06).

<sup>8</sup>This article does not address other risks a physician may face from prescribing off-label, such as malpractice suits. We note only that some state courts have held that the fact that a physician prescribed a drug off-label could be introduced as evidence that the physician deviated from the standard of care. See e.g. *Richardson v. Miller*, 44 S.W.3d 1 (Tenn. Ct. App. 2000).

Prescribing off-label also triggers the doctrine of informed consent. This doctrine mandates that a physician provide patients with material information about proposed treatments. What constitutes material information is determined by each state. Depending on a given state's interpretation of the doctrine, a physician may need to inform a patient that the proposed use of a drug or device is off-label. Courts have traditionally been unwilling to find liability based on a failure to inform a patient off an off-label use. See e.g. *Alvarez v. Smith*, 714 So.2d 652 (Fla. Ct. App. 1998) (rejecting plaintiff's contention that by failing to inform him that the screws used in his spine surgeries were not approved for such use, the surgeons did not obtain his informed consent).

This may change, however, as new lawsuits make their way through the courts with sympathetic scenarios, such as those relating to the off-label use of anti-depressants in children. Thousands of lawsuits have been filed, for example, over off-label prescribing of Paxil to children, which has been linked to increased risk of suicide, with plaintiffs asserting they were never informed by their physicians that the drug was given off-label.

<sup>9</sup>An area under scrutiny by the Senate Finance Committee is Continuing Medical Education ("CME"), and in particular the pharmaceutical's financial support of CMEs.

<sup>10</sup>Orphan was acquired by Jazz Pharmaceuticals in June 2005.

<sup>11</sup>On July 25, 2007, the government filed a superseding indictment, adding former Orphan sales representative Alfred Caronia as a co-defendant. The superseding indictment alleges a conspiracy to introduce a misbranded drug and the actual introduction of a misbranded drug into interstate commerce.

<sup>12</sup>*N.Y. Times* (7/22/06).

<sup>13</sup>*Id.*

<sup>14</sup>The government further alleged that Dr. Gleason made additional misrepresentations about Xyrem. The active ingredient in Xyrem was GHB, which the Government describes as a fast-acting depressant that was subject to recreation abuse, and which was classified as a "date rape" drug. See Superseding Indictment filed against Gleason and Caronia, Cr. No. 06-229, at ¶ 5. According to the government, Dr. Gleason allegedly denied that GHB was a "date rape" drug, and instead insisted in his talks that GHB was as safe as table salt. *Id.* at ¶ 14.

<sup>15</sup>Press Release of the United States Attorney's Office for the Eastern District of New York (7/13/07).

<sup>16</sup>The AMA published a comprehensive analysis of the effectiveness of recent Vermont and Minnesota disclosure laws. See 297 *JAMA* (3/21/07). In addition to Vermont, Minnesota and the District of Columbia, California, Maine and West Virginia all have mandatory disclosure laws on the books.

<sup>17</sup>*N.Y. Times* (3/21/07) at A1.