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THE THERAPEUTIC PLACEBO: THE CASE FOR PATIENT DECEPTION

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I. INTRODUCTION

Placebos, by their very nature, should have no effect on a patient's health. Nonetheless, there is a widespread belief that placebos can make patients feel better, and even contribute to their cure. Physicians have long been fascinated by the "placebo effect," which they steadfastly believe exists, while not understanding how it works. Many physicians have such confidence in placebos' therapeutic potential that they urge their use in treating patients.[1] Howard Brody, a nationally recognized family practice physician and bioethicist, recently published a book for patients entitled *Placebo Response: How You Can Release the Body's Inner Pharmacy for Better Health.*[2] Other placebo believers direct their advocacy toward physicians, urging them to employ the power of the placebo; one scenario imagines the placebo-prescribing physician explaining to her patient that he is receiving a "new powerful medication without side effects that will help reduce your pain."[3]

In response to this growing interest in the therapeutic potential of placebos, the National Institute of Health hosted a gathering of scientists from around the world in November 2000.[4] Certain of the power of this elusive phenomenon,[5] these scientists articulated a research agenda geared toward placebo treatment of patients.[6]

Stunningly, less than six months later, a study published in the New England Journal of Medicine announced that the placebo effect does not exist.[7] The study's Danish authors suggested that the supposed placebo

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1. Frederick J. Evans, *Expectancy, Therapeutic Instructions, and the Placebo Response*, *in* PLACEBO: THEORY, RESEARCH AND MECHANISMS 215, 215 (L. White et al. eds., 1985).

2. HOWARD BRODY & DARALYN BRODY, THE PLACEBO RESPONSE: HOW YOU CAN RELEASE THE BODY'S INNER PHARMACY FOR BETTER HEALTH (2000).

3. *Id.* at 225. In January 2001, the New York Times Magazine dedicated its cover story to placebos. *See* Margaret Talbot, *The Placebo Prescription*, N.Y. TIMES MAG., Jan. 9, 2001, at 34.

4. The Science of the Placebo: Toward an Interdisciplinary Research Agenda (Nov. 19-21, 2000) (conference program on file with author); *see generally* Christine Wade et al., *Conference Report: The Science of the Placebo: Toward an Interdisciplinary and Research Agenda*, November 2000, 7 J. ALT. COMPLEMENTARY MED. 383 (2001) (discussing the educational objectives of the conference).

5. Robert Ader, *True or False: The Placebo Effect as Seen in Drug Studies Is Definitive Proof that the Mind Can Bring About Clinically Relevant Changes in the Body*, 16 ADVANCES IN MIND-BODY MED. 7, 10 (2000).

6. As explained by two of the presenters, "placebos work, yet we do not understand how they work (their mechanism of action), to what degree they work (how much of the outcome variance they account for), and under what circumstances they work (the ability to predict their effect and to use that prediction in research and therapy)." Richard R. Bootzin & Opher Caspi, *Explanatory Mechanisms for Placebo Effects: Cognition, Personality, and Social Learning* 2 (conference paper on file with author).

7. Asbjorn Hrobjartsson & Peter C. Gotzsche, *Is the Placebo Powerless?: An Analysis of Clinical Trials Comparing Placebo with No Treatment*, 344 NEW ENG. J. MED. 1594 (2001); *see*

effect detected in prior studies was likely attributable to poor research methods, and otherwise could be explained upon closer examination.

The "placebo community" is unpersuaded by the Danish study, raising questions about both the study and its conclusions.[8] One editorial responding to it observed that the belief in the placebo effect is too strong to be dispelled by one study which, the author opined, was overly broad in its conclusions and left open too many questions.[9]

Discovering which of these conclusions is correct will have powerful repercussions for the practice of medicine. If the placebo effect is real, physicians must reconsider how they treat their patients. Most fundamentally, physicians, ethicists and lawyers would have to reexamine the prohibition against patient deception and the requirements of informed consent. Placebo research suggests, for example, that pretreatment emphasis on success improves positive outcomes.[10] Second, placebos also produce a negative, or "nocebo effect." Thus, it should be medically contraindicated for physicians and pharmaceutical companies to disclose to patients the potential adverse effects of a drug, lest they cause patients to experience those side effects.[11] Finally, using patient conditioning, but without revealing the truth to patients, physicians could intersperse placebos with analgesics, thereby allowing smaller doses of drugs to avoid strong side effects, or to save money. These three novel treatment scenarios, however, would require physicians to deceive (or at least conceal information from) their patients.

New insights about the placebo effect should also cause us to rethink the physician-patient relationship at the end of life. If, as researchers suggest, patients are more likely to experience what they are led to expect, the legions of physicians who have persistently resisted legal and ethical imperatives to be forthcoming with clear diagnoses for terminally ill patients may end up being vindicated. Placebo research suggests that anticipating

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also Gunver S. Kienle & Helmut Kiene, *The Powerful Placebo Effect: Fact or Fiction?*, 50 J. CLIN. EPIDEMIOL. 1311, 1316 (1997) ("we have not found any reliable demonstration of the existence of placebo effects; [t]here can be no doubt that the extent and frequency of placebo effects as published in most of the literature are gross exaggerations").

8. *See* Kienle & Kiene, *supra* note 7, at 1316-17.

9. John C. Bailar, III, M.D., Ph.D., *The Powerful Placebo and the Wizard of Oz*, 344 NEW ENG. J. MED. 1630, 1631-32 (2001).

10. *See* Miroslav Backonja & Walter A. Brown, *Harnessing the Placebo Effect, at* http://www.hospprac.com/issues/1998/07/cebrown.htm (1998) (suggesting that in certain pre-surgical scenarios, it is better to unwaveringly ensure a patient of a good outcome, rather than list possible complications and mortality risks).

11. Steven F. Bierman observes, "In many studies patients have reacted to informed consent—the procedure whereby the many possible risks and benefits of an agent or action are disclosed—by exhibiting one or more of the named complications or benefits." Steven F. Bierman, *Of Course Mental Events Affect Physical Events*, 16 ADVANCES IN MIND-BODY MED. 11, 11 (2000).

death may very well hasten its arrival. Currently, neither law nor ethics acknowledges the common human response to medical crises—the desire to be shielded from the truth. If sustaining hope triggers a placebo effect that reduces pain or extends life, the law and ethics of end-of-life care must be reconceptualized to allow physicians to nurture patient optimism. Unyielding pursuit of patient autonomy can undermine a patient's conviction that she will outlive the statistics, thereby destroying the placebo effect.

More radically, proof of a powerful placebo effect would force us to rethink what constitutes medical treatment. If placebos are therapeutically beneficial, then physicians should incorporate them into their care of patients, at least where placebos are more effective than extant treatments "proven to work." Thus, many alternative therapies, whose principles and mechanisms are inexplicable in the biomedical model, may be deemed efficacious as placebos. Introduction of placebos into clinical practice would compel physicians to address numerous ethical and legal issues. For example, what is the appropriate charge for therapies whose sole benefit is placebo? How should physicians discuss their treatment plans with patients in a way that averts the traditional prohibition against physicians lying to their patients?

Greater understanding of the mechanisms of the placebo effect could have systemic implications as well. The research that increasingly points to the therapeutic relationship as a primary source of the placebo effect suggests that payment mechanisms that discourage physician-patient "face time" may undermine one of the most important aspects of the healing process. If "bed-side" interactions and holistic health care are as instrumental to the patient's recovery as a drug or surgery, then third party payors may find themselves pressed to pay for such care.[12] Indeed, it may even be cost-effective.

What if the placebo effect is in fact a chimera? If this were to be definitively determined, then physicians would be legally and ethically compelled to discontinue using placebos for therapeutic purposes. Despite years of admonitions to the contrary, physicians have persisted in prescribing placebos, both for potentially legitimate (to evoke the placebo effect) and illegitimate (with patients who are suspected to be somatizers) reasons. Claiming that hope is important to patient health and well-being, physicians continue to avoid telling patients the truth about their prognosis, especially if it is terminal. Proof that the placebo effect does not exist will

12. Recent studies suggest that the process and length of time involved in workers compensation systems create nocebo effects—participants in the system remain disabled longer, perhaps to ensure that their claims are provable by the time they are finally considered. Changes to the Canadian system which have shortened the time for recovery of benefits also have shortened the time for recovery from illness.

eliminate the physicians' final reason to avoid honest conversation with their patients.

More dramatically, the nonexistence of a placebo effect would also radically shift the debate about alternative medicine. Increasingly, conventional medical practitioners are integrating complementary and alternative modalities (CAM) into their treatment regimes. Although much of CAM lacks empirical support of its efficacy, many physicians believe that alternative practitioners are particularly effective at evoking the placebo response, especially in patients with chronic illnesses for which conventional medicine has little to offer.[13] If the placebo effect is a mirage, then little justification exists for physicians to integrate unproven alternative therapies,[14] or for payors to cover them.[15] Such an outcome would have a devastating impact on what has become a significant segment of the health care industry.[16]

This Article considers the implications of both scenarios—that the placebo effect is real, therapeutically powerful and can be harnessed to predictably benefit particular patients, or, alternatively, that the placebo effect is nonexistent, and physicians should abandon use of placebos altogether. Part II explains the competing definitions of placebos, as well as the various hypotheses about the placebo effect. Part III examines the literature that denies the existence of the placebo effect. It critiques the primary studies, and concludes, as does the scientific community, that more research is necessary before any conclusion can be reached. If it is ultimately determined that the placebo effect does not exist, Part III considers the implications for current medical practice which will necessarily result if physicians must discontinue their use of therapeutic placebos.

Part IV explores myriad potential opportunities if the placebo effect proves to be real, and the countervailing ethical and legal barriers to employing placebos. Ultimately, Part IV concludes that, when the placebo effect's benefits to the patient potentially exceed those of alternatives, it may be ethical, as well as consistent with the doctrine of informed consent and the law governing fraud, for the physician to withhold from the patient the fact that she is receiving a placebo. Depending upon the context, the

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13. *See generally* BRODY & BRODY, *supra* note 2, at 143-44 (discussing the role a placebo response plays in alternative and conventional medicine).

14. It could reasonably be argued that this point should be limited to disproven CAM modalities. Those that are merely unproven *might* be efficacious.

15. Kathleen M. Boozang, *Is the Alternative Medicine? Managed Care Apparently Seems to Think So*, 32 CONN. L. REV. 567, 567-68 (2000).

16. David M. Eisenberg, M.D. et al., *Trends in Alternative Medicine Use in the United States, 1990-1997: Results of a Follow-up National Survey*, 280 JAMA 1569, 1569 (1998); David M. Eisenberg, M.D. et al., *Unconventional Medicine in the United States: Prevalence, Costs, and Patterns of Use*, 328 NEW ENG. J. MED. 246, 251 (1993).

physician may be able to present the therapeutic placebo in a manner that does not violate the prohibition against lying to patients. Specifically, if the physician has a sufficient degree of certainty that she will achieve a therapeutic placebo effect for the patient, then the physician's representation to the patient that she is receiving an effective therapy is the truth. Alternatively, patients may explicitly or implicitly agree not to be told that they are receiving placebo therapy, thereby extricating the physician from any ethical dilemma. Finally, withholding the fact that a patient is receiving a placebo should not violate the legal doctrine of informed consent: if the professional standard evolves such that physicians who employ placebos do not tell their patients, then the physician who so acts does so consistent with the doctrine of informed consent. Likewise, if the physician concludes that the reasonable patient would not want to be advised that she is receiving a placebo, then the physician may use the placebo treatment without violating informed consent. The inappropriate prescription of a therapeutic placebo can be addressed through a negligence analysis.

II. FORGING A CONSENSUS: WHAT, IF ANYTHING, DO RESEARCHERS AGREE UPON ABOUT PLACEBOS?

It is best to begin by asking what makes sick patients "get better." Generally, patients recover good health for one or more of the following reasons: (1) the illness ran its natural course, or, "she got better by herself"; (2) the patient responded to her treatment; and/or[17] (3) the patient responded to a host of other factors, that cannot be specifically identified, but are collectively labeled *placebo effect*.[18] In this sense, of course, "placebo" is simply a name placed on factors which cannot be identified. It reflects the notion that some things in medicine are still a black box. Physicians seeking to exploit the power of the placebo want to unpack the black box, and understand what is hidden within. Some believe that substantial progress has occurred in this direction. Others, of course, believe that any placebo effect is really attributable to the illness running its own course.

A. *Sorting Through the Competing Definitions*

Even among placebo believers, much disagreement exists over the proper definitions of placebo and placebo effect, mainly because each

17. These three phenomena may operate simultaneously. *See* Howard Brody, *Placebo Effect: An Examination of Grunbaum's Definition*, *in* PLACEBO, *supra* note 1, at 37, 43 (L. White et al. eds., 1985).

18. Judith A. Turner, Ph.D. et al., *The Importance of Placebo Effects in Pain Treatment and Research*, 271 JAMA 1609, 1609 (1994).

competing definition incorporates a bias toward a particular explanatory theory of the placebo effect, about which there also is no agreement.[19] This section briefly explores the competing definitions of placebo to provide a background to the competing theories on the mechanism by which placebos work.

Arthur Shapiro provides a robust etymology of the term placebo,[20] explaining that, although it originally referred to medicines and methods,[21] for most of its history from 1785 to 1951, it "describe[d] a medication, often commonly in use, knowingly prescribed by a physician 'to please a patient' rather than for its specific effect on a symptom or illness."[22] When physicians were still struggling to gain a foothold as professionals, and to achieve professional superiority over their competitors,[23] they often employed the term placebo pejoratively, to refer to the medicines offered by non-physicians,[24] not knowing, or unwilling to acknowledge, that most of their own offerings were no better.

Throughout this period, physicians sought to understand, just as we do, why patients got better.[25] Physicians vacillated between two theories. One model rested upon belief in the healing power of nature, accompanied by skepticism that physicians' interventions actually made a difference (especially positive), except in the rarest cases.[26] The alternative approach rested upon a confidence in the power of the imagination, conceding that physicians might help patients, not because of the specific properties of the treatment, but rather because physicians' care stimulated patients' emotions to a cure.[27] Today, while we obviously believe in the power of medicine, we

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19. *See* Shepard Siegel, *Explanatory Mechanisms of the Placebo Effect: Pavlovian Conditioning* 1 (conference paper on file with author).

20. ARTHUR K. SHAPIRO, M.D. & ELAINE SHAPIRO, PH.D., THE POWERFUL PLACEBO FROM ANCIENT PRIEST TO MODERN PHYSICIAN 28 (1997). Dr. Brody explains the pre-medical use of the word placebo:

> The word *placebo* entered the English language in the fourteenth century as the name for the vespers sung for the dead (Shapiro 1968). The word was derived from the Latin version of Psalm 116:9: "Placebo Domino in regione vivorum" (Pepper 1945), usually translated "I shall walk before the Lord in the land of the living," although the literal translation of *placebo* is "I shall please."

HOWARD BRODY, PLACEBOS AND THE PHILOSOPHY OF MEDICINE 9 (1980); *see also* HOWARD M. SPIRO, DOCTORS, PATIENTS, AND PLACEBOS 10 (1986).

21. SHAPIRO & SHAPIRO, *supra* note 20, at 38.

22. *Id.* at 31; *see also* BRODY, *supra* note 20, at 9.

23. *See generally* Ted Kaptchuk & David M. Eisenberg, *Varieties of Healing. 1: Medical Pluralism in the United States*, 135 ANNALS INT. MED. 189, 189-91 (2001).

24. SHAPIRO & SHAPIRO, *supra* note 20, at 29, 39.

25. *See generally* Brody, *supra* note 17, at 40-41.

26. *Id.* at 41.

27. *Id.*

are also revisiting the mind-body debate, conceding the possibility that in adopting the biomedical model, we may have discarded some important understandings about healing.

Richard Cabot, an eminent Harvard Medical School professor of the late nineteenth and early twentieth centuries, confirmed that physicians eventually came to rely intentionally on placebos in their practice: "I was brought up, as I suppose every physician is, to use placebo, bread pills, water subcutaneously, and other devices . . . ."[28] Placebos were thought to be inert substances, intended to ease patients' concerns.[29] Henry K. Beecher summarized the common reasons for placebo use in his important article on placebos in 1955, including mention of its use "as a psychological instrument in the therapy of certain ailments arising out of mental illness, [and] as a resource of the harassed doctor in dealing with the neurotic patient."[30]

Beecher's dramatic thesis was that there exists a powerful, and previously undetected, placebo effect that is not merely psychological but physiological as well.[31] In a review of 15 studies involving over a thousand patients, Beecher found that an average of 35.2% of the subject patients were "satisfactorily relieved by a placebo,"[32] ranging from 21% to 58%.[33] While debate persists even today about Beecher's article,[34] no one questions that his work was instrumental in invigorating serious consideration of placebos as an extraordinarily powerful agent.[35]

Following Beecher's study, the placebo effect was primarily thought of as the "black box" of the countless variables in a patient's recovery[36] that

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28. Ted J. Kaptchuk, *Powerful Placebo: The Dark Side of the Randomised Controlled Trial*, 351 LANCET 1722, 1722 (1998) (quoting Richard Cabot, *The Use of Truth and Falsehood in Medicine: An Experimental Study*, AM. MED. 1903, 5:344-49 (1903)).

29. *See generally* BRODY, *supra* note 20, at 9.

30. Henry K. Beecher, *The Powerful Placebo*, 159 JAMA 1601, 1601 (1955).

31. *Id.* at 1605.

32. *Id.* at 1604 (table 2), 1605.

33. *See* SHAPIRO & SHAPIRO, *supra* note 20, at 78 (discussing Beecher's work). A subsequent study by Kissel and Barrucand also observed placebo effects ranging from 28.5%-58%. *Id.* Frederick J. Evans estimated placebos to be 55%-60% as effective as most over-the counter analgesics. *Id.*

34. *See, e.g.*, Hrobjartsson & Gotzsche, *supra* note 7, at 1594 (arguing that the method used by Beecher and others in measuring the placebo effect make it impossible to distinguish placebo effect from "natural course of the disease, regression to the mean, and the effects of other factors"); Gunver S. Kienle & Helmut Kiene, *Placebo Effect and Placebo Concept: A Critical Methodological and Conceptual Analysis of Reports on the Magnitude of the Placebo Effect*, 2 ALTERNATIVE THERAPIES HEALTH & MED. 39 (1996) (arguing that not a single study relied upon by Beecher demonstrates a placebo effect).

35. *See generally* Anne Harrington, *"Seeing" the Placebo Effect: Historical Legacies and Present Opportunities* 6 (conference paper on file with author).

36. T.D. Borkovec, *Placebo: Defining the Unknown*, *in* PLACEBO, *supra* note 1, at 59, 63.

had to be controlled in the context of clinical trials for a new treatment.[37] The "gold standard" for establishing the efficacy of a new drug requires that the experimental drug undergo a randomized double-blind placebo controlled study.[38] The placebo effect itself has not been much studied. A great deal is known about the "variables that control placebo effects . . . [b]ut that is not an explanation of the placebo effect."[39] Only now are researchers seeking to unpack what causes the placebo effect, and whether placebos can themselves be therapeutically effective.

To provide some overview of the nuances of the various definitions of placebo as therapy,[40] and the placebo effect, this Article will next briefly

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37. *See generally* Kaptchuk, *supra* note 28. This Article does not address clinicians' use of placebos in a research context, which generally is considered the standard and appropriate method for the conduct of a clinical trial of a new drug or, less often, procedure. A patient control group receives a placebo, or "dummy," to enable the researchers to identify and quantify the existence of the *specific* effect of the unproven therapy. *See generally* SPIRO, *supra* note 20, at 11-12. In short, researchers use the placebo "to control for all the nonbiological therapeutic variance that might contaminate the results" of the clinical trial. Seymour Fisher & Roger Greenberg, *The Curse of the Placebo: Fanciful Pursuit of a Pure Biological Therapy, in* FROM PLACEBO TO PANACEA PUTTING PSYCHIATRIC DRUGS TO THE TEST 4 (Seymour Fisher & Roger P. Greenberg eds., 1997).

This is not to suggest that contemporary placebo usage in clinical trials is uncontroversial. One body of criticism goes to the sufficiency of the comparison between the drug group and the placebo group, arguing that a no-treatment group should be added as well (to distinguish between nonspecific effects and the natural course of the disease), and that the research design should better control for patients' expectancies. *See* Connie Peck & Grahame Coleman, *Implications of Placebo Theory for Clinical Research and Practice in Pain Management*, 12 THEORETICAL MED. 247, 257-58 (1991); Turner et al., *supra* note 18, at 1612; *see also* SPIRO, *supra* note 20, at 12-13 (complaining about the inadequate attention researchers give to the placebo effect in control groups which experience substantial improvement, suggesting that researchers should wonder whether improved clinician/patient relationship, participation in a study, or some other identifiable factor cause the patients' improvement). It is also unclear what role the Hawthorne Effect (the effect of an observer on a study) plays in clinical trials. *Id.* at 14.

Other concerns about the use of placebos in clinical trials are ethical. Researchers were sharply criticized when they published a paper on fetal tissue transplants in which they employed sham brain surgery as a control. *See* Peter Clark, *Placebo Surgery for Parkinson's Disease: Do the Benefits Outweigh the Risks?*, 58 J.L. & MED. ETHICS 69 (2002); Ruth Macklin, *The Ethical Problems with Sham Surgery in Clinical Research*, 341 NEW ENG. J. MED. 992 (1999); W. John Thomas, *Informed Consent, The Placebo Effect, and the Revenge of Thomas Percival*, 22 J. LEGAL MED. 313, 346 (2001). Many also criticize the use of a placebo as a control where effective therapy exists, arguing that the new therapy's effectiveness should be judged against extant treatment, and that no patient should be asked to forgo effective treatment for the sake of research. *See, e.g.*, Sharona Hoffman, *The Use of Placebos in Clinical Trials: Responsible Research or Unethical Practice?*, 33 CONN. L. REV. 449 (2001); Timothy S. Jost, *The Globalization of Health Law: The Case of Permissibility of Placebo-based Research*, 26 AM. J.L. & MED. 175 (2000); Kenneth J. Rothman & Karin B. Michels, *The Continuing Unethical Use of Placebo Controls*, 331 NEW ENG. J. MED. 394 (1994).

38. Kaptchuk, *supra* note 28, at 1724.

39. Ader, *supra* note 5, at 9.

40. Each definition of placebo includes a reference to its use as a control in experimental

discuss the different perspectives on placebos offered by Arthur Shapiro and Howard Brody. The discussion then turns to Howard Spiro, who insists that the placebo effect produces only subjective relief for patients.

Arthur Shapiro hypothesizes that

> [a] *placebo* is any therapy (or that component of any therapy)[41] that is intentionally or knowingly used for its nonspecific, psychological, or psychophysiological, therapeutic effect, or that is used for a presumed specific therapeutic effect on a patient, symptom, or illness but is without specific activity for the condition being treated.[42]

As do most researchers in the area, Shapiro recognizes that a placebo may not produce a placebo effect,[43] and that a placebo effect may be positive or

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medicine. Shapiro, for example, states that "[a] placebo, when used as a control in experimental studies, is a substance of procedure that is without specific activity for the condition being treated." SHAPIRO & SHAPIRO, *supra* note 20, at 41. Brody explains:

> In medical research, a placebo is an intervention designed to mimic the modality or process being studied, but without any of its nonsymbolic healing properties, so as to serve as a control in a double-blind trial (in which the control group gets a dummy treatment, and neither the subjects nor the investigators know which group gets the active treatment and which gets the dummy).

Brody, *supra* note 17, at 14; *see also* BRODY, *supra* note 20, at 43 (referring to placebo use to "eliminate observer bias in an experimental setting"); SPIRO, *supra* note 20, at 11 (distinguishing placebo in research protocols from placebo in clinical practice). This Article does not address the issues that arise from the use of placebo controls in the experimental setting.

41. Shapiro assumes that active treatments may contain placebo components, a proposition with which both Adolf Grunbaum and Howard Brody would agree. Grunbaum makes this point by distinguishing between the "characteristic" and "incidental" factors of a therapy, whereby the incidental factors may enhance the remedial effects of the treatment. Adolf Grunbaum, *Explication and Implications of the Placebo Concept*, *in* PLACEBO, *supra* note 1, at14-16. Brody focuses on the benefits of the *therapeutic context*, which he suggests boosts the effectiveness of the active medication. BRODY, *supra* note 20, at 32.

42. SHAPIRO & SHAPIRO, *supra* note 20, at 41. Grunbaum differentiates the two scenarios posed in Shapiro's definition by labeling them as "intentional placebo" and "inadvertant placebo." Grunbaum, *supra* note 41, at 13. Enhancing Shapiro's approach, Grunbaum creates an umbrella category of the *genus placebo*, of which intentional and inadvertant placebos are species. What intentional and inadvertant placebos share, Grunbaum argues, is the objective property that they are not remedial for the patient's condition. *Id.* at 17, 22. Any therapy that includes at least one factor that is remedial will qualify as a nonplacebo (Grunbaum rejects the terms specific and non-specific, and discusses instead whether an intervention contains a remedial component). *Id.* at 23. Brody rejects the concept of *placebo genus*, for reasons exemplified by an example: under Grunbaum's approach, Brody asserts, potassium cyanide could be a generic placebo for a cold, which, Brody suggests, cannot be what Grunbaum intends. Brody, *supra* note 17, at 44.

43. SHAPIRO & SHAPIRO, *supra* note 20, at 42.

negative.[44] Significant to Shapiro's definition is an objective determination of whether something is a placebo;[45] the physician's intent or belief being irrelevant (although the definition recognizes that the physician's use of the placebo may be "unwitting").[46]

Howard Brody prefers, on the other hand, a subjective definition of placebo:[47] "In therapeutic healing, a placebo is a treatment modality or process administered with the belief that it possesses the ability to affect the body only by virtue of its symbolic significance."[48] Differentiating himself sharply from Shapiro, Brody's definition relies on the physician's therapeutic beliefs.[49] Brody carries this subjectivity into his definition of *placebo effect*, into which he also incorporates the patient's beliefs, which he culturally contextualizes[50] "[a] change in the body (or the body-mind unit) that occurs as the result of the symbolic significance which one attributes to an event or object in the healing environment."[51] Brody situates the placebo effect in the category of "general therapies," because of its ability to "effect change in virtually any potentially reversible disease or disorder in medicine."[52] Brody speculates that while "specific" treatments have approximately a 75%-95% probability of being efficacious for a few illnesses, "a placebo has a 30%-40% probability of being

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44. Grunbaum, *supra* note 41, at 15-16; SHAPIRO & SHAPIRO, *supra* note 20, at 42; Brody, *supra* note 17, at 10. Some have adopted the term nocebo effect to refer to the negative effects of a placebo. *See, e.g.*, Daniel E. Moerman, *Meaningful Dimensions of Medical Care* 2 (conference paper on file with author).

45. SHAPIRO & SHAPIRO, *supra* note 20, at 41. As such, a therapy does not qualify if the physician thinks that it is a placebo but it actually turns out not to be. Grunbaum, *supra* note 41, at 13. Brody takes a subjective approach. *See infra* notes 47-48 and accompanying text.

46. Grunbaum, *supra* note 41, at 12-13. Spiro would seem to take this position as well: "A placebo therapy may be used with or without knowledge that it is a placebo. Included among placebos are treatments that are given in the belief that they are effective but that actually are placebos by objective evaluation." SPIRO, *supra* note 20, at 1-2.

47. *See* Brody, *supra* note 17, at 44.

48. BRODY & BRODY, *supra* note 2, at 14; *see also* BRODY, *supra* note 20, at 43.

49. Brody, *supra* note 17, at 44. Brody also allows for alternative paradigms of belief. BRODY, *supra* note 20, at 42.

50. BRODY, *supra* note 20, at 42.

51. BRODY & BRODY, *supra* note 2, at 9. The Brodys' reference to the "healing environment" seeks to exclude from placebo effect "any form of autosuggestion or self-fulfilling prophecy, whether or not connected with disease or healing." Brody, *supra* note 17, at 45; *see also* BRODY & BRODY, *supra* note 2, at 9. As long as the patient believes he is in the healing context, he need not believe the treatment being given is efficacious, but only that it is treatment, a deliberate intervention given in response to his illness with beneficial intent." BRODY, *supra* note 20, at 35 (Brody looks then at intent of the caregiver, and belief of the patient). Thus, the meaning of placebo effect is "context-dependent." *Id.* at 36.

Spiro takes a much broader approach. For him, placebos include "any treatments, no matter how potentially specific and no matter who administers them." SPIRO, *supra* note 20, at 1-2.

52. BRODY, *supra* note 17, at 46.

efficacious for almost any disorder."[53] Thus, Brody analogizes placebos to "general" therapies along with diet, exercise and rest.[54]

While adopting Howard Brody's definitional approach, with its emphasis on physician intent,[55] Howard Spiro departs from both Brody and Shapiro in his understanding of the scope of the placebo effect. Spiro believes that the placebo effect is limited to subjective complaints and pain relief.[56] He observes, "The placebo response may ameliorate diseases, but the evidence is not available, or at least I have not found it."[57] After years of rejection by the medical community, Spiro's position may now be supported by the Danish study.

This Article proceeds on the premise that placebos comprise any intervention (whether a pill, surgery or the therapeutic relationship), administered in a healing context, that is not specific[58] to the patient's condition,[59] but nonetheless may hold the potential to induce a

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53. *Id.*

54. *Id.*

55. SPIRO, *supra* note 20, at 19.

56. *Id.* at 85.

57. *Id.* at 85; *see also id.* at 88-89. *But see* Ian Wickramasekera, *A Conditioned Response Model of the Placebo Effect: Predictions from the Model, in* PLACEBO, *supra* note 1, at 255-56 ("Placebo effects are not limited to the relief of acute pain. Placebos may be useful in the therapy of coughs, headaches, asthma, multiple sclerosis, the common cold, diabetes, ulcers, arthritis, emesis, seasickness, cancer, parkinsonism, and other ailments.").

58. Daniel Moerman provides one of the better explanations of the distinction between "specific effect" and "placebo effect." "Generally speaking, there are three sorts of healing processes: *autonomous ones* based on the immunological and homoeostatic processes of the body, *specific ones* based on the pharmacological or physical dimensions of the healing process, and *meaningful ones* based on knowledge and interaction." Daniel E. Moerman, *Cultural Variations in the Placebo Effect: Ulcers, Anxiety, and Blood Pressure*, 14(1) MED. ANTHROPOLOGY Q. 51, 56 (2000).

59. Arthur Shapiro defines "specific activity" as "the therapeutic influence attributable solely to the contents or processes of the therapies rendered." A.K. Shapiro & L.A. Morris, *The Placebo Effect in Medical and Psychological Therapies, in* S.L. GARFIELD & A.E. BERGIN, HANDBOOK OF PSYCHOTHERAPY AND BEHAVIOR CHANGE (1978), *quoted in* Grunbaum, *supra* note 41, at 12. Some avoid reference to specific vs. non-specific, complaining that it creates too many ambiguities. *See, e.g.*, Grunbaum, *supra* note 41, at 21. Grunbaum thinks about whether a therapy is remedial. If it is, it is not a placebo. *Id.* at 23; *see also* Brody, *supra* note 17, at 46. Others suggest beginning with an entirely new vocabulary to talk about the placebo phenomenon. *See generally* Peck & Coleman, *supra* note 37, at 248-29. Peck and Coleman criticize the current use of singular terminology because it suggests a unitary effect, *id.* at 248, when the term actually describes "a group of effects whose specific mechanisms of action we do not yet understand, but whose efficacy has been demonstrated in thousands of studies." *Id.* at 249.

Some would argue that a placebo is in fact "specific" to certain conditions, such as "hypochondriasis, psychophysiologic disturbances, and most emotional disorders." Herbert M. Adler & Van Buren O. Hammett, *The Doctor-Patient Relationship Revisited: An Analysis of the Placebo Effect*, 78 ANNALS INTERNAL MED. 595, 595 (1973). Further, Bootzin and Caspi claim that "the effects of the placebo can be highly specific. They include effects, such as pain reduction,

psychological or physiologic therapeutic response in some patients, by a mechanism not yet understood.[60] This approach embraces the contemporary understanding of placebo effect, which focuses upon the positive[61] healing[62] effects resulting from the symbolic import of the placebo, as well as the context (a setting understood by the patient to be a healing environment) in which the placebo is used.[63] This concept of placebo effect encompasses effective treatments that may have placebo effects in addition to what are understood to be their specific curative or ameliorative effects.[64]

B. *Hypotheses About How Placebos Work*

Most frustrating to those interested in therapeutic utilization of the placebo effect is that it remains unknown why or on whom placebos work. An initial question is whether placebos, to the extent they exist at all, affect subjective well-being, symptoms, or biological-functioning.[65] Those who believe that placebos contribute to healing subscribe to two very different concepts of healing: (1) the biological events that result in cure, or (2) the therapeutic process which enhances health and well-being.[66] Those in the first group believe that placebos can catalyze the body's ability to spontaneously begin to heal: "[p]lacebo effects are not limited to the relief of acute pain. Placebos may be useful in the therapy of coughs, headaches, asthma, multiple sclerosis, the common cold, diabetes, ulcers, arthritis,

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healing of a peptic ulcer, bronchodilation in asthmatics and the like." Bootzin & Caspi, *supra* note 6, at 3.

60. *See* Irving Kirsch, *Specifying Nonspecifics: Psychological Mechanisms of Placebo Effects*, *in* THE PLACEBO EFFECT 166-67 (Harrington ed. 1997). *See generally* Bootzin & Caspi, *supra* note 6, at 2.

61. Obviously, a nocebo (negative) effect can also occur. Sheperd Siegel suggests the possibility that nocebo effects might be compensatory reactions to placebos. *See infra* note 62.

62. Siegal notes that the definitions can be distinguished by whether the definition of placebo effect refers to *"any* physiological response to an innocuous treatment that is not explained by the properties of the treatment," Siegal, *supra* note 19, as opposed to whether the placebo must have a *therapeutic* effect, which is, for example, Brody's view, Brody, *supra* note 17, at 46.

63. *See generally* Bootzin & Caspi, *supra* note 6.

64. Henry K. Beecher described this as early as 1956, when he explained that "[t]he total drug effect is equal to its 'active' effect plus its placebo effect." Henry K. Beecher, *The Powerful Placebo*, 159 JAMA 1659, 1606 (1956). The assumption is, of course, that placebos have only the non-specific psychological component. *See* Richard R. Bootzin, *The Role of Expectancy in Behavior Change*, *in* PLACEBO, *supra* note 1, at 196, 197. Many researchers criticize this model, which assumes an independence between the psychological and the physiologial. *Id.* Researchers suggest that the "so-called 'nonspecific' psychological component of taking medication for a particular problem could affect the same specific physiological mechanisms that are affected by pharmacologically active agents." *Id.*

65. Bootzin & Caspi, *supra* note 6, at 13-14.

66. *Id.* at 14.

emesis, seasickness, cancer, parkinsonism, and other ailments."[67] Those in the second group refer to the patient's "spiritual, emotional, cognitive, physical, social, and environmental functioning which facilitate the individual's development."[68]

Howard Brody proposes a model for thinking about placebo effect theories within three categorical explanations.[69] The first level of explanations attempts to explain the clinical operation of placebos.[70] The second level of explanations theorizes the placebo action.[71] The third level of explanations seeks to explain the mind-body interaction that occurs when placebos affect the patient's status.[72] In short, level one explanations seek to identify the stimuli that will cause the placebo effect; level two theories explain how these stimuli affect the brain; level three theories explain how the brain communicates with the body. The following represents a categorization of placebo theories in three levels of explanations:

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67. BRODY, *supra* note 20.

68. *Id.* at 16. Explaining characteristic versus incidental, Drs. Bootzin and Caspi introduce the hypotheses about how placebos work by describing the "schools of thought" into which the various approaches fall:

> (1) Directly—through the activation of innate homeostatic healing processes, often referred to as spontaneous healing regardless of what the biological treatment might be. For instance, the characteristic elements of antibiotics in the case of viral pharyngitis may by ineffective, yet the incidental ones may trigger the placebo effect . . . .
> (2) Indirectly—through patient behavior as a mediating variable. For instance Horowitz and Horowitz found that patients who adhered more to the placebo treatment, in clinical trials across conditions, had better outcomes than those who did not. One plausible explanation might be that those who adhered might also have engaged in other good health-related activities, and that the incidental element of adhering to the treatment protocol may have affected their outcome.
> (3) Interaction of active and indirect effects with the total package of care . . . . That is, treatments may be more or less effective depending on the interaction of meaning with active change ingredients.

Id. at 14-15 (citations omitted).

69. *See generally* Howard Brody, *The Placebo Response: Recent Research and Implications for Family Medicine*, 49 J. FAM. PRAC. 649 (2000).

70. *See generally id.*

71. *See generally id.*

72. *See id.* at 651. Anne Harrington provides a categorization of every placebo theory advanced since the 1950s that remains viable, which is a helpful introduction into the literature, and in sorting through the various explanations of the placebo effect. Harrington, *supra* note 35, at 12.

FIRST LEVEL	SECOND LEVEL	THIRD LEVEL
a. Identifying the Placebo Reactor	a. Conditioning	Brain biochemistry: e.g., endorphins
b. The meaning model	b. Expectancy	

1. First Level Explanations

a. Identifying the "Placebo Reactor"

Characterizing the person who is susceptible to placebos, the "placebo reactor," has proven to be one of the most fruitless enterprises pursued by placebo researchers,[73] who have concluded that the placebo reactor does not exist.[74] Consequently, the generally accepted wisdom is that "demographic variables such as age, sex, intelligence, race, social class, ethnicity, religiosity, or religious background" are unreliable predictors of who will respond to placebos.[75] Neither is susceptibility to hypnosis nor suggestibility indicative of response to placebos.[76] More recently, researchers still on the trail of characterizing the placebo reactor have, with some empirical support, suggested that individuals who tend to be anxious,[77] are Type A personalities,[78] or are sociable[79] react to placebos.[80]

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73. Physicians of prior times have variously speculated that placebo reactors are "compliant, religious, hypochondriac, anxious, as less educated and frequently using cathartics; disturbed and likely to react to drugs with atypical reactions; anxious and depressed; dependent; ideational; neurotic; extroverted; and so on." SPIRO, *supra* note 20, at 91-92. The Brodys assert that the entire enterprise of identifying placebo responders was unscientific; they suggest that it was pursued by researchers seeking to eliminate from clinical trials those who might taint the outcomes by being too susceptible to placebos. BRODY & BRODY, *supra* note 2, at 35.

74. *See* BRODY & BRODY, *supra* note 2, at 35; SPIRO, *supra* note 20, at 91.

75. *See* SHAPIRO & SHAPIRO, *supra* note 20, at 234.

76. *Id.* at 234. *But see* Wickramasekera, *supra* note 57, at 272-74 (critiquing studies which concluded that susceptibility to hypnosis is not a predictor of placebo responsiveness).

77. *See* D.M. Chaput de Saintonge & Andrew Herxheimer, *Harnessing Placebo Effects in Health Care*, 344 LANCET 995, 996 (1994) (placebo response strongest in those who are "anxious, dependent, and non-critical"); N.K. Rosenberg et al., *Characteristics of Panic Disorder Patients Responding to Placebo*, 365 ACTA PSYCHIATRICA SCANDANAVICA 33, 36-37 (Supp. 1991) (finding significant placebo response in patients with non-severe panic disorder); SHAPIRO & SHAPIRO, *supra* note 20, at 235; SPIRO, *supra* note 20, at 92.

78. *See* Milou-Daniel Drici et al., *Influence of the Behaviour Pattern on the Nocebo*

Many agree that "high acquiescers"[81] are not only more susceptible to the effects of placebos, but to active drugs as well.[82] When all is said and done, though, "the placebo effect is regarded as a contextual situational phenomenon more than an enduring personality trait."[83]

So, what do we do with a conclusion that suggests that we cannot predict who will successfully respond to placebos? One obvious response is that physicians should not employ placebos for therapeutic purposes until more is understood. Dr. Brody argues otherwise—that everyone is a potential placebo reactor, and that physicians should therefore regularly incorporate placebos into their clinical practice.[84] The next sections describe how this might be done.

b. The Meaning Model

The "meaning model" of the placebo effect[85] hypothesizes that the placebo effect mostly depends upon the therapeutic relationship and its

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Response of Healthy Volunteers, 39 BR. J. CLIN. PHARMACOL. 204, 204 (1995) (confirming that Type A personalities are more likely to report side effects of placebo).

79. *See* Fisher & Greenberg, *supra* note 37, at 33 (discussing trend in research suggesting greater placebo response in persons "described as sociable or interested in relating to others than in those who are characterized as self-sufficient and inclined toward being distant from others").

80. *See* Bootzin & Caspi, *supra* note 6, at 6-7 (summarizing literature rebutting recent attempts at identifying the placebo responder, and affirming that no such person exists).

81. *See, e.g.*, Fisher & Greenberg, *supra* note 37, at 34, 39 (advocating that desire to please, or acquiescence, predicts placebo response); MICHAEL JOSPE, THE PLACEBO EFFECT IN HEALING 90-91 (1978) (summarizing research which suggests that the placebo reactor personality does exist, focusing particularly on acquiescence, those who become anxious, and those who rely on others); C. Crowe McMann et al., *The Role of Personality Factors and Suggestion in Placebo Effect During Mental Stress Test*, 33 BR. J. CLIN. PHARMACOL. 107, 109 (1991) (surveying research suggesting correlation between placebo response and tendency to acquiesce, and concluding that non-responders to placebo were more authoritative and aggressive).

82. Fisher & Greenberg, *supra* note 37, at 39 (acquiescence predicts positive therapeutic response to placebos and frequently negative response to active drugs, which establishes overlap between "active" drug and placebo).

83. Bootzin & Caspi, *supra* note 6, at 7.

84. BRODY & BRODY, *supra* note 2, at 36.

85. Anxious to shed the negative implications of the "placebo effect", many advocates of placebo theory suggest renaming it, with competing alternatives including "remembered wellness" and context effects. Herbert Benson & Richard Friedman, *Harnessing the Power of the Placebo Effect and Renaming It "Remembered Wellness,"* 47 ANN. REV. MED. 193, 195 (1996) (remembered wellness suggests that an anxiety-reducing relationship with the physician, and environmental factors such as the treatment room, will enable the patient to recall previously successful treatments, thereby contributing to the alleviation of symptoms). *See, e.g.*, Chris van Weel, *Examination of Context of Medicine*, 357 LANCET 733, 733 (2001); Zelda Di Blasi et al., *Influence of Context Effects on Health Outcomes: A Systematic Review*, 357 LANCET 757, 757 (2001) (context effects refers to the various environmental factors that may enhance the effect of the specific interventions used to treat the patient).

constituent elements. The research in this area "suggests that the placebo response is more likely to occur in the clinic when the patient regards the clinician as experienced, competent, and optimistic, and when the clinician expects the treatment to help."[86] This approach asserts that the clinical encounter can evoke both psychological and physiological responses, and is, therefore, itself active treatment, or a method of enhancing the specific effect of the medicine or procedure provided by the physician.[87]

So, for example, Howard Brody posits that the physician-patient encounter can itself act as placebo[88] if the patient feels heard and is satisfied with the explanation of his illness; the patient feels cared for; and the patient feels some sense of control over his symptoms.[89] Capitalizing on the placebo effect in the treatment setting is argued to be particularly important in the primary care context, where a positive therapeutic encounter may be the most efficacious treatment available.[90] A few studies support this proposition.[91] For example, one study suggested that patients with minor illnesses for which no definitive diagnosis could be made showed greater satisfaction, and recovered more quickly, when they received a positive consultation—either a placebo prescription or a confident indication that they would recover quickly, than when they received a negative consultation—expression of uncertainty about what was wrong or a placebo prescription with an expression of doubt that it would work.[92]

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86. Bootzin & Caspi, *supra* note 6, at 7.

87. Moerman, *supra* note 44, at 1-2.

88. *See* Brody, *supra* note 69, at 649, 650.

89. *Id.*; Howard Brody & David B. Waters, *Diagnosis is Treatment*, 10 J. FAM. PRAC. 445, 448-49 (1980); *see also* Benson & Friedman, *supra* note 85, at 195 (emphasizing positivism in physician-patient encounter).

90. It is estimated that physicians are unable to diagnose a high proportion of the symptoms they encounter (40-60%), B.K. Thomas, *General Practice Consultations: Is There Any Point in Being Positive?*, 294 BRIT. MED. J. 1200, 1200 (1987), and that stress and anxiety are frequently determined to be the underlying cause of the patient's complaints. *See* Benson & Friedman, *supra* note 85, at 195; Brody & Waters, *supra* note 89. It is hypothesized that empathy and conversation designed to identify the source of the patient's symptoms can double as effective treatment methods where drugs or surgery are useless. K.B. Thomas, *The Placebo in General Practice*, 344 LANCET 1066 (1994) (hereinafter *General Practice*) (declaring that doctor's use of their own therapeutic power "would result in the making of less illness, the prescribing of less medication, and a better understanding by the patient of his or her condition").

91. *See* Moira A. Stewart, *Effective Physician-Patient Communication and Health Outcomes: A Review*, 152 J. CAN. MED. ASSOC. 1423, 1429 (1996) (reviewing several studies of effect of physician style on patient outcomes and concluding that "effective communication exerts a positive influence not only on the emotional health of the patient but also on symptom resolution, functional and physiologic status, and pain control"). *See generally* Nancy Leopold et al., *Sustained Partnership in Primary Care*, 42 J. FAM. PRAC. 129 (1996).

92. Thomas, *supra* note 90, at 1201-02. Another study suggests that compassionate emergency room treatment can decrease the number of repeat visits and substantially improve patients' perception of the quality of their care. *See generally* Donald A. Redelmeier et al., *A*

Brody and Waters suggest that even the process of explaining a patient's diagnosis carries meaning for the patient and her family, and can negatively or positively impact the patient's health.[93] Negative attributions can produce the nocebo effect. In taking the patient's history, placebo researchers recommend that physicians identify prior treatments or settings that have been unsuccessful for the patient, and avoid reintroducing treatments that have negative meanings for the patient.[94]

The physician and patient's confidence in a treatment, and the positive beliefs and expectations they ascribe to it, can convert an "ineffective" treatment into an effective one.[95] Effective sham surgeries, as well as surgeries believed to be successful when popular, but later proven to be ineffective, are the more prevalently cited examples of this phenomenon.[96] Some suggest that chiropractic therapy, which is widely believed by patients to be effective,[97] epitomizes the power of meaning in the treatment context:

Randomised Trial of Compassionate Care for the Homeless in an Emergency Department, 345 LANCET 1131, 1133 (1995).

93. Brody & Waters, *supra* note 89, at 445. Their observations are grounded in a belief that physical and mental health are inextricably linked, requiring the physician to always be attendant to both mind and body. *Id.* at 449. DiBlasi and colleagues propose a similar analytical model, embracing the concepts of cognitive care and emotional care within the term "context effects." DiBlasi et al., *supra* note 85. Cognitive care refers to the effect physicians can have on patient expectations by their positive or negative descriptions of the patient's condition or treatment. *Id.* Emotional care refers to physician alleviation of fear and anxiety. *Id.* Context effects refers to the placebo effects that derive from these techniques, which, Di Blasi et al. posit, do have positive effects on patient outcomes. *Id.* van Weel suggests that context effects have their greatest value "in their enhancement of specific interventions—so that efficacy of a dose is maximized, or so that the dose or number of medicines required can be reduced." van Weel, *supra* note 85, at 733.

94. Benson & Friedman, *supra* note 85, at 195. de Saintonge and Herxheimer suggest that awareness of the placebo effect is essential throughout the physician-patient encounter. *See* de Saintonge & Herxheimer, *supra* note 77, at 995. The history should elicit information about prior bad experiences with treatments or health care providers; problems that are undiagnosable require explanation and reassurance; placebo options should be analyzed from an effectiveness, toxicity and cost perspective. *See id.*

95. Benson & Friedman, *supra* note 85, at 197.

96. *See generally* Moerman, *supra* note 44, at 6 (discussing several examples of placebo surgery, including the famous experience with bilateral internal mammary artery ligation (BIMAL), which was deemed very effective treatment for angina until subjected to a clinical trial in which patients who received the sham surgery did better than those subjected to BIMAL; this experience is frequently cited as evidence of the placebo effect that is possible from ineffective surgery, because physicians and their patients believed in it).

97. T.W. Meade, et al., *Randomized Comparison of Chiropractic and Hospital Outpatient Management for Low Back Pain: Results from Extended Follow-up*, 311 BRIT. MED. J. 349 (1995); T.W. Meade et al., *Low Back Pain of Mechanical Origin: Randomised Comparison of Chiropractic and Hospital Outpatient Treatment*, 300 BRIT. MED. J. 1431 (1990); Shekelle et. al., *Spinal Manipulation for Low-Back Pain*, 117 ANNALS INTERNAL MED. 590 (1992).

> The chiropractor immediately carries out a focused, pointed, attentive examination asking pertinent questions about history, injury, mobility and so on, asking you to bend this way and that, usually taking x-rays and showing them to you, pointing out misaligned vertebrae, explaining the course of treatment, its goals and likelihood of success. The walls in a chiropractor's office are frequently hung with large posters displaying the spine, explaining its function and workings; there are colorful brochures explaining the history and value of chiropractic treatment. Occasionally one finds articles, popular or scholarly, photocopied perhaps, showing the results of studies on the effectiveness of chiropractic. One may even see a model of an actual spine with simulated spinal nerves arrayed along it, hanging from a doorknob. The entire experience is validating, encouraging, supportive and positive. We haven't yet had an adjustment and we feel better already. The adjustment, on an elaborate adjustable table, is itself replete with satisfying pops and snaps, rolling over, and just enough pain to suggest that something good may come from it.
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> . . . .
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> In this way, the case of chiropractic is similar to the abandoned treatments discussed earlier: 70 or 80% of patients achieve satisfactory treatment outcomes marked by measurable subjective and objective improvement with enthusiastically employed techniques—rich in meaning—which seem not to be substantially more effective than sham treatments in blind trials.[98]

Today, the placebo effect is frequently relied upon to justify integration of complementary and alternative therapies, even if they are not proven to be efficacious through clinical trials, because patients have such confidence in CAM.[99]

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98. *See generally* Moerman, *supra* note 44, at 13-14.

99. *See* BRODY & BRODY, *supra* note 2, at 143-44 (stating that alternative medicine relies more on placebo effect than conventional medicine, which is particularly important with patients for whom conventional medicine is ineffective, or who fail to respond to placebo stimuli in the context of conventional medicine); Backonja & Brown, *supra* note 10 (web article indicating that alternative medicine placebo effect may be safer choice "[w]ith conditions that are self-limited, or are relatively minor, or for which there is no fully satisfactory conventional treatment"); *see also* C.R.B. Joyce, *Placebo and Complementary Medicine*, 344 LANCET 1279, 1281 (1994) (indicating that inadequate evidence exists to establish definitively whether complementary methods are placebos).

2. Second Level Explanations

Second level explanations elucidate the connection between the placebo and the brain. They seek to explain the mechanism of the placebo effect. This section discusses conditioning and expectancy theories.

a. Conditioning

The conditioning theory rests on the premise that neutral stimuli, when paired with a biologically significant stimulus, can produce conditioned responses.[100] For example, clinic odors associated in the patient's mind with chemotherapy-induced nausea can cause nausea.[101] Researchers interested in therapeutic use of placebos hope to use them, through conditioning, to ameliorate pain or induce recovery.[102] Consequently, they focus on the relationship between active medication and placebo effect. Specifically, they foresee two different ways that conditioning can be employed to achieve a

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100. Michael Jospe provides a helpful explanation of conditioning or learning theory generally:

> The two major approaches in learning theory are classical (or respondent or Pavlovian) conditioning and instrumental (or operant or Skinnerian) conditioning. In classical conditioning, an unconditioned stimulus such as food is presented to a subject. The response, salivation, that is elicited is known as the unconditioned response. Now, if another stimulus, such as the sound of a bell, is presented simultaneously with or just after the food, the previously neutral bell may, after a number of pairings, elicit the response, salivation, when it is presented to the subject without food. The response the bell alone elicits is called a conditioned response. The persistent absence of the unconditioned stimulus (food) will result in a weakening and eventual diminution or cessation of the conditioned response (salivation) in a process known as extinction.
>
> A conditioned response, once acquired, is not solely elicited by stimuli identical to the original stimulus. Other similar stimuli may elicit the response in a process known as generalization. The degree to which the new stimulus is similar to the original stimulus will affect the strength of the response, with the amount of generalization being positively correlated with the similarity of the second stimulus with the original stimulus situation.

JOSPE, *supra* note 81, at 10-11; *see also* Siegel, *supra* note 19.

101. Siegel, *supra* note 19, at 4.

102. *See* Wickramasekera, *supra* note 57, at 259, 263; *see also* BRODY, *supra* note 20, at 21. Similarly, neutral stimuli can have nocebo effects. "Neutral stimuli (CSs) associated with the *onset* and course of the disease reactions (UCRs) may become negative CSs. These CSs may elicit CRs that potentiate the UCRs or disease reactions, by either directly or indirectly inhibiting mechanisms of immunocompetence." Wickramasekera, *supra* note 57, at 263. For a more skeptical review of conditioning theorists' work, *see* SPIRO, *supra* note 20, at 211-26.

therapeutic placebo effect: with active medication alone or with medication plus stimuli.[103]

Dr. Ian Wickramasekera sees conditioning as an opportunity to increase the potency of active medication.[104] Drug administration is generally preceded by a variety of events, such as the appearance of a medical professional, or the preparation of the patient for a shot.[105] Wickramasekera posits, then, that active interventions elicit both the specific effect of the intervention (the nonplacebo response), and the learned response to the treatment setting (the placebo response).[106] The resultant hypothesis: "that intrinsic to all *effective* interventions or events (chemical, surgical, psychological, or psychophysiological) . . . is the potential for Pavlovian conditioning, and therefore for placebo learning."[107] The therapeutic potential is the use of active ingredients to produce more, stronger, and longer lasting placebo effects with an efficacious intervention.[108] The conditioning theory suggests that health care professionals should attempt to increase the specific effect of a therapeutic intervention by engaging in a routine when administering treatment to patients that the patients will associate with the effects of the active intervention, thereby potentially increasing the power of those effects through a conditional response. As explained by Dr. Wickramasekera,

> [t]hese credible signals may be quite diverse: (1) The labeling of the therapist (e.g. "doctor," "swami," "professor," etc.) can influence his or her attention and arousal stimulus value in a given culture. (2) The credibility of the therapeutic setting (e.g., emergency room of a hospital, temple, university medical center, park bench) can also influence the above-described mechanisms of learning. The university medical

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103. In describing the goal of placebo treatment, de Saintonge and Herxheimer state:

> We need to choose a combination of non-specific treatment with specific treatments with a view to maximising the total absolute benefit (i.e., benefit minus risk) to the patient. This combination uses the smallest amount of each treatment to give the specified effect and is therefore likely to be most cost-efficient.

de Saintonge & Herxheimer, *supra* note 77, at 996.

104. *See generally* Wickramasekera, *supra* note 57.

105. Siegel, *supra* note 19, at 9.

106. Wickramasekera, *supra* note 57, at 265. Robert Ader questions whether a neutral stimulus that has a therapeutic effect on a patient is properly called a placebo: "A conditioned stimulus is neutral only the first time that it is presented; once it has been paired with an unconditioned stimulus, it is no longer neutral." Ader, *supra* note 5. The first part of Shapiro's placebo definition would seem to encompass conditioning theory, as would Brody's.

107. Wickramasekera, *supra* note 57, at 265.

108. *Id.*

> center, in North American culture, is the new temple of healing.[109]

The mode of treatment can influence the treatment's effectiveness, largely depending upon the meanings the patient attributes to its characteristics.[110] For example, two tablets are more effective than one, red tablets act as stimulants, and blue as depressants, and brand named drugs work better than generics.[111] This suggests that the recent trend toward integrating biomedicine with complementary therapies,[112] whether they are remedies that are ethnically, culturally, or religiously derived,[113] is not merely a matter of patient respect and cultural sensitivity, but may indeed contribute to the patient's cure by increasing the therapeutic effect of the therapy capitalizing on the placebo effect. Because meaning is culturally mediated,[114] it is important to provide health care with stimuli relevant to the patient's personal history.

The second conditioning approach explores the placebo possibilities of interspersing active medications[115] with neutral stimuli.[116] Research suggests

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109. *Id.* at 271.

110. Research also suggests that the placebo effect can vary by condition within a culture. Moerman, *supra* note 58, at 63. So, for example, an ulcer study observed very high placebo rates in Germany, but extremely low rates in Brazil. *Id.* Italians were most resistant in a multi-national comparison to placebos for anxiety disorder. *Id.* Several fascinating studies establish a connection between patients' cultural understanding of disease and longevity. One study links decreased life expectancy for Chinese-American patients who believe in Chinese astrology and are diagnosed with the condition for which their birth year is unfavorable. David P. Phillips et al., *Psychology and Survival*, 342 LANCET 1142 (1993). Adler and Hammett hypothesize that the placebo effect enables patients to fulfill their need for meaning in a group system, whether it be through the physician-patient relationship, Alcoholics Anonymous, faith healing or psychotherapy. Adler & Hammett, *supra* note 59, at 597-98.

111. *See* Moerman, *supra* note 58, at 2-3 (surveying the literature). The meaning attributed to certain characteristics can vary by culture; however, one study showed that using blue sleeping pills may not be effective for Italian men, who associate blue with the national soccer team. *Id.* at 9.

112. *See generally* Boozang, *supra* note 15, at 572-76.

113. *See generally* BARRIE R. CASSILETH, THE ALTERNATIVE MEDICINE HANDBOOK 16-47 (1998) (surveying "routes to health and spiritual fulfillment" that derive from early healing systems rooted in spiritual beliefs and particular cultures).

114. Wickramasekera elaborates: "the culture-specific context of learning can influence placebo learning through the determination of attentional and arousal mechanisms and the specification of what is a 'credible' CS for a given subject." Wickramasekera, *supra* note 57, at 271-72.

115. *See* SPIRO, *supra* note 20, at 215 (citation omitted). Peck and Coleman elaborate:

> Since one of the benefits of partial reinforcement (as has been shown by numerous conditioning studies) is increased resistance to extinction, it is conceivable that by interspersing conditioned placebo and nonplacebo treatments (once conditioning has been acquired), one might be able to maintain therapeutic

that, once an effective drug treatment regime has commenced,[117] patients can be conditioned to experience the same pharmacotherapeutic benefits of the drug regime from an active drug/placebo combination.[118] Robert Ader suggests the following therapeutic benefits if this research holds true:

> For patients maintained on long-term pharmacotherapeutic regimens, especially in the case of drugs with noxious or deleterious "side effects" such as adrenal steroids or other immunosuppressive agents, the prescription of partial schedules of drug reinforcement might reduce the total amount of drug required to treat some pathophysiological condition or maintain some physiologic state within homeostatic limits . . . .
>
> Conversely, under conditions in which the clinician might want to increase the dose of medication but is constrained by toxic target organ effects, an ostensible increase in the amount of drug being taken might be achieved by keeping the dose constant but using placebos to increase the number of occasions per day or per week on which medication would be taken . . . .
>
> Treatment under a partial schedule of drug reinforcement is likely to reduce the magnitude of side effects because CRs are not typically as large as UCRs. If side effects are reduced,

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benefits over the long-term with only small amounts of nonplacebo reinforcement in order to avoid extinction of the conditioned placebo response.

Peck & Coleman, *supra* note 37, at 263.

116. Robert Ader, *The Role of Conditioning in Pharmacotherapy*, *in* THE PLACEBO EFFECT 138, 140 (Harrington ed., 1997). Important to this is the observation that "the effectiveness of the drug treatment and placebo treatment are related—as placebo effect increases, overall drug effect increases, too." Moerman, *supra* note 58, at 58. Patients need not have extensive experience with a medication to elicit a placebo effect; pharmacological conditioning is also possible even where there is a delay between administration of the medication and the neutral stimuli. Siegel, *supra* note 19, at 4.

117. What is known as the "sequence effect" becomes important to this discussion. Sequence effect suggests that the placebo effect is most effective if the active medication precedes the placebo. Several experiments have shown that the "effectiveness of the placebo in attenuating pain depended on the preceding drug—the placebo elicited analgesia only when it followed an effective analgesic." Siegel, *supra* note 19, at 12. In addition, however, if the placebo response is a conditioned response, "it should be subject to extinction; the effectiveness of the placebo should decrease over the course of repeated administrations." *Id.*

118. Ader, *supra* note 116, at 140. So, for example, researchers have found that "patients with prior experience with immunosuppressants may acquire an immunosuppressive CR to drug-associated stimuli." *See* Siegel, *supra* note 19, at 10. Anginal patients have also been found, in a number of studies, to display conditioned responses to placebos associated with previously-used active drugs. *Id.* at 11.

> adherence to the treatment protocol may increase . . . . The fact that less active drug is present could also have consequences for target organ damage . . . .[119]

Obviously, the potential to achieve good patient outcomes with a smaller cumulative amount of an expensive drug also offers the possibility of cost-savings.[120] Of course, if conditioning theory is accurate, placebos should produce both the benefits and side effects of a treatment to which the patient has become accustomed.[121] Moreover, if the placebo fails to induce side effects, the patient may realize that she is receiving a placebo, thereby undermining its effects.[122]

Although researchers are confident that a significant proportion of patients can respond positively to placebos offered under the proper circumstances, they have yet to discover which patients will so respond, or to definitively identify the proper circumstances.[123] In addition, adherents of the conditioning theory readily acknowledge that it cannot be the sole explanation of the placebo effect, since placebo effects on patients do not always mimic the drug effects and placebo effects can occur without prior drug exposure.[124] According to some, expectancy theory explains those placebo responses not explicable by conditioning analysis.[125]

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119. Ader, *supra* note 116, at 156-57.

120. Ader explains the concept, although he does not suggest it for the utilization benefits that I am suggesting here: "By capitalizing on conditioning effects, it might be possible to approximate the therapeutic effects of a continuous schedule of pharmacologic reinforcement, that is, to relieve pain or maintain some physiologic state within homeostatic limits, using lower cumulative amounts of drug." *Id.* at 143.

121. *Id.* at 150.

122. *Id.* at 151. "Conditioned side effects would increase the similarity between drug and placebo conditions and amplify placebo effects." *Id.* Another less understood aspect of conditioning may lead to insights for treatment of drug addiction. The discussion thus far has focused on placebos that mimic drugs. Other experiments suggest that, in some situations, placebos cause the body to compensate for the drug effect. "The existence of compensatory pharmacological CRs has implications for understanding the role of conditioning in the phenomena of drug addiction—specifically, drug tolerance and withdrawal symptoms." Siegel, *supra* note 19, at 15. Tolerance refers to the decreasing effect of drugs over the course of administration. Tolerance increases when the drugs are administered in a regularized setting and way—the placebo effect of the environment causes the body to anticipate and compensate for the drugs, thereby decreasing their effectiveness. *Id.* Researchers suggest that this mechanism can be employed to decrease drug lethality. *Id.* at 16. In addition, "[d]rug tolerance is highly correlated with drug withdrawal symptoms. Moreover, withdrawal symptoms are compensatory responses." *Id.* at 16. Thus, it is thought that withdrawal symptoms occur in response to cues that cause anticipation of drugs. In other words, withdrawal symptoms are placebo effects. *Id.*

123. Wickramasekera, *supra* note 57, at 256.

124. Siegel, *supra* note 19, at 17.

125. *See generally id.*

b. Expectancy Theory

Expectancy theory acknowledges the possibility that a number of variables may evoke the placebo response,[126] but proposes that the placebo effect largely results from patient learning and interactions which suggest what the patient might anticipate from the prescribed treatment. While conditioning involves learning based upon past experiences (and therefore requires prior exposure to treatment), expectancy relies upon multiple forms of learning (which can include conditioning), such as "knowledge about the therapeutic agent, the circumstances under which it is administered, and the condition which is to be treated."[127] Expectancy theory hypothesizes an immediate relationship between some cognitions[128] and expectancy responses.

Changing people's expectations regarding pain, depression or anxiety can change their experiences; "expectancy-induced changes in experience are always accompanied by at least some physiological changes."[129] So, expectancy theory hypothesizes that learning about the increased efficacy of a new treatment can produce an expectancy of relief or cure, which can either affect physiological functions (blood pressure, heart rate), or produce subjective relief (amelioration of depression, avoidance of panic attack).[130] Likewise, expecting particular side effects, whether positive or negative, can evoke their occurrence.[131]

Expectancy theory offers much potential for treating a variety of conditions.[132] Expectancy can contribute to asthma attacks in patients who are aware that certain situations or substances act as triggers.[133]

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126. *See, e.g.*, Kirsch, *supra* note 60, at 174-76.

127. Donald D. Price & Howard L. Fields, *The Contribution of Desire and Expectation to Placebo Analgesia: Implications for New Research Strategies*, *in* THE PLACEBO EFFECT 123 (Harrington ed., 1997).

128. "People respond cognitively, affectively, and behaviorally to environmental events, but through cognition they also exercise control over their own behavior, which then influences not only the environment but also cognitive, affective, and biological states." James E. Maddux, *Expectancies and the Social-Cognitive Perspective: Basic Principles, Processes, and Variables*, *in* HOW EXPECTANCIES SHAPE EXPERIENCE 19 (Kirsch ed., 1999) [hereinafter EXPECTANCIES].

129. Irving Kirsch, *Response Expectancy: An Introduction*, *in* EXPECTANCIES, *supra* note 128, at 7.

130. Price & Fields, *supra* note 127, at 123; Kirsch, *supra* note 60, at 178-80.

131. Kirsch, *supra* note 60, at 176-77.

132. *See, e.g.*, Irving Kirsch & Guy Sapirstein, *Listening to Prozac but Hearing Placebo: A Meta-Analysis of Antidepressant Medications*, *in* EXPECTANCIES, *supra* note 129, at 303 (suggesting that the response to anti-depressant medication is substantially placebo); Eileen M. Palace, *Response Expectancy and Sexual Dysfunction in Women*, *in* EXPECTANCIES, *supra* note 129, at 173 (proposing employment of cognitive-physiological pathways to treat mental and physical sexual health problems in women).

133. Samantha C. Sodergren & Michael E. Hyland, *Expectancy and Asthma in*

Presumably, an understanding of this phenomenon can aid patients in self-regulating their responses to asthma triggers. In contrast, patients' expectations about the effect of their asthma medication may enhance the relief the patient experiences from the medication.[134] To illustrate, Drs. Sodergren and Hyland have recommended that "when asthma is being treated in the emergency room after an asthma attack, it might be helpful to tell patients 'We are now going to give you a powerful bronchodilator,' as this suggestion could possibly have a positive effect on outcome."[135]

A better understanding of expectation offers possibilities to exploit placebo analgesia for pain reduction.[136] Several studies undermine the classical conditioning theory as an explanation of placebo analgesic,[137] although conditioning "may lead to the acquisition of expectancies."[138] Thus, according to Dr. Kirsch, although prior exposure to treatment is not necessary to the placebo effect, it can certainly enhance it.[139]

3. Third Level Explanations

Mediational theories comprise the third level explanations. Some argue that the placebo effect is primarily psychological, as opposed to biological.[140] Others advocate that the placebo response is more likely a psychophysiological response that includes cognitive-verbal and physiochemical responses.[141]

The cognitive-verbal theory suggests the occurrence of conscious and sub-conscious processing of cognitive and emotional information in such a way that it operates safety signals which can, for example, reduce anxiety or generate hope.[142] So, the theory suggests, neutral stimuli associated with illness or treatment, such as seeing the doctor, or receiving a prescription,

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EXPECTANCIES, *supra* note 128, at 210.

134. *Id.*

135. *Id.*

136. *See generally* Donald D. Price & James J. Barrell, *Expectation and Desire in Pain and Pain Reduction*, *in* EXPECTANCIES *supra* note 128, at 145.

137. *See id.* at 154. Likewise, one of the biggest challenges to expectancy theory is whether its observations are really supportive of conditioning theory. *See* Price & Fields, *supra* note 127, at 124. *But see* Kirsch, *supra* note 60, at 173-74 (discussing experiment in which subjects' response to conditioning stimulus was ameliorated by advising subjects of manipulation, which, Kirsch claims, supports expectancy theory).

138. Kirsch, *supra* note 60, at 155.

139. *Id.* at 156, 175.

140. William B. Potkin, *A Psychological Approach to Placebo: The Role of Faith in Therapy and Treatment*, *in* PLACEBO, *supra* note 1, at 237, 238.

141. *See* Wickramasekera, *supra* note 57, at 266-67.

142. *See* Bootzin, *supra* note 64, at 200-01 (discussing various theories relating cognitive and/or expectancy theories to Pavlovian conditioning). Conditioning theory relies on covert stimuli to elicit a response from the subject, whereas cognitive theory assumes that the subject's reactions are centrally controlled. *Id.*

which patients associate with imminent relief, can themselves operate to produce relief.[143]

The physiochemical aspect of the placebo effect arguably encompasses psychoneuroendocrine and psychoneuroimmunological components. First, it "appears that there are descending pain inhibitory pathways from the medial brain stem to the dorsal horn of the spinal cord."[144] These pathways involve opiate and non-opiate mechanisms which can be activated by endorphins and electrical stimulation.[145] The theory suggests, then, that stimulation of endorphins may be instrumental in achieving placebo analgesic effect as well as reduction in depression.[146]

It is also now thought that the central nervous system can alter the immune system, which suggests that Pavlovian conditioning associated with the placebo effect may influence immunocompetence.[147]

III. THE DANISH VIEW—THE PLACEBO EFFECT IS A CHIMERA

Since the publication of Beecher's 1955 classic article, *The Powerful Placebo*, there has been little dissent from the orthodoxy proclaiming the existence of the placebo effect. The first crack in this artifice appeared in the mid-1990s, when two German researchers, Drs. Kienle and Kiene, published scathing critiques of Beecher's article, as well as all literature supporting the existence of the placebo effect.[148] This study was met with a rather muted response. In 2001, however, Drs. Asbjorn Hrobjartsson and Pete C. Gotzsche published a very thoughtful study raising serious questions about the placebo effect that has generated significant discussion.[149]

Drs. Kienle and Kiene enumerated several categories of methodological errors committed by Beecher and subsequent researchers looking for the placebo effect.[150] They cite studies in which they claim that researchers attributed spontaneous improvement or fluctuation of symptoms to placebos; failed to account for regression to the mean;[151] observed placebo effects where patients were receiving placebos in addition to some other therapy,[152] or no placebo at all;[153] relied upon patient self-reports of

143. Wickramasekera, *supra* note 57, at 266-67.
144. *Id.* at 267.
145. *Id.*
146. *Id.* at 268.
147. *Id.*
148. Kienle & Kiene, *supra* note 34; Kienle & Kiene, *supra* note 7.
149. *See generally* Hrobjartsson & Gotzsche, *supra* note 7.
150. Kienle & Kiene, *supra* note 7, at 1311.
151. Kienle & Kiene, *supra* note 34, at 45.
152. Kienle & Kiene, *supra* note 7, at 1313.
153. *Id.* at 1315.

improvement that should be discounted or ignored due to "experimental subordination"[154] or psychotic misjudgment;[155] or, in the case of meta-analysis, misquoted other studies' conclusions.[156]

Endemic to any study disputing the existence of the placebo effect is disagreement about the definition of placebo. Both sets of researchers define away some of the most significant examples of placebos. Kienle and Kiene,[157] as well as the Danish study,[158] distinguish between the effects of the therapeutic relationship and the placebo effect. As discussed earlier in this Article, the therapeutic relationship is thought by many to be essential to many placebo opportunities. Similarly, Kienle and Kiene suggest that sham surgery can have a specific effect, and therefore cannot be considered placebo.[159] This distinction exploits the confusion about what "specific effect" encompasses, and whether a placebo effect should be considered the specific effect of a placebo once it is reliably identified and its mechanism is understood. Finally, Kienle and Kiene distinguish between psychosomatic effects, which they believe are potentially significant, and placebo effects, which they believe are not.[160] Others would consider these phenomena to be categorically equivalent.[161]

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154. *Id.* at 1314 (experimental subordination refers to the phenomenon whereby the subject of an experiment "says what he thinks he is expected to say, rather than what he really observes or experiences").

155. *Id.* at 1315.

156. *Id.* at 1316.

157. Kienle & Kiene, *supra* note 34, at 40 (rejecting conceptualization of effects of therapeutic relationship as nonspecific or placebo).

158. Hrobjartsson & Gotzsche, *supra* note 7, at 1599 (acknowledging that they did not study the effect of the patient-provider relationship which, in their view, may be independent of placebo effect).

159. Kienle & Kiene, *supra* note 34, at 45.

160. *Id.* at 50.

161. David Kernick et al., *Context and Health Outcomes*, 357 LANCET 2059 (June 23, 2001) (discussing a report on a systematic review of studies focusing on the effects of doctor-patient interactions on treatment results); van Weel, *supra* note 85 (stating that "bedside manners, the warmth of the doctor-patient relationship and other features of good doctoring contribute to the outcome of medical care, yet they have been treated contemptuously by the biomedical community as factors that produce placebo (or context, or non-specific) effects that should not work even if they do"); Di Blasi et al., *supra* note 85, at 757 (describing a comprehensive search for objective studies on the effects, if any, a doctor's emotional support and establishing of expectations might have on the patient's recovery and concluding that an attitude of reassurance and friendly manner seems to be more effective than a formal attitude when treating patients); Turner et al., *supra* note 18 (commenting on a systematic review on pain and the placebo effect which concluded that "the quality of the interaction between physician and patient can be extremely influential in patient outcomes, and . . . patient and provider expectations may be more important than specific treatments"); Anne D. Walling, *Placebos and Placebo Effect*, 62 AM. FAM. PHYSICIAN 658 (2000) (noting that the placebo effect can be enhanced by strongly positive physician-patient relationships); Brody, *supra* note 69 (commenting that "the placebo response is commonly invoked as a factor in the therapeutic relationship between the family physician and the patient"); Herbert

Further, Kienle and Kiene reject conditioning theory as an explanation of placebo effect, stating that "*clinical experience* contradicts the assumption that health can be conditioned."[162] To support their proposition, Kienle and Kiene note that "[r]ecurrent or chronic disorders (recurrent infections, tumor recurrence, recurrent ulcers, chronic osteomyelitis, etc.) are more difficult to treat than first occurrences."[163] The authors' overview of the conditioning literature, however, is inadequate to support their point. In addition, conditioning theorists themselves admit that conditioning is not a complete explanation of the placebo effect, and concede that in some areas, conditioning studies have produced mixed outcomes.[164] Ultimately, Kienle and Kiene seem to acknowledge that their quibble may be largely definitional, as they acknowledge the "possibility that the patient's self-healing powers may be influenced by a wide variety of non-pharmacological approaches."[165] In sum, then, Kienle and Kiene's work is not fully pursuasive, and further study is surely required.

Is the Placebo Powerless?,[166] co-authored by Asbjorn Hrobjartsson and Peter C. Gotzsche and published in 2001, is a careful meta-analysis[167] that deserves much more attention. The article questions the extent of reliable research[168] that exists about the placebo effect (preferably three arm studies with treatment, placebo and no treatment groups),[169] and concludes that in

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Benson, *Commentary: Self-Care, the Three-Legged Stool, and Remembered Wellness*, 10 J. CARDIOVASCULAR NURSING 1 (1996) (explaining that three factors contribute to a positive placebo effect: "(1) The positive beliefs and expectations on the part of the health care professional, (2) the positive beliefs and expectations on the part of the patient, and (3) the beliefs evoked by a good relationship between the two parties.").

162. Kienle & Kiene, *supra* note 7, at 1314 (emphasis added). "Clinical experience" seems to be a euphemism for anecdote, which is not generally perceived to be a sufficient basis for reaching conclusions in scientific discourse.

163. Kienle & Kiene, *supra* note 34, at 49. Without discussing extinction, which conditioning theorists acknowledge as a phenomenon, Kienle and Kiene rely upon the dissipation of the placebo effect with the passage of time as evidence that the placebo effect is not real. Kienle & Kiene, *supra* note 7, at 1314.

164. Kienle & Kiene, *supra* note 7. This section of the article would have also benefitted from a discussion of extinction and sequencing.

165. Kienle & Kiene, *supra* note 34, at 51.

166. Hrobjartsson & Gotzsche, *supra* note 7.

167. Brody and Weismantel point out that Hrobjartsson and Gotzsche have extended meta-analysis methodology beyond its usual parameters by combining studies that have not necessarily employed "similar protocols, interventions, and outcome measurements." Howard Brody & David Weismantel, *A Challenge to Core Beliefs*, 17 ADVANCES IN MIND-BODY MED. 6, 7 (2001).

168. Hrobjartsson and Gotzsche observe that most placebo studies fail to control for regression to the mean and natural history of the disease. Hrobjartsson & Gotzsche, *supra* note 7, at 1594; *see also* Brody & Weismantel, *supra* note 167, at 6.

169. Howard Brody and David Weismantel note that "[t]here may be other control conditions, such as having multiple placebo groups, or the hidden administration of an "active" medication, which would serve as well as a no-treatment comparison." Brody & Weismantel, *supra* note 167,

those that exist, they do not generally support the existence of a placebo effect. An important exception exists with respect to pain, where twenty-seven trials did indeed show a significant placebo effect as compared to no treatment.[170] This conclusion might be more broadly stated to indicate that the authors' research observes placebo effect for subjective but not objective outcomes.[171]

Several caveats exist.[172] The researchers did not include within their conception of "placebo" the physician-patient relationship,[173] about which many studies exist supporting the proposition of a placebo effect. More specifically however, is how many independent studies existed for each placebo scenario studied.[174] Additionally, the studies seem to have been categorized according to condition studied (obesity, smoking),[175] rather than form of placebo (pill, counseling, sham surgery).[176] As such, one could imagine that placebo pills studied in the treatment of asthma do not work, but that some other placebo, inhaling an innocuous herbal substance, for example, might.

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at 7.

170. Hrobjartsson & Gotzsche, *supra* note 7, at 1596.

171. *See* Brody & Weismantel, *supra* note 167, at 6 (who also note that this conclusion contradicts much recent research about mind-body interactions).

172. The researchers themselves suggest several possible biases in their conclusions: subjective outcomes were not subject to blind evaluation; studies did not control for untreated patients seeking treatment outside of the trial, which would reduce evidence of placebo effect; questions exist about the quality of methodology in small trials which reported larger placebo effects. Hrobjartsson & Gotzsche, *supra* note 7, at 1597-99.

173. *Id.* at 1599.

174. In those studies involving binary outcomes, nausea, relapse after the cessation of smoking, and depression had been subjected to at least three independent studies. *Id.* at 1596. For continuous outcomes, pain, obesity, asthma, hypertension, insomnia, and anxiety were each the subject of at least three independent studies. *Id.* at 1596; *see also* Brody & Weismantel, *supra* note 167, at 7 (noting that very few studies were found for any particular condition, and that "adding relatively few more studies to any of those sub-analyses could have greatly changed the outcome").

175. The trials investigated forty clinical conditions: 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 dilation, labor, menopause, prostatism, depression, schizophrenia, insomnia, anxiety, phobia, 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 tunnel syndrome, and undiagnosed ailments. Hrobjartsson & Gotzsche, *supra* note 7, at 1596.

176. The typical pharmacological placebo was a lactose tablet. The typical physical placebo was a procedure performed with a machine that was turned off (e.g., sham transcutaneous electrical nerve stimulation). The typical psychological placebo was a nondirectional, neutral discussion between the patient and the treatment provider, referred to as an "attention placebo." Hrobjartsson & Gotzsche, *supra* note 7, at 1596.

Alternatively, the studies considered might not sufficiently consider placebo trials designed to test the variety of competing theories, such as conditioning, expectancy and cognitive learning. Obviously, there may be an insufficient number of trials of any particular placebo that tests each hypothesis of the placebo mechanism for each of the specific conditions for which placebos are thought to be possibly relevant. This suggests, of course, that much additional research is required. As evidenced in part by the Danish study, researchers have yet to agree on a number of other questions necessary to pursue research in this area.[177] What outcomes are to be measured, and a definition of health, continue to elude agreement in studying this area. The Danish study authors note that few studies reported on quality-of-life or patient well-being,[178] which are, of course, areas where significant claims of success are made by many placebo theorists.

Obviously, these questions require resolution before any particular legal or ethical conclusions are reached. If it is concluded, however, that placebos (or at least some form of placebos) produce no beneficial effect for their patients, then many contemporary medical practices must be modified. First, some justify and encourage continued use of unproven CAM therapies for their presumed placebo effect. If no such therapeutic benefit actually exists, then no medical or ethical justification exists to support the continued prescription of no-benefit treatments. Further, one would have to wonder over the public policy choice to continue licensing practitioners whose primary or sole techniques are likely to be nothing more than placebo which, we would have established, is worthless. State agencies responsible for enforcing consumer fraud laws might have good reason to begin prosecuting purveyors of alternative modalities that have no proven medical benefit. More specifically, physicians who engage in alternative practices, or consciously misprescribe active treatments for their placebo effect, should find that such practices run afoul of their state licensing laws, exposing them to sanctions.

Establishing the complete non-existence of a placebo effect would dramatically affect certain areas of conventional medical practice, including much mental health treatment, and pain management. A rejection of the placebo effect could well require rejection of much of these disciplines, leaving many patients without hope.

177. *See supra* notes 167-71 and accompanying text.

178. Hrobjartsson & Gotzsche, *supra* note 7, at 1599.

IV. OPPORTUNITIES AND OBSTACLES: WHAT IF A POWERFUL PLACEBO REALLY EXISTS?

A. *Opportunities*

Placebo research is currently at its apex, with the NIH funding myriad studies to explore the phenomenon. Should the research yield a conclusion that the placebo effect truly exists, with an understanding of how and on whom it works, and with a predictive sense of its power, the implications on medicine and health care would be enormous. Frederick Evans suggests that placebo therapy might be useful where the most appropriate drug for a patient is contraindicated or is working too slowly.[179] A placebo might aid the drug addict during withdrawal or the chronically ill patient for whom a drug is no longer safe or necessary.[180] But, says Evans,

> [t]he most important single use of placebo, . . . is diagnostic, . . . positive response to placebo not only indicates that, for the [pain] patient, expectancy and hope for further success in therapy is realistic; for the therapist, it indicates that the patient, at some cognitive level, has the resources to be able to influence, modulate, and control his or her pain (or other symptom)."[181]

Initially, then, those with the most to gain are patients whose pain remains unresolved by conventional treatment methods.

Even those researchers who are generally skeptical of the existence of a placebo effect have concluded that placebos are likely effective in pain management, particularly with chronic pain.[182] Two lessons already appear to be emerging—one focused on the placebo benefits lost when chronic pain patients are inappropriately treated or given placebos, and the other geared towards effective use of placebos with patients in pain. Many chronic pain patients experience serial disappointments with the health care system. Unable to diagnose the cause of their pain, some physicians haphazardly prescribe ineffective treatments (active placebos) as a means to pacify these patients, while other physicians decide that patients with persistent pain of unknown etiology are somatizing, and give them inert placebos.[183] The patient's positive response confirms the physician's

179. Evans, *supra* note 1, at 225.

180. *Id.*

181. *Id.*

182. *Id.* at 261. Chronic pain patients refer to those whose pain has not been successfully treated. *See* Peck & Coleman, *supra* note 37, at 262-63.

183. It has been suggested that chronic pain patients are the most frequent recipients of pure placebos. Peck & Coleman, *supra* note 37, at 262.

suspicion that the patient was not sick. This conclusion, of course, reveals the physician's misunderstanding of the placebo effect,[184] and exposes the patient to a continued course of inappropriate care.

The patient who does not improve has been set up, or conditioned, to expect future failures from medicine. Such conditioning increases the probability that she will experience "placebo sag," or extinction of the placebo response associated with future treatments (whether placebo or nonplacebo).[185] Alternatively, an unsuccessful experience with a placebo may cause a chronic pain patient to believe that her medical problem is more serious than it may actually be, thereby increasing her anxiety.[186] In sum, one conclusion that can be drawn from current understanding of the placebo effect is that physicians can diminish patients' opportunities for successful future medical care by misusing placebos.

Of equal interest and importance is the potential offered by "appropriate" placebo treatment, or enhancement of the placebo component of nonplacebo treatment. Numerous studies have shown that a significant percentage of patients experience a substantial (at least half) reduction of severe clinical pain with the introduction of an inert substance or drug.[187]

B. *Obstacles: The Prohibition on Lying*

The major barrier to physicians unabashedly passing placebos out to their patients has been the assumption that it requires lying,[188] and that physicians should not lie to their patients.[189] The essential thrust of the

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184. Research has confidently established that "a placebo response is not due to some psychological pathology in the patient and does not indicate the absence of organic pathology." *Id.*

185. *Id.* at 261.

186. *Id.* at 262; Turner et al., *supra* note 18, at 1613.

187. *See* Wickramasekera, *supra* note 57, at 255 (claiming that approximately 35% patients experience this drop off in pain). Studies also show stunningly high patient satisfaction and success rates with treatments later found not to be efficacious. *See* Turner et al., *supra* note 18, at 1610; *see also* de Saintonge & Herxheimer, *supra* note 77, at 995 ("Good or excellent relief of pain has been obtained in about 70% of patients by procedures later shown to have no specific effects . . . ."). Patients have also been quite satisfied with sham treatments. "For example, 64% of patients who underwent a sham tooth-grinding procedure for myofascial pain dysfunction (Temporomandibular disorder) reported total or near-total symptom remission." Turner et al., *supra* note 18, at 1610 (citing Goodman, Green et al., *Response of Patients with Myofascial Pain-dysfunction Syndrome to Mock Equilibration*, 92 J. AM. DENT. ASSOC. 755, 755-78 (1976)). *See generally* David J. Rowbotham, *Endogenous Opioids, Placebo Response, and Pain*, 357 LANCET 1901 (2001).

188. *See generally* Howard Brody, *The Lie that Heals: The Ethics of Giving Placebos*, 97 ANNALS INTERNAL MED. 112, 117 (1982).

189. There are many fine resources on the philosophy of lying, providing overviews on the myriad philosophical positions on the prohibition against lying, and when exceptions to the prohibition might exist. I will not reprise those here. *See generally* Anita Allen, *Lying to Protect*

objection is that lying undermines patients' exercise of their autonomy by interfering with their ability to engage in informed decisionmaking.[190] Interestingly, even while balking at patient deception, most ethical literature reserves the right to lie under necessary circumstances, including, in the medical context, the administration of placebos.[191]

An application of the precepts about lying in the therapeutic placebo context requires consideration of two fundamental questions. First, is deception in fact necessary to effective use of placebos? Second, do the benefits of therapeutic placebos justify an exception to the maxim against patient deception? The first is a fact question; the second, an ethical and legal dilemma.

1. Is Deception Necessary to Placebo Use?

Researchers disagree about whether deception is necessary to the effective use of placebos, with the traditional assumption being that it is necessary. This part begins by exploring the validity of that starting point. There are several contexts in which placebos can be used without misleading the patient in any way. For example, patient deception is absent from many of the placebo scenarios contemplated by the "meaning model."[192] In its most basic iteration, which encourages a positive physician-patient relationship and the performance of rituals that are important to the patient in the treatment setting, deception is absent from the placebo experience. Clearly, the physician who hangs her diplomas on the wall, wears a white coat, and takes a thorough patient history, is adhering to American customs associated with providing good medical care, which also causes the placebo effect, according to "meaning model" adherents.

Privacy, 44 VILL. L. REV. 161, 167-69 (1999) (surveying Catholic theological tradition, and the concept of "mental reservation," Kant, and contemporary philosophers, who "have argued that the wrongness of lying is to some extent contingent upon the circumstances"); SISSELA BOK, LYING 33-56 (3rd ed., 1999) (surveying Augustine and Kant, both of whom are generally interpreted as absolute prohibitionists, as well as a variety of religious scholars and utilitarianism); CHARLES FRIED, RIGHT AND WRONG 60 (1978) (explicating Kant and Augustine's views that lying is always wrong; Kant argued that "lying undermines confidence and trust among men generally," and is a "perversion of one's uniquely human capacities irrespective of any consequences of the lie, and thus lying is not only intrinsically bad but wrong"); Marshall B. Kapp, *Placebo Therapy and the Law: Prescribe with Care*, 8 AM. J.L. & MED. 371, 376-77 (1983) (surveying deontological and utilitarian views on deception); Mark C. Murphy, *Natural Law and the Moral Absolute Against Lying*, 41 AM. J. JURIS. 81 (1996) (critiquing Finis' natural law analysis of the prohibition against lying, and, while agreeing with the conclusion, offering an alternative analysis).

190. *See generally* Kapp, *supra* note 189, at 391-94; Alan Strudler, *Incommensurable Goods, Rightful Lies, and the Wrongness of Fraud*, 146 U. PA. L. REV. 1529, 1546-51 (1998).

191. BOK, *supra* note 189, at 61-68; Kapp, *supra* note 189, at 382-85.

192. *See supra* notes 85-87 and accompanying text.

Likewise, deceit is wholly absent when a healer recommends a treatment that both treater and patient believe is efficacious, but whose sole power is subsequently understood to have been the placebo effect.[193] Today, this is most frequently assumed to be true in the case of unproven CAM modalities, which alternative providers, and some physicians and nurses, sincerely believe are effective treatments.[194] If CAM interventions are regularly observed to help patients, and the provider has no reason not to believe that the intervention works, then the provider cannot be deceiving the patient. It is only when the provider learns that the modality has been disproven by a reliable study, that she will be faced with an ethical dilemma about its continued use.[195] Interestingly, this might suggest that for those CAM modalities that are harmless,[196] and whose effectiveness is probably attributable to the placebo effect, it would be counterproductive to conduct research to establish that the treatment has no specific effect.[197] Publication of such data might undermine the placebo effect.

The research supporting the meaning model encourages physicians to be confident and positive, even when unsure of the patient's diagnosis.[198] This self-confidence is thought to contribute to the placebo effect, whereas expressions of doubt or uncertainty are thought to contribute to longer recovery, and return visits to the doctor's office.

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193. What Grunbaum refers to as the "unwitting" use of the placebo. *See supra* notes 46 and accompanying text.

194. Dr. Brody's definition of placebo contemplates this scenario, where, a treatment is believed to be efficacious at the time rendered, and does indeed help the patient, but only later is found to be ineffective. *See* Brody, *supra* note 188, at 113.

195. *See, e.g.*, de Saintonge & Herxheimer, *supra* note 77, at 991:

> Improve publicity about successes, and suppress publicity about complaints. Better publicity about medical successes should increase expectations of benefit.... Suppression of publicity about complaints may be beneficial because the effectiveness of a doctor will be reduced by anything that undermines faith. Journalists usually assume that the publicity given to medical accidents will, on balance, benefit the health of the public, but it may in fact cause considerable worsening.

Id. Further, under the current informed consent regime, definitive data that therapeutic effect is limited to placebo effect might preclude providers from continuing to use a CAM modality that had been providing a benefit to patients.

196. Assuming that the patient is not foregoing known efficacious treatments that are curative or ameliorative.

197. The decision could be made either not to conduct the research at all or, to ensure that placebo and no treatment arms are included, to establish placebo effect.

198. *See supra* text accompanying notes 85-98; *see also* de Saintonge & Herxheimer, *supra* note 77, at 997 who advise: "Make sure the patient sees no reason for doubting the effectiveness of treatment."

A final example that could be unproblematic, but nonetheless might suggest something akin to deceit, arises when a clinician withholds from her patient the true nature of his condition. This dilemma confronts the rehabilitative specialist who meets the stroke patient whom she knows will never recover use of his arm, though he will likely walk again, with physical therapy, a brace, and a cane.[199] The meaning model suggests that physicians can instigate the placebo effect by putting the most positive spin on prognostic information. In many instances, this can be done truthfully; but sometimes it cannot. In the words of a stroke patient's treating physician: "Having reviewed the data and examined him, I know he is unlikely to recover much use of his arm. I couch my answer carefully, full of caveats and uncertainty that I do not completely feel."[200] In such instances, the lines separating hope, concealment and outright deceit become much more difficult to negotiate.

Taken to its full potential, the meaning model unquestionably encourages physician deception. Research suggests, for example, that patients are more likely to experience the placebo effect if they receive some kind of treatment instruction or prescription. This poses no problem if the patient is satisfied with a recommendation for sleep, exercise and proper diet. But some patients are not satisfied with such quotidian disposition, and demand something more. A prescription for a placebo, whether pure or impure,[201] constitutes a deception, even if the physician believes that the placebo will benefit the patient.[202]

Proponents of the conditioning theory, who would intersperse an active drug with a placebo in order to lower dosages and side-effects,[203] suggest that maximum effect is obtained by deceiving not only the patient, but also the clinician treating the patient.[204] Frederick Evans explains:

> [I]t appears that when the patient as well as the physician believe that a powerful drug is being used, a strong placebo

199. Joel Stein, *A Fragile Commodity*, 283 JAMA 305, 305 (2000).

200. *Id.*

201. The prescription for a pure placebo would contain no active ingredients; the impure placebo, would comprise a misapplied active medication (e.g., an antibiotic for a virus). In either case, the physician is engaged in a deception—she is representing to the patient that she is receiving a medication designed to affect a cure—in the case of the pure placebo, she is receiving no medication, and in the case of the impure placebo, she is not receiving a medication designed to cure what ails her. While in practice physicians continue to this day to prescribe impure placebos, in writing they universally deplore the practice. *See, e.g.*, Alan Leslie, *Ethics and Practice of Placebo Therapy*, AM. J. MED. 854, 856 (1954) (stating that "[i]t is poor practice for the physician to prescribe an impure placebo").

202. *See infra* text accompanying note 227.

203. *See supra* text accompanying notes 115-20.

204. Evans, *supra* note 1, at 224. Research indicates that in addition to lying to patients, physicians lie to each other.

> effect is obtained in a double-blind administration. If, however, it is assumed that the medication is less effective, a much smaller placebo effect is obtained, even though it is still proportionately about half as effective as the actual analgesic. The conviction of the therapist about the drug's potency—which presumably communicates itself to the hopeful patient in terms of the plausibility and expectation that it will work, and the consequent reduction of anxiety—seems to be a powerful mediator of therapeutic effectiveness.[205]

Such an approach maximizes the clinician's ability to convey enthusiasm and hope about the expected benefits of the therapeutic placebo.[206] So, the suggestion is that neither the patient nor the nurse actually administering treatment to the patient would be able to distinguish between drug and placebo.[207] Presumably, the patient will have every reason to believe that she is receiving an analgesic with each administration, which is, of course, what is intended she believe.

Although deception may be desirable to achieve the best results, the question researchers must answer is whether such deception is necessary. If it is not, many argue that the most ethically and legally correct resolution to the placebo dilemma is that physicians obtain patient consent to administer a placebo.

In this scenario, the physician should clearly explain to the patient that there is no biochemical reason for the placebo to work, but that scientific studies have shown that inert substances or otherwise ineffective treatments may psychologically benefit the patient. "This obligation to disclose should not be altered because the patient might therefore refuse this mode of therapy or because the placebo's effectiveness might decrease somewhat."[208]

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205. *Id.* (Evans is a proponent of the expectancy theory of the placebo effect).

206. *Id.* This is generally the procedure followed in a double-blind trial.

207. *See* Thomas B. Freeman et al., *Use of Placebo Surgery in Controlled Trials of a Cellular-Based Therapy for Parkinson's Disease*, 341 NEW ENG. J. MED. 988, 988 (1999). In order to determine the effectiveness and safety of fetal-tissue transplantation in Parkinson's disease patients, a double-blind, placebo-controlled study was performed. *Id.* This study was designed to control for placebo effects, effects of patient selection, treatment, and evaluator bias. *Id.* at 989. In order to account for the blinding of investigators, the surgical and evaluation sites were assigned separate locations. *Id.* at 990. The surgeon was the only research team member aware of an individual subject's group assignment. *Id.* In addition, all surgical records were kept in a locked cabinet, and all of the communications between the surgeons and subjects or investigators followed a standardized script. *Id.*

208. Kapp, *supra* note 189, at 402 (citing BENARD HARING, ETHICS OF MANIPULATION: ISSUES IN MEDICINE, BEHAVIOR CONTROL AND GENETICS 89 (1975)).

Professor Kapp rejects the notion that physicians will subscribe to this approach, and he is probably correct.[209] The physician who believes that placebo treatment is appropriate for her patient is unlikely to risk either undermining the placebo effect or rejecting placebo therapy by disclosing the truth to her patient. So, although there are at least some uses of placebos for which deception is unnecessary, particularly in the primary care setting, it remains an open question whether deception can be somehow excused or justified in those instances where it appears therapeutically necessary.

2. Making the Case for Physician Deception of Patients

a. What Is a Lie?

Everyone lies.[210] Parents lie to their children when they tell them about Santa Claus, the Tooth Fairy and the Easter Bunny; lawyers lie to opposing counsel during negotiations,[211] and to clients about the status of their work;[212] police lie to extract confessions;[213] United States Presidents lie about a lot of things.[214]

Doctors lie, too. They lie to obtain insurance coverage for their patients,[215] they lie to protect their patients from family discord or humiliation;[216] they conceal medical errors from patients and their families;[217] they hide medication in mentally disabled patients' food;[218] they

209. Kapp, *supra* note 189, at 403.

210. *See generally* Allen, *supra* note 189, at 175.

211. *See generally* Alan Strudler, *Moral Complexity in the Law of Nondisclosure*, 45 UCLA L. REV. 337, 337 (1997); Gerald Wetlaufer, *The Ethics of Lying in Negotiations*, 75 IOWA L. REV. 1219, 1220 (1990).

212. *See generally* Lisa G. Lerman, *Lying to Clients*, 138 U. PA. L. REV. 661, 662 (1990).

213. *See generally* Deborah Young, *Unnecessary Evil: Police Lying in Interrogations*, 28 CONN. L. REV. 425, 425-26 (1996).

214. *See generally* Allen, *supra* note 189; BOK, *supra* note 189.

215. *See generally* Gregg M. Bloche, *Fidelity and Deceit at the Bedside*, 283 JAMA 1881, 1882 (2000); Victor Freeman et al., *Lying for Patients*, 159 ARCHIVES INTERNAL MED. 2263, 2263 (1999); Dennis H. Novak et al., *Physicians' Attitudes Toward Using Deception to Resolve Difficult Ethical Problems*, 261 JAMA 2980, 2980 (1989).

216. *See generally* Novak, *supra* note 215.

217. *Id.*

218. Adrian Treloar et al., *Concealing Medication in Patients' Food*, 357 LANCET 62, 62 (2000).

lie to each other;[219] they withhold information about research;[220]they conceal from terminally ill patients that they are going to die;[221] and they give placebos to patients.[222] Some of these lies are motivated by self-interest.[223] But many of the deceptions and lies of physicians to their patients are benevolent[224]—they are not designed to obtain a benefit against an adversary, or to cheat; they are intended to help the patient.[225] The question then becomes whether the benevolent lie, in this case to evoke the placebo effect in a patient, is unethical. To resolve this question, we must first sort out what counts as a lie versus deception, whether the difference matters, and whether deception may be ethically permissible.

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219. Kevin F. Foley, *Physician Advocacy and Doctor Deception: A Double-Edged Attack on Due Process*, FED. LAW. July 2001, at 24, 27 ("Many physicians-in-training admit that they have covered up mistakes in medical records and lied to attending physicians about things that they had neglected to do.").

220. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 485 (Cal. 1990).

221. *See* Eric J. Cassell, *The Principles of the Belmont Report Revisited*, 30 HASTINGS CENTER. REP. 12, 16-17 (July 2000) (explaining that until the 1970s, physicians often failed to disclose the truth to patients with life-threatening diseases); Denise Ann Dickerson, *A Doctor's Duty to Disclose Life Expectancy Information to Terminally Ill Patients*, 43 CLEV. ST. L. REV. 319, 321 (1995) (commenting that "[h]ealth care professionals are sometimes reluctant to disclose diagnoses and prognoses to dying patients"). Elizabeth B. Lemont & Nicholas A. Christakis, *Prognastic Disclosure to Patients with Cancer Near the End of Life*, 134 ANNALS INTERNAL MED. 1096, 1102 (2001); Peter A. Ubel, *Truth in the Most Optimistic Way*, 134 ANNALS INTERNAL MED. 1142-43 (2001).

222. *See, e.g.*, Union County v. Hughes, 2001 WL 56441 at *2 (Ark. App. Jan. 24, 2001) (recounting that "appellee was in significant pain when she concluded Dr. Safman's 30-day inpatient program in June 1998 because Dr. Safman had replaced all of her pain medication with placebos"); Freeman v. Luppes Transp. Co., 227 N.W.2d 143, 145 (Iowa 1975) (recounting recommendations of physicians in treatment of anxiety to include "exercises for placebo effect"); State v. Barry, 533 P.2d 1308, 1312-13 (Kan. 1975) (stating that "[h]e was not in need of treatment, but the doctor directed the injection of a placebo—consisting of a pure saline solution—to alleviate the emotional condition"); Helton v. Liberty Mut. Ins. Co., 1994 WL 901471, at *1 (Tenn. Jun. 6, 1994) (recounting that "the plaintiff was given two series of injections for the pain. The first series of injections were epidural blocks. The second set of injections were placebos."). *See also* Alex Silberman, *It's All in Your Head and That's the Good News*, VEGETARIAN TIMES 72, 73 (June 2000); Walter A. Brown, *The Best Medicine?*, 30 PSYCHOL. TODAY 56 (Sept./Oct.,1997); McCaffery et al., *Pain and Placebos: Ethical and Professional Issues*, 16 ORTHOPAEDIC NURSING 61 (May/June 1997); Margaret Talbot, *The Placebo Prescription*, N.Y. TIMES, Jan. 9, 2000, at 34, 36.

223. *See Moore*, 793 P.2d at 485.

224. The term "benevolent lie" is borrowed from J.A. Barnes, who adopts the term "to refer specifically to lies in which the liar merely intends to enhance the dupe's interests by deceiving him or her . . . the liar has no intention to harm a third party." J.A. BARNES, A PACK OF LIES: TOWARDS A SOCIOLOGY OF LYING 14 (1994). Barnes distinguishes "malicious lies" which are "told with the intention of benefiting the liar at the expense of the dupe." *Id.*

225. Paul Ekman, *Why Don't We Catch Liars*, 63 SOC. RES. 801, 810 (1996).

We must first distinguish the lie from deception. Deception is an umbrella category into which lying falls as a specific type.[226] Most agree that one may deceive without lying,[227] but, because of the varying definitions of what it means to "lie," the line between deception and lying is unclear. Nonetheless, deceit certainly entails the intentional communication of a message "meant to mislead them, meant to make them believe what we ourselves do not believe."[228] Nonetheless, it is implicit in the literature that lying is worse than other forms of deception, though not always for reasons that are clear.

The definitions of lying fall across a spectrum, eventually merging conceptually with deception generally; obviously, the choice of a narrow conception of lying is one way to eliminate many of the obstacles presented by a prohibition on lying. A narrow definition is also analytically efficient—it precludes the necessity of considering whether a lie is, under the circumstances, justifiable or excusable. One author who takes the narrowest approach to lying is Sissella Bok.[229]

Bok's book, *Lying: Moral Choice in Public and Private Life*, requires intent to mislead[230] and an actual false statement.[231] This definition allows one to deceive without lying, and to avoid lying by not speaking. Other definitions of lying are difficult to distinguish from deceit. Gerald Wetlaufer, a legal commentator, defines lying to include "all means by which one might attempt to create in some audience a belief at variance with one's own."[232] This definition does not require an actual statement,[233] and also avoids the necessity of ascertaining the truth or falsity of the understanding at issue.[234] Notably, neither definition would seem to require a physician to dispel a patient's misunderstanding—the prohibition is on the *creation* of a misconception.

Paul Ekman also goes beyond "the statement" upon which Bok's definition hinges.[235] Ekman asserts that "one can falsify without words, and one need not falsify, verbally or nonverbally, to lie. Concealment is just as

226. BOK, *supra* note 189, at 14.

227. BARNES, *supra* note 224, at 17.

228. BOK, *supra* note 189, at 13.

229. *See infra* notes 230-34 and accompanying text.

230. BOK, *supra* note 189, at 7-8; *see also* Ekman, *supra* note 225, at 801.

231. BOK, *supra* note 189, at 13. Lying, she declares, is a subset of deception which, while clearly not a good thing, is not the subject of her book. *Id.* at 13-14.

232. Wetlaufer, *supra* note 211, at 1223.

233. *See* FRIED, *supra* note 189, at 57 (Fried's definition of lying uses the word "assertion," which, he concludes, means that someone can lie without using words. "Surely, if a person nods assent to a proposition, this should stand as an assertion of the truth of that proposition. Under appropriate circumstances, even remaining silent may constitute an assertion.").

234. Wetlaufer, *supra* note 211, at 1224.

235. Ekman, *supra* note 225, at 803.

much a lie as falsification, if there is an expectation that information will be revealed."[236] The fulcrum for Ekman is motive; concealment and falsification are merely alternative techniques to accomplish the same thing, which is to mislead.[237] Ekman's approach might require a physician to clarify a patient's misconception, even if the physician did not create the patient's misunderstanding, as long as the physician believed that the patient relied upon the physician to resolve her misunderstandings. Even with this definition, there is a loophole: the subjective element of his definition—is there an expectation that the information will be revealed?

Those who focus on "escape routes" approach the definition of lying as "strict constructionists."[238] Mary Mothersill, for example, enumerates some of the several ways one can mislead without actually having to lie: "[e]quivocation, hyperbole, irony, unspoken qualifications," value judgments and "lawlike generalizations."[239] Even Bok, while certainly not subscribing to this last approach, acknowledges that the expectation of truthtelling does not require "truthdumping"—the choice, she explains, is not between "lying or constant, no-holds-barred truth-telling."[240]

The difficulty comes in attempting to identify a way to choose among these definitions in the context of the physician-patient relationship, which, unlike many of the other contexts in which lying has been analyzed—buyer/seller, police/arrestee—is a special relationship of a fiduciary nature. Looking to the law that governs the physician-patient relationship suggests two obvious starting places for choosing among the definitions. First, we might select from the perspective of the reasonable patient—what is the foundation of the patient's relationship with her physician?[241] One appeal of this is that it enables the analysis to occur "from the perspective of the deceived."[242] As it turns out, however, this approach does not bring us to ready conclusions. As shall be discussed shortly, it is not at all clear that most patients expect or desire a relationship built upon absolute truth-telling at every turn.[243] Patients sometimes seek perpetuation

236. *Id.*

237. *Id.*

238. Mary Mothersill, *Some Questions About Truthfulness and Lying*, 63 SOC. RES. 913, 922 (1996).

239. *Id.* at 922.

240. BOK, *supra* note 189, at xxiii.

241. This might be analogized to the "rules of the game" analysis used by some to indicate that there are certain contexts when it is understood that the participants will lie, e.g., poker, and that the situation is fair, because either participant can exit at any time.

242. BOK, *supra* note 189, at 20-21.

243. *See* Alycia C. Regan, *Regulating the Business of Medicine: Models for Integrating Ethics and Managed Care*, 30 COLUM. J.L. & SOC. PROBS. 635, 648 (1997) (stating that "'[t]ruth-telling' generally requires physicians to be honest with their patients, but the scope of the principle remains uncertain").

of self-deception.[244] It could very well be, then, that most patients would elect the narrowest definition of lying, so that their physicians have plenty of room to hedge, in case the patient does not seem interested in receiving too much or too accurate information.

Problematically, a significant minority of patients could have views about physicians lying to them that diverge sharply from the majority that comprises the "reasonable patient."[245] This raises serious questions about relying upon the "reasonable patient" perspective as a baseline from which ethics should operate. Ultimately, we have no way of knowing what definition of lying a reasonable or any patient would choose, and cannot reliably use this mechanism to resolve the ethical dilemma.

A second way of selecting the appropriate definition of lying would be to rely upon what physicians do or believe they should do. This approach, adopted by half the jurisdictions in establishing the standards of disclosure for informed consent, looks to what physicians, according to their professional judgment, would ordinarily disclose under the circumstances.[246] In essence, custom, as defined by physicians, would determine which definition of lying should apply to the physician-patient relationship. Surely, there is something amiss in relying upon the liar's perspective to determine what constitutes a lie. As observed by Professor Wetlaufer, the argument that "relies entirely upon the claim that custom is the full measure of ethics, [is] an understanding of ethics that is impoverished and unacceptably narrow."[247]

The most appealing alternative from an ethical, if not from a legal,[248] perspective is the individual patient's view about lying in the particular circumstances of the relationship with her physician or state of mind when confronting a specific medical crisis. Subsequent discussion will suggest

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244. *See infra* notes 263-66 and accompanying text.

245. This objection arises in the informed consent context as well, with some arguing that individualized informed consent is not achieved for the patient whose personal values, beliefs and goals diverge from those of the "typical" patient, even under the reasonable patient standard of informed consent. *See* JESSICA BERG ET AL., INFORMED CONSENT 50 (2001).

246. *Id.* at 46; 61 AM. JUR. 2d *Physicians, Surgeons, and Other Healers* § 188 (1981). "The traditional view or views, apparently still in effect in most jurisdictions, are that the duty is measured by a professional medical standard: either the customary disclosure practices of physicians or what a reasonable physician would disclose under the same or similar circumstances." *Id.*; Laurent B. Frantz, Annotation, *Modern Status of Views as to General Measure of Physician's Duty to Inform Patient of Risks of Proposed Treatment*, 88 A.L.R.3d 1020, § 2(a) (1978).

247. Wetlaufer, *supra* note 211, at 1249.

248. A minority of courts have adopted a subjective patient-oriented standard for determining what disclosures physicians must make to their patients under the doctrine of informed consent, which requires physicians to disclose what the specific patient would want to know. BERG ET AL., *supra* note 245, at 50. This standard has been rejected by the overwhelming majority of courts because it makes it too difficult for physicians to determine their legal obligations. *Id.*

various ways physicians might determine whether patients want a relationship founded upon a robust conception of disclosure in informed consent. Unquestionably, significant problems inhere in this approach. It establishes no firm parameters for physicians in defining their obligations to patients, thereby introducing a high level of unpredictability and uncertainty into the physician-patient relationship and physicians' potential legal liability. Such an approach can fairly be said to require physicians to read their patients' minds. However, many human relationships require extraordinary effort at attempting to understand the other party's desires: spouses frequently and accurately observe that they are expected to read their partners' minds, and while there is a world of difference between such an intimate relationship and others, the need for empathy in many professional relationships may not be so far from "mind-reading" of this sort.

Ultimately, it becomes unnecessary to commit to a specific definition of lying. In some instances, the choice may not even make a difference. In others, the answer should depend upon what the patient seems to want. To determine whether the choice of definition even matters, this section analyzes the ethical dilemmas of using therapeutic placebos under the alternative definitions of lying. The next section then explores whether patients sometimes want to be "lied to," regardless of the definitions under which we are working.

Beginning with examples drawn from the meaning model, patients are said to respond more effectively when physicians convey confidence in a speedy recovery, even if they are not sure what ails the patient. This raises the question of whether it is appropriate, legally and ethically, for a physician to convey confidence in his knowledge of the patient's condition, if such confidence is really limited to the belief that the patient will get better soon.[249] In short, the question is whether the principle of truth-telling requires a physician to volunteer that he has no idea what is wrong with his patient,[250] when the patient suffers from a minor ailment which will resolve itself, and when, according to placebo research, such disclosure could retard recovery.

The physician in this scenario is behaving ethically according to Bok, who requires an intent to mislead, and a false statement.[251] The physician is truly confident of the patient's speedy recovery, and as long as she does not affirmatively state that the patient has a specific condition, the physician avoids lying. A vague reference to a "bug," to employ Mary Mothersill's

249. Obviously, the analysis is easier if the patient does not press with a question so specific that an unequivocal answer is unavoidable, and the physician feels certain that the patient is not suffering from anything serious or threatening.

250. *See supra* note 230 and accompanying text.

251. *See supra* notes 230-34 and accompanying text.

"equivocation" approach, would suffice.[252] Further, the physician has not created in the patient a "belief at variance with his own" because the physician is confident in a speedy recovery; thus, he averts lying under Wetlaufer's definition.[253]

Ekman's definition demands that things should not be concealed if the patient expects disclosure.[254] So when the patient is satisfied with the news that he has a bug, and will be better in a few days, it is reasonable for the physician to conclude that the patient expects no further information; there is neither a lie nor a deception. If, however, the patient seeks more definitive information about what is wrong with her, and seeks assurances that the doctor is confident in his diagnosis, the physician risks deception, because he is no longer attempting to represent confidence in speedy recovery, but is being asked to convey confidence in his diagnosis, which the physician does not have. Likewise, under any of these scenarios, if the physician is indeed doubtful about the diagnosis, or that the patient will recover in short order, she is lying to her patient when she projects confidence.

Some respond that physicians can preserve the placebo effect and the truth by simply telling the truth[255] in a less "in your face" way.[256] Thus, the physician offering a patient an herb with no known therapeutic benefit beyond the placebo effect might say, "Studies haven't proven this to be effective, but I know a lot of patients find it helpful." The physician has made no false assertions, but has left unsaid that if the herb helps, it is a result of the placebo effect, rather than as a result of the active ingredients in the herb. The question becomes, then, whether this formulation sufficiently avoids the prohibition against lying. Some would say no: knowing that the patient infers that the herb contains some ingredient that will help her, the physician has deceived the patient by specifically withholding that he is recommending the herb as a placebo, albeit to avoid undermining its effectiveness.

Relevant research also suggests that informing patients of potential adverse side-effects of prescription drugs increases the probability of the patient experiencing those side effects.[257] Currently, the doctrine of

252. *See supra* notes 238-239 and accompanying text.

253. *See* Wetlaufer, *supra* note 211, at 1223.

254. *See supra* notes 234-37 and accompanying text.

255. This Article does not explore the suggestion that physicians are not engaging in deception, but rather in a form of psychotherapy. *See generally* Alan Leslie, *Ethics and Practice of Placebo Therapy*, 79 AM. J. MED. 854, 855 (1954).

256. *See, e.g.*, Thomas, *supra* note 37, at 339 (noting that some physicians accompany the administration of placebos to their patients by using "duplicitous language carefully couched to disclaim and endorse the artifice simultaneously").

257. *See supra* note 131 and accompanying text.

informed consent,[258] as well as federal drug regulations,[259] compel disclosure of potential adverse consequences of the proffered treatment.[260] Avoidance of nocebo effects would commend withholding this information. This scenario does not involve lying—there is no false statement, and no

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258. The "informed consent doctrine" provides that the consent necessary to constitute effective authority for medical treatment only arises from the patient's understanding of the various alternatives to and risks of treatment. Canterbury v. Spence, 464 F.2d 772, 780 n.15 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *see, e.g.*, Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW. U. L. REV. 628, 629 (1970). Generally physicians have a "duty to warn of the dangers lurking in the proposed treatment." *Canterbury*, 464 F.2d at 782. Due care normally requires that the physician warn the patient of the risks to his well-being which may result from the proposed medical treatment. *Id.* Informed consent forms frequently list possible side effects of the therapy. *See also* Plumber v. Dep't of Health & Human Servs., 634 So. 2d. 1347 (La. Ct. App. 1994) (holding that plaintiff gave informed consent for chemotherapy treatments when she signed an informed consent form listing potential side effects and received explanations from her physician specifically addressing possible complications). In New Jersey, informed consent provisions have been statutorily prescribed to include

> as a minimum the specific procedure or treatment, the medically significant risks involved, and the possible duration of incapacitation, if any, as well as an explanation of the significance of the patient's informed consent. The patient shall be advised of any medically significant alternatives for care or treatment, however, this does not include experimental treatments that are not yet accepted by the medical establishment.

N.J. STAT. ANN. § 26:2H-12.8 (d) (2000).

259. Pursuant to 21 U.S.C. § 352, Misbranded Drugs and Devices, prescription drug advertisements and other printed material included with the drug shall include the following:

> established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances.

21 U.S.C. § 352 (2001).

260. Courts have recognized two exceptions to the general duty of disclosure. The first exception is triggered "when the patient is unconscious or otherwise incapable of consenting, and harm from a failure to treat is imminent and outweighs any harm threatened by the proposed treatment." *Canterbury*, 464 F.2d at 788. In the case of an emergency, conferring with the patient about the treatment is impractical and as such the physician should proceed with treatment if time does not allow for discussion. *Id.* at 789 (citing Dunham v. Wright, 423 F.2d 940, 941-42 (3d Cir. 1970); Koury v. Follo, 158 S.E.2d. 548, 555 (1968); Woods v. Brumlop, 377 P.2d 520, 525 (1962); Gravis v. Physicians & Surgeons Hosp., 415 S.W.2d. 674, 677 (Tex. Civ. App. 1967)). The second exception is available when disclosing the risks to the patient would be detrimental to the patient to such a degree that the information would "foreclose a rational decision, or complicate or hinder the treatment, or perhaps even pose psychological damage to the patient." *Id.* (citing Salgo v. Leland Stanford, Jr. Univ. Bd. of Trustees, 317 P.2d 170, 181 (1967)); Waltz & Scheuneman, *supra* note 258, at 641-43. Under such circumstance, courts have generally held that the physician has a privilege to withhold the information from the patient for therapeutic reasons. *Id.*

intent to mislead. As long as the physician truthfully represents his belief that the patient is better with the treatment than without, he does not run afoul of Wetlaufer's construction of a lie, either. Of course, there may be legal or other ethical problems with nondisclosure of potential adverse side effects.

The final nondisclosure scenario involves the stroke patient with a useless arm and lame leg, who desperately wants to hear that he will fully recover his physical functioning, but whom the physician knows (believes?) will not be able to regain much functioning in his arm. The treating physician describes her approach this way:

> I knew when I met Mr. Burton that he would very unlikely recover significant use of his arm. Trained in the era of patient autonomy, I once felt I should share all available information I could provide about prognosis as early as possible. Arguably, unfavorable news regarding arm recovery would be tempered by favorable predictions of a return to walking and living independently . . . . When good news is delivered with bad news, the good news often is submerged beneath the bad. It quickly became apparent to me that most of my patients were not ready for the cold hard facts the minute they arrived at the rehabilitation hospital. They needed time to come to terms with the reality of their disabilities, while simultaneously regaining lost function. This is a process that shouldn't be rushed.
>
> Patients with severe illnesses are looking for a mix of hope and reality, and providing either one alone is a disservice. Hope is a fragile commodity, easily crushed by careless provision of the "facts." There is a fine line between paternalistic withholding of the truth and leaving some imprecision regarding prognosis in order to maintain hope. In our zeal for patient autonomy, we should not forget the importance of nurturing that hope.[261]

Bok's condemnation of lying does not compel revelation of the complete truth. Thus, the rehab doctor can conceal her doubts about the patient's recovery of her arm, without lying. Once we revert to the more broad definitions of lying, a physician will naturally fall upon the defense that the answers to the stroke patient's questions can never be certain; that she seeks to provide the best scenario, which is on the spectrum of truth; or that she is simply rendering an opinion, which cannot be objectively judged.

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261. Stein, *supra* note 199.

Wetlaufer has anticipated these defenses, of course, by focusing not on the truth or falsity of the statement, but on whether the statement deviates from the speaker's own beliefs. Thus, as conceived by Wetlaufer, the physician would be compelled to forthrightly respond to the patient's questions, lest she be lying. Not yet considered, however, is whether eliciting the placebo effect, by preserving hope, would justify or excuse the physician's lie.

Some placebo scenarios may require actual deceit, as opposed to mere non-disclosure. Conditioning theorists anticipate capitalizing on the placebo effect by interspersing active drugs with placebos. Assuming that the physician has not revealed her plan, this deception can be analyzed in multiple ways. First, it can be said that the physician has represented to the patient, either actually or by reasonable inference, that each time she takes a pill, or pushes a button, she is receiving a drug that will relieve her pain.[262] There would seem to be no question that the physician intends to deceive the patient; the physician's statement or inference constitutes a falsification or concealment under any of the definitions available.

But is it really so clear cut? An equally valid rendition of the interaction between physician and patient is that the physician explained that the patient will receive a treatment regime designed to reduce pain, with the fewest side effects. There is no false statement since the drug/placebo combination comports precisely with the physician's representation. If the placebo works, it will have the same effect as the drug and will deliver pain relief, which is what the patient was promised. That is, it will have a specific effect on the patient, due to patient conditioning, even absent the presence of any active ingredients in the placebo. Arguably, most patients would be happy to have been relieved of the pain and to have experienced fewer side effects, even if their relief was the result of deception.

b. When Lying Is Not Lying

This part makes two arguments: one ethical, and one legal. First, in many instances, patients want to be lied to, and physicians generally realize this, and should pursue the humane course of fulfilling their patients' desires. Many such lies will enable patients to maintain hope, or elicit the placebo effect. In essence, the patient desires to be deceived. That the deception is consented to, even if implicitly, renders it ethical. Of course, patients may explicitly consent to be deceived, but this solution is impracticable. The legal argument is that patient deception in the placebo

262. Leslie suggests that a misrepresentation occurs because "the patient is led to believe that he has been given a substance of inherent therapeutic value." Leslie, *supra* note 255, at 855. Once we understand the mechanisms of the placebo effect, it might very well be that placebos satisfy this criteria, thereby averting entirely the question of deception.

context is consistent with the doctrine of informed consent, whether analyzed according to the professional standard or the patient-oriented standard. Further, if a physician appropriately provides a therapeutic placebo to his patient, he is not engaging in fraud, because he is presenting something that does have the potential to benefit the patient.

3. Patients Implicitly Consent to Physician Deception

Years of bioethical literature heralding the primacy of patient self-determination and autonomy[263] lay the foundation for the concept that physicians must fully disclose to patients their condition, and their treatment options, or that they are going to die. Interestingly, four decades later, studies have found that many physicians persist in practices of partial disclosures to their patients,[264] thereby facing the disapprobation of bioethicists. Not usually addressed by this vast body of ethical and legal analysis, and empirical studies, is how the physician should respond to the patient whom she believes either wants to be deceived or seeks connivance[265] in self-deception.[266]

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263. *See generally* TOM L. BEACHAMP & LEROY WALTERS, CONTEMPORARY ISSUES IN BIOETHICS (1999); JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984).

264. *See* Eric J. Cassell, *The Principles of the Belmont Report Revisited*, 30 HASTINGS CENTER. REP. 12 (July 2000) (explaining that until the 1970s, physicians often failed to disclose the truth to patients with life-threatening diseases); Denise A. Dickerson, *A Doctor's Duty to Disclose Life Expectancy Information to Terminally Ill Patients*, 43 CLEV. ST. L. REV. 319, 321 (1995) (commenting that "[h]ealth care professionals are sometimes reluctant to disclose diagnoses and prognoses to dying patients").

265. J.A. Barnes suggests that the term connivance is more accurate than the term collusion.

> Dupes who connive at the deceit may pretend to remain deceived but this is only a pretence. The dupe becomes an unacknowledged partner with the liar in a *folie a deux*. Here we should make a distinction between conscious and unconscious connivance, between recognition that one is being targeted as an intended dupe and an unconscious accommodation to this situation.

BARNES, *supra* note 224, at 94.

> If the liar realizes that the lie has been detected and joins the dupe in the pretence that it has not, we have mutual connivance; both parties shut their eyes to the deceit attempted by the other. If their mutual connivance is more or less openly acknowledged by both parties, neither party is deceived; they join in a pretence. If they start to treat the pretence as authentic, they become self-deluded.

Id. at 97.

266. In some cases, it may be that the term self-delusion is more apt, but self-deception suffices for purposes of this discussion. J.A. Barnes explains the distinction, employing the term "self-deception" to refer

None of us can deny that these patients and moments exist,[267] because most of us have been one of those patients, or, at one time or another, have sought to preserve our self-imposed disconnect from reality, whether to cope "with fear, . . . to tolerate stress, (or) to gain a sense of control."[268] Paul Ekman suggests that people sometimes want to be misled, and therefore "collude unwittingly because [they] have a stake in not knowing the truth."[269] Other times, we simply choose "to not know what we know."[270] Thus, it has been suggested that physicians, in particular, should frame the information that they provide to their patients in response to what the patients signal they want to hear:

> What is wanted is co-conspiracy; the patient needs to be able to work out an appropriate schema for understanding and dealing with the unpleasantness she or he faces, and it is hard to say anything very definite about what this will be like in the abstract. It certainly means that there will be well-told lies told in the interest of a larger truth.[271]

In many instances, that larger truth is optimism.[272] Nyberg observes: "[p]hysically ill patients can contribute significantly to their own recovery by maintaining a possibly unrealistic optimism about, or a sense of personal control over, their own wellness and the future."[273] This, Nyberg observes, is the placebo effect.[274]

What the various ethical theories fail to account for then, but which doctors surely face in their daily practice, is the self-deceiving patient:

> to the process whereby there is an inner dialogue in which one segment of a personality deceives another segment, and where the lying segment remains aware of the deceit. Self-delusion seems an appropriate label for the state of affairs reached when a liar begins to believe that his or her lie is not a lie at all but is true.

Id. at 89.

267. Professor Fried might disagree: "much of the peculiarity about lying to oneself consists in the fact that it seems not so much bad as downright self-contradictory, logically impossible . . . ." FRIED, *supra* note 189, at 66.

268. DAVID NYBERG, THE VARNISHED TRUTH 1 (1993).

269. Ekman, *supra* note 225, at 812.

270. Lore Segal, *My Grandfather's Walking Stick, or The Pink Lie*, 63 SOC. RES. 931, 935 (1996).

271. Alan Ryan, *Professional Liars*, 63 SOC. RES. 619, 627 (1996). Nyberg observes a similar phenomenon: "when the truth we know is either insufficient or unpleasant or both, distortion is sometimes needed to maintain coherence and stability." NYBERG, *supra* note 268, at 99.

272. NYBERG, *supra* note 268, at 105.

273. *Id.* at 106.

274. *Id.* at 106-07.

> [W]hen we believe, or at least strongly suspect, something to be true and yet turn away from it, disbelieve it on purpose, in order to evade the consequences of facing it—then we are deceiving ourselves. When we declare one belief for the purpose of denying another that we take to be true—that is self-deception .... Self-deception is skillful maneuvering to achieve ignorance when clear, conscious understanding threatens to break through.[275]

The question, then, is whether the physician treating the terminally ill patient who insists on using a CAM modality that she believes is totally useless, but which may indeed be providing some placebo relief, and which the patient believes is extending her life, may suggest that the physician, too, believes that the CAM treatment is keeping her alive. If the patient knows in her heart that the CAM intervention does not work, and knows that the physician does not think so either, such a statement would not count as a lie.[276] What we certainly have is connivance in the patient's self-deception.

This scenario is one in which the patient implicitly consents to being deceived by her physician. Physicians should, in appropriate circumstances, honor the wishes of the patient who seeks to be deceived. The key is whether society is willing to trust physicians to use deception in their relationships with their patients "thoughtfully and judiciously, charitably, humanely and with discretion."[277] The first challenge, of course, is whether physicians are able to correctly "divine" which patients are "implicitly consenting" to a deceptive relationship.[278] Presumably, the physician must also guess the extent to which the patient desires to engage in deception. Further, the contention that deceit of a patient is occasionally justified rests entirely on a presumption that the patient will derive some benefit, whether psychic, emotional or physical, from the deceit, and that this benefit, from the patient's perspective, outweighs any downsides. It is doubtful that physicians have the tools to either identify, measure, or weigh such benefits to be sure that they are making the right decision.

Conceptions of informed consent, whether ethical or legal, should allow for those instances and patients who want to be deceived, or for whom the truth would be therapeutically counterproductive. Hope feeds the placebo effect. Hope that shark cartilage will cure the lung cancer that conventional

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275. *Id.* at 90-91.

276. Professor Fried would call this an "attempted lie." FRIED, *supra* note 189, at 59.

277. NYBERG, *supra* note 268, at 61-62.

278. Nyberg observes: "We can never know for sure what is in other people's minds, and it is presumptuous to assume to know what other people 'really' need." *Id.* at 139.

medicine cannot;[279] hope that massage therapy will resolve infertility; hope that physical therapy will restore use of the arm disabled by a stroke. Physicians who provide care at the end of life have long struggled with the questions of whether they may perpetuate untruths to preserve hope; whether hope plays a positive role in patient care; or whether the unrealistic perpetuation of hope is cruel or otherwise harmful.

> Doctors tell us that hope assists the process of healing. Perhaps our very instincts lose courage where we stop hoping .... Hope's necessary falsehoods are the tools in our survival kit and blessedly preserve us from intellectual despair, the sin accounted as the seventh and deadliest because it demonstrates an absence of Faith.
>
> Hope's rose-colored falsehoods function to deceive ourselves and to participate in the deceptions practiced by our community. Hope ignores the evidence of history and experience; it lies in face of its better knowledge in order to con us out of knowing what we know and into thinking what we wish.[280]

And so, law and ethics should recognize that patients may explicitly and, sometimes implicitly, consent to be deceived.

4. Patient Deception Is Consistent with Informed Consent and Fraud

This part presents three legal arguments: first, that a patient may consent to being lied to, thereby negating any legal problems; second, that patient deception to facilitate a therapeutic placebo does not deviate from the legal standard of informed consent; and, finally, that physicians' use of placebos does not constitute fraud.

One may consent to being lied to.[281] When a patient consents to being uninformed, or misled, the physician does nothing legally or ethically wrong

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279. *NCCAM Research Progress Update: A Report for Fiscal Year 2000*, *at* http://nccam.nih.gov/about/plans/researchprogress/index/htm. NCCAM's cancer research portfolio includes studies involving shark cartilage co-funded with the NCI. *Id.* "These studies include an ongoing Phase III clinical trial involving over 700 lung cancer patients in the United States and Canada. A second trial will examine safety and efficacy of shark cartilage in patients with a variety of advanced cancers." *Id.*

280. Segal, *supra* note 270, at 932.

281. *See generally* Strudler, *supra* note 190, at 1553-55. Bok would say that the physician has an excuse to lie, and that it is fair under the circumstances, because the patient has "agreed in advance to a practice involving deception. They have set rules for what is fair, for what can be expected." BOK, *supra* note 189, at 83.

by lying.[282] Professor Marshall Kapp proposes a "patient-mediated interaction model [that] presents a framework for a disclosure process that can maximize the patient's opportunity for exercising judgment by giving the patient affirmative control over the scope of information shared or withheld."[283] Kapp anticipates a scenario in which the physician and patient would negotiate the terms of their relationship, and the conditions under which the physician may conceal information about placebo use,[284] or presumably, mislead the patient about her treatment for purposes of eliciting the placebo effect. In this way, Kapp argues, the physician can achieve voluntary and knowing relinquishment by the patient of her decisionmaking prerogatives, to enable the physician to employ placebo therapy.[285]

An earlier example involving conditioning illustrates this approach. When a physician contemplates alternating between an analgesic and placebo, she could, at the commencement of treatment, advise the patient of the precise plan, and that the placebo will have the same effect as the drug. The unanswered question is whether revelation of this information will reduce the placebo effect to a negligible degree.[286] Possibly more important is whether such an approach will undermine not only the placebo effect, but the specific effect of the analgesic as well. The outlines of Kapp's proposal are broad. It remains unclear whether the negotiated agreement would occur when one becomes a particular physician's patient; it might occur at the beginning of a particular treatment regime, or upon diagnosis of a particular condition. While this negotiated arrangement might make sense in a physician-patient relationship that is long-standing, with a strong interpersonal foundation, fewer such relationships exist in a world of managed care. Further, when patients are seriously ill, they are frequently shuttled from one specialist to the next, and it is unlikely that physicians could comfortably negotiate with a short-term patient in crisis the kind of delegated authority this scenario contemplates. Further, while Kapp states that he expects that most of the "deals" between physician and patient to be explicit, he also leaves open the possibility that the "specifications" could be *implicit*.[287]

A scenario involving implicit consent to the provision of a placebo must comport with the doctrine of informed consent to be of practical value to physicians. Assuming that the physician appropriately selects a therapeutic placebo for a given patient, he does not violate the legal duty to obtain the

282. *See* Ryan, *supra* note 271, at 1555.
283. Kapp, *supra* note 189, at 404.
284. *Id.*
285. *Id.*
286. *See* Brody, *supra* note 188, at 117.
287. Kapp, *supra* note 189, at 404.

patient's consent, irrespective of whether the relevant jurisdiction adheres to the professional or patient-oriented standard of informed consent. The legal doctrine of informed consent, which seeks to ensure the patient's exercise of her autonomy in medical decision-making, requires physicians to disclose the patient's diagnosis, the proposed treatment options, and risks and benefits of each alternative.[288] Two standards have evolved to guide physicians in determining precisely what information, especially with respect to risk, they must disclose to patients. The professional standard of informed consent requires physicians to make those disclosures which a reasonable physician would make under the circumstances.[289] The patient-oriented standard requires physicians to provide patients with that information which the "reasonably prudent person would find material to making a decision."[290]

If physicians begin to prescribe placebos for therapeutic purposes, without disclosing their true nature to patients, the professional standard among physicians will evolve into one of non-disclosure. That is, if physicians typically decline to reveal to patients that they are receiving a placebo, then they will create a professional standard of nondisclosure such that none of them would be deviating from the requirements of the doctrine of informed consent.

Neither will physicians encounter legal hurdles under a patient-oriented standard. If, as earlier 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 not compel the physician to advise the patient that she is receiving a placebo.

If informed consent is not a problem, we must consider fraud. Returning to the meaning model, presumably, patients can ascribe meaning to almost any ritual, which can range from harmful to useless. When otherwise useless modalities are used with a physician's complicity or are provided or recommended by a physician, are there limits as to what a licensed physician can do, and might the physicians' behavior, even if done for symbolic import, become fraudulent?[291] Going along with a patient's belief in a folk remedy with no specific effect may be fairly characterized as benignly dishonest. It could be more harmful if patients attribute a resultant cure to the folk remedy rather than the conventional treatment. Beyond this, however, physicians could arguably integrate meaningless routines or

288. *See* BERG ET AL., *supra* note 245, at 46.

289. *See id.*

290. *See id.* at 49.

291. *See* Kapp, *supra* note 189, at 387-90 (stating that a survey of limited case law is not particularly supportive of fraud cause of action in placebo context and a third party payor charged for placebos may have greater chance of recovery).

treatments into their practices on the theory that they are seeking to achieve the placebo effect. Since they will undoubtedly be charging for these ministrations; is it possible to distinguish between "legitimate" employment of the placebo effect, and consumer fraud?

Jurcich v. General Motors Corp.,[292] the only relevant case, suggests that in the proper circumstances, the prescription of placebos may be medically appropriate.[293] The Missouri appellate court determined that a suit contesting the provision of placebos to plaintiff for his pain sounded in malpractice, rather than fraud.[294] *Jurcich* involved a situation in which a nurse employed by a company infirmary repeatedly administered placebo pills to an injured employee, rather than the pain pills he requested and believed he was receiving.[295] In rejecting plaintiff's claim for deceit, the Missouri court observed that the prescription of placebos "is, in appropriate cases, a recognized form of medical treatment."[296] The court also accepted the expert's testimony that a physician would not advise the patient he is receiving a placebo, because then it would not work.[297]

The Uniform Consumer Sales Practices Act (UCSPA) states that representing to a consumer that "the subject of a . . . transaction" has "performance characteristics . . . uses, or benefits it does not have" is deceptive.[298] It is unpredictable how this would apply where a physician argues that the placebo, when effective, can elicit positive outcomes in a patient. Under the UCSPA, can a pure placebo be represented to a patient as possessing curative or ameliorative characteristics without the representation being considered deceptive?[299]

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292. 539 S.W.2d 595 (Mo. Ct. App. 1976).

293. *Id.* at 602.

294. *Id.* at 600.

295. *Id.* at 598. It was not until plaintiff received his medical records in connection with his Workers' Compensation claim that he learned the truth. *Id.* at 599.

296. *Id.* at 600.

297. *Id.*

298. Uniform Consumer Sales Practices Act, 1970 Act § 3(b)(1). The Act has been held to apply to claims against physicians for breach of express warranties or misrepresentations where a physician has guaranteed a particular result. *See, e.g.*, Sorokolit v. Rhodes, 889 S.W.2d 239, 242-43 (Tex. 1994) (breast augmentation); Smith v. Elliott, 68 S.W.3d 844, 846 (Tex. App. 2002) (breast reduction). The act does not require proof of intent to deceive. Riley v. Enter. Furniture Co., 375 N.E.2d 821, 823 (1977).

299. Marshall Kapp concludes that a physician who administers placebo therapy to a patient would satisfy the common law elements of fraud:

> (1) a statement, a guilty silence, or a concealment by the defendant of a fact . . .;
>
> (2) the inaccuracy of the statement or of the impression created by the silence or concealment;
>
> (3) the objective materiality of the fact to the plaintiff's decision;
>
> (4) an actual subjective reliance by the plaintiff on the statement or

If placebos work, the *Jurcich* case seems to have gotten the analysis right, and should dictate the outcome under the UCSPA as well. Physicians are not engaging in fraud if they provide placebos to patients while representing that they will provide relief. The real question should be, as the *Jurcich* court notes, whether the circumstances for the physicians' administration of the placebo were appropriate—the question is one of malpractice, not fraud.

Concerns may remain about physicians' therapeutic employment of placebos that should not escape regulatory attention. Provision of placebos might become a source of easy additional revenue to physicians, at a cost to both patients and the health care system. Even in those instances when the physician appropriately prescribes an (inert) placebo, ethical guidance would be helpful in aiding physicians in determining appropriate price schemes. Placebos could also present a harm to patients who share their medications. Presumably, the placebo effect might also aid the second-hand recipient, but where the placebo effect is the result of conditioning, for example, it would provide no benefit, and conceivably result in delayed treatment for someone at risk.

C. *Justifying Lying to Achieve the Placebo Effect*

Some will reject the notion of consent to deception, especially implicit consent, preferring perhaps the traditional analytical approach outlined by Bok, which requires an excuse or moral justification for lying. The category of excuse most relevant to this analysis is one where "the liar admits the lie, accepts responsibility for it, but offers reasons to show that he should be partially or even wholly cleared of blame."[300] This excuse "offers moral reasons for a lie, reasons to show that a lie ought, under the circumstances, to be allowed."[301] In the placebo context, the principle that might possibly excuse the physician who lies to her patient is "that the lie was told in an attempt to achieve an overriding *benefit*."[302] That the benefit sought to be achieved is for the patient makes the excuse more appealing than it

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impression;

(5) the defendant's knowledge of the falsity of the statement or impression (or reckless or negligent disregard of falsity);

(6) an intent by the defendant to produce reliance and to induce action by the plaintiff;

(7) a loss suffered by the plaintiff; and

(8) causation-in-fact of the loss by the induced action or inaction.

Kapp, *supra* note 189, at 387 (quoting Halligan, *The Standard of Disclosure by Physicians to Patients: Competing Models of Informed Consent*, 41 LA. L. REV. 9, 26 (1980)).

300. BOK, *supra* note 189, at 75.

301. *Id.*

302. *Id.* at 76.

otherwise might be had the benefit been for society generally, or for the physician himself. If the lie does not benefit the physician, say, by letting him avoid an emotionally difficult conversation with his patient, the claim of excuse appears unsuspicious.

In the alternative, however, the physician may claim that she is *justified* in deceiving the patient in order to achieve the placebo effect. To claim justification, the physician is defending "as just, right, or proper, by providing adequate reasons," that she lied to her patient.[303] The physician's claim to moral justification must be publicly defensible—in this instance, presumably, physicians, as a profession, would have to convince us that there are instances in which they may morally deceive us, to achieve the benefits of the placebo effect. Physicians are justified in engaging in patient deceit in administering placebos if the idea survives this public vetting.[304] Anticipating the objection that public revelation will undermine the effectiveness of the lie in the individual case, Bok responds that "[i]t would certainly be self-defeating to preface any one lie by consultation with the dupe. But it is not at all self-defeating to discuss deceptive policies beforehand, nor to warn the deceived themselves."[305] Furthermore, according to Bok, before the individual physician can be assured that her deception of her patient is justified, she must ensure that no alternatives of a non-deceptive nature exist.[306] So, in the instance of placebo administration, the physician would have to decide that obtaining patient consent to be lied to, as proposed by Marshall Kapp,[307] is not feasible under the circumstances. Further, the physician must believe that no non-placebo alternative can accomplish what she expects the placebo to produce. It could also be that the physician fairly believes that the patient will be satisfied with nothing less than placebo administration—that integrating aroma therapy with essential conventional medicine is the only treatment plan upon which physician and patient can agree—which might justify the physician's endorsing the patient's choice even though the physician thinks that the CAM selection is bunk.

D. *The Harms of Lying to Patients*

The difficulty in this entire discussion derives primarily from our insufficient understanding of the placebo effect. Medically, even if the placebo effect is real, physicians are not sure on whom placebos will work, or what the strength of the placebo effect will be. Ethically and legally, it cannot be predicted which patients will agree that the benefits achieved

303. *Id.* at 91.
304. *See id.* at 94-98.
305. *Id.* at 98.
306. *Id.* at 103.
307. *See* Kapp, *supra* note 189, at 404.

from placebos are worth the cost to autonomy—lying, withholding information, denying choice about one's medical care. Even worse, the patient who learns that she has been deceived may lose faith in her physician, and perhaps all physicians. This cost would be huge, and can neither be predicted nor underestimated. We have already experienced a medical model founded upon paternalism and rejected it. The question then becomes whether physicians can be sufficiently disciplined to deceive their patients sparingly, such that the trust that is essential to the physician-patient relationship remains intact.

Every consideration of lying focuses on the harms that lying inevitably causes to the one lied to, to the liar, to the system of which the liar is a part, and to the community as a whole. The philosophical objection to lying is that it is a form of coercion.[308] It ostensibly removes from the patient her ability to direct her own care, based upon complete information about her condition and the recommended treatment. Instead, the physician lies, and relegates to herself the power to decide the patient's medical future. Further, a misrepresentation about the patient's alternatives may distort the decisionmaking process, by, for example, confusing the weights to be accorded the various treatments' probabilities of success. A physician who allows a patient to choose an alternative modality, over conventional therapy, based solely on the physician's confidence in producing a placebo effect, obscures the patient's understanding of her choice—between a hoped for placebo effect and a treatment with known efficacy. Similarly, a patient may believe she has a real choice that does not really exist, if the alternative to the placebo is clearly superior.[309]

However, these arguments overstate the frequency with which therapeutic placebos will be appropriate choices, as well as the frequency with which deception will be necessary to effectively administer placebo therapy. As discussed earlier, the assumption that lying is necessary to placebo treatment is simply not true. Whether due to the kind of placebo being employed (rituals), or because of more careful analysis of what constitutes deception, often neither lying nor deception is necessary to evoke the placebo effect.

Nonetheless, there will be instances in which lying will, admittedly, be necessary. Most of these times, conventional options will have already failed, should no longer be relied upon exclusively, or will not exist. At these moments, therapeutic placebos should be taken seriously because they might offer real benefit to patients, particularly those with pain, who have exhausted the armamentarium of biomedicine, or for whom conventional medicine's options are simply inadequate. The arguments weighing in favor

308. BOK, *supra* note 189, at 18.

309. *See id.* at 19-20 ("a lie may lead to the unnecessary loss of confidence in the best alternative," or create a false certainty or uncertainty).

of therapeutic placebos rest on a convincing assumption that most such patients, if consulted, would choose relief, amelioration of side effects, cure, or maybe even cost reduction, even at the cost of their autonomy.

The objections to therapeutic placebos enumerated above also fail to acknowledge that with all therapies, whether specific or placebo, effectiveness is about probabilities. Physicians attempt to glean as much information about the specific patient, her condition, and her past treatment efforts to make very educated guesses about which treatments offer the highest probability of success. The patient is not choosing between efficacious conventional medicine with certain relief and some hoped for benefit of a placebo. The choice is between two therapeutic options, which, considering potential for success, benefits, risks and side effects, are reasonable alternatives for successful treatment of the patient's condition. If placebo research bears out, physicians will not be engaging in some nefarious enterprise, but will be giving a patient a choice between two real therapies, with dramatically different mechanisms of operation.

Further, engaging in deception to evoke the placebo effect will frequently comport with patient autonomy. For patients who fervently believe in CAM and desperately want to hang on to their hopes for rehabilitation, or simply believe that they will live longer than the statistics foretell, compelling them to "deal with the cold hard facts" undermines their autonomy, precisely because it is not what they choose to hear or know. Neither the ethical conceptions of autonomy, nor the legal precepts of self-determination, compels patients to accept reality. Further, if extinguishing hope is medically contraindicated because it will also destroy the effect of an efficacious placebo, then physicians should stop ignoring this clinical opportunity to help their patients.

Unresolved is the patient who deviates from what the "reasonable patient" would choose—the patient who fears deception.[310] If it becomes widely known that physicians lie to patients about placebos (even if only sometimes), patients may come to believe that physicians lie in general, undermining their confidence in physicians and leading to a diminution of the physician's power in the patient's eyes. This would be ironic, since a patient's confidence in her physician is an important contributing factor to the placebo effect.[311] Undoubtedly, there will be patients who will become distrustful of physicians if they begin to use placebos. These patients could protect themselves from receiving placebos by advising the physician at the commencement of the doctor-patient relationship that the physician may

310. Thomas, *supra* note 37, at 345 (commenting that patients will tend to know the circumstances under which doctors consider placebos effective and that knowledge will likely anger the patient and may cause future doubt in medication that the patient is told will help).

311. One wonders whether this phenomenon might not occur, but that, like politicians, patients would believe that while most physicians can't be trusted, their physician can.

not, at any time or for any reason, use a placebo.[312] Again, the argument in support of placebo usage, with those patients whom the physician believes will not object, rests on an assumption that patients focus on the end result—whether or not they have been helped, regardless of whether the treatment involved placebo and deception. For chronically ill patients for whom medicine has provided insufficient relief, the conjecture is that what was involved will be irrelevant.

Physicians' judicious use of placebos, and even more conservative reliance on patient deception, is essential to avoiding the very real danger of a "slippery slope"—that giving physicians permission to lie will signal to physicians that they can lie in other contexts as well. It has been argued that allowing police to lie to extract confessions has freed them to lie more generally, undermining society's faith in their veracity overall.[313] This is a large risk to the medical profession. The prescription of placebos may be harder to monitor than other medical treatment—if it occurs primarily in the physician's office, it will not be subject to the systemic oversight that occurs in hospitals; if physicians do not bill third party payors for placebos, their prescribing patterns will not be monitored by the insurance companies; because placebos are not regulated, their use will not be subject to the checks of the laws governing prescriptions of controlled substances. Because patients will be unaware that they are receiving placebos, the physicians will never be subject to patient inquiry. In short, physicians are likely to be subject to little accountability in their decisions to lie to their patients in an effort to achieve the placebo effect.

Not only are lies harmful but so might placebos be harmful. Numerous critics of placebos have recounted the several potential and serious harms that could result from their use. Physicians who too readily rely upon placebos, without spending sufficient time to ensure an accurate diagnosis, may end up missing the patient's true diagnosis,[314] and the opportunity to provide effective curative treatment. Physicians dealing with patients whom they believe are psychosomatic frequently resort to placebos. This might very well constitute mistreatment of undiagnosed patients. The short answer to these concerns is that inappropriate use of placebos—deviation from the standard of care—should be treated no differently than prescribing the wrong drug, and should be addressed by tort law.

Almost all of the placebo discussion of potential harms assumes that the placebo of choice will be some kind of medicine, or massage, or herb. Not frequently discussed is placebo surgery, which has recently been used by

312. This is the reverse of Professor Kapp's proposal. I readily acknowledge that patients who distrust physicians in the first instance will likely not find this solution to be very responsive or comforting.

313. *See* Young, *supra* note 213, at 468-71.

314. *See, e.g.*, BOK, *supra* note 189, at 63.

researchers, and continues to be the subject of clinical study.[315] It may well be necessary to devise special rules for this situation, even if placebo therapy in general becomes accepted. Placebo surgery that requires general anesthesia potentially places patients at more risk than if they were receiving a placebo by another medium, but whether this risk exceeds the potential benefits would have to be determined on an individual basis. Any invasive procedure presents risk of infection or cardiac arrest; a hospital stay risks iatrogenic injury. The treating physician would have to be highly confident in a substantial placebo effect, and lack reasonable alternatives, to justify first, the sham surgery, and second, lying to a patient about the surgery. The prospect of malpractice liability in such circumstances is surely more serious than in other placebo contexts.

V. CONCLUSION

All of this is impossible to sort out until we have a sufficient understanding of whether placebos work, and their mechanism. If the Danish study is correct and there is no placebo effect, a radical reconceptualization of much present practice would be required. Conversely, assuming there is a placebo effect, and we can predict with a reliable degree of certainty on whom placebos will work, they could offer an extraordinarily potent addition to the treatments available to physicians. The first analytical difficulty would seem to be getting beyond the point of thinking of placebos as a sham, or as non-treatment. In the scenario where they have been proven to be efficacious, they should be considered as a specific treatment, just like a drug, or surgery. Physicians should then be able to present them as an alternative treatment, with a quantifiable probability of success, an expected magnitude of power, and potential side effects.

If the placebo effect is proven to be as powerful as many researchers believe, then it should be viewed as an effective treatment, legitimately used by practitioners and patients, rather than a "dirty trick" that is unprofessional, and beneath physicians. If the physician has a sufficient degree of certainty that she will achieve a therapeutic placebo effect for the patient, then the representation that the placebo is therapy or a medicine is not untrue. Assuming that the placebo effect is achieved, the patient will have received a therapeutically beneficial intervention, which was what she was told she was receiving. Thus, no deceit.

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315. *See, e.g.*, Freeman et al., *supra* note 207, at 988. *See also* Alan G. Johnson, *Surgery as a Placebo*, 344 LANCET 1140 (1994); Ruth Macklin, *The Ethical Problems with Sham Surgery in Clinical Research*, 341 NEW ENG. J. MED. 992 (1999).