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## Advance Directives, Dementia and Alzheimer's Disease

By

Angela T. Burnette and Hannah Heck<sup>1</sup>

While advance directives for health care are an important tool for protecting personal autonomy, unique questions arise for individuals who have symptoms of dementia or Alzheimer's disease. This article provides an overview of advance directives generally and issues related to individuals who have dementia and/or Alzheimer's disease.<sup>2</sup> The article also notes state laws which specifically address advance directives in the context of dementia and/or Alzheimer's. As explained below, advance directives offer significant opportunities for patients to express their treatment preferences. Moreover, some patients who have dementia or Alzheimer's disease may well have the capacity to execute an advance directive.<sup>3</sup>

### Dementia and Alzheimer's Disease

One in eight Americans age 65 or older has been diagnosed with Alzheimer's disease, which is the most common cause of dementia, and that number increases to almost 50 percent of those Americans age 85 and older.<sup>4</sup> Dementia is often described as a cluster of symptoms including, but not limited to, memory loss, difficulty in making decisions, and

personality changes; it is "a gradual deterioration of mental functioning" but is not the natural consequence of the aging process.<sup>5</sup> Dementia may have physical causes, such as head injury, infection, medication side-effects, stroke and dehydration.<sup>6</sup> Dementia symptoms often appear incrementally over time rather than as the result of a sudden event. Additionally, dementia symptoms and progression may vary among those who have been diagnosed. Data suggests that most individuals with dementia live alone or with family or an informal caregiver.<sup>7</sup>

Alzheimer's disease is viewed as a diagnosis, not a symptom, and it accounts for as many as 70-80 percent of all dementia cases.<sup>8</sup> It is possible a patient may be told by a medical professional that he has "a little bit of dementia" or that she has "probable Alzheimer's."<sup>9</sup> Alzheimer's often is seen as a diagnosis by exclusion which is not definitively diagnosed until after death. Unfortunately, Alzheimer's can have a dramatic impact on an individual's cognitive abilities.<sup>10</sup> Thus, many patients diagnosed with Alzheimer's may face medical decisions and end of life planning at a point when they have already been determined to lack capacity to make health care decisions.

<sup>1</sup> Ms. Burnette and Ms. Heck are health care attorneys in Alston & Bird LLP's Atlanta office. Ms. Burnette dedicates this article to the memory of her grandmother and also expresses her appreciation to Claire M. Hagan, a 2012 summer associate at Alston & Bird, for her valuable research assistance. Ms. Burnette can be reached at Alston & Bird LLP, 1201 West Peachtree Street, Atlanta, GA 30309-3424. Her telephone number is 404.881.7665, and her email is [angie.burnette@alston.com](mailto:angie.burnette@alston.com).

<sup>2</sup> This article examines some potential legal issues involving advance directives and the commonly used lay terms of "dementia" and "Alzheimer's." Keep in mind that a physician diagnoses these clinical conditions, and often a second opinion from a neurologist or geriatric specialist is helpful or appropriate.

<sup>3</sup> See Alzheimer's Ass'n, *End of Life Decisions*, available at [http://www.alz.org/professionals\\_and\\_researchers\\_end\\_of\\_life.asp](http://www.alz.org/professionals_and_researchers_end_of_life.asp) (last visited Oct. 11, 2012) ("A person with Alzheimer's may lack capacities to drive, handle financial affairs or live independently but still may have the capacity to make independent decisions about his or her medical care or place of residence.")

<sup>4</sup> Alzheimer's Ass'n, *2012 Alzheimer's Disease Facts & Figures*, 14, available at [http://www.alz.org/downloads/facts\\_figures\\_2012.pdf](http://www.alz.org/downloads/facts_figures_2012.pdf)

<sup>5</sup> Robert Stern, M.D., *What's the Difference Between Alzheimer's and Dementia?*, Alzheimer's Reading Room, available at (posted May 14, 2011), <http://www.alzheimersreadingroom.com/2010/06/whats-difference-between-alzheimers-and.html>. See also Bob DeMarco, *What is Dementia?*, Alzheimer's Reading Room, available at (posted Apr. 3, 2012 8:57 p.m.), <http://www.alzheimersreadingroom.com/2010/06/whats-difference-between-alzheimers-and.html>.

<sup>6</sup> *Id.* See also *Dementia: Causes*, available at <http://www.mayoclinic.com/health/dementia/DS01131/DSECTION=causes> (last visited Oct. 11, 2012).

<sup>7</sup> American Bar Ass'n Comm'n on Law & Aging & American Psychological Ass'n, *Assessment of Older Adults with Diminished Capacity: A Handbook for Lawyers*, available at <http://www.apa.org/pi/aging/programs/assessment/capacity-psychologist-handbook.pdf>.

<sup>8</sup> *What's the Difference Between Alzheimer's and Dementia?*, available at <http://www.alzheimersreadingroom.com/2010/06/whats-difference-between-alzheimers-and.html>.

<sup>9</sup> *Id.*

<sup>10</sup> Alzheimer's Association, *2012 Alzheimer's Disease Facts & Figures*, *supra* note 4.

### Advance Directives Generally

Historically, physicians exercised decision-making authority for an individual with cognitive impairment, with the assumption that a physician's decision for the patient would reflect the patient's best interests.<sup>11</sup> In recent decades, an individual's autonomy and right to refuse medical treatment have been addressed both in well-publicized court decisions and federal law.<sup>12</sup> State legislatures have enacted advance directive laws which place the decision-making capacity back with the individual. Through an advance directive, an adult individual (also known as the declarant) can state in advance his or her written preferences for medical treatment and designate a health care agent to make health care decisions in case the declarant becomes incapacitated.<sup>13</sup>

Advance directives are increasingly available to the public, often through lay-friendly model forms provided by a state legislature, an attorney general's office or another state agency.<sup>14</sup> In some states, an advance directive known as a "living will" permits the declarant to list treatment preferences which will take effect if the declarant later has a particular condition enunciated by statute (e.g., terminal condition, permanent vegetative state, or coma). Through an advance directive known as a "durable power of attorney for health care," a declarant can designate a health care agent (e.g., a proxy or surrogate decision maker) who is authorized by the declarant to make

health care decisions if the declarant later becomes incapacitated.<sup>15</sup> Some states, such as Georgia, offer a model advance directive form which combines the two, permitting a declarant to state treatment preferences and also designate a health care agent in one document.<sup>16</sup>

While federal law requires that health care facilities accepting Medicare or Medicaid reimbursement discuss advance directives with patients,<sup>17</sup> advance directive forms and laws vary among states. This article summarizes some commonly found state law requirements, but counsel should check applicable state law before drafting an advance directive for a particular patient.

### Why Consider Advance Directives Now?

There are several reasons why advance directives should be considered now. Alzheimer's causes a progressively severe dementia, usually resulting in persons eventually losing the capacity to make their own health care decisions.<sup>18</sup> As the disease progresses, patients frequently begin exhibiting uncharacteristic behaviors and require increased assistance with daily self-care.<sup>19</sup> The initial symptoms of dementia or Alzheimer's disease generally include minor changes in a patient's cognition; however, most patients will retain capacity to execute an advance directive, according to the

<sup>11</sup> U.S. Dep't of Health & Human Servs. Assistant Secretary for Planning and Evaluation Office of Disability, Aging & Long-Term Care Policy, *Advance Directives & Advance Care Planning: Report to Congress*, ix (Aug. 2008) (hereinafter "ODA Report"), available at <http://aspe.hhs.gov/daltcp/reports/2008/ADCongRpt.pdf>.

<sup>12</sup> See e.g., *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 110 S. Ct. 2841, 111 L. Ed. 2d 224 (1990); see also 42 U.S.C. § 1395cc(f) (Patient Self Determination Act requires that certain recipients of federal health care funds inform patients about advance directives).

<sup>13</sup> A health care agent is sometimes referred to a "durable power of attorney for health care." State statutes and forms may use different terminology.

<sup>14</sup> See Nat'l Healthcare Decisions Day, *Legal Resources*, available at <http://www.nhdd.org/public-resources> (providing links to an ABA toolkit and to various websites that offer advance directive forms). See also Az. Atty's Gen. Office, Task Force Against Senior Abuse, *Life Care Planning Packet Materials*, available at [http://www.azag.gov/life\\_care/#Materials](http://www.azag.gov/life_care/#Materials).

<sup>15</sup> A durable power of attorney for health care would generally constitute a Personal Representative under HIPAA's Privacy Rule; the HIPAA Privacy Rule would permit a Personal Representative to have access to the declarant's medical records and discuss the declarant's care with treating health care providers. 45 C.F.R. § 164.502(g).

<sup>16</sup> See O.C.G.A. § 31-32-4. Depending on the state, a declarant may also be able to express other preferences as part of an advance directive. For example, Georgia's Advance Directive for Health Care form also permits, but does not require, a declarant to express wishes regarding guardianship. *Id.*

<sup>17</sup> See 42 U.S.C. §§ 1395cc(a)(1)(Q), 1395cc(f)(1)(A); 42 C.F.R. § 489.102(a)(1). Under 42 U.S.C. § 1395cc(f)(3), an advance directive is defined as a "written instruction, such as a living will or durable power of attorney for health care, recognized under State law . . . and relating to the provision of such care when the individual is incapacitated."

<sup>18</sup> Alzheimer's Ass'n, *What is Alzheimer's?*, available at [http://www.alz.org/alzheimers\\_disease\\_what\\_is\\_alzheimers.asp](http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp). (last visited Oct. 11, 2012) and *Seven Stages of Alzheimer's*, available at [http://www.alz.org/alzheimers\\_disease\\_stages\\_of\\_alzheimers.asp](http://www.alz.org/alzheimers_disease_stages_of_alzheimers.asp) (last visited Oct. 11, 2012).

<sup>19</sup> *Id.*

Alzheimer's Association.<sup>20</sup> Only in later stages will many patients lose capacity.<sup>21</sup> Execution of advance directives helps to document the patient's wishes and treatment preferences in case a patient later becomes unable to make her own health care decisions.

While many people with early dementia or Alzheimer's disease may possess sufficient capacity to execute advance directives, studies suggest most adults have not signed advance directives.<sup>22</sup> Relatively few Americans complete advance directives; among the general adult population, only about 18–36 percent of all adults reportedly have such directives in place.<sup>23</sup> This number is higher among patients with dementia, but researchers estimate that still only 36–60 percent of nursing home residents with dementia have executed advance directives.<sup>24</sup>

An advance directive can also offer meaningful benefits to the individual client and family involved. For example, an advance directive may offer peace of mind to individuals who fear they might later develop dementia. An advance directive may be helpful for those individuals who fear their initial dementia symptoms may worsen or they might later be diagnosed with Alzheimer's. Consideration and discussion of advance directives now could enhance individuals' autonomy if and to the extent their cognition later significantly declines. Additionally, advance directives could assist a client's family who otherwise might not have 1) known his or her wishes; or 2) felt as comfortable asking health care providers to carry out the expressed wishes.

### State Law Requirements To Consider

Generally, state requirements for the execution of an advance directive for health care (including a living will and a durable power of attorney for health care) fall within three categories:

- Capacity requirements: *Who is eligible to execute?*
- Witness requirements: *Who is eligible to attest and what are the required witness formalities?*

<sup>20</sup> See 2012 Alzheimer's Disease Facts and Figures, *supra* note 4, at 7–10 (discussing Alzheimer's symptoms).

<sup>21</sup> Seven Stages of Alzheimer's, *supra* note 18.

<sup>22</sup> See ODA Report, *supra* note 1, at 15–17 (reviewing data regarding use of advance directives by individuals with dementia).

<sup>23</sup> ODA Report, *supra* note 11, at x.

<sup>24</sup> ODA Report, *supra* note 11, at 16.

- Language/form requirements: *What must the directive include?*

If another advance directive form is used rather than a state's model form, counsel should take care to confirm compliance with applicable state law requirements.

### (a) Capacity requirements

Counsel should consider whether the client (the potential declarant) has the "capacity" to make health care decisions. Although not required, an evaluation by a physician, including a medical history, physical exam, mental status testing and other assessments, may help rule out physical (e.g., reversible or partially reversible) causes of dementia-like symptoms, such as medication side effects or dehydration. Physical evaluation may also provide strong evidence of a declarant's capacity before an advance directive is executed. Even if a diagnosis of dementia or Alzheimer's disease is given by the evaluating physician, "early diagnosis is important because it gives the person and family time to make financial, legal, and medical decisions while the person is capable."<sup>25</sup> Although some patients who have dementia or Alzheimer's disease may lack certain capacities, they may still have the capacity to execute advance directives.<sup>26</sup>

State advance directive laws generally presume declarants have capacity to execute advance directives.<sup>27</sup> The legal capacity to make an advance directive is often defined by state law, which may refer broadly to the individual's ability to understand the nature of the decisions being made.<sup>28</sup> The initial presumption of capacity should generally remain intact unless, for example, the individual has been adjudicated by a court as incompetent, has been appointed a guardian, or there are other unique facts. This presumption of capacity, combined with

<sup>25</sup> Assessment of Older Adults with Diminished Capacity: A Handbook for Lawyers, *supra* note 7, at Appendix 4, p. 69.

<sup>26</sup> End of Life Decisions, *supra* note 3.

<sup>27</sup> See N.Y. Pub. Health Law § 2981; Tenn. Code Ann. § 68-11-1812 (Tennessee law stating that an individual is "presumed to have capacity... to give or revoke an advance directive").

<sup>28</sup> See Cal. Prob. Code § 4609 (defines capacity as "a person's ability to understand the nature and consequences of a decision and to make and communicate a decision, and includes in the case of proposed health care, the ability to understand its significant benefits, risks and alternatives.")

the recognized right to execute these directives,<sup>29</sup> leaves little case law interpreting capacity issues in the advance directives context. However, a few courts have examined these questions involving Alzheimer's and dementia, and those cases are instructive.

A New York case, *In re Rose S.*, involved a patient who signed a health care proxy but was formally diagnosed with dementia the next day.<sup>30</sup> Evidence indicated Rose had suffered from dementia before she signed the proxy.<sup>31</sup> The court stated generally that "persons suffering from a disease such as Alzheimer's are not presumed to be wholly incompetent."<sup>32</sup> The court noted, however, that evidence of a mental defect, such as a physician's testimony that the patient was incompetent and medical record references to the patient's "confusion and disorientation," shifts the burden.<sup>33</sup> The court held that with such evidence, the party asserting the directive's validity must prove by clear and convincing evidence that the declarant was competent at the time he or she executed the document.<sup>34</sup> The *Rose* court held the proxy was not valid because she had suffered from dementia for ten years prior, the proxy was signed after hospital staff had stated she was incompetent, and there was no formal evaluation confirming competency before the proxy was signed.<sup>35</sup>

In the case of *In re Roche*, a court in New Jersey addressed the competency to make health care decisions and the capacity to execute an advance directive. In that case, Mrs. Roche, an adult diagnosed with senile dementia with delusions, was adjudicated by a court as mentally incompetent, and a public guardian was appointed for her.<sup>36</sup> Two years later, Mrs. Roche executed an advance directive while in a nursing home, prompting her guardian to ask the court whether the advance directive was valid.<sup>37</sup> The court recognized that in some cases, a

person could be competent to make a health care decision even after being adjudicated as incompetent, noting specifically that "[s]ome elderly nursing home patients . . . have lucid periods during which they can once again communicate their wishes clearly."<sup>38</sup> The *Roche* court ultimately concluded that a person who has been adjudicated as mentally incompetent and who has been appointed a guardian "cannot execute a valid and enforceable advance directive."<sup>39</sup> The *Roche* court noted the guardian could possibly consider Mrs. Roche's signed document (although not a binding advance directive) as some evidence of Mrs. Roche's subjective intent going forward, in addition to other information the guardian might gather.<sup>40</sup>

If there are questions regarding whether a client is competent or has capacity to execute an advance directive, such as in the *Roche* case, counsel should consider recommending the client obtain a physician evaluation. Additionally, there are resources available for attorneys facing these client issues. For example, the American Bar Association and the American Psychological Association have created a handbook to aid lawyers in identifying and assessing competency issues for aging clients.<sup>41</sup> The handbook offers varying models of assessing client competency, including clients with diminished capacity. In particular, the handbook contains a "Dementia Overview," which provides information on the causes and different types of dementia, the stages of dementia, and treatment approaches.<sup>42</sup> Additionally, a helpful planning guide for dementia is available on the Wisconsin Department of Health Services website.<sup>43</sup> The planning guide, with input from the Alzheimer's Association for South Central Wisconsin, identifies three stages of dementia;

<sup>29</sup> *Cruzan*, 497 U.S. 261.

<sup>30</sup> *In re Rose S. (Anonymous)*, 293 A.D.2d 619, 741 N.Y.S.2d 84, 85 (2002).

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* (internal citations omitted).

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 621.

<sup>36</sup> *In re Roche*, 296 N.J. Super. 583, 687 A.2d 349 (Ch. Div. 1996).

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 351–52.

<sup>39</sup> *Id.* at 353. *See also id.* ("Clearly the Legislature intended to give the right to execute advance directives to competent persons, declarants who may someday lose decision making capacity, and not to incompetent persons who already have lost independence.").

<sup>40</sup> *Id.* at 354.

<sup>41</sup> *Assessment of Older Adults with Diminished Capacity: A Handbook for Lawyers*, *supra* note 7.

<sup>42</sup> *Id.* at Appendix 4.

<sup>43</sup> *See* Wisconsin Dep't of Health Servs., Alzheimer's Disease and Dementia Resources, available at <http://www.dhs.wisconsin.gov/aging/dementia/homecare.htm>.

the guide also identifies advance directive planning and execution as goals during the early and middle stages of dementia, as permitted according to cognitive status.<sup>44</sup> The website also contains a helpful summary of the stages of Alzheimer's Disease, including typical characteristics, behaviors and symptoms during early, middle and late stage Alzheimer's.<sup>45</sup>

### (b) Witness requirements

Specific witness requirements in state advance directive laws may vary, both as to who can serve as a witness and the formalities for witnessing a declarant's advance directive. First, state laws often impose witness requirements which are intended to prevent conflicts of interest or undue influence. For example, often such witnesses cannot also be heirs of the declarant's estate.<sup>46</sup> Additionally, state laws often prevent the designated health care agent from serving as a witness and may prevent or limit the declarant's medical professionals or family members from serving as witnesses to the advance directive.<sup>47</sup> Second, state laws may vary as to the number of witnesses and the manner in which they witness the declarant signing the advance directive. For example, Georgia's advance directive law requires two or more witnesses but does not require that both witnesses be present at the same time or that they see the declarant sign the advance directive.<sup>48</sup> However, Virginia law states an advance directive must be signed in the presence of two or more witnesses.<sup>49</sup>

<sup>44</sup> See *id.*

<sup>45</sup> See *id.*

<sup>46</sup> See Okla. Stat. tit. 63, § 3101.4 (witnesses to advance directive cannot be "heirs at law"); N.H. Rev. Stat. § 137-J:14(I)(a) (witnesses to advance directive cannot be heirs at law or "a person entitled to any part of the estate").

<sup>47</sup> See N.H. Rev. Stat. § 137-J:14 (restricting health care agents, attending physicians and others acting in control of medical professional from witnessing advance directive; also stating "[n]o more than one such witness may be the principal's health or residential care provider."); see also Tenn. Code Ann. § 68-11-1803 (Tennessee law stating witness to advance directive cannot be the health care agent, and at least one witness cannot be related by blood to the declarant).

<sup>48</sup> See O.C.G.A. § 31-32-5(c)(1) (requiring two or more witnesses but expressly not requiring that they be together or present when the declarant signs the advance directive).

<sup>49</sup> See Va. Code Ann. § 54.1-2983.

### (c) Advance Directive form requirements

In some states, use of a statutory model for an advance directive may act similar to a safe harbor regarding statutory language requirements.<sup>50</sup> While many state laws recognize language in an advance directive which is "substantially similar" to the state-provided form,<sup>51</sup> some states may require specific language, including information that must be provided to declarants.<sup>52</sup> Additionally, there are unique state requirements that might impact the disclosures and signatures needed to execute an advance directive. Under Vermont's law, for example, an advance directive executed at the time a patient is admitted to or is a patient in a hospital is not effective, "unless an ombudsman, a recognized member of the clergy, an attorney licensed to practice in the state" or another court or statutorily designated person signs a statement certifying they have advised the declarant of the "nature and effect" of the advance directive.<sup>53</sup> Accordingly, counsel should verify any state-specific forms and requirements before proceeding, including limitations or additional requirements for advance directives signed while the declarant is a patient at a health care facility.

### Some State Advance Directive Laws Specifically Mention Dementia

While many advance directive laws do not mention dementia, some state laws specifically address dementia in their statutory advance directive forms. For example, the model form for a living will in North Carolina prompts individuals to specify whether they would want aggressive treatment in the event they develop "advanced dementia."<sup>54</sup>

<sup>50</sup> See N.C. Gen. Stat. Ann. § 90-321 (statutorily created form "is specifically determined to meet" the legislated requirements in North Carolina).

<sup>51</sup> See *e.g.*, Okla. Stat. tit. 63, § 3101.4.

<sup>52</sup> See *e.g.*, N.H. Rev. Stat. § 137-J:19 (requires multi-paragraph disclosure to declarant about content and legal effect of health care power of attorney document).

<sup>53</sup> Vt. Stat. Ann. tit. 18, § 9703(e).

<sup>54</sup> See N.C. Gen. Stat. Ann. § 90-321 (the "Advance Directive for a Natural Death or Living Will" prompts individuals to select several situations where directions about prolonging or not prolonging life apply including when, "[t]he declarant suffers from advanced dementia or any other condition resulting in the substantial loss of cognitive ability and that loss, to a high degree of medical certainty, is not reversible.")

The Texas model form for an advance directive lists “Alzheimer’s dementia” as an example of a type of irreversible condition for which a patient may choose to express wishes regarding life-sustaining treatment.<sup>55</sup> In Pennsylvania, the model form for appointment of a health care agent includes a provision for individuals to specify whether they would want aggressive treatment if they have a “severe and irreversible brain damage or brain disease with no realistic hope of recovery.”<sup>56</sup>

Additionally, some have advocated the use of mental health advance directives (MHADs)<sup>57</sup> as a type of advance planning for individuals who have or later develop dementia or Alzheimer’s disease.<sup>58</sup> Generally, a MHAD is used by individuals who wish to designate their preferences in the event of a mental health crisis or if they lose capacity to make health care decisions due to mental illness. MHADs might be used as planning tools for those with dementia or Alzheimer’s disease, depending on the state law’s specific language.<sup>59</sup> Some publicly available

MHAD documents may specifically be titled as an Alzheimer’s Disease MHAD, but counsel should consult applicable state law for any specific requirements which the client’s advance directive may also need to meet.

### Conclusion

Advance directives are important planning tools which should be considered to provide documentation and dignity to an adult’s expressed preferences. These directives also offer clients who are worried about dementia or Alzheimer’s disease a meaningful opportunity now to maintain a higher level of autonomy later, to the extent their symptoms or conditions progress.

Even if an adult has not been diagnosed with dementia or Alzheimer’s disease, he may wish to specify treatment preferences or designate a health care agent now, in case he later becomes unable to make his own health care decisions. Although many states’ advance directive laws do not specifically mention dementia or Alzheimer’s disease, a state’s model form can provide an essential mechanism for clients to express their wishes, including clients who have been diagnosed with dementia or Alzheimer’s disease. Evaluation of a client by a physician, neurologist or geriatric specialist may be helpful or appropriate to confirm the client’s current capacity to execute an advance directive. A patient with dementia or Alzheimer’s disease is not necessarily precluded from executing an advance directive but counsel should provide particular attention to the unique issues involved. Advance directives should be considered now to prevent the unfortunate situation in the *Roche* case, as described by the court:

It is too late for Mrs. Roche, whatever degree of lucidity she may have regained, to execute an advance directive, as she is not a competent person, and her guardian does not assert that she should be so found. There is no need to provide for a time when Clementine Roche may be found incompetent; the time is already upon us.<sup>60</sup>

<sup>55</sup> See Tex. Health & Safety Code § 166.033 (advance directive allows patient to choose that life-sustaining treatment be either discontinued or used when, “in the judgment of my physician, I am suffering with an irreversible condition so that I cannot care for myself or make decisions for myself and am expected to die without life-sustaining treatment. . .”).

<sup>56</sup> See 20 Pa. Cons. Stat. § 5471 (“If I should suffer from severe and irreversible brain damage or brain disease with no realistic hope of significant recovery, I would consider such a condition intolerable and the application of aggressive medical care to be burdensome.”) Physician input may be helpful in confirming whether an individual’s advanced dementia or Alzheimer’s disease is consistent with this criteria and prognosis.

<sup>57</sup> See, e.g., New Jersey Advance Directives for Mental Health Care Act, N.J. STAT. ANN. § 26:2H-103, *et seq.*

<sup>58</sup> Lisa Brodoff, *Planning for Alzheimer’s Disease with Mental Health Advance Directives*, 17 Elder L.J. 239, 248–52, n.19 (2009) (describing MHADs).

<sup>59</sup> See e.g., 20 Pa. Cons. Stat. §§ 5821–26 (Pennsylvania’s Advance Directive for Mental Health); Wash. Rev. Code § 71.32.010 (Washington’s Mental Health Advance Directive); and 3A Mich. Legal Forms § 6C:45.50 (Michigan’s Advance Directive for Mental Health Care). The planning guide for Michigan’s Advance Directive for Mental Health Care, available on the State of Michigan’s website, explains to individuals they “might become unable to make mental health decisions if severe depression, bipolar disorder, schizoaffective disorder or schizophrenia affects your mood or thought process, or **dementia affects your memory**.” (emphasis added). Bradley Geller, *Advance Directive Questions & Answers Pamphlet*, Mich. Dep’t Cmty. Health, available at [http://www.michigan.gov/mdch/0,4612,7-132-2941\\_4868\\_41752--,00.html](http://www.michigan.gov/mdch/0,4612,7-132-2941_4868_41752--,00.html) (follow “Advance Directive Questions and Answers Pamphlet” hyperlink).

<sup>60</sup> *Roche*, 687 A.2d at 354–55.

## MEALEY'S CORNER

*Recent Abstracts & Bulletins from Mealey Publications*

### EMERGING DRUGS & DEVICES

9-20-2012

#### Woman Prosecuted For Using Abortifacient Can Challenge Idaho Abortion Law

A federal appeals court panel on Sept. 11 retained a preliminary injunction against an Idaho state prosecutor for criminally prosecuting a woman who obtained an abortifacient drug over the Internet while the woman challenges the constitutionality of the state's stringent anti-abortion law (*Jennie Linn McCormack v. Mark L. Hiedeman, et al.*, Nos. 11-36010 and 36015, 9th Cir.; 2012 U.S. App. LEXIS 19051).

(Opinion available 28-120920-010Z)

In 2010, Jennie Linn McCormack became pregnant and sought an abortion. The nearest provider was about 138 miles away and charged \$400 to \$2,000.

McCormack learned that her pregnancy could be terminated with an approved abortifacient drug that could be purchased over the Internet. She pursued that option, and the drug was prescribed by an unidentified health care provider outside of her county.

McCormack took the unidentified drug, and her fetus was aborted. Someone tipped police that McCormack had an aborted fetus.

#### Felony Charge

Afterward, Braddock County Prosecuting Attorney Mark L. Hiedeman filed a felony criminal complaint against McCormack, charging her with receiving an unlawful abortion under Idaho Code Section 18-606. The law makes it a felony for a woman to undergo an abortion in a manner not authorized by the statute.

McCormack faced up to five years' imprisonment.

In 2011, a judge in the Braddock County District Court dismissed the criminal complaint without prejudice. Hiedeman has not decided if he will refile the criminal complaint.

#### Constitutional Challenge

In September 2011, McCormack sued Hiedeman in the U.S. District Court for the District of Idaho,

saying Section 18-606 is unconstitutional. The District Court issued a preliminary injunction preventing Hiedeman from enforcing Subsections 18-606 and 18-608(1) of the state law.

Hiedeman appealed, arguing that the federal court erred in determining that McCormack would likely succeed on the merits of her case and that the injunction was overbroad. McCormack cross-appealed, arguing that the District Court erred by not enjoining all of Section 18-606.

McCormack also argued that she had standing to challenge the enforcement of Chapter 5 of the law, the Pain-Capable Unborn Child Protection Act (PUCPA). That law prohibits abortions after 20 weeks because the fetus can feel pain.

#### Challenge Likely Successful

The Ninth Circuit panel affirmed the District Court's determination that McCormack will likely succeed with her constitutional challenge to Subsection 18-606 and 18-601(1). The court also affirmed the lower court ruling that McCormack lacked standing to seek pre-enforcement relief against enforcement of the PUCPA.

However, the panel reversed the scope of the preliminary injunction, limiting its relief to McCormack only. In addition, the panel reversed the District Court's determination that McCormack did not have standing to enjoin enforcement of Section 18-608(2) in conjunction with Section 18-606.

Circuit Judge Harry Pregerson wrote the opinion. Other panel members were Circuit Judge Betty B. Fletcher and Senior U.S. Judge Donald E. Walter of the Western District of Louisiana, sitting by designation.

#### Counsel

McCormack is represented by Richard A. Hearn of Racine, Olson, Nye, Budge & Bailey in Pocatello, Idaho. Hiedeman is represented by Idaho Attorney General Clay R. Smith of the Attorney General's Office in Boise, Idaho.

Amicus curiae Legal Voice, Center for Reproductive Rights and National Advocates for Pregnant Women



is represented by Kathleen M. O'Sullivan of Perkins Coie in Seattle.

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## EMERGING DRUGS & DEVICES

10-4-2012

### Summary Judgment Granted In Aredia/Zometa Jaw Injury Case After Expert Is Excluded

A Washington federal judge on Oct. 1 granted summary judgment in an Aredia/Zometa jaw injury case after excluding the plaintiff's causation expert testimony (Duane E. Luttrell v. Novartis Pharmaceuticals Corporation, No. 2:07-3015, E.D. Wash.; 2012 U.S. Dist. LEXIS 142816).

(Opinion available 28-121004-024Z)

In June 2005, Duane Luttrell was diagnosed with multiple myeloma and was given Zometa as part of his treatment. After Luttrell reported symptoms, his oncologist switched him to Aredia.

Aredia and Zometa are made by Novartis Pharmaceuticals Corp. Aredia is now also available as a generic drug, pamidronate.

#### Jaw Problems Begin

In July 2005, after his first dose of Aredia, Luttrell had a tooth extracted. Luttrell complained of sores in his mouth.

In June 2006, a radiation oncologist diagnosed Luttrell with bisphosphonate-related osteonecrosis of the jaw (BRONJ) and said Aredia should be stopped.

In 2007, Luttrell sued Novartis in the U.S. District Court for the Eastern District of Washington, alleging that Aredia and Zometa caused osteonecrosis of the jaw (ONJ). The case was transferred into the Aredia/Zometa multidistrict litigation in the Middle District of Tennessee and in January was remanded to the Washington court for trial.

Luttrell's two surviving claims were for strict liability and failure to warn. Novartis moved to exclude Luttrell's expert witnesses and for summary judgment.

#### Treating Doctors Limited

Luttrell named five of his treating doctors as experts: Dr. Albert Brady, an oncologist; Dr. Sean Cleary, a radiological oncologist; Dr. Dolphine Oda, an oral pathologist; Dr. Darrell Tew, an oral surgeon; and Dr. Mark Young, a dentist. Judge Thomas O. Rice said the treating physicians could testify about opinions they formed while treating Luttrell but could not offer testimony about specific causation.

The plaintiff also named Dr. Richard Jackson as a causation expert. Judge Rice said Jackson is qualified to render a causation opinion even though he has not published articles, given lectures or read medical literature.

However, Judge Rice said Jackson never gave a definite opinion that Luttrell's ONJ was caused by Aredia or Zometa. "Based on the record before the Court, there is simply not enough evidence one way or the other to determine whether Dr. Jackson's testimony will be helpful to the jury on the issue of causation," the judge wrote.

"By the slightest of margins, the Court finds that Novartis' argument as to the relevance of Dr. Jackson's testimony goes only to its weight and not its admissibility," the judge said.

#### No Scientific Method

However, the judge also said Luttrell has not show that Jackson used valid scientific methods to reach a conclusion that Luttrell has ONJ or that Aredia or Zometa caused it. "Thus, the Court finds that Dr. Jackson's opinions as to causation are unsupported by reliable scientific methodology, and grants Novartis' motion to exclude his causation testimony."

"Without any admissible testimony as to legal causation, as opposed to diagnosis, there can be no genuine issue of material fact on the causation issue," Judge Rice wrote.

The judge did find that there was a genuine issue of material fact as to whether Luttrell was given six initial doses of Aredia or its generic version, pamidronate.

As to his failure-to-warn argument, Judge Rice said Luttrell made no argument why, under the Washington Products Liability Act, Novartis' warnings were not adequate.

### No Prescribing Change

Judge Rice also found no issue of material fact as to whether Luttrell's prescribing oncologist would have prescribed Aredia or Zometa if the warnings about BRONJ were different.

Finally, the judge found no genuine issue of material fact to support Luttrell's claim of breach of implied warranty.

Luttrell is represented by John J. Beins of Beins, Goldberg & Hennessey in Chevy Chase, Md., and David P. Abeyta of Abeyta Nelson in Ellensburg, Wash. Novartis is represented by Donald R. McMinn and Rachel E. Paul of Hollingsworth in Washington, D.C., and James B. King of Evans, Craven & Lackie in Spokane.

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## EMERGING DRUGS & DEVICES

10-4-2012

### Judge Denies Dismissal Of Periodontists' Class Action Over Dirty Dental Scalers

A Pennsylvania federal judge on Sept. 28 denied a motion to dismiss or to grant summary judgment in a class action complaint by two periodontal practices against Dentsply International Inc. for producing a dental scaling device that allegedly allows harmful biofilm to form in its water reservoir and water lines (Center City Periodontists, P.C., et al. v. Dentsply International, Inc., No. 2:10-774, E.D. Pa.).

(Order available 28-121004-021R)

In 2010, Center City Periodontists P.C. and Affiliated Periodontists of North Jersey P.A. sued Dentsply in the U.S. District Court for the Eastern District of Pennsylvania. The plaintiffs say they purchased Cavitron ultrasonic scaler devices from Dentsply.

The plaintiffs say Dentsply represented to periodontal and dental practices that the Cavitron devices, which uses a fine, pulsating stream of water to clean scale and tartar from teeth, were safe to use. Instead, they say the devices allow the growth of bacteria-laden biofilm that can infect patients.

The plaintiffs seek certification of a class of all periodontists and dentists who bought the Cavitron,

which they say cost from \$1,500 to \$3,500 depending on the model. They assert theories of breach of warranty, negligent design and violation of the New Jersey Consumer Fraud Act.

### Not Duplicative Of Other Case

Dentsply moved to dismiss or for summary judgment.

Judge C. Darnell Jones III denied the motion.

The judge said Dentsply's initial argument for dismissing the case is that it duplicates another case bought by one of the periodontists, Carol N. Hildebrand, D.D.S., in Carol N. Hildebrand, D.D.S., et al. v. Dentsply International, Inc. (No. 06-5439, E.D. Pa.; See February 4, 2010, Page 24). Judge Jones said that he dismissed that case for lack of subject matter jurisdiction and that Hildebrand did not appeal.

Dentsply also argued that the court should exercise its inherent power to control its own docket. It cited case law dealing with failure to appear or prosecute or to reach a settlement in a timely manner.

### Abuses In Other Case Unrelated

Judge Jones said plaintiffs' counsel's prior discovery abuses in Hildebrand, "while problematic in the context of that now completed litigation, do not necessitate dismissal of the current action in order for the Court to maintain control over its docket."

Dentsply also argued that the plaintiffs' case should be dismissed under the doctrines of equitable estoppel and/or unclean hands. Judge Jones said those doctrines apply only when a plaintiff's unconscionable conduct relates directly to the equity he seeks.

The judge said "no record has been established in this action or in Hildebrand to show any sort of misconduct relation to Plaintiffs' use of these dental and periodontal tools."

### No Statement Of Material Facts

In addition, Judge Jones said Dentsply's failure to submit a statement of undisputed material facts in conjunction with the motion for summary judgment made it impossible for the plaintiffs to respond with a counterstatement and gave him no factual record to rely on. "The Court here does not reach whether, upon development of an adequate factual record, equitable tolling of the relevant statute of limitations would apply to preserve Plaintiffs' claim in the current action."

The plaintiffs are represented by Alan Klein, Andrew J. Kenis, Sean S. Zabaneh, Catherine E. Beideman and John M. Lyons of Duane Morris in Philadelphia, Paul D. Nelson of Bullivant Houser Bailey in San Francisco and Edwin J. Zinman of the Law Offices of Edwin J. Zinman in San Francisco.

Dentsply is represented by Brandon L. Goodman of Goodell, DeVries, Leech & Dann in Philadelphia and Derek M. Stikelather, Kamil Ismail, Linda S. Woolf and Richard M. Barnes of Goodell DeVries in Baltimore.

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## EMERGING DRUGS & DEVICES

10-4-2012

### Merck Agrees To Pay Millions To Settle Coppertone False Ad Class Suit

Merck & Co. Inc., MSD Consumer Care Inc. and Merck Sharp & Dohme Corp. have agreed, via a settlement agreement filed in New Jersey federal court on Sept. 21, to stop using certain terms when labeling, promoting and advertising their Coppertone sunscreen products and pay between \$3 million and \$10 million to end the false advertising suit brought on behalf of a nationwide class of purchasers (Steven Brody, et al. v. Merck & Co., Inc., et al., No. 12-4774, D.N.J.).

(Settlement agreement available 43-121005-002P)

#### California Class

In October 2003, Joseph Goldstein sued Merck in the Los Angeles County, Calif., Superior Court.

He brought claims on behalf of a putative class of consumers regarding alleged misrepresentations concerning the nature and extent of the benefits provided by various Coppertone sunscreen products. The following month, three similar complaints were filed in the Los Angeles and Alameda County Superior Courts. More class complaints were filed in the Los Angeles County Superior Court in 2004 and 2005.

The lawsuits were ultimately coordinated in the Los Angeles County Superior Court. On May 30, 2008, one of the plaintiffs, Robert Gaston, moved to certify a California statewide class of purchasers

of Coppertone Sport SPF 30. His motion was denied based on the predominance of individual questions of fact regarding reliance, causation, deception and injury. The trial court acknowledged that its decision was the result of confusion about the impact of California's Proposition 64 on the elements of proof for unfair competition law (UCL) class action claims. The trial court stated that it did not believe that California voters intended Proposition 64 to require absent class members to prove actual reliance and damages and that no class would ever be certified under such a rigorous standard. Gaston appealed, arguing that in light of the California Supreme Court's holding in *In re Tobacco II* (46 Cal. 4th 298, 93 Cal. Rptr. 3d 559, 207 P.3d 20 [2009]), the trial court's ruling should be reversed because it was grounded in erroneous legal assumptions. The appellate panel agreed.

Merck's petition for writ of certiorari to the California Supreme Court was denied Nov. 2, 2011.

On July 31, Gaston and Merck submitted a settlement agreement in the coordinated proceeding that provided injunctive relief to a California class of purchasers of the eligible Coppertone products.

#### Nationwide Class

On the same day the California settlement agreement was submitted, Steven Brody, Chaim Hirschfeld and Suzanne Grunstein, through the same counsel representing the California class, sued Merck in the U.S. District Court for the District of New Jersey, alleging substantially similar claims on behalf of a putative nationwide class.

Under the terms of the settlement in the federal suit, Merck agreed to stop using the terms "sunblock," "waterproof," "sweatproof," "all day" and/or "all day protection" in the labeling, advertising, marketing or promotion of its Coppertone products. In addition, it will pay a minimum of \$3 million and a maximum of \$10 million to be used for payments to claimants, claim administration and associated costs, payments to named plaintiffs for incentive awards, the guaranteed cy pres awards and residual payments, if any, to the cy pres recipients.

Settlement class members who purchased an eligible Coppertone product between July 31, 2006, and the date that notice is first disseminated will be eligible to receive up to \$1.50 per product purchased. Claimants may seek reimbursement for purchases of

up to six eligible Coppertone products without proof of purchase.

The guaranteed cy pres payments of \$333,333.333 will be paid to the Legal Aid Foundation of Los Angeles and Legal Services of New York City. Legal Services of New Jersey will receive \$333,333.34.

Counsel

Gary S. Graifman of Kantrowitz, Goldhamer & Graifman in Montvale, N.J., represents the class.

Eric F. Gladbach of Reed Smith in New York represents Merck.

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## EMERGING DRUGS & DEVICES

10-4-2012

### Watson Pain Patch MDL Judge Names Plaintiff, Defense Lead Counsel, Alternates

The Illinois federal judge overseeing the new Watson Pharmaceutical Inc. fentanyl patch multidistrict litigation on Sept. 24 appointed lead and alternative lead counsel for the litigation (*In re* Watson Fentanyl Patch Products Liability Litigation, MDL Docket No. 2372, No. 1:12-cv-6296, N.D. Ill., E. Div.; See August 9, 2012, Page 19).

Michael Heygood of Heygood, Orr & Pearson in Dallas was named plaintiffs' lead counsel. James Orr, Charles Miller and David Pitcher of Heygood Orr were named alternative plaintiffs' lead counsel.

Joseph Thomas of Ulmer Berne in Cincinnati was named defendants' lead counsel. Jeffrey Peck, K.C. Green and Jeffrey Geoppinger were named alternative defendants' lead counsel.

No Plaintiffs' Steering Committee

U.S. Judge Matthew F. Kennelly of the Northern District of Illinois said that at this time, he did not believe it was necessary to appoint a plaintiffs' steering committee.

Watson makes generic fentanyl pain patches, which consist of flat, adhesive fabric envelopes containing fentanyl gel that are prescribed to treat moderate to severe pain. The fentanyl narcotic is absorbed into the skin of patients for pain relief.

Plaintiffs allege that Watson used a defective envelope design rather than a matrix design for the patch and that patients received too much fentanyl too fast, resulting in respiratory depression, injury and even death.

Other Patch Makers Excluded

Watson supported the creation of an MDL but asked the Judicial Panel on Multidistrict Litigation to include cases against all fentanyl patch defendants. Other manufacturers objected, saying they use the matrix design rather than the envelope design.

The judicial panel centralized only Watson cases.

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## EMERGING DRUGS & DEVICES

8-23-2012

### U.S. Supreme Court Won't Review Medical Device Parallel Claim Argument

The U.S. Supreme Court on Oct. 1 declined to review an appeals court ruling that the accuracy range for a drug pump is not part of federal requirements for approval of a device, an appeal ruling that rejected the plaintiff's argument that he claimed paralleled federal requirements and was therefore not preempted by federal regulation (*Sherry Ann Walker, et al. v. Medtronic, Incorporated*, No. 11-1418, U.S. Sup.; 2012 U.S. LEXIS 7789; See February 1, 2012, Page 7).

In 2003, Arnold L. Walker Jr. was implanted with a Medtronic Model 8627-18 SynchroMed EL Programmable Pump to treat chronic back pain. The device consisted of a small drug pump implanted in Walker's abdomen that pumped the prescription narcotic hydromorphone through a catheter into his spine.

In 2005, Walker died from an overdose of hydromorphone and three other prescription pain drugs he was taking. An expert witness for Walker's widow, Sherry Ann Walker, examined the pump and said that 568 milligrams of hydromorphone were unaccounted for and that the pump had malfunctioned and injected Arnold with a fatal overdose.

### Waiting For Riegel

Sherry Ann Walker sued Medtronic Inc. in the U.S. District Court for the Southern District of West Virginia. The case was pending while the U.S. Supreme Court considered medical device preemption in *Riegel v. Medtronic, Inc.* (552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 [2008]; See June 1, 2006, Page 6).

After the high court ruled in *Riegel*, Walker filed an amended complaint arguing that Food and Drug Administration approval required the pump to accurately dispense drugs within plus or minus 15 percent of the set dose. Sherry Ann Walker said that because the pump dispensed hydromorphone outside that limit, her claim paralleled federal requirements for the pump and, thus, is excepted from preemption under *Riegel*.

The District Court granted summary judgment to Medtronic, saying that the accuracy range was not a formal performance standard and that a failure by the device to operate within the 15 percent range is not a violation of premarket approval. Walker appealed.

### 4th Circuit Divided

A divided panel of the Fourth Circuit U.S. Court of Appeals in January said that an accuracy range for the drug pump is not part of federal requirements for approval of the device and that the widow's overdose lawsuit is preempted because it does not parallel federal requirements (See December 2, 2010, Page 13).

Circuit Judge James A. Wynn dissented, saying that the accuracy rate specification is a requirement and that because the device failed to meet that requirement, Walker's claim is not preempted. He noted that she claims that the pump dispensed 258 percent more hydromorphone than it was programmed to.

Walker is represented in the Supreme Court petition by Christopher Brinkley of the Masters Law Firm in Charleston, W.Va. Medtronic is represented by Andrew E. Tauber of Mayer Brown in Washington.

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## MANAGED CARE LIABILITY REPORT

9-19-2012

### California Federal Judge Dismisses Reimbursement Suit, Allows Plaintiff To Amend

A California federal judge on Sept. 14 dismissed a reimbursement suit, saying that a health care provider failed to plead facts sufficient to support its allegation that an insurer had agreed to pay 60 percent of costs related to surgery performed by an out-of-network provider, but allowed the plaintiff to amend its complaint (*Bay Area Surgical Management v. Principal Life Insurance Co.*, No. 12-1140, N.D. Cal.; 2012 U.S. Dist. LEXIS 131639).

(Opinion available 31-120919-033Z)

### Reimbursement Sought

Dr. Marshal Rosarios, a doctor with Bay Area Surgical Management, performed surgery on a patient who had health insurance with Principal Life Insurance Co. Pursuant to the patient's contract with Principal, Principal was required to pay 60 percent of the billed services for qualified surgical procedures.

Prior to the surgery, a Bay Area employee telephoned a Principal employee and was informed that the patient was insured by Principal and that no preauthorization was necessary. Following the surgery, Bay Area billed Principal, but Principal paid only 10 percent of the bill.

Bay Area sued Principal in the U.S. District Court for the Northern District of California, saying that Principal was required to pay 60 percent of the cost of the approved surgical procedures for out-of-network providers. Bay Area asserted claims for breach of contract, violation of California unfair competition law, negligent misrepresentation, promissory estoppel and equitable estoppel.

Principal moved to dismiss, arguing that the Employee Retirement Income Security Act completely preempted the claims and that Bay Area failed to allege any facts supporting a finding that an agreement independent of an ERISA-governed employee medical plan exists between Principal and Bay Area.

### No Preemption

Judge Edward J. Davila denied Principal Life's motion to dismiss based on preemption. Bay Area's claims for breach of contract and unfair competition arise from a contract between Principal and Bay Area and, thus, could not have been brought by a patient against Principal pursuant to ERISA, Judge Davila said.

Further, Bay Area's claims for negligent misrepresentation, promissory estoppels and equitable estoppels all arise from representations made by Principal to Bay Area, stating or implying that Principal would pay for the surgery; therefore, they are not preempted under ERISA, Judge Davila said.

### Conclusory Allegation

However, Bay Area's allegation that Principal was required to pay 60 percent of the cost of approved surgical procedures for out-of-contract providers is conclusory and need not be accepted as true, Judge Davila said.

Bay Area has not alleged any facts in support of its conclusory allegation; thus it has not pleaded facts sufficient to state a plausible claim that the telephone conversation between Bay Area and Principal formed an agreement requiring Principal to pay 60 percent of the surgery costs, Judge Davila said.

Because all of Bay Area's claims depend on the existence of such an agreement, Principal's motion to dismiss for failure to state a claim must be granted, Judge Davila said. He granted the dismissal with leave to amend.

Heather Elizabeth Gibson and Nicolas Matthew Lezotte of The Law Offices of Nicolas Lezotte in Saratoga, Calif., represented Bay Area. Donald Patrick Sullivan of Wilson Elser Moskowitz Edelman & Dicker in San Francisco and Edna Sybil Bailey of Wilson Elser in Chicago represented Principal.

(Additional documents available: Second-amended complaint 31-120919-034C

Dismissal brief 31-120919-035B

Opposition brief 31-120919-036B)

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## MANAGED CARE LIABILITY REPORT

9-19-2012

### N.Y. Federal Judge Dismisses 4 Claims From Breach Of Health Care Contract Suit

A New York federal judge on Aug. 27 dismissed four claims in a breach of contract dispute between an employee benefit fund and a preferred provider network organizer but allowed another claim to continue, saying dismissal would be premature because it was closely tied to another claim not subject to the motion to dismiss (United Benefit Fund, et al. v. MagnaCare Administrative Services, et al., No. 11-4115, E.D.N.Y.; 2012 U.S. Dist. LEXIS 122920).

(Opinion available 31-120919-024Z)

#### Bills Unpaid

United Benefit Fund is an employee benefit fund.

David DeLucia administers the fund, and Andrew Talamo and Thomas D. Ambrosio are trustees of the fund.

MagnaCare Administrative Services and MagnaCare (collectively, MagnaCare) sell access to a network of medical and diagnostic providers in a preferred provider network. The network's participating providers fall into three categories - medical providers, diagnostic providers and hospitals.

In 2006, the fund and MagnaCare entered into an agreement whereby the fund's members would have access to the PPO network in exchange for a per-member monthly access fee. When a fund member receives services from a medical provider, the doctor submits the claim to MagnaCare, which reprices the claim and forwards it to the fund so that the fund can pay the doctor directly. The arrangement differs for diagnostic providers. For diagnostic providers, the fund pays a fee for services provided to a fund member directly to MagnaCare. MagnaCare retains a portion of that money as a management fee and forwards the balance directly to the diagnostic provider. This management fee is different than the monthly fee the fund pays for its members to access the network.

In March 2011, the fund notified MagnaCare that it would be terminating the agreement according to the

agreement's provisions. In May and June 2011, the fund asked MagnaCare for copies of all bills that had been submitted for payment, the amount MagnaCare paid in response to the bills and the amount charged to the fund for each of those bills. MagnaCare refused to provide the information. MagnaCare also stopped processing and repricing claims for the fund despite a contractual obligation to do so during the agreement's 90-day termination notice period.

The fund, fund administrator and trustees sued MagnaCare in the U.S. District Court for the Eastern District of New York, asserting claims for breach of fiduciary duty, breach of contract, fraud and unjust enrichment and seeking injunctive relief.

MagnaCare moved to dismiss all but the breach of contract claim.

#### Fiduciary Duty

MagnaCare argued that it was not a fiduciary and, thus, did not owe the fund any duty.

Under the Employee Retirement Income Security Act, a fiduciary is one who "exercises any discretionary authority or discretionary control respecting management of such plan."

In this case, the question turns on whether the portion of the scheduled diagnostic fee that MagnaCare retained as its management fee was a plan asset, Judge Joanna Seybert said.

The fund has not alleged any contractual basis for considering the scheduled diagnostic fee as a plan asset; in fact, the agreement provides that diagnostic fees "shall not be considered for any purposes as Health Plan assets," Judge Seybert said.

Further, the fund has not alleged that it is entitled to the return of any portion of the diagnostic fees it paid MagnaCare or that it was contingently liable to a diagnostic provider if MagnaCare failed to satisfy its obligation to the provider directly, Judge Seybert said in dismissing the breach of fiduciary duty claim.

#### Dismissed Claims

Judge Seybert dismissed the fraud claim for failure to plausibly plead reasonable reliance, saying the fund's theory offers "no hint why the Fund would continue to pay money on behalf of plan members whom MagnaCare was falsely telling providers were no longer active. Thus, the fund cannot be said to have reasonably relied on MagnaCare's alleged misstatements to providers."

The judge also dismissed the fraudulent concealment claim, saying that because MagnaCare is not plausibly alleged to have been a fiduciary, it had no duty to disclose the billing information the fund requested.

The unjust enrichment claim also must be dismissed because beyond a fiduciary obligation, which MagnaCare does not have, and a contract obligation, which is not the subject of the instant motion, the fund has not alleged an obligation running from MagnaCare to the fund that would support an independent unjust enrichment claim, Judge Seybert said.

#### Claim Continues

The fund's injunctive relief request essentially seeks to enjoin MagnaCare to require the company to process the fund's claim in accordance with the party's agreement. The request, however, is closely tied with the breach of contract claim, which is not subject to the pending motion, so dismissal would be premature, Judge Seybert said.

Andrew A. Gorlick and Deke W. Bond of Gorlick, Kravitz & Listhaus in New York represent the plaintiffs. Daly Temchine of Epstein Becker Green in Washington, D.C., and John William Cook of Epstein Becker & Green in New York represent the defendants.

(Additional documents available: Dismissal brief 31-120919-025B

Opposition brief 31-120919-025B)

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## MANAGED CARE LIABILITY REPORT

9-19-2012

### Federal Judge Declines To Reconsider Dismissal Of Contraceptive Mandate Case

A District of Columbia federal judge on Sept. 5 denied a motion for reconsideration made by a Christian university challenging the dismissal of its case alleging that the Patient Protection and Affordable Care Act (PPACA) mandate requiring all health plans to provide "preventative services" for free, including those for birth control, violates the rights of religious organizations, saying that the plaintiff's motion stated arguments already presented to the

court (*Belmont Abbey College v. Kathleen Sebelius, et al.*, No. 11-1989, D.D.C.; 2012 U.S. Dist. LEXIS 125519; See August 1, 2012, Page 5).

(Order available 31-120919-016R)

On July 18, U.S. Judge James E. Boasberg of the District of Columbia District Court dismissed Belmont College Abbey's case against Kathleen Sebelius, secretary of Health and Human Services; the Department of Health and Human Services; Hilda Solis, secretary of Labor; the U.S. Department of Labor; Timothy Geithner, secretary of Treasury; and the Department of Treasury, saying that the plaintiff's injury is "too speculative" to confer standing and that the case is not ripe.

In the case, Belmont Abbey alleged that the mandate contained in the PPACA requiring that all health plans provide free "preventative services" unconstitutionally coerces the college into violating its religious beliefs under the threat of penalties and fines. The preventive services include vaccines and routine screenings such as cholesterol checkups and mammograms. Belmont Abbey also contended that the mandate forces the college "to fund government-dictated speech that is directly at odds with its own speech and religious teachings."

#### Old Matters

Belmont Abbey asked the court to reconsider the dismissal, but Judge Boasberg said the university was "simply re-raising arguments set forth" in its opposition to dismissal and that motions to reconsider could not be used to relitigate old matters.

Belmont Abbey attached a declaration and eight Equal Employment Opportunity Commission determination letters, which indicated that it has been the subject of several equal opportunity complaints regarding its denial of contraceptive benefits. The complaints, however, do not relate to the PPACA's regulation but arise under Title VII's sex-discrimination provisions, Judge Boasberg said. Further, the letters are all dated July 30, 2009, and Belmont did not offer any reason why it could not have submitted the documents with its opposition to dismissal, the judge added.

Eric Rassbach, Mark Rienzi, Hannah C. Smith and Eric N. Kniffin of The Becket Fund for Religious Liberty in Washington represent Belmont Abbey. Assistant Attorney General Tony West, Deputy Assistant Attorney General Ian Heath Gershengorn,

U.S. Attorney Ronald C. Machen Jr., Deputy Director Sheila M. Lieber and attorney Michelle R. Bennett of the U.S. Department of Justice in Washington represent the defendants.

(Additional document available Motion for reconsideration 31-120919-017M)

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## MANAGED CARE LIABILITY REPORT

10-3-2012

### Health Insurer's Antitrust Claims Against Physicians May Continue, Federal Judge Rules

Humana Health of Puerto Rico Inc., a health insurer, sufficiently alleged that eight physicians violated federal and state antitrust laws by price fixing, a federal judge in Puerto Rico ruled Sept. 17 in denying the physicians' motion to dismiss (*Humana Health of Puerto Rico, Inc. v. Juan L. Vilaro, et al.*, No. 12-1445, D.P.R.).

(Opinion and order available 81-120927-011Z)

Humana administers certain regions of the Puerto Rico government's health insurance program, known as Mi Salud, providing healthcare coverage to indigent individuals in those regions who are eligible for Mi Salud. Humana signed contracts with Juan L. Vilaro and seven other nephrologists for the provision of nephrology services to Mi Salud beneficiaries in the Southwest and Southeast regions. The contracts included language governing the coordination of benefits (COB) for Mi Salud patients when Medicare is the primary payer.

Humana alleged that the nephrologists demanded that Humana pay them higher COB payments than those contractually agreed upon and notified Humana that they were terminating their provider agreements. According to Humana, the termination of the provider agreements was "a coordinated and concerted effort by [the eight nephrologists] to force Humana to pay them higher prices for their services."

Humana sued the eight nephrologists, alleging that the doctors violated Section 1 of the Sherman Act and the Puerto Rican Antitrust Act by engaging in



price fixing and group-boycott activities. Humana alleged that the physicians “are deliberately creating a health crisis,” and Humana sought injunctive relief and damages. Humana also alleged tortious interference with contractual relations and breach of contract.

The nephrologists moved to dismiss and counter-claimed, alleging that Humana breached its contracts with them by failing to pay them according to the coordination of benefits provisions of their contracts.

#### ‘Concerted Behavior’

U.S. Judge Gustavo A. Gelpi of the District of Puerto Rico denied the nephrologists’ motion to dismiss, concluding that “the complaint sufficiently raise[s] the right to relief beyond a speculative level.”

Humana “specifically sets forth that Defendants included one another in attempted negotiations with Plaintiff via email, copied one another on each other’s notifications of termination to Plaintiff, and jointly provided a table setting forth proposed, higher rates required as a condition to continue providing services to certain patients. . . . Such actions ostensibly reflect concerted behavior, rather than unilateral conduct. Unilateral decisions to rebuke an agreement or breach a contract do not give rise to antitrust infringement; however, collaborative efforts to boycott and price-fix offend Section 1,” the judge said.

Judge Gelpi rejected the physicians’ claim that Humana “cloaks a contract claim in an antitrust claim,” noting that Humana alleges physician price-fixing and boycotting and “consequent injuries to itself and the community due to Defendants’ refusal to treat certain patients.”

Humana is represented by Herman G. Colberg-Guerra and Jason R. Aguilo Suro of Pietrantonio Mendez & Alvarez in San Juan. The physicians are represented by Carlos A. Del Valle Cruz of Del Valle Law in Old San Juan.

(Additional documents available: Complaint 81-120927-012C

Amended counterclaim 81-120927-013C

Motion to dismiss complaint 81-120927-014B

Humana’s opposition 81-120927-015B)

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## MANAGED CARE LIABILITY REPORT

10-3-2012

### Maine Federal Judge Orders State To Pay Attorney Fees In Drug Privacy Case

A Maine federal judge on Sept. 28 ordered the State of Maine to pay attorney fees to plaintiffs who won a challenge to stop the state from implementing the state’s prescription privacy law (IMS Health Corp., et al. v. Schneider, attorney general of the state of Maine, No. 07-127, D. Maine; 2012 U.S. Dist. LEXIS 140180; See March 5, 2008, Page 17).

(Opinion available 31-121003-022Z)

Order Vacated

IMS Health Corp., Verispan LLC and Source Healthcare Analytics sued Maine’s attorney general in the U.S. District Court for the District of Maine to stop enforcement of Maine’s Prescription Privacy Law. The plaintiffs are prescription drug information intermediaries.

The law would have amended 22 Maine Revised Statute Annotated (M.R.S.A.) Sections 1711-E, 8704 and 8713 (2007) and allowed prescribers of medication to demand confidentiality by preventing pharmaceutical companies from using their individualized prescribing information to market them or others.

Besides the suit in Maine, the plaintiffs challenged similar laws in New Hampshire and Vermont with the U.S. Supreme Court, ultimately ruling in the Vermont case of William H. Sorrell, et al. v. IMS Health Inc., et al. (131 S. Ct. 2653, 180 L. Ed. 2d 544 [2011; See July 6, 2011, Page 21]) that law restricting prescribing data is unconstitutional. Following the Supreme Court’s decision in Sorrell, the parties in the Maine case filed in August 2011 a stipulation with the First Circuit U.S. Court of Appeals - where an appeal of the dismissal of the case was pending - agreeing that the case should be remanded to the District Court with instructions to vacate the order of dismissal.

The District Court retained jurisdiction to determine entitlement and amount of attorney fees, if any, to be awarded to the plaintiffs.

The plaintiffs moved for \$1,307,252.15 in attorney fees, expenses and costs. The defendants opposed the motion, saying the plaintiffs were requesting a “kingly sum.” Should the court grant the motion, the defendants contended that the hourly fees should be reduced by 80 percent to reflect “over-staffing,” “duplication” and work “spent on failed claims.”

#### Award Granted

Judge John A. Woodcock Jr. granted a reduced amount of \$678,189.64. In granting the motion, Judge Woodcock said the plaintiffs were clearly entitled to an award, saying the statute “would have had a profound, potentially devastating impact on Plaintiffs’ business.”

“In seeking to have the statute declared an unconstitutional infringement of their First Amendment right to free speech, the Plaintiffs were not merely fighting for their economic survival, they were also seeking more generally to vindicate the preeminence of the First Amendment over a legislative enactment,” Judge Woodcock said.

In reducing the amount, Judge Woodcock said the plaintiffs were entitled to reimbursement for approximately 30 percent of their appellate time at the First Circuit, which is an amount that roughly coincides with the fact that the plaintiffs were successful on one out of the three issues on appeal.

Judge Woodcock also excluded some entries as unnecessary, reduced the amount of hours billed and reduced some of the hour rates after finding them excessive.

Jamie Zysk Isani and Thomas R. Julin of Hunton & Williams in Miami, John H. Montgomery of Bernstein Shur in Portland and Mark A. Ash of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan in Raleigh, N.C., represented the plaintiffs. Thomas A. Knowlton, Nancy M. Macirowski, Thomas C. Bradley and Paul Stern of the Attorney General’s Office in Augusta, Maine, represented the attorney general.

(Additional documents available: Motion/brief for fees 31-121003-023B

Opposition brief 31-121003-024B)

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## MANAGED CARE LIABILITY REPORT

10-3-2012

### Federal Judge Affirms HHS Ruling That Hospitals Are Not ‘New’ Under Medicare

A federal judge on Sept. 19 denied a motion for summary judgment against the U.S. Department of Health and Human Services (HHS) challenging a department order by Secretary of Health and Human Services Kathleen Sebelius that denied the plaintiff hospitals’ request to special status as a “new” hospital for purposes of reimbursement under the Medicare statute (Select Specialty Hospital - South Dallas, et al., v. Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services, No. 09-2008, D.D.C., 2012 U.S. Dist. LEXIS 134795).

(Opinion available 31-121003-506Z)

The plaintiffs, Select Specialty Hospital-owned hospitals, originally filed the challenge to their status as “new” hospitals pursuant to the Administrative Procedure Act (APA). The plaintiff facilities argued that HHS’s Provider Review and Reimbursement Board incorrectly determined that the facilities were not new hospitals under 42 Code of Federal Regulations Section 412.300(b), which provides special reimbursement status under the Medicare statute. The U.S. District Court for the District of Columbia on March 31, 2011, denied the Select Specialty Hospitals’ motion for summary judgment, saying the board’s interpretation of the regulation was reasonable and supported by substantial evidence.

However, the District Court found that there were insufficient facts to determine whether the board intended to treat Select Specialty-South Dallas Inc. and Victoria Healthcare Inc. - both freestanding hospitals - as “new hospitals,” and the issue was remanded to HHS for further explanation.

Upon remand to the department, Sebelius determined that the freestanding hospitals were not new hospitals under the regulation and the instant lawsuit was filed, challenging the decision under the APA.

### Section 412.300(b)

Under Medicare, new hospitals are reimbursed for capital-related costs at 85 percent of their “reasonable” costs. Section 412.300(b) states that a hospital is new if it “has operated (under previous or present ownership) for less than two years” and specifically excludes a hospital that builds new or replacement facilities at the same or another location; a hospital that closes and subsequently reopens; a hospital that has been in operation for more than two years but has participated in the Medicare program for less than two years; or a hospital that changes its status from a hospital that is excluded from Medicare’s prospective payment system to a hospital that is subject to the capital prospective payment systems, U.S. Judge Richard J. Leon of the District of Columbia explained.

The rule in Section 412.300(b) was designed to assist hospitals “without a historic asset base to cover the start-up costs associated with their entry into the Medicare program,” Judge Leon said.

The South Dallas and Victoria freestanding hospitals challenged the HHS’s interpretation of section 412.300(b), calling the regulation ambiguous.

#### Operated As Medical Facilities

South Dallas began operating in August 2002 at a site that from August 1994 to February 2000 was operated as a medical facility. Between 2000 and 2002, the site was not operated as a medical facility or hospital. Victoria began operating in 2003 at a facility site that from October 1982 to September 1993 was used as a “going medical concern.” However, between 1993 and 2003, the facility was used for nonmedical purposes. Both freestanding hospitals redesigned and reconstructed the facilities and sought reimbursement of these start-up costs as capital-related costs for a new hospital.

HHS determined that these two freestanding hospitals did not qualify as new hospitals under Section 412.300(b).

While Judge Leon agreed that the regulation is ambiguous, he found that HHS’s interpretation of the regulation was reasonable.

#### New Hospital Status Rejected

“Relying on ‘the plain reading of the regulation,’ the Secretary found that the freestanding hospitals did

‘not qualify as new hospitals’ because (1) the freestanding hospitals had ‘both occupied buildings which had previously operated as hospitals for longer than two years;’ (2) ‘the regulation did not require that the two years of operation under present or prior ownership . . . occur immediately preceding the start-up cost reporting period;’ and (3) ‘requiring the two years to occur immediately preceding would conflict with the purpose of the new hospital exemption and produce illogical results,’ ” the judge explained.

South Dallas and Victoria argued that while the HHS originally concluded that the term “hospital” includes both the physical facility and the operation of the facility, HHS concluded that it will consider a freestanding hospital in the context of “only the physical structure of the building in which the hospital occupies.” The plaintiff facilities stated, therefore, that the new application of the term “hospital” is unreasonable because it ignores the plain meaning of the regulation and the HHS’s original interpretation leads to “illogical” results.

However, Judge Leon disagreed, saying that the secretary’s analysis in both cases reflects that a hospital is composed of both an operating entity and a physical facility.

“[T]he Secretary’s most recent decision required in ‘inquiry into whether either the operating institution or the physical facility has previously operated for a period of two years,’ ” Judge Leon said. “The freestanding hospitals’ physical facilities had operated as hospitals for more than two years and ‘the fact that there was a time gap between the operation of the previous hospitals . . . and the subsequent start-up of the two free-standing hospitals at issue here did not change the fact that the hospital asset in use by these Providers is a hospital asset which was previously used for more than two years.’ ”

South Dallas and Victoria are represented by Andrew C. Bernasconi and Daniel Z. Herbst of Reed Smith and Jason M. Healy of the Law Offices of Jason M. Healy. HHS is represented by Javier M. Guzman and Mitchell P. Zeff of the U.S. Attorney’s Office. All attorneys are in Washington.

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