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### ARTICLE

#### **CLINICAL USE OF PLACEBOS: MEDICINE, NEUROSCIENCE, ETHICS AND THE LAW**

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"Be enthusiastic. Remember the placebo effect:  
30% of medicine is showbiz." ~ Ronald Spark

*My patient, a twenty-eight year old woman, presented with a three-week history of constant twitching of her left lower eyelid. She found it distracting and annoying, albeit it did not impair her vision. She had no other ocular symptomatology. Past ocular and medical histories were unremarkable, and she took no medications. She was preoccupied with a toxic divorce, which was traumatizing her eight-year-old son. She noted difficulty falling and staying asleep. Six weeks prior, her internist pronounced her a healthy but stressed woman. My examination revealed left lower orbicularis myokymia, i.e., spontaneous, involuntary twitching of the left lower eyelid. Her ocular examination was otherwise unremarkable, with no signs of foreign body, allergy, or dryness.*

*Myokymia is usually caused by anxiety and insomnia. I offered her a choice of two highly successful but fundamentally different treatments. Treatment #1 relies on the alternate use of hot packs and ice packs in succession for five minutes, four times a day, along with artificial tears. She was instructed to perform this regimen for one week then report the results directly to me. I*

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*assured her that over ninety percent of my patients had success with this intervention; however, I did not know how or why it works. I hypothesized that the temperature differential shocks the muscle and restores normal tone. Treatment #2 relies on the pharmaceutical, botulinum toxin (Botox). Ten micrograms of Botox injected into the lower eyelid will paralyze the twitching muscle within forty-eight hours. The effect lasts three to four months. Potential complications include superficial hemorrhage and a sagging eyelid.*

*Patients invariably ask what I suggest, often framing the question, "What would you recommend if I were your daughter/mother/father/brother?" In my view, the choice was clear. I suggested trying treatment #1 and holding #2 in reserve. Treatment #1 was cheap, easy, and free from side effects. Treatment #2 had a higher success rate (98%) but was expensive (\$300) and riskier. Treatment #1 has been the unanimous selection for over two decades. Treatment #1 is a placebo. There is no scientific basis for its efficacy. In fact, the "shocks the muscle" theory is ipse dixit. Is this good medicine? Did I do the right thing for my patient? Should I have injected Botox into her eyelid and given her "real" medicine? This paper will discuss those considerations.*

### **I. Introduction**

When I am sick, I go to my doctor. She takes a history, does a physical examination, and tells me what is wrong. I expect that she will tell me what medicine to take, what exercises to do, what to eat or what surgery is needed. I want an answer and a solution. My thinking can be summed up in just one phrase, "Fix it!" But what if there is no medicine, no treatment, nothing to do about the condition? What then? I still want some remedy that will help me. My doctor wants me to be satisfied with her care and to feel better. Perhaps she will recommend a pill or an

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exercise with no inherent therapeutic value—a placebo—instead of sending me on my way, empty-handed. Is it a good idea? Would other doctors do the same thing?

This paper scrutinizes the use of placebos in clinical medicine from four different perspectives. Section I introduces the subject. Section II defines the essential terms and considers the power of the placebo effect in medical practice. Section III evaluates the clinical treatment of patients with placebos from the physician's perspective. The neuroscience of the placebo effect is explicated in Section IV. Section V contemplates the ethical implications of placebo treatment. Jurisprudential concerns are the subject of Section VI. Section VII discusses inappropriate and appropriate clinical use of placebos. Section VIII contains my conclusion.

### II. Definitions and Initial Considerations

Placebo is Latin for, "I shall please."<sup>2</sup> In order to discuss placebos or the placebo effect, it is necessary to define the terms. The most famous description of a placebo was written by J.H. Gaddum.

Such tablets are sometimes called placebos, but it is better to call them dummies. According to the Shorter Oxford Dictionary the word placebo has been used since 1811 to mean a medicine given more to please than to benefit the patient. Dummy tablets are not particularly noted for the pleasure which they give to their recipients. One meaning of the word dummy is "a counterfeit object." This seems to me the right word to describe a form of treatment

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<sup>2</sup> Sissela Bok, *The Ethics of Giving Placebos*, SCI. AM., Nov. 1974, at 17.

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which is intended to have no effect and I follow those who use it. A placebo is something which is intended to act through a psychological mechanism. It is an aid to therapeutic suggestion, but the effect which it produces may be either psychological or physical. It may make the patient feel better without any obvious justification, or it may produce actual changes in such things as the gastric secretion. . . . Dummy tablets may, of course, act as placebos, but, if they do, they lose some of their value as dummy tablets. They have two real functions, one of which is to distinguish pharmacological effects from the effects of suggestion and the other is to obtain an unbiased assessment of the result of the experiment.<sup>3</sup>

A placebo is defined as a substance with no known specific pharmacological activity for the condition being treated.<sup>4</sup> Broadly speaking, any therapeutic procedure lacking potency to treat the disorder in question is a placebo.<sup>5</sup> A placebic intervention is a diagnostic or therapeutic pretense—an intervention using substances or physical methods having no direct pharmacological, biochemical, or physical mechanism of action. Therefore, the term includes not only the administration of sugar tablets or isotonic

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<sup>3</sup> J. H. Gaddum, *Walter Ernest Dixon Memorial Lecture: Clinical Pharmacology*, 47 PROC. ROYAL SOC'Y MED. 195, 197 (1953).

<sup>4</sup> Howard Brody, *Placebo*, in ENCYC. OF BIOETHICS 1951-52 (W.T. Reich, ed., 1995).

<sup>5</sup> Arthur K. Shapiro, *The Placebo Effect in the History of Medical Treatment: Implications for Psychiatry*, 116 AM. J. PSYCHIATRY 298, 289-99 (1959).

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saline solution, as is commonly thought, but also a wide variety of non-drug interventions.<sup>6</sup>

Placebos are further subdivided into three types. The first type, "pure" placebo, is an inert substance without known pharmacological effect, such as a sugar pill, isotonic saline solution or colored water. "Impure" placebos, the second type, are substances or methods that have known pharmacological or physical activity but have no direct therapeutic effect on the disease extant.<sup>7</sup> In other words, an impure placebo is a real drug, i.e., an ethical pharmaceutical with a physiological effect, used to treat a disorder for which it is known to be ineffective. Any prescription medication may be used as an impure placebo. Common examples include antibiotics, thyroid hormone, or megavitamins prescribed when there is no bacterial infection, hypothyroidism, or vitamin deficiency. Alternatively, pharmacologically active substances may be prescribed in doses so miniscule that they have no significant therapeutic value. Highly diluted medications used in homeopathy or naturopathy arguably constitute impure placebos. The third category is a subdivision of the pure placebo, which constitutes intervention. Classic examples include simulated surgery and hypodermic saline injections. Other modalities such as acupuncture, behavior modification and biofeedback are probably placebic as well.<sup>8</sup>

The use of placebos relies on the placebo effect or placebo response. Placebos can be therapeutically beneficial to some patients when they give rise to the

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<sup>6</sup> Margrit Fässler, Markus Gnädinger, Thomas Rosemann & Nikola Biller-Andorno, *Use of Placebo Interventions Among Swiss Primary Care Providers*, BMC HEALTH SERVICES RES. 3 (2009), <http://www.biomedcentral.com/content/pdf/1472-6963-9-144.pdf>.

<sup>7</sup> *Id.* at 2.

<sup>8</sup> Marshall B. Kapp, *Placebo Therapy and the Law: Prescribe With Care*, 8 AM. J. L. & MED. 371, 374 (1982).

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placebo effect.<sup>9</sup> As explained by Howard Brody, M.D., Ph.D., “the ‘placebo effect’ refers to an intervention in which the psychological and psychosomatic benefits cannot be fully explained by the strictly biochemical aspects of the therapy. While pharmacologically ‘inert,’ the placebo is not truly ‘inert’ in any useful sense; an intervention which fails to follow our preconceived mechanisms is no less of an intervention.”<sup>10</sup> Any change in a patient’s condition attributable to symbolic aspects of the overall care in lieu of the medicinal qualities of the substance prescribed signifies the placebo effect.<sup>11</sup> The placebo effect is “assumed to occur in patients taking active drugs and therefore to account for some fraction of that drug’s total therapeutic effect.”<sup>12</sup>

If placebos were ineffective, there would be little interest in the subject, but they are anything but ineffective. Henry K. Beecher, M.D., performed a meta-analysis of fifteen studies involving over 1000 subjects. He determined that placebos have an average effectiveness rate of 35.2% ± 2.2%.<sup>13</sup> Other studies document the placebo effect in five percent and forty-two percent of individuals.<sup>14</sup> For example, in the prospective study of psychiatric patients, forty-five percent of the placebo administrations were rated as successful.<sup>15</sup>

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<sup>9</sup> Brody, *supra* note 4, at 1952.

<sup>10</sup> Howard Brody, *On Placebos*, 5 HASTINGS CTR. REP. 17, 18 (1975).

<sup>11</sup> Howard Brody, *The Placebo Response: Recent Research and Implications for Family Medicine*, 49 J. FAM. PRAC. 649, 650 (2000).

<sup>12</sup> Arthur J. Barsky, Ralph Saintfort, Malcolm P. Rogers & Jonathan F. Borus, *Nonspecific Medication Side Effects and the Nocebo Phenomenon*, 287 JAMA 622, 623 (2002).

<sup>13</sup> Henry K. Beecher, *The Powerful Placebo*, 159 JAMA 1602, 1604-05 (1955).

<sup>14</sup> Margrit Fässler, Karin Meissner, Antonius Schneider & Klaus Linde, *Frequency and Circumstances of Placebo Use in Clinical Practice - A Systematic Review of Empirical Studies*, BMC MED. 5 (2010), [www.biomedcentral.com/content/pdf/1741-7015-8-15.pdf](http://www.biomedcentral.com/content/pdf/1741-7015-8-15.pdf).

<sup>15</sup> *Id.*

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Conversely, not all physicians are convinced about the power of the placebo. Asbjorn Hrobjartsson systematically reviewed 114 clinical trials in which 8,525 patients with various clinical conditions were randomized to placebo or to no active treatment.<sup>16</sup> Both groups actually received a placebo but only one group was informed it was a placebo; the other group was led to believe active medication was being dispensed. Consequently, both the placebo group and the “no treatment” group received exactly the same treatment. The placebos used were: (1) sugar pills; (2) procedures performed with nonfunctioning equipment (e.g., transcutaneous electrical nerve stimulation with the device unplugged); and (3) pseudo-psychotherapy (nondirectional, neutral discussion between patient and treatment provider). No treatment entailed observation only or standard therapy only; when standard therapy was employed, the placebo was additional.

Forty different clinical conditions were investigated including, *inter alia*, pain, high blood pressure, high cholesterol, smoking, depression and obesity. Only trials involving analgesia showed a statistically significant difference in effect between the placebo and the “no treatment” groups. Slight but insignificant placebo effects were observed for obesity, hypertension, and insomnia. No effects were evident for all the remaining conditions. The authors concluded that the “use of placebo outside the aegis of a controlled, properly designed clinical trial cannot be recommended.”<sup>17</sup>

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<sup>16</sup> Asbjørn Hróbjartsson & Peter C. Gøtzsche, *Is the Placebo Powerless? An Analysis of Clinical Trials Comparing Placebo with No Treatment*, 344 NEW ENG. J. MED. 1594, 1594 (2001).

<sup>17</sup> *Id.* at 1599 (The forty conditions investigated were hypertension, asthma, anemia, hyperglycemia, hypercholesterolemia, seasickness, Raynaud’s disease, alcohol abuse, smoking, obesity, poor oral hygiene, herpes simplex infection, bacterial infection, common cold, pain, nausea, ileus, infertility, cervical dilatation, labor, menopause, prostatism, depression, schizophrenia, insomnia, anxiety, phobia,

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The degree of placebo effect often depends on the nature of the intervention, i.e., some treatment modalities are more efficacious than others. In general, injections are more potent than oral medication, capsules work better than tablets, brightly colored remedies are more efficacious than muted colors, and two pills work better than one.<sup>18</sup>

### III. Placebos in Clinical Medicine

For practicing physicians, there are clear advantages and disadvantages to the clinical use of placebos. Each practitioner must weigh the benefits and risks in any given circumstance and decide whether placebo use is indicated. This section will consider the pros and cons of placebo use as well as its impact on health care.

#### A. Pros

Placebos are arguably an ideal treatment. Numerous studies demonstrate the efficacy of the little “sugar pill.” These inert substances or simulated treatments fundamentally lack organic side effects.<sup>19</sup> Placebos are considerably less dangerous than genuine drugs because they confer no direct toxicity.<sup>20</sup> There is no physical risk; thus, the dominant consideration is efficacy.

In general, doctors are acutely aware of the vicissitudes of medicine and the challenge of giving meaningful, comprehensible and correct answers to

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compulsive nail biting, mental handicap, marital discord, stress related to dental treatment, orgasmic difficulties, fecal soiling, enuresis, epilepsy, Parkinson’s disease, Alzheimer’s disease, attention-deficit-hyperactivity disorder, carpal syndrome, and undiagnosed ailments).

<sup>18</sup> DAN J. TENNENHOUSE, 3 ATTORNEY’S MEDICAL DESKBOOK § 38.2.40 (4th ed. 2006 & Supp. 2010).

<sup>19</sup> Brody, *supra* note 10, at 18.

<sup>20</sup> Paul Enck, Fabrizio Benedetti & Manfred Schedlowski, *New Insights into the Placebo and Nocebo Responses*, 59 NEURON 195, 202 (2008).



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patients. There are diseases that are untreatable but patients insist on some instrumentality. If nothing is offered, patients depart feeling dissatisfied, neglected, and shortchanged. If they feel worse at the conclusion of the visit than at its inception, the encounter has been a disaster and the doctor-patient relationship is in peril. The placebo effect can confer a therapeutic advantage even when there is no effective treatment. When the disease is incurable and the situation is hopeless, the placebo offers a “treatment” option. When their physical or psychological needs remain unattended, there is a danger that patients will go doctor-shopping and receive inappropriate or overly aggressive medical care from a less skilled or more self-serving healthcare provider. Perhaps the patient will resort to dangerous Google self-treatment.

Patients often present with vague, non-specific complaints that are not pathognomonic for any particular illness. Underlying psychological or situational difficulties are frequently the genesis of these symptoms. Rather than resort to speculative polypharmacy, a placebo may be both less toxic and more effective. If the problem disappears with the placebo, it was most likely psychogenic. Side effects and drug habituation are avoided.

A study of Swiss healthcare providers revealed the most common indications or reasons for placebo use:

1. pain
2. insomnia
3. anxiety
4. risk of substance abuse
5. difficult or demanding patients
6. patient request
7. to invoke the placebo effect
8. to avoid conflict with patients
9. as a supplement to standard treatment
10. for non-specific symptoms

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11. to avoid informing patients that treatment possibilities were exhausted.<sup>21</sup>

### B. Cons

When placebo use displaces comprehensive medical evaluation and treatment, the placebo effect may mask symptoms and delay the indicated treatment of the medical condition.<sup>22</sup> One of the most egregious examples of placebo use in lieu of well-established treatment occurred in rural Alabama between the years 1932 and 1972.<sup>23</sup> During the period, African-American men were screened for “bad blood” and then lured into a government sponsored “treatment” program. In reality, the United States Public Health Service screened these men for tertiary syphilis. Rather than receiving penicillin, 399 infected men were treated with placebos. They were neither informed about their syphilitic infection nor given information regarding its treatment or prevention. The purpose of the study, inconceivable in this day and age, was to study the long-term effects of an untreated disease.<sup>24</sup> Catastrophes like this remind us of other dark periods in human history when people were abused or tortured based solely on their race or religion. Unfortunately, the use of placebos is sometimes viewed through this lens.

The antithesis of the placebo effect is the “nocebo phenomenon.”<sup>25</sup> While placebos produce beneficial results, like genuine therapeutic agents, they can have associated toxic, or nocebo, effects. Beecher observed thirty-five

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<sup>21</sup> Fässler, *supra* note 6, at 5.

<sup>22</sup> Paul Hébert, Barry Hoffmaster, Kathleen Glass & Peter Singer, *Bioethics For Clinicians: Truth Telling*, 156 CAN. MED. ASS’N J. 225, 226 (1997).

<sup>23</sup> Amy L. Fairchild & Ronald Bayer, *Uses and Abuses of Tuskegee*, SCIENCE, May 7, 1999, at 919.

<sup>24</sup> *Id.*

<sup>25</sup> Barsky, *supra* note 12, at 622.

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different toxic effects of placebos. The incidence of side effects was: dry mouth, nine percent; nausea, ten percent; sensation of heaviness, eighteen percent; headache, twenty-five percent; difficulty concentrating, fifteen percent; drowsiness, fifty percent; warm glow, eight percent; relaxation, nine percent; fatigue, eighteen percent; and sleep, ten percent.<sup>26</sup> Professor Marshall B. Kapp noted placebo-related side effects in five to ten percent of patients.<sup>27</sup> His list of observed nocebo effects was even more comprehensive: nausea, thirst, headache, dizziness, sleepiness, insomnia, fatigue, depression, numbness, vomiting, tremor, fast heart beat, hives, diarrhea, blood pressure changes, pallor, skin rashes, swelling, and unsteady gait.<sup>28</sup>

Medical students were evaluated in a clinical trial using placebos to assess nocebo effects on otherwise normal subjects.<sup>29</sup> Twelve subjects were each given red and white gelatin capsules with lactose, green, and yellow gelatin capsules with lactose, or a drink of water.<sup>30</sup> The students taking the colored capsules reported the following fourteen symptoms: flushing of face, euphoria, anxiety, irritability, restlessness, inability to concentrate, thirst, tremors, sedation, headache, bradycardia, dysphoria, flatulence, and diuresis.<sup>31</sup> Moreover, eight of twelve of the red/white group and ten of twelve of the green/yellow group reported side effects from the placebos.<sup>32</sup>

Placebo treatment can be costly. Many individuals correlate effectiveness with cost. In other words, *the cheap*

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<sup>26</sup> Beecher, *supra* note 13, at 1603.

<sup>27</sup> Kapp, *supra* note 8, at 375.

<sup>28</sup> *Id.*

<sup>29</sup> C.W. Gowdey, J.T. Hamilton & R.B. Philp, *A Controlled Clinical Trial Using Placebos in Normal Subjects: A Teaching Exercise*, 96 CAN. MED. ASS'N J. 1317, 1317 (1967).

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 1318.

<sup>32</sup> *Id.* at 1319-20.

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*stuff is garbage.* Spurious procedures still require equipment and professional time. Taken to extremes, the cost of a fictitious surgical procedure complete with an operating room, personnel, and surgical packs would be enormous. Even when the patient pays the price, the efficacy of the placebo effect is still questionable in any given circumstance.

There are emotional risks to the long-term use of placebos. In general, the potency of the placebo effect diminishes with time, inducing something akin to tachyphylaxis. Psychological dependency may develop, requiring increasingly large doses of placebo and withdrawal symptoms when administration ceases.<sup>33</sup>

Fässler<sup>34</sup> extensively analyzed the frequency of placebo use in clinical medicine by reviewing twenty-two studies conducted from 1973 to 2009. The percentage of physicians who reported using placebos at least once was highly variable. Between seventeen and eighty percent used pure placebos; fifty-four to fifty-seven percent used impure placebos; and forty-one to ninety-nine percent used pure and/or impure placebos. Saline injections, sugar pills or prepared placebo tablets were the most popular modalities. Impure placebos included antibiotics for viral infections as well as vitamins and analgesics for problematical indications. The results indicated that a significant proportion of physicians and nurses have used pure placebos at some point in clinical situations, but the number of frequent users was *de minimis*. Impure placebos, especially superfluous antibiotics, were more likely to be used with frequency.

Placebo use among Swiss primary care providers has been closely studied.<sup>35</sup> Seventy-six percent of the two

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<sup>33</sup> Oldrich Vinar, *Dependence on a Placebo: A Case Report*, 115 BRIT. J. PSYCHIATRY 1189, 1190 (1969).

<sup>34</sup> Fässler, *supra* note 14, at 2.

<sup>35</sup> Fässler, *supra* note 6, at 1.

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hundred doctors polled have used bland ointments and/or bandages for contusions without any apparent skin damages. Sugar pills and saline injections were only used by ten percent. Almost two thirds of doctors have prescribed therapies, such as vitamins or antibiotics, without an approved indication or an expectation of efficacy. Regarding diagnostic exams, the sophistication of the test was inversely proportional to the frequency of its use. Eighty-nine percent of physicians admitted to performing unnecessary physical exams; sixty-nine percent ordered non-essential technical exams with no inherent risk (e.g., ultrasound, MRI); and thirty-one percent prescribed non-essential technical exams with some inherent risk (e.g., CT scans).

Americans receive a considerable amount of placebo-related care without being cognizant of it. One-third of Americans turn to alternative medicine, including massage, homeopathy, spiritual healing, and megavitamins.<sup>36</sup> Evidently, the total number of visits to non-allopathic care providers each year exceeds the number of visits to primary care physicians. While self-styled healers and their patients are convinced of the efficacy of megavitamins and herbal potions, these popular remedies derive their benefit predominantly from the placebo effect.<sup>37</sup>

There is considerable evidence to suggest that homeopathy is placebo medicine. Dr. Wayne B. Jonas analyzed four independent, comprehensive reviews to evaluate whether homeopathic remedies and placebos were equivalent in double-blind, randomized studies.<sup>38</sup> All homeopathic remedies are highly diluted; a small quantity

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<sup>36</sup> Walter A. Brown, *The Placebo Effect*, SCIENTIFIC AMERICAN, Jan. 1998 at 90, 95.

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

<sup>38</sup> Wayne B. Jonas, Ted J. Kaptchuk, & Klaus Linde, *A Critical Overview of Homeopathy*, 138 ANNALS INTERNAL MED. 393, 395 (2003).

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of either a 1:10 or 1:100 solution is further diluted six to twelve times.<sup>39</sup> For the higher dilution (1:100 x 12), the probability of finding a single molecule of the “active” ingredient in a one-liter volume is sixty percent. In other words, if you drink a quart of the concoction, about one half of the time you will ingest a single molecule of the “active” ingredient. Because the doses are virtually non-existent, most authorities assume that homeopathy is safe and its elixirs will not interact with conventional drugs.<sup>40</sup> This is invariably true since the compounds are not pharmacologically active. Jonas’ study concluded that there is scant evidence that homeopathy is effective for any specific clinical condition.<sup>41</sup> In other words, the homeopathic remedy itself functions as a placebo.

### IV. Neuroscience

A neurologist injures her knee skiing and visits the orthopedist. The orthopedist asks, “Where does it hurt?” The neurologist smiles and says, “In my head, of course.”

Neuroscience has taken a perspicacious look into the effects of placebos on the brain, usually in the context of pain relief. A considerable amount of information has already been amassed. Tor Wager is widely recognized for studying the nexus between placebos, the experience and anticipation of pain, and functional magnetic resonance imaging (fMRI) changes.<sup>42</sup> His work was further confirmed

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<sup>39</sup> *Id.*

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

<sup>41</sup> *Id.* at 397.

<sup>42</sup> Tor Wager, James Rilling, Edward Smith, Alex Sokolik, Kenneth Casey, Richard Davidson, Stephen Kosslyn, Robert Rose & Jonathan Cohen, *Placebo-Induced Changes in fMRI in the Anticipation and Experience of Pain*, SCIENCE, Feb. 20, 2004, at 1162.

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by Dr. Jon-Kar Zubieta using positron emission tomography (PET scan).<sup>43</sup>

Wager found that placebo manipulations decrease brain activity in regions known to be pain-sensitive, and that this decrease correlates with a reduction in subjective pain.<sup>44</sup> Two studies involving induced pain with electric shock or thermal stimulus demonstrated these findings. Previously identified placebo responders were randomized into two groups.<sup>45</sup> The placebo group was told that they were getting a pharmacologically active analgesic; the control group was told that their pill was ineffective against pain. Only the placebo group evinced a statistically significant reduction in perceived pain and a divergence in brain activity. First, placebo analgesia was correlated with decreased brain activity in pain-sensitive brain regions, including the thalamus, insula, and anterior cingulate cortex, and with increased activity in the prefrontal cortex. Second, there was an increase in prefrontal activity even before the pain stimulus was administered. The anticipation of a painful stimulus coupled with expectations of pain relief was associated with heightened activity in the dorsolateral prefrontal cortex (associated with cognitive control) and the orbitofrontal cortex (associated with allocation of control).<sup>46</sup>

Placebo analgesia is mediated by both opioid and non-opioid pathways. Analgesia can be partly blocked by the drug, Naloxone, a competitive antagonist of the  $\mu$ -opioid receptor frequently used to treat opioid overdose. The blockade confirms the importance of endogenous opioids in the placebo response. Moreover, the effect of

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<sup>43</sup> Jon-Kar Zubieta, Joshua A. Bueller, Lisa R. Jackson, David J. Scott, Yanjun Xu, Robert A. Koeppe, Thomas E. Nichols & Christian S. Stohler, *Placebo Effects Mediated by Endogenous Opioid Activity on  $\mu$ -Opioid Receptors*, 25 J. NEUROSCIENCE 7754, 7755, 7760 (2005).

<sup>44</sup> Wager et al., *supra* note 42, at 1165.

<sup>45</sup> *Id.* at 1162-66.

<sup>46</sup> *Id.* at 1163-64.

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Naloxone was greater when the subjects had strong expectations regarding the pain relieving effects of the placebo. This was consistent with the notion that expectations of analgesia were associated with increased local release of endogenous  $\mu$ -opioids. On the other hand, even when subjects had no expectation cues, the placebo still manifested pain relieving effects not blocked by Naloxone, supporting the existence of the non-opioid pathway.<sup>47</sup>

Neuropharmacologists have further differentiated placebo analgesia pathways based on whether the analgesia was activated by the expectation of relief or by prior conditioning. Experimental subjects underwent pretreatment conditioning with morphine or Ketorolac, an anti-inflammatory medication with analgesic effects, prior to the application of painful tourniquet pressure. Groups were then given morphine, Ketorolac, Naloxone, or a placebo to attenuate the pain. Two main findings emerged from the study. Those subjects who believed they had received an analgesic and expected relief of pain noted significantly less pain. Therefore, endogenous opioid systems are triggered by cognitive factors, specifically verbal expectation. In contrast, placebo responses induced by conditioning were not exclusively mediated by endogenous opioids. While placebo analgesia after morphine conditioning did utilize the opioid pathway, Ketorolac conditioning did not. Ketorolac used the cyclooxygenase pathway characteristic of all non-steroidal anti-inflammatory drugs at the level of peripheral and central sites in the spinal cord.<sup>48</sup>

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<sup>47</sup> Fabrizio Benedetti, Helen S. Mayberg, Tor D. Wager, Christian S. Stohler, and Jon-Kar Zubieta, *Neurobiological Mechanisms of the Placebo Effect*, 25 J. NEUROSCIENCE 10390, 10390 (2005).

<sup>48</sup> Martina Amanzio & Fabrizio Benedetti, *Neuropharmacological Dissection of Placebo Analgesia: Expectation-Activated Opioid Systems versus Conditioning - Activated Specific Subsystems*, 19 J. NEUROSCIENCE 484, 490 (1999).



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In 2011, Wager reanalyzed his original studies to assess individual variations in the robustness of placebo effect. fMRI activity was observed at two points – during the anticipation of pain and while experiencing pain. The fMRI showed that increased anticipatory activity in the frontoparietal network and decreased activity in the posterior insular/temporal network were predictive of the magnitude of placebo analgesia. The most predictive regions were those associated with emotional appraisal rather than cognitive control or pain processing. Wager concluded that engagement of emotional appraisal circuits is the driving force behind the perceived individual variation in placebo analgesia, rather than early suppression of nociceptive processing.<sup>49</sup>

While most placebo-related neuroscientific inquiries have considered analgesia, there is growing interest in the effect of placebo on motor control in Parkinson's disease.<sup>50</sup> Patients who exhibited improved motor control after placebo administration demonstrated activation of endogenous dopamine release on Positron Emission Tomography (PET) scans.<sup>51</sup>

PET scans were obtained on a group of clinically depressed men who participated in an inpatient, randomized, placebo-controlled study of the antidepressant, Fluoxetine (Prozac). Scans were performed at three separate intervals: before treatment (baseline), at one week, and at six weeks. After six weeks, subjects who experienced a clinical response were assessed and change patterns for each individual were determined; then scans from the treatment and placebo groups were compared. Anatomically overlapping changes were evident at six

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<sup>49</sup> Tor D. Wager, Lauren Y. Atlas, Lauren A. Leotti & James K. Rilling, *Predicting Individual Differences in Placebo Analgesia: Contributions of Brain Activity during Anticipation and Pain Experience*, 31 J. NEUROSCIENCE 439, 439 (2011).

<sup>50</sup> Benedetti, *supra* note 47, at 10392.

<sup>51</sup> *Id.*

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weeks between the Fluoxetine and placebo groups. Both groups manifested corresponding increases in glucose metabolism in the prefrontal, parietal, and posterior cingulate regions, as well as a decrease in subgenual cingulate. The only variation was that the regional changes in the Fluoxetine-treated group were of greater magnitude than the placebo group.<sup>52</sup>

In summary, placebo analgesia is mediated by both opioid and non-opioid pathways, just like pharmacologically active substances. The placebo effect in Parkinson's disease and depression correlates with altered metabolic activity in neuroanatomical areas known to be impaired in these conditions.

## V. Ethics

The use of placebos poses four ethical questions regarding deception, autonomy, malfeasance, and justice. Ethicists find deception the most problematic. Conceptually, many individuals maintain that deception of any kind is morally objectionable. Truth in disclosure is a fundamental aspect of the autonomy and dignity of human beings. Deontology considers manipulation and deception to be a manifestation of disrespect between people. Deception is condemned because it “violates an a priori moral rule—a priori because the rule appeals to the very nature of our beings (that is, persons deserving respect) rather than to the good or bad consequences of our actions.”<sup>53</sup>

Most people believe that doctors should be prescribing genuine medication. The prescription of

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<sup>52</sup> Helen S. Mayberg ET AL., *Regional Metabolic Effects of Fluoxetine in Major Depression: Serial Changes and Relationship to Clinical Response*, 48 *BIOLOGY PSYCHIATRY* 830, 836 (2000).

<sup>53</sup> Howard Brody, *The Lie That Heals: The Ethics of Giving Placebos*, 97 *ANNALS INTERNAL MED.* 112, 113 (1982).

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placebos can be deceptive in three ways. Doctors may: (1) lie about what the medication is; (2) make vague statements about the medication; and (3) say nothing about the medication.<sup>54</sup> The utilitarian responds, “So what? Who cares as long as it works?” The utilitarian summates all the favorable consequences attributable to placebos, and argues (or assumes) that these outweigh the evils of deception. To prove value, it is necessary only to show that using placebos will increase the sum total of happiness in the world.<sup>55</sup>

Armageddon occurs when the patient discovers that a placebo has been used. Physicians who endeavor to deceive patients by representing placebos as pharmacologically active medications risk undermining their patients’ trust.<sup>56</sup> Once trust and confidence are undermined, any hope for a productive physician-patient relationship is decimated. Every treatment or intervention is suspect. The motives and candor of the doctor will always be uncertain. The consequences go well beyond individual relationships. Patients, in general, may relinquish trust and confidence in the entire medical profession. The efficacy of bona fide prescription pharmaceuticals will be suspect. Other options, such as medication with greater toxicity or frank quackery, may be selected. In addition to rejecting proper care, patients may opt for uninformed or misinformed self-care.<sup>57</sup> A computer trip to “Dr. Google” could supplant a visit to the old style, bricks and mortar medical office when illness strikes. Deception is a two-way street; the doctor deceives the patient, and the patient deceives the doctor. Future care would be based on inadequate patient histories and failure to disclose self-

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<sup>54</sup> Kapp, *supra* note 8, at 376.

<sup>55</sup> Brody, *supra* note 53, at 114.

<sup>56</sup> Irwin Kleinman, Peter Brown, Larry Librach, *Placebo Pain Medication: Ethical and Practical Considerations*, 3 ARCH FAMILY MED. 453, 453 (1994).

<sup>57</sup> See Kapp, *supra* note 8, at 377-78.

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treatment. The public may perceive doctors as charlatans, and charlatans are not likely to promote healing with caring explanations or the laying on of hands. To paraphrase Simon and Garfunkel, “[Deception], like a cancer, grows.”<sup>58</sup> By their very nature, deceptive practices fester, and, as a result, defeat the conventional restraints of obligation. Other parties in the healthcare system, such as the nurse, pharmacist and medical assistant, become co-conspirators.

Placebos are not simply inconsequential “white lies.” The monetary cost of prescription placebos is considerable. In order to be “potent,” placebos cannot be free of charge. If the fee for the placebo prescription is considerable, someone will be making an unjustifiable profit. If it is too low, the patient may be suspicious of a contrivance.<sup>59</sup> Large expenditures of both time and money may be required for placebo therapy. There is evidence that increasing the cost of a prescription, thus making the remedy appear more valuable and exotic, enhances the placebo effect. This can result in financial loss to private and public third-party insurers who pay the pharmacy fees.

The Council on Ethical and Judicial Affairs of the American Medical Association concluded that, “the deceptive use of placebos is not ethically acceptable because it may harm patients to a greater degree than it helps them.”<sup>60</sup> Using placebos in a duplicitous fashion is disfavored because it fundamentally conflicts with a

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<sup>58</sup> See generally SIMON & GARFUNKEL, *The Sound of Silence*, on WEDNESDAY MORNING, 3 A.M. (Columbia Records 1964).

<sup>59</sup> See Brody, *supra* note 53, at 114.

<sup>60</sup> Robert M. Sade, *Placebo Use in Clinical Practice*, CEJA Report 2-I-06, 2006 AMA HOUSE OF DELEGATES, available at [http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=OCBOQFjAA&url=http%3A%2F%2Fwww.ama-assn.org%2Fresources%2Fdoc%2Fethics%2Fceja\\_recs\\_2i06.pdf&ei=R7jVTpyoK4iXgweZkNG\\_AQ&usg=AFQjCNHP1TUFFnONow6ViQsY\\_5qCpJnsOA&sig2=\\_XNilpMgbUCHE-BAGamaiA](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=OCBOQFjAA&url=http%3A%2F%2Fwww.ama-assn.org%2Fresources%2Fdoc%2Fethics%2Fceja_recs_2i06.pdf&ei=R7jVTpyoK4iXgweZkNG_AQ&usg=AFQjCNHP1TUFFnONow6ViQsY_5qCpJnsOA&sig2=_XNilpMgbUCHE-BAGamaiA).

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doctor's professional obligation to promote patient welfare and respect patient autonomy. The Council has elucidated the three most objectionable circumstances where placebos are utilized: (1) to serve the convenience of the physician rather than to promote patient welfare; (2) to mollify the demanding and difficult patient; and (3) to assuage a patient with a complex problem that frustrates the physician.<sup>61</sup>

Since the emergence of the movement away from paternalistic medicine, patient autonomy has become of paramount importance in the physician-patient relationship. Placebos are the antithesis of patient autonomy. Autonomy and dignity are violated when the patient is deprived of an opportunity to play a meaningful role in her care. It is the patient's prerogative to make significant life decisions, to participate fully, and to cooperate effectively. The physician has an ethical and fiduciary duty to disclose material facts and the patient has a duty to share responsibility for the treatment.<sup>62</sup>

Malfesance is a concern when physical harm is directly or indirectly inflicted. Placebo-induced side effects are considered a direct harm. Harm is also caused when a doctor prescribes a placebo to ameliorate subjective symptoms either before or in lieu of a comprehensive medical or psychiatric examination, when that examination would have revealed a significant, treatable illness. Placebos can induce dependency on a number of levels. By its very nature, the dependency is psychological and, arguably, a falsity. This dependency is unhealthy and may result in actual addiction. Individuals may evolve into "professional patients" – every symptom must be treated; unexplained maladies come and go with the assistance of a doctor who uses her sample closet and prescription pad liberally. Constant treatment with magical liquids or

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<sup>61</sup> *Id.*

<sup>62</sup> See Kapp, *supra* note 8, at 378-79.

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capsules can supplant the preventative paradigm. No longer will people feel the need to maintain a healthy lifestyle and use common sense.<sup>63</sup>

It is axiomatic that similar individuals with similar medical problems should be treated equally, or at least similarly. This basic principle of justice is easily violated when placebo therapy leads to disparate treatment. The risk is especially acute in the context of overly demanding and querulous patients who are given placebos based on the likelihood that they are overstating their level of pain. Physicians may feel the need to prove that the patient is not actually sick.<sup>64</sup>

There are, however, a number of arguments in favor of the ethical acceptance and use of placebo. First, contemptible deception can be eliminated by telling the patient the nature of the treatment. Once prevarication is eliminated, the ethical problem is defused. While the outcome for an informed patient may not be comparable to one who is deceived, undisguised placebo treatment is still associated with a modest rate of success. The earliest empirical rejection of the traditional deception-based heuristic of the placebo response was a non-blind placebo trial of fourteen psychiatric outpatients with somatic symptoms. Each was treated for one week with sugar pills. Subjects were candidly informed that they were taking sugar pills with the caveat that many patients experienced relief with such medication despite the absence of active ingredients. Thirteen patients (ninety-three percent) experienced some degree of subjective or objective symptom reduction.<sup>65</sup>

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<sup>63</sup> See *id.* at 380.

<sup>64</sup> James S. Goodwin, Jean M. Goodwin & Albert V. Vogel, *Knowledge and Use of Placebos by House Officers and Nurses*, 91 ANNALS INTERNAL MED. 106, 109 (1979).

<sup>65</sup> Lee C. Park & Uno Covi, *An Exploration of Neurotic Patients' Responses to Placebo When Its Inert Content is Disclosed*, 12 ARCH. GEN. PSYCHIATRY 336, 338 (1965).

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Certain levels of deception may be acceptable. Placebo treatment can be used without the need for an outright verbal lie. It may be more palatable to deceive a patient in a nonverbal fashion using gestures or visual clues. The placebo effect can be enhanced by the environment in which the prescription is written. “The setting in a doctor's office or hospital room, the impressive terminology, the mystique of the all-powerful physician prescribing a cure - all of these tend to give the patient faith in the remedy.”<sup>66</sup>

If a deception is benevolent, is it any less objectionable? Physicians use placebos for benevolent purposes, i.e., to improve the well-being of their patients. A benevolent lie used to evoke a placebo effect may be sufficiently virtuous for some.<sup>67</sup> In addition, patients sometimes prefer to be lied to. It is not improper to oblige them. Patients commonly return decision-making power to physicians by not asking for information or recommendations, “but instead pledge – by word or conduct – to follow whatever course of action the physician feels is appropriate.”<sup>68</sup> A patient's implicit or explicit consent to be deceived renders a lie ethical. There are situations in which lying to a patient is considered humane if it fulfills the patient's wishes. For some, maintaining hope or even the illusion of hope even in the face of near hopelessness improves the quality and duration of life over the short term by eliciting a placebo effect.<sup>69</sup>

Swiss health providers have tried to justify placebo use by differentiating between pure and impure placebos. They contend that use of pure (inert) placebos is ethically unacceptable because it dupes the patient and promotes an

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<sup>66</sup> See Bok, *supra* note 2, at 19.

<sup>67</sup> Kathleen M. Boozang, *The Therapeutic Placebo: The Case for Patient Deception*, 54 FLA. L. REV. 687, 725 (2002).

<sup>68</sup> See Kapp, *supra* note 8, at 385.

<sup>69</sup> See Boozang, *supra* note 67, at 753.

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outdated, unduly paternalistic relationship. These practitioners justify the use of impure (pharmacologically active) placebos with the casuistic argument that active drugs, even those not indicated for the disease in question, could conceivably confer a positive effect on the health of the patient.<sup>70</sup>

### VI. Law

Legal issues regarding placebo treatment have not materialized in court cases, legislation, or federal and state regulation because patients have not been informed that they are taking placebos. The law does not specifically and overtly regulate the use of placebos except in the context of the patient's right to pain management.<sup>71</sup> When the United States Supreme Court considered an individual's right to choose physician-assisted suicide, it affirmed an individual's right to refuse pain management and appropriate palliative care.<sup>72</sup>

Timothy Quill, M.D. challenged the illegality of prescribing lethal medication to terminally ill, mentally competent patients in *Vacco v. Quill*.<sup>73</sup> The United States Supreme Court held that physician-assisted suicide was impermissible based on the theory of causation and intent. Justice O'Connor, concurring in another "right-to-die" case, affirmed that a terminal patient in great pain "has no legal barriers to obtaining medication . . . to alleviate that suffering, even to the point of causing unconsciousness and

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<sup>70</sup> See Fässler, *supra* note 6, at 7.

<sup>71</sup> Karen J. Nichols ET AL., *AOA's Position Against Use of Placebos for Pain Management in End-of-Life Care*, 105 J. AM. OSTEOPATHIC ASS'N S2, S3-4 (2005) (discussing legislation regarding a patient's right to pain management).

<sup>72</sup> *Vacco v. Quill*, 521 U.S. 793, 808 (1997).

<sup>73</sup> *Id.* at 793.



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hastening death.”<sup>74</sup> Placebo substitution for active analgesic medication, however, without the express informed consent of the individual violates the precepts of the American Bar Association.<sup>75</sup>

A cause of action for placebo-related damages can be brought under the theories of fraud, false advertising, lack of informed consent and medical malpractice.

### A. Fraud

The elements of fraud giving rise to the “tort action for deceit are: (a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or ‘scienter’); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage.”<sup>76</sup> It is apparent that each element of the cause of action is potentially present in a case where placebos are mendaciously used, regardless of whether an outright lie, a vague and non-committal statement, or silence concerning the nature of the treatment is involved. Intent to harm the plaintiff is not requisite.<sup>77</sup>

In *Jurcich v. General Motors Corp.*, an employee brought an action in fraud and deceit against the corporation and its nurse employee for repeatedly treating him for pain with sugar pills, without his knowledge, after a job-related injury.<sup>78</sup> The issue for the court was whether this case should be brought under the rubric of fraud or

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<sup>74</sup> *Washington v. Glucksberg*, 521 U.S. 702, 737 (1996) (O’Connor, J., concurring) (Justice O’Connor’s concurring opinion also applies to *Vacco*, 521 U.S. at 809).

<sup>75</sup> *Nichols*, *supra* 71, at S4.

<sup>76</sup> *Southern Union Co. v. Southwest Gas Corp.*, 180 F. Supp. 2d 1021, 1030 (D. Ariz. 2001) (internal quotations and citations omitted).

<sup>77</sup> *See Kapp*, *supra* note 8, at 388.

<sup>78</sup> *Jurcich v. General Motors Corp.*, 539 S.W.2d 595, 595 (Mo. Ct. App. 1976).

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medical malpractice.<sup>79</sup> The court held that medical malpractice was the appropriate theory, not fraud and deceit. Further, the court observed that the prescription of placebos “is, in appropriate cases, a recognized form of medical treatment.”<sup>80</sup> The court concluded that the plaintiff was not injured by the placebo by holding that “[t]here is not a scintilla of evidence in this record that by the dispensing of placebos to him his back injuries were worsened nor that any new injuries resulted. He simply obtained no relief from his pain.”<sup>81</sup> The court viewed the use of a placebo as proper under certain circumstances, and the issue in the case was the medical standard of care.<sup>82</sup>

### B. Fraudulent Advertising

Courts have strongly disfavored the promotion and advertising of over-the-counter placebos. The Federal Trade Commission filed an action against the promoter of a worthless hair loss product in *FTC v. Pantron I Corp.*<sup>83</sup> The defendant-promoter asserted that there was scientific evidence to support his claim of efficacy, but the court established that any benefit was placebo.<sup>84</sup> A seller may not claim that a product is effectual when its effectiveness is predicated solely on the placebo effect. That representation “constitutes a ‘false advertisement’ even though some consumers may experience positive results.”<sup>85</sup>

The court in *FTC v. QT, Inc.* arrived at a similar conclusion.<sup>86</sup> The defendants used infomercials and print advertising to market the Q-Ray Ionized Bracelet® as a

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<sup>79</sup> *Id.* at 600.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.* at 601.

<sup>82</sup> Boozang, *supra* note 67, at 740.

<sup>83</sup> *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1088 (9th Cir. 1994).

<sup>84</sup> *See id.* at 1097.

<sup>85</sup> *Id.* at 1100.

<sup>86</sup> *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 908 (N.D. Ill. 2006).

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device that provided significant, immediate, and complete pain relief for conditions such as migraines and back pain by emitting an unspecified ionizing force. The court found no scientific evidence to substantiate the claims and held that the bracelet was advertised in a dishonest and materially misleading manner since any benefit from the product was based solely on the placebo effect.<sup>87</sup> The court quoted *United States v. An Article...ACU-DOT*, “[a] kiss from mother on the affected area would serve just as well to relieve pain, if mother’s kisses were marketed as effectively....”<sup>88</sup>

### C. Informed Consent

Under the professional standard of informed consent, a physician is required to make disclosures that a reasonable physician would make under the circumstances. The patient-oriented standard, on the other hand, “requires physicians to provide patients with that information which the ‘reasonably prudent person would find material to making a decision.’”<sup>89</sup> To establish a *prima facie* case against a physician for failure to obtain informed consent, the plaintiff must prove that:

1. the physician had a duty to disclose sufficient information about a proposed treatment to obtain the patient's informed consent;
2. the physician breached that duty;
3. the physician's failure to disclose adequate information was the proximate cause of the patient's decision to consent to a treatment to which the patient would have withheld consent if he or she had been adequately informed; and

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<sup>87</sup> *See id.* at 965.

<sup>88</sup> *Id.* at 964 (citing *United States v. An Article...ACU-DOT*, 483 F. Supp. 1311, 1315 (N.D. Ohio 1980)).

<sup>89</sup> Boozang, *supra* note 67, at 739.

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4. a potential adverse consequence of the treatment materialized, resulting in a detriment to the patient.<sup>90</sup>

Hospital organizations promote the concept of informed consent to their patients through brochures distributed at the time of admission. The American Hospital Association's brochure entitled, "The Patient Care Partnership," urges patients to be actively involved in their care:

### *INVOLVEMENT IN YOUR CARE*

*You and your doctor often make decisions about your care before you go to the hospital. Other times, especially in emergencies, those decisions are made during your hospital stay.*

*When decision-making takes place, it should include:*

- *Discussing your medical condition and information about medically appropriate treatment choices.*

*To make informed decisions with your doctor, you need to understand:*

- *The benefits and risks of each treatment.*
- *Whether your treatment is experimental or part of a research study.*
- *What you can reasonably expect from your treatment and any long-term effects it might have on your quality of life.*
- *What you and your family will need to do after you leave the hospital.*

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<sup>90</sup> Bennett v. Surgidev Corp., 710 A.2d 1023, 1026 (N.J. Super. Ct. App. Div. 1998) (citing Largey v. Rothman, 540 A.2d 504 (N.J. 1988); Caputa v. Antiles, 686 A.2d 356 (N.J. Super. Ct. App. Div. 1996)).

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- *The financial consequences of using uncovered services or out-of-network providers.*<sup>91</sup>

The use of placebos creates a number of problems with informed consent. In general, informed consent for placebo use is not sought for two reasons: (1) the usefulness of a placebo is abrogated when the patient knows what it is; and (2) placebos have been considered sufficiently harmless and beneficial to render disclosure unnecessary.<sup>92</sup> Some legal professionals surmise that informed consent does not apply to the use of placebos. An intervention must be potentially hazardous for issues of informed consent to apply. Since placebos are prescribed in clinical practice solely for symptomatic relief and not for disease treatment, it has been argued that no ongoing harm will result from substituting a placebo in place of a prescription drug.<sup>93</sup>

Several other reasons circumventing full disclosure have been articulated. First, one may construe a patient's initial consent to treatment as ongoing consent to all specific treatments that a physician employs, including the use of a pure placebo.<sup>94</sup> Second, under existing consent law, a patient does not need to be informed when a physician chooses Treatment A over Treatment B, because of the added placebo effect.<sup>95</sup> Third, when considering the explication of potential treatment side effects, it is the prerogative of the patient to decide whether he/she would like to hear about them. Both legal and ethical ideations of

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<sup>91</sup> *The Patient Care Partnership*, BROCHURE (AMER. HOSP. ASSOC. 2003).

<sup>92</sup> Bok, *supra* note 2, at 19.

<sup>93</sup> DAN J. TENNENHOUSE, 3 ATTORNEYS MEDICAL DESKBOOK § 38:2.50 (4th ed. 2006 & Supp. 2010).

<sup>94</sup> Anup Malani, *Regulation with Placebo Effects*, 58 DUKE L.J. 411, 449 (2008).

<sup>95</sup> *See id.* at 450-51.

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informed consent should provide for patients who truly want to be deceived, or for whom the truth would be therapeutically counterproductive.<sup>96</sup> The physician may also take into account whether the side effects are material and whether current medical custom demands their disclosure.<sup>97</sup>

When enough physicians use placebos for therapeutic purposes without disclosure, the lack of disclosure evolves into the professional standard of care and reframes notions of informed consent.<sup>98</sup> In other words, the absence of disclosure will be consistent with the “exercise [of] that degree of care, skill and learning expected of a reasonable, prudent health care provider in the profession or class to which he belongs within the state acting in the same or similar circumstances.”<sup>99</sup> Neither will physicians encounter legal hurdles under a patient-oriented standard. If, as previously argued, the reasonable patient would opt to experience the benefits of placebo therapy without having the truth revealed to her, then the legal standard of disclosure, as determined by the reasonable patient, would abide the deception.

### D. Medical Malpractice

In Arizona, there are two elements of proof necessary to show that an injury resulted from the failure of a health care provider to follow the accepted standard of care:

1. The health care provider failed to exercise that degree of care, skill and learning expected of a reasonable, prudent health care provider in the

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<sup>96</sup> Boozang, *supra* note 67, at 737.

<sup>97</sup> Malani, *supra* note 94, at 452.

<sup>98</sup> Boozang, *supra* note 67, at 739.

<sup>99</sup> ARIZ. REV. STAT. § 12-563 (LEXIS through 2011 legislation).

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profession or class to which he belongs within the state acting in the same or similar circumstances.

2. Such failure was a proximate cause of the injury.<sup>100</sup>

Plaintiffs must present facts from which negligence and a causal relation between the injury and the defendant's acts may be reasonably inferred.<sup>101</sup> The court "must find for the defendant unless [it] finds a probability that defendant's negligence was a cause of plaintiff's injury."<sup>102</sup>

With regard to the use of placebos, the basic rules of medical malpractice hold. The issue in malpractice cases is whether a doctor's treatment of a patient was negligent. The answer hinges on whether the treatment works, not on how it works.<sup>103</sup> "The test for negligence is the same in all cases: does the treatment conform to medical custom, or, would a reasonable physician administer this treatment?"<sup>104</sup> There are three major considerations when a malpractice action is based on the use of a placebo: (1) when a patient suffers a negative placebo reaction reasonably foreseeable to a competent doctor; (2) when appropriate treatment is improperly impeded by the use of a placebo; and (3) when the doctor's treatment of the patient with a placebo deters the patient from obtaining effective treatment from another practitioner.<sup>105</sup>

### E. Defenses

There are four main defenses to a placebo-related claim. First, the patient suffered no harm; it is necessary to

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<sup>100</sup> *See id.*

<sup>101</sup> *Harvey v. Kellin*, 566 P.2d 297, 302 (Ariz. 1977).

<sup>102</sup> *Thompson v. Sun City Community Hosp., Inc.*, 688 P.2d 605, 616 (Ariz. 1984).

<sup>103</sup> *Melani*, *supra* note 94, at 455.

<sup>104</sup> *Id.*

<sup>105</sup> *See Kapp*, *supra* note 8, at 395.

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prove injury caused by the placebo treatment itself.<sup>106</sup> Second, use of the placebo was not negligent; similarly trained professionals would also have prescribed a placebo under comparable circumstances, consistent with the accepted standard of care.<sup>107</sup> Third, treatment without informed consent and disclosure is conditionally permissible where there is a reasonable likelihood that exposing the nature of the treatment will cause psychological harm, hinder or complicate treatment, or impair the patient's ability to assent to treatment.<sup>108</sup> Thus, therapeutic privilege is a well-recognized exception to the objective standard of disclosure, and excuses the withholding of information where disclosure would be unhealthy to the patient. The privilege is applicable only if disclosure of the information would complicate or hinder treatment, cause such emotional distress as to preclude a rational decision, or cause psychological harm to the patient."<sup>109</sup>

Fourth, while the patient has the right to know the risks, benefits and alternatives of a medical intervention, the patient similarly possesses "the prerogative to waive or relinquish that right."<sup>110</sup> According to the California Supreme Court, "a medical doctor need not make disclosure of risks when the patient requests that he not be so informed...Such a disclosure need not be made if the procedure is simple and the danger remote and commonly appreciated to be remote."<sup>111</sup>

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<sup>106</sup> See *id.* at 396.

<sup>107</sup> See *id.*

<sup>108</sup> See *id.* at 397.

<sup>109</sup> *Canterbury v. Spence*, 464 F.2d 772, 789 (D.C. Cir. 1972).

<sup>110</sup> *Kapp*, *supra* note 8, at 399.

<sup>111</sup> *Cobbs v. Grant*, 502 P.2d 1, 12 (Cal. 1972).



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### VII. Recommendations

Each Monday, hundreds of thousands of doctors return to work, evaluate patients, and select the most effective treatment available under the circumstances. At some point in her professional practice, a doctor has to decide if and when a placebo might be appropriate. This section will look at possible uses of placebos that may be sanctioned by ethicists and legalists.

#### A. When Placebos May Not Be Used

There is a consensus against placebo therapy being used as a tool of convenience for the practitioner. Placebo therapy is not a tool of mollification for demanding patients or those with frustrating and complex medical problems.<sup>112</sup> It is not a profit center for dispensing physicians. It is not a substitute for practicing medicine.

Bona fide treatments that are safe and effective for the patient's condition are preferable to placebos. The use of a placebo is unwarranted before a careful history and physical exam is performed, a differential diagnosis is established, the appropriate laboratory and radiological investigation have been carried out, and necessary consultations have been obtained. No impure placebo should ever be used.

When the placebo treatment has been selected, it should only be used for a specific purpose. Therapeutic results must be carefully monitored and the duration of treatment must be strictly defined. Placebos should be dispensed or administered by a doctor's orders. There is no place for over-the-counter placebos.<sup>113</sup> Healthcare facilities

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<sup>112</sup> Kapp, *supra* note 8, at 381-82.

<sup>113</sup> Christie Aschwanden, *Experts Question Placebo Pill for Children*, N.Y. TIMES, May 27, 2008, at F5 (Jennifer Buettner successfully treated her hypochondriacal niece with a placebo in order to avoid the

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need written policies governing their use.<sup>114</sup> Outright lies are unacceptable and patient questions must be answered candidly.<sup>115</sup> Placebos should not be dispensed to patients who specifically ask not to receive them.<sup>116</sup>

### B. When Placebos May Be Used

Placebo treatment has been suggested in the following situations:

- (1) Patient shows no benefit from standard therapy;
- (2) Patient is dependent on morphine or other addictive narcotics or sedatives and needs to be gradually weaned off of them;
- (3) Patient has a mild condition and the risk-to-benefit ratio militates against the use of potent medications with significant risks of toxicity or addiction;
- (4) Patient is psychologically unable to deal rationally with candid evaluation of their medical condition;
- (5) Parents who insist that treatment must be prescribed for their children;
- (6) Patients who demand treatment preceding a thorough diagnostic evaluation;

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potential side effects of unnecessary antibiotics or other medications. She started Efficacy Brands, a company that markets a supplement, Obecalp (placebo spelled backwards). It is a cherry-flavored sugar pill designed to simulate the texture and flavor of medication and is marketed as a dietary supplement with no active drug. The placebo was supposed to be available on the website, <http://www.inventedbyamother.com/>, at fifty tablets for \$5.95 or in liquid form at retail locations across the country. However, as of January 8, 2012, it is not. The only available placebo is "Placebo Pilules," sold by Universal Placebos, \$20 Australia for 700 small pills, available at <http://www.placebo.com.au>).

<sup>114</sup> Kapp, *supra* note 8, at 402.

<sup>115</sup> *See id.*

<sup>116</sup> *See id.*; Bok, *supra* note 2, at 22.

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- (7) Patients who are terminally ill and require reduction in analgesic medication due to severe side effects; and
- (8) Patients who may benefit from an adjunct to standard therapy.<sup>117</sup>

For example, the following are circumstances where a placebo may prove exceedingly helpful:

- An overly anxious patient who recently sustained a myocardial infarction and is at risk for a fatal arrhythmia, but refuses tranquilizers to reduce her stress level.<sup>118</sup>
- A patient who presents with significant symptoms from a treatable condition but refuses medication because of potential side effects. An example is a post-menopausal woman with irritability and depression who refuses estrogen replacement.<sup>119</sup>
- A child with attention deficit hyperactivity disorder who requires progressively more medication with attendant side effects. The placebo is given to enhance the effect of smaller doses of the active drug.<sup>120</sup>

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<sup>117</sup> Kapp, *supra* note 8, at 383-84.

<sup>118</sup> *See id.* at 402.

<sup>119</sup> *See id.* at 403.

<sup>120</sup> Adrian S. Sandler, Corrine E. Glesne, James W. Bodfish, *Conditioned Placebo Dose Reduction: A New Treatment in Attention-Deficit Hyperactivity Disorder?*, 31 J. DEV. & BEHAV. PEDIATRICS 369, 372-73 (2010) (Children with attention deficit hyperactivity disorder who took half their usual dosage of active medication in conjunction with an undisclosed placebo had the same therapeutic effect as their prior full dosage. Patients who took half their dose without placebo showed a reduced therapeutic effect).

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### **VIII. Conclusion**

Placebos will always have a place in clinical medicine. They are useful for individuals who manifest a significant placebo effect, especially when their symptoms do not justify intervention with potent medications. But, there will never be a substitute for a competent and comprehensive diagnostic evaluation. The neuroscience of placebos shows activation and inhibition of the same anatomical pathways and receptors that are targeted by standard pharmaceuticals.

Most of the ethical objections focus on the issue of deception and its capacity to destroy both the doctor-patient relationship and the standing of physicians in society. Placebo law is not well developed, but placebo use does raise issues of fraud, lack of informed consent, and medical malpractice. Their use may be defended by their relative safety and efficacy. There are solutions to deception and informed consent problems, including the use of limited or full disclosure. In certain circumstances, where treatment is not warranted or not possible, the placebo effect can be utilized to make certain patients feel better. Any intervention in medicine is always a question of whether the benefits outweigh the risks. There are numerous cases in which placebos confer enormous benefits with minimal risk. They should be used sparingly and circumspectly, but they should be used.