Informed Consent, Psychotropic Medications, and a Prescribing Physician's Duty to Disclose Safer Alternative Treatments

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I. INTRODUCTION

The parents of 8-year-old Sophie, a young girl who seems to be both inattentive and hyperactive at school, take their daughter to a pediatrician after Sophie’s third-grade teacher suggests that Sophie may have Attention Deficit Hyperactivity Disorder (“ADHD”), the most commonly diagnosed mental health disorder of childhood. During the initial visit, Sophie’s parents ask the pediatrician about possible food-based causes of Sophie’s problematic behaviors, based on certain observations of Sophie at home. The pediatrician, however, informs the parents that the evidence does not support any diet-based connection to ADHD. Instead, after a 15-minute consultation, the pediatrician recommends that Sophie be put on methylphenidate, a Schedule II Controlled Narcotic, to control the identified behavioral symptoms. The pediatrician does not discuss any alternative treatment options.

Trusting in their pediatrician and thus believing there are no viable alternative treatments to psychotropic medication, Sophie’s parents put their daughter on the methylphenidate, but soon grow concerned over a number of disturbing side-effects. Later, while attending a parent support group for children with ADHD, Sophie’s parents discover that there are, in fact, a number of recent scientific studies positively linking the behaviors associated with ADHD to diet. This new information corroborates their own observations of their daughter’s
behavior at home. Sophie's parents elect to discontinue giving Sophie the methylphenidate and begin a carefully restricted diet instead. Within two months, Sophie's ADHD symptoms have completely disappeared. Sophie's parents are now understandably upset that their pediatrician, whom they believe had -- or should have had -- information regarding the most recent scientific studies linking diet and ADHD, did not disclose this material information to them before recommending psychotropic medication for their child. The parents insist that had they known about the evidence linking diet to ADHD, they would not have chosen methylphenidate first – and were accordingly deprived of giving true informed consent to the recommended treatment of psychotropic medication. The pediatrician insists that he did not have any duty to disclose such information, both because he did not personally believe in the effectiveness of any diet-based alternative treatment options, and because, regardless of the recent studies to the contrary, the mainstream medical community to which he belongs has not recognized any diet-based alternative treatments to psychotropic medication.

The use of psychotropic medication to treat any presumed mental health disorder always involves serious risks of harm. Accordingly, before prescribing psychotropic medication to control the behaviors associated with a presumed mental health disorder, under various medical ethical guidelines and informed consent laws, prescribing physicians must first disclose available information regarding not only the risks of taking the recommended medication, but also the availability of alternative treatment options, and the risks and benefits of choosing such alternative treatment options. Indeed, given the highly intrusive nature of psychotropic medication and the concededly unknown etiology of most mental health disorders, disclosing information in support of safer alternative treatments seems a particularly critical aspect of a prescribing physician's informed consent obligations in the mental health arena.

Unfortunately, in practice, studies suggest that prescribing physicians rarely disclose any safer alternative treatment options to psychotropic

1 See Myers v. Alaska Psychiatric Inst., 138 P.3d 238, 241 (Alaska 2006) ("Psychotropic drugs affect the mind, behavior, intellectual functions, perception, moods, and emotions and are known to cause a number of potentially devastating side effects"); see generally GRACE E. JACKSON, RETHINKING PSYCHIATRIC DRUGS: A GUIDE FOR INFORMED CONSENT (2005) (discussing numerous dangers of psychotropic medications).
2 See discussion infra Sec. II.
3 See discussion infra Sec. II and III.
medication, even where there is persuasive evidence that such safer alternatives exist.\(^4\) To use an example: with respect to treating Attention Deficit Hyperactivity Disorder ("ADHD"), the most commonly diagnosed childhood mental health disorder in the United States, a number of recent randomized controlled trials (RCT's) have indicated that a sizable majority of children diagnosed with ADHD are actually suffering from allergies to certain additives and preservatives in food.\(^5\) Indeed, one RCT conducted in 2011 by the ADHD Institute of the Netherlands and published in *The Lancet* indicated that once the identified irritants were removed from the children's diets, the behavioral symptoms associated with ADHD were completely eliminated in 64% of the children.\(^6\) Nevertheless, despite these encouraging findings, and consequent calls to incorporate safer first-line diet-based treatment interventions to the standard ADHD protocol outside of the United States, evidence suggests that the relevant prescribing physician communities within the United States have largely ignored these RCT's, and continue to recommend psychotropic medication, typically stimulants, as the first, and often only, treatment option for this purported disorder.\(^7\) Given that this information regarding a diet-based approach would undoubtedly be material to an ADHD patient or his or her legal surrogate, it can hardly be said that patients deprived of this information are giving true informed consent to treatment with psychotropic medication.

Yet, as this article describes, informed consent law in this country provides very little incentive for prescribing physicians to disclose information regarding alternative treatment options that might lie outside of their particular medical community's recognized forms of treatment,

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\(^4\) See discussion infra Sec. III.

\(^5\) See discussion infra Sec. III; see also Centers for Disease Control and Prevention, *Increasing Prevalence of Parent Reported Attention Deficit/Hyperactivity Disorder Among Children - United States 2003 and 2007*, 59 MORTALITY & MORTALITY WEEKLY REPORT 1439-43 (Nov. 12, 2010), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5944a3.htm?s_cid=mm5944a3_w [hereinafter CDC] ("ADHD is the most commonly diagnosed neurobiological disorder of childhood, with previous reports documenting increasing trends in prevalence during the past decade and increases in ADHD medication use."); see also JACKSON, supra note 1, at 17 (A "randomized controlled trial" is defined as "a prospective scientific experiment comparing the value of a treatment strategy in an experimental group with an alternative strategy in a control group, in which allocation to experimental or control group is determined by chance." Such RCT's are considered the "gold standard" for both scientific research and evidence-based medicine).

\(^6\) Liddy M. Pelsser et al., *Effects of a Restricted Elimination Diet on the Behaviour of Children with Attention-Deficit Hyperactivity Disorder (INCA Study): A Randomised Controlled Trial*, 377 THE LANCET 494, 500 (Feb. 5, 2011).

\(^7\) See discussion infra Sec. III; see also JACKSON, supra note 1, at 263-64 (Some typical stimulant medications used to "treat" ADHD are d-amphetamine (Dexedrine), methylphenidate (Ritalin, Concerta), pemoline (Cylert) and amphetamine and dextroamphetamine combos (Adderall). Atomoxetine (Strattera), allegedly a non-stimulant, is also prescribed for ADHD.).
and very little legal recourse for patients or their legal surrogates who are deprived of such material information. Instead, in roughly half of U.S. jurisdictions, mainstream physician communities are specifically allowed by law to set their own disclosure standards, and have not surprisingly limited disclosure of alternatives to their own recognized courses of treatment, rendering informed consent meaningless in such “medical community” standard jurisdictions.\(^8\) As for the other half, because courts even in the purportedly more patient-centered “reasonable patient” jurisdictions have thus far refused to require physicians to disclose available alternative treatments outside of the mainstream’s recognized treatments, treatment decisions even in those jurisdictions also amount to no more than what the doctor ordered.\(^9\)

While failing to require physicians to disclose material information regarding available but unrecognized alternative treatments has potentially devastating consequences for patients in all areas of medical practice, this article argues that such paternalistic deference is particularly unwarranted in the context of experimental treatment with high-risk psychotropic medication. Indeed, as this article further suggests, negligence-based informed consent laws are simply unsuitable to protect mental health patients in this experimental but high-risk context, and should be replaced entirely by statutory-based dignitary models.\(^{10}\)

Part II of this article describes the basic ethical and legal obligations acknowledged by or imposed upon physicians with respect to the disclosure of alternative treatment options, both in general and in the context of prescribing psychotropic medication. Part III then discusses the available scientific literature establishing an alternative treatment option to stimulant medication for the treatment of ADHD, and argues that the relevant prescribing physician communities have collectively failed to disclose such alternative treatment information to their ADHD patients, apparently without consequence. Part IV of this article explores case law that suggests that court-based deference to mainstream physicians regarding disclosure of available but unrecognized alternative treatments continues to deprive patients of material information, regardless of the disclosure standard purportedly adopted by the particular jurisdiction. Part IV also discusses why such court-based deference is particularly unwarranted in the context of experimental treatments with psychotropic

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8 See discussion infra Sec. II & Sec. IV.
9 See discussion infra Sec. II & Sec. IV.
10 See discussion infra Sec. IV-C (A dignitary-based model would provide protection for a patient’s bodily dignity and allow patients to sue for violations of informed consent that do not result in any injury other than the denial of the information itself.).
medication. Part V concludes that general negligence-based informed consent laws meant for traditional medical practice fail to ensure disclosure of alternative treatments to psychotropic medication, and recommends that legislatures adopt dignitary-based informed consent provisions that will better ensure both adequate physician disclosure of alternative treatments to psychotropic medication, and provide an actual remedy for patients in the event of a physician's breach.

II. INFORMED CONSENT AND THE DUTY TO DISCLOSE ALTERNATIVE TREATMENT OPTIONS TO RECOMMENDED TREATMENTS

The doctrine of informed consent evolved in response to a number of breaches by health care practitioners in treating patients beyond the consented for treatment.\(^\text{11}\) First articulated by the court in Schloendorff v. Society of New York Hospital, where Justice Cardozo famously declared that "every human being of adult years and sound mind has a right to determine what shall be done with his own body," the doctrine first emerged as a cause of action in battery and was limited solely to actions for treatment which the patient had not consented.\(^\text{12}\) Gradually, the courts recognized a cause of action for situations where the patient consented to the particular treatment, but was not provided with adequate information regarding the recommended treatment, including risks, benefits, and any available alternative treatment options to such recommended treatment.\(^\text{13}\) The doctrine of informed consent today is both an ethical mandate under relevant medical ethical guidelines, and a legal duty imposed either by common law or as codified by legislation.

In general, the term "informed consent" encompasses five primary elements: voluntarism, capacity, disclosure, understanding, and decision.\(^\text{14}\) "Voluntarism" requires that the patient be free from coercion or unfair persuasions and inducements in making a treatment decision. "Capacity"
refers to the patient’s mental ability to make health care decisions. "Disclosure" requires that a physician provide all material information needed by the patient to make a treatment decision, while "Understanding" requires that the patient comprehend the information and appreciate its relevance to his or her individual situation. Finally, "Decision" refers to a patient’s ultimate authorization allowing the physician to execute the proposed treatment. Although all elements are necessary to determine whether “informed consent” was truly given to any particular course of treatment, this article is concerned primarily with the element of disclosure – a physician’s obligation to provide his or her patient with the material information needed in order to make a particular treatment decision. Implicit in such a disclosure obligation is the obligation to provide patients with all information that would be material to a patient’s decision – including any available treatment alternatives to the physician’s recommended course of treatment.

A. Medical Ethical Disclosure Obligations and Alternative Treatment Options

Before considering what current disclosure obligations are legally imposed upon physicians, it is helpful to consider the obligations the mainstream medical community has chosen to ethically impose upon itself. Today all relevant medical communities acknowledge a physician’s ethical obligation to provide information to his or her patient that would be material to his or her treatment decision. In its Code of Medical Ethics, the American Medical Association (AMA) states that:

The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician’s obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient’s care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is
In order to allow patients to exercise this right of self-determination, the AMA specifically advises its physicians to disclose to the patient or the patient’s legal surrogate:

(1) the patient’s diagnosis, if known;

(2) the nature and purpose of a proposed treatment or procedure;

(3) alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);

(4) the risks and benefits of the alternative treatment or procedure; and

(5) the risks and benefits of not receiving or undergoing a treatment or procedure.\textsuperscript{17}

The AMA further notes that withholding this type of material medical information from patients without their knowledge or consent would be "ethically unacceptable."\textsuperscript{18}

While the AMA Guidelines were likely intended to broaden the historically limited scope of physician disclosure, it appears that disclosure of alternative treatment options is limited to those that are "consistent with good medical practice."\textsuperscript{19} Such a qualifier begs the question of whether the AMA would consider it ethically necessary to disclose available alternative treatments beyond those that would need to be considered under the particular physician’s ordinary standard of care obligations.\textsuperscript{20}


\textsuperscript{17}AMA supra note 16; see also H-140.989 Informed Consent and Decision-Making in Health Care, AMERICAN MEDICAL ASSOCIATION, http://www.ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-140.989.HTM (last accessed March 16, 2014).


\textsuperscript{19}See AMA, supra note 16; see also Morris, supra note 13, at 313 (discussing the historical reluctance of physicians to disclose any information to their patients, and noting that physicians only recently began to acknowledge that “patients today no longer accept their place as obedient children, powerless even to question the decisions of their physician-fathers”).

\textsuperscript{20}See James A. Bulen, Complementary and Alternative Medicine: Ethical and Legal Aspects of Informed
Perhaps in response to such an ambiguity, a number of physicians have individually begun to recognize an ethical obligation to disclose alternative treatment options that might exist outside of their own conventional treatments where reliable evidence warrants. According to one practitioner:

A physician’s duty of care does not necessarily include the obligation to provide information about therapies outside the range of conventional treatment or those not yet supported in the medical literature. However as [complementary and alternative] therapies such as acupuncture become better studied and their safety and efficacy are established, the scope of disclosure required may expand to include them. The legal and ethical obligation to obtain informed consent to treatment requires disclosure and discussion of therapies when there is reliable evidence of potential therapeutic benefit.2

Despite individual acknowledgement, however, the AMA’s current ethical disclosure guidelines remain unclear as to what extent it believes physicians have an ethical obligation to consider “reliable evidence” regarding alternatives to recommended treatments that reside outside of a physician’s traditional medical practice – or to disclose such material information to their patients.

B. Legal Informed Consent and the Disclosure of Alternative Treatment Options

Beyond ethical guidelines, the law also purportedly imposes upon physicians a duty to inform patients of the material risks, benefits, and alternative treatment options to any recommended course of treatment.22 This duty of disclosure is presented as a separate and distinct obligation from a physician’s legal duty to use due care.23 Thus, even if a physician

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22 See, e.g., Flanagan v. Wesselhoeft, 712 A.2d 365, 371 (R.I. 1998) (“[I]nformed consent is not possible when a physician has failed to address both the material risks associated with and the viable alternatives to a recommended surgical procedure.”).
23 Flanagan, 712 A.2d at 370 (“This theory, which today is known as the doctrine of informed consent,
complies with his standard of care obligations by treating the patient as a reasonable physician would under similar circumstances, a physician could presumably still be liable for failing to discuss with the patient any and all available alternative treatment options to the choice of care selected by the physician.\footnote{See, e.g., Matthies v. Mastromonaco, 733 A.2d 456, 463 (N.J. 1999) (“Because the patient has a right to be fully informed about medically reasonable courses of treatment, we are unpersuaded that a cause of action predicated on the physician’s breach of a standard of care adequately protects the patient’s right to be informed of treatment alternatives.”).}

Yet, the actual parameters of required disclosure are not uniform throughout the United States. Instead, physicians are governed by one of two disclosure standards: (1) the medical community standard, and (2) the reasonable patient standard.\footnote{See \textit{Bulen}, supra note 20, at 335-40.}

\section*{1. Medical Community Standard}

The medical community standard, although no longer the majority standard in the United States, nevertheless still governs in a sizable number of United States jurisdictions.\footnote{See \textit{Talati}, supra note 11, at 178-80.} Under this medical community standard, physicians are required to disclose to patients only those risks, benefits, and alternative treatment options to a recommended course of treatment that a reasonable physician with similar training and experience would consider material to a treatment decision.\footnote{See, e.g., Foster v. Oral Surgery Ass’n, 940 A.2d 1102, 1106 (Me. 2008) (“The scope of a physician’s duty to disclose is measured by those communications a reasonable medical practitioner in that branch of medicine would make under the same or similar circumstances.”); see also, e.g., Eady v. Lansford, 92 S.W.3d 57, 60 (Ark. 2002) (“The duty of a physician to disclose is measured by the customary disclosure practices of physicians in the community or a similar community.”). The medical community standard is also sometimes referred to as the physician-oriented standard or the medical custom standard.} Because this standard simply follows a physician’s standard of care obligations, it is hard to see any real distinction between a claim for a failure to use due care and a failure to obtain informed consent in such a jurisdiction. Under this standard, the physician is only required to inform the patient about treatments generally recognized by similar physicians in the same or similar area of practice. Thus, as long as the physician discloses what is generally recognized within his or her own medical community as an available treatment option, there would presumably be no viable claim against that physician for a failure to inform the patient of other available but unrecognized alternative treatments, regardless of the amount of evidence supporting such an alternative treatment, and regardless of
whether the patient himself would have found the available alternative treatment information material to his or her own treatment decision. Indeed, the medical community standard erroneously assumes that how much information should be disclosed to a patient is a judgment requiring medical expertise.\textsuperscript{28} Accordingly, although disclosure and competent practice are purportedly different legal obligations, by tying the disclosure obligation to the physician's medical community's customs, "informed consent" in a medical community jurisdiction is, in reality, nothing more than a patient agreeing to what the doctor ordered.

2. Reasonable Patient Standard

Recognizing that "unlimited discretion in the physician is irreconcilable with the basic right of the patient to make the ultimate decision regarding the course of treatment to which he knowledgeably consents to be subjected," both the California Supreme Court in \textit{Cobbs v. Grant} and the United States District Court for the D.C. Circuit in \textit{Canterbury v. Spence}, began the shift from the medical community-created standard to the judicially-imposed, reasonable patient standard.\textsuperscript{29} Under the reasonable patient standard, a physician is required to disclose all information regarding the risks, benefits, and alternative treatment options that a reasonable patient in the patient's shoes would find material to a treatment decision.\textsuperscript{30} The standard is purportedly set by "law" and not by the medical community of which a defendant physician is a part, and presumably expands beyond a physician's duty to exercise due care.\textsuperscript{31}

Unfortunately, the reasonable patient standard is still not concerned with what a particular patient would want to know before making a treatment decision. Instead, both the \textit{Cobb} and the \textit{Canterbury} courts

\textsuperscript{28} See Bulen, \textit{supra} note 20, at 336 (noting that requiring patients to find medical experts to testify as to what should have been disclosed per medical community standards is a significant burden for patients who might face a "conspiracy of silence" in the relevant medical community).

\textsuperscript{29} Cobbs, 502 P.2d at 1, 10; Canterbury v. Spence, 464 F.2d 772, 783-84 (D.C. Cir. 1972); see also Talati, \textit{supra} note 11, at 178 (the reasonable patient standard now is in the slight majority within the United States).

\textsuperscript{30} See, e.g., Levesque v. Bristol Hosp., 943 A.2d 430, 443 (Conn. 2008) ("[A] physician is obligated to provide the patient with that information which a reasonable patient would have found material for making a decision."); see also, e.g., Miller-McGee v. Wash. Hosp. Ctr., 920 A.2d 430, 440 (D.C. 2006) ("The test for mandatory disclosure of information on treatment of the patient's condition is whether a reasonable person in what the physician knows or should know to be the patient's position would consider the information material to his decision.").

\textsuperscript{31} See Canterbury, 464 F.2d at 784 ("Respect for the patient's right of self-determination on a particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."); see also Bulen, \textit{supra} note 20, at 341 (noting that the reasonable patient standard must be understood to be broader than the physician's standard of care if it is to have any meaning. Otherwise, the patient-oriented standard would simply "collapse" into the physician-oriented standard).
limited required disclosure to what a "reasonable person" would likely consider material to a treatment decision under the same or similar circumstances. Still, courts operating in a reasonable patient jurisdiction would presumably find a breach of a physician's disclosure obligations if a physician failed to disclose alternative treatment information that a reasonable patient would find material, even if the alternative treatment was not recognized or recommended by the particular physician or his or her medical community.

The reasonable patient standard is now the majority disclosure standard in the United States, and is seemingly more protective of patients' self-determination rights than the medical community standard. However, as case law below will illustrate, courts in reasonable patient jurisdictions are often indistinguishable from medical community jurisdictions, and often simply defer to the challenged physician or medical community itself to determine which alternatives are "reasonable" or "available" to the patient, regardless of the patient's own interests. This in turn severely limits disclosure of alternative treatment options outside of the mainstream's preferred treatments.

C. Informed Consent and Disclosure of Alternatives in the Mental Health Context

In the mental health context, informed consent is often complicated by additional questions regarding a mental health patient's competency to consent. As a result, specific statutory informed consent rules may govern the involuntary treatment of mental health patients, as well as the treatment of certain vulnerable populations deemed legally incapable of giving consent. Outside of these involuntary or potentially coercive

32 Cobb, 502 P.2d at 11-12; Canterbury, 464 F.2d at 791.
33 See, e.g., Mathies, 723 A. 2d at 462 (N.J. 1999) ("[P]hysicians do not adequately discharge their responsibility by disclosing only treatment alternatives that they recommend."); see also, e.g., Saks v. Ng, 890 A.2d 983, 992 (N.J. Super. Ct. App. Div. 2006) ("[F]or a patient's consent to be informed, the physician must discuss with the patient medically reasonable alternatives that the physician does not recommend."). Indeed, the court in Canterbury stated that it was incumbent upon the physician himself to be familiar with the availability of alternative treatments, so that the patient could weigh and consider all of the available options. See Canterbury, 464 F.2d at 781, stating:

To the physician, whose training enables a self-satisfying evaluation, the answer may seem clear, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie. To enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards becomes essential.
34 See Talati, supra note 11, at 178.
35 See discussion infra Sec. IV-A(2).
36 See generally Talati, supra note 11, at 181-86.
37 See, e.g., Myers, 138 P.3d at 242 (discussing Alaska's informed consent statute for the involuntary
Physicians engaged in treating presumed mental health disorders, including members of the American Academy of Child and Adolescent Psychiatrists (AACAP) and the American Academy of Pediatrics (AAP), similar to the AMA, also profess their ethical disclosure obligations to their mental health patients. Thus, the various ethical guidelines for these prescribing physician communities also acknowledge that informed consent disclosure generally requires disclosure of: (1) the nature of the ailment or condition; (2) the nature of the proposed diagnostic steps and/or course of treatment(s), and the probability of their success; (3) the existence and nature of the risks involved in the recommended treatment; and (4) the existence, potential benefits, and risks of recommended alternative treatments, including the choice of no treatment.

Similar to the AMA Guidelines, however, the AAP’s ethical guidelines also seem to limit the disclosure of alternative treatments to “recommended” alternative treatments. This leaves it unclear as to whether the AAP believes that a physician treating a mental health patient has an ethical obligation to disclose alternative treatment options that may lie beyond the physician’s preference or medical bailiwick. However, at least administration of psychotropic medications to patients). Other involuntary contexts where treatment with psychotropic medication may be involved include children in the foster care system or prison populations. This article does not address informed consent disclosure issues in the involuntary or coercive contexts. For interesting reading on some of these contexts: see Matthew M. Cummings, Sedating Forgotten Children: How Unnecessary Psychotropic Medication Endangers Foster Children’s Rights and Health, 32 B.C. J.L. & SOC. JUST. 357 (2012); see also Dana E. Prescott, Cosas and Psychopharmacological Interventions: Informed Consent and a Child’s Right to Self-Determination, 11 J. L. & FAM. STUD. 97 (2008).

38 A few states have enacted informed consent provisions with respect to the administration of psychotropic medications for children in particular. See, e.g., IND. CODE ANN. § 25-1-9-6.8 (2013) (requiring practitioners to follow the most recent AAP or AACAP guidelines for diagnosing and evaluating a child before prescribing psychotropic medications).


40 See AAP COMMITTEE, supra; see also, AACAP CONSENT, supra.
some mental health practitioners have acknowledged this ethical obligation:

The ethical practitioner needs to keep up-to-date with empirical findings on all somatic and psychosocial treatments, including their indications, adverse effects, and contraindications. Moreover, clinicians who prescribe medications should be prepared to recommend relevant data-driven psychotherapies and psychosocial interventions that may be indicated as a first-line treatment or as important adjunctive treatments—even if these must be provided by another practitioner. 41

Today, the most pervasive form of treatment in the mental health context involves the use of psychotropic medication to control the behaviors typically associated with the presumed mental health disorder. 42 In a nutshell, psychotropic medications are "toxic substances that act directly on the brain to chemically alter mood, cognition, or behavior, their effect being achieved by altering the processes of brain neurotransmission." 43 Typically psychotropic medications are classified into four sub-types: (1) stimulant medications (used to treat ADHD, such as Ritalin and Adderall), (2) anti-depressant and anti-anxiety medications (used to treat depression, OCD, and related disorders, such as Zoloft, Anafranil, and Prozac), (3) anti-psychotic medications (used to treat bipolar disorder, schizophrenia, autism, Tourette's syndrome, and severe conduct disorders and aggression, such as Haldol, Seroquel, and Risperdal), and (4) "mood stabilizing" medications (used to treat bipolar disorder, such as Depakote and Lithobid). 44 The risks of using any of these psychotropic medications are high, with well-documented side effects such as tardive dyskinesia, liver damage, growth retardation, suicide, psychosis, permanent brain damage, heart failure, and even death. 45 Indeed, "it is

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41 Laura Weiss Roberts & Shali Jain, Ethical Issues in Psychopharmacology: Considerations for Clinical Practice, 28 PSYCHIATRIC TIMES 50, 50-56 (2011) (noting that: "throughout treatment, a high standard of informed consent—along with other safeguards essential to clinical practice—should be maintained.").
42 Id.
43 Angela Olivia Burton, They Use It Like Candy: How the Prescription of Psychotropic Drugs to State-Involved Children Violates International Law, 35 BROOK. J. INT'L L. 453, 466 (2010); see also Myers, 138 P.3d at 241.
45 See, e.g., Peter Breggin, Psychostimulants in the Treatment of Children Diagnosed with ADHD, 12 INT'R. JOURNAL OF RISK & SAFETY IN MED. 3, 29 (1993); see also JACKSON, supra note 1, at 267-97; Burton, supra note 43, at 467; Talati, supra note 11, at 187; Myers, 138 P.3d at 241-42 ("Tardive dyskinesia involves 'slow, rhythmical, repetitive, involuntary movements of the mouth, lips, and tongue; it is permanent, and its symptoms cannot currently be treated.'").
difficult to imagine intrusions on the body that are more significant than the administration of psychotropic medication.\textsuperscript{46}

Moreover, because the underlying causes of all mental health disorders remain unknown, any treatment for such presumed disorders with psychotropic mediation is necessarily experimental.\textsuperscript{47} As one scholar has aptly noted:

The approach to treating a patient with mental illness is, as a whole, not a precise science. While there is a substantial degree of variability that accompanies the treatment of any condition with medication, in the treatment of mental illness, "trial and error" is more norm than the exception. Knowledge regarding treatment is incomplete largely because knowledge about mental illness is itself incomplete. Therefore, it will be difficult, if not impossible, for the physician to assert that treatment for mental illness will be beneficial in any given case because she simply cannot know this a priori. Antipsychotic drugs do not promise to cure mental illness; at best, they offer a reduction in some, but not all, debilitating symptoms associated with mental illness. In a substantial number of patients, medication will not provide any benefit, and rarely will medication provide complete relief. Because of the lack of effective interventions in treating mental illness, the physician faces special problems in meeting her duty of disclosure in a meaningful way. The physician will be able technically to meet her duty of disclosure because the duty expects her to reveal what she knows (and logically cannot expect more); however, while legally appropriate, this still may leave the patient to decide without information that is material to an adequately weighed decision.\textsuperscript{48}

Considering the high risks and uncertain benefits of psychotropic medication to treat mental health disorders of unknown origins, it is not

\textsuperscript{46}Talati, supra note 11, at 187; see Myers, 138 P.3d at 242 ("[M]any states have equated the intrusiveness of psychotropic medication with the intrusiveness of electroconvulsive therapy and psychotherapy.").

\textsuperscript{47}See ROBERT WHITTAKER, ANATOMY OF AN EPIDEMIC: MAGIC BULLETS, PSYCHIATRIC DRUGS, & THE ASTONISHING RISE OF MENTAL ILLNESS IN AM. 77-78 (2010) (noting that although mental health disorders are often touted as diseases caused by "chemical imbalances," there is no evidence to support such claims); see also Samantha Godwin, Bad Science Makes Bad Law: How the Deference Afforded to Psychiatry Undermines Civil Liberties, 10 SEATTLE J. FOR SOC. JUST. 647, 649 (2012) ("Authoritative research has not conclusively demonstrated any specific biological causes for mental disorders."); THOMAS S. SZASZ, THE MYTH OF MENTAL ILLNESS, Preface xii (2010) ("The claim that "mental illnesses are diagnosable disorders of the brain" is not based on scientific research; it is a lie, an error, or a naive revival of the somatic premise of the long-discredited humoral theory of disease."); Burton, supra note 43, at 498 ("[T]he DSM-IV editors candidly acknowledge that "there is no objective marker that can identify a large majority of mental disorders; diagnosis is a judgment call based on an interview and/or observation of behavior.”").

\textsuperscript{48}See Talati, supra note 11, at 186.
surprising that studies have consistently indicated patient preference for drug-free alternatives to medication, as well as a desire for more information regarding the availability of such drug-free alternatives. Unfortunately, other studies have also indicated that many prescribing physicians do not provide such alternative treatment options to psychotropic medication to their mental health patients, even where compelling evidence suggests that effective alternatives exist. One apparent example of collective physician non-disclosure of available alternatives to medication arises in the context of treatment for ADHD.

III. A CASE STUDY IN PHYSICIAN NON-DISCLOSEMENT OF A SAFER ALTERNATIVE: ADHD, PSYCHOTROPIC MEDICATION, AND THE ADHD-DIET LINK

It would seem axiomatic that what a person chooses to eat, or fails to eat, would have a significant impact not only on one’s physical health, but also one’s mental health. Nevertheless, despite the fact that numerous scientific studies have positively linked various mental health issues and specific learning disorders to nutritional factors, there remains a lack of disciplinary convergence between nutritional health and mental health.

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49 See JACKSON, supra note 1, at 1-7.
50 See generally JACKSON, supra note 1, at 148-50, 259 & 200-301 (noting a number of studies showing successful non-pharmacological approaches to treating various mental health disorders – and the lack of disclosure of such alternatives); Connie Lenz, Prescribing a Legislative Response: Educators, Physicians and Psychotropic Medication for Children, 22 J. CONTEMP. HEALTH L. & POLY’Y 72, 92 (2006) (noting that physicians rarely disclose risks or alternative treatment options to stimulant medications).
51 See, e.g., CAROL SIMONTACCHI, THE CRAZYMAKERS: HOW THE FOOD INDUSTRY IS DESTROYING OUR BRAINS & HARMING OUR CHILDREN 2 (2007) (Simontacchi, a registered dietician, presents a compelling history of the decline of American children’s mental health as a result of the chemicals, additives, and preservatives contained in their daily food supplies, noting that “Food is different now. Now, we are sold packages, boxes, artificial flavors, coloring agents, and pseudo-foods that strip the body and leave the brain poverty-stricken. The product is colorful and flavorful, but not from natural goodness. The colors come from a chemist’s beaker, from FD & C Blue No. 1, Red No. 40, and Yellow No. 5, or from cochineal (from the female insect, coccus cacti from the West Indies). The flavor comes from allyl antranilate or isopulegol or linalyl benzoate or methyl delta-ionone, while gravies and sauces are thickened with wood fiber and emulsified by diocyl sodium sulfo-succinate. While some of these agents have been tested for carcinogenic properties, virtually none have been studied to learn their impact on brain chemistry... We carve a culture out of our favorite food icons and we don’t link the food artifacts with the depression, the anger, and the heartbreaking assortment of mental illnesses that beset us.”).
52 See discussion infra Sec. III-B; see also, e.g., Shaheen E. Lakhan & Karen F. Viera, Nutritional Therapies for Mental Disorders, NUTRITION JOURNAL 7:2 (2008), available at http://www.nutritionj.com/content/7/1/2 (“researchers have observed that the prevalence of mental health disorders has increased in developed countries in correlation with the deterioration of the Western diet.”); Luke T. Curtis & Kalpana Patel, Nutritional and Environmental Approaches to Preventing and Treating Autism and Attention Deficit Hyperactivity Disorder: A Review, 14 JOURNAL OF ALT. & COMPLEMENTARY MED. 79, 79 (2008) (“much recent research has suggested that nutritional and environmental factors also play a major role in the development of autism and ADHD disorders.”). For other studies linking particular mental health or specific learning disorders with diet-based causes, see Michael Huss et. al, Supplementation of Polyunsaturated Fatty Acids, Magnesium, and Zinc in Children Seeking Medical...
This disconnect is apparent in both the suggested clinical treatment protocols for various mental health conditions promulgated by the relevant prescribing physician communities such as the APA, the AAP, and the AACAP, as well as in the standard "informed consent" forms that mental health patients are routinely given by their treating physicians when psychotropic medication is prescribed.\(^5\) Nowhere is this lack of disciplinary convergence between mental health and physical health more noticeable than in the treatment of Attention-Deficit Hyperactivity Disorder, where the connection between the behavioral symptoms associated with ADHD and diet has been hypothesized, studied, and, some would argue, ignored, by the mainstream prescribing physician community for over forty years.\(^5\)\(^4\)

A. ADHD and the Current Recommended Treatment of Psychotropic Medication

ADHD, now the most commonly diagnosed childhood mental health disorder in the United States, did not show up in psychiatry's Diagnostic and Statistical Manual (DSM) as a recognized and separate mental health disorder until 1980.\(^5\)\(^5\) Like every other presumed mental health disorder in the DSM, there is no laboratory or other definitive medical test to...
determine whether a person "has" ADHD. Instead, an individual is diagnosed with the ADHD disorder based on an assessment of certain behavioral criteria. In the case of ADHD, a person must show six or more symptoms of either inattention or hyperactivity for at least six months, and some "impairment" from these symptoms must be present in two or more settings, generally home and school.

Despite the DSM inclusion, the very authenticity of ADHD as a true mental health disorder has provoked considerable controversy over the last few decades. On one side of the controversy are those who believe that ADHD is a serious, well-documented "chronic disorder" affecting millions of children and adults, and that treatment with ADHD stimulant medications, most commonly methylphenidate, is the safest and most effective treatment protocol to unlock such ADHD sufferers' true potential. On the other side of the controversy are those who question the ADHD diagnosis itself, or who believe that even if certain behavioral symptoms associated with the purported disorder are genuine, the single modality method of "treating" the symptoms with dangerous psychotropic medications with known serious side effects is morally reprehensible, particularly when the decision is being made for someone other than the person taking the medication, such as a child.

Regardless of the debate, the diagnosis of childhood ADHD continues to rise at epidemic rates, along with a concurrent rise in prescriptions for psychotropic medication to control the behavioral symptoms associated with this disorder. The United States is now the consumer of over 85% of the world's supply of methylphenidate, a controlled Schedule II narcotic, despite early consensus that psychotropic medication such as methylphenidate should only be used in the most severe cases of ADHD, and only after other, safer treatment alternatives had proven ineffective. Indeed, in the 2011 American Academy of

56 See CDC, supra note 5 (ADHD is characterized by "developmentally inappropriate levels of inattention and hyperactivity, resulting in functional impairment in academic, family, and social settings.").
57 See DSM-V, supra note 55; see also Lenz, supra note 50, at 74-75.
58 Lenz, supra note 50, at 73 ("the very existence of ADHD as a valid disorder has fueled much debate"); see St. Luke's Health Initiatives, supra note 44, at 2.
60 Id. at 2; see Burton, supra note 43.
61 See CDC, supra note 5.
62 See St. Luke's Health Initiatives, supra note 44, at 11 (United States is consumer of over 85% of the world's supply of methylphenidate). A "controlled narcotic" is a drug deemed to have great potential for addiction, abuse and diversion into the illegal drug trade. Because of these dangers, such narcotics are designated as controlled substances and their medicinal uses are stringently regulated by the international community under the 1971 United Nations Convention on Psychotropic Substances ("1971 Convention"). Because of its high potential for abuse, methylphenidate was one of the first substances placed under
Pediatrics' (AAP) Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of ADHD in Children and Adolescents, the AAP now recommends psychotropic medication as the first line of treatment for ADHD-diagnosed children as young as five years old, and as a viable treatment option for children as young as four. The American Academy of Child and Adolescent Psychiatry (AACAP) offers similar recommendations. The shift to using psychotropic medication as the primary method of treatment for a disorder still the subject of considerable controversy seems near complete.

Yet, even proponents of this pharmacological approach acknowledge that stimulant medication is hardly risk-free. Side effects range from mild nervousness, nausea, insomnia, and decreased appetite, to heart irregularities, suicidal ideations, increased risk of violent and addictive behavior, and even death. Moreover, despite earlier claims that stimulant medication such as methylphenidate was “highly effective” in treating ADHD, a number of recent studies have indicated otherwise. In fact, in the most significant long-term study conducted on the effects of stimulant medication on ADHD children, the Multisite Multimodal Treatment Study (the “MTA Study”), the authors noted that at the 36-month mark, “medication use was a significant marker, not of beneficial outcome, but of deterioration.” Follow up and additional studies on the use of stimulants to treat ADHD have supported this negative assessment. As one physician and author notes:


64 American Academy of Child and Adolescent Psychiatry, Practice Parameter for the Assessment and Treatment of Children and Adolescents with Attention-Deficit/Hyperactivity Disorder, 46 J. AM. ACAD. CHILD. ADOLESC. PSYCHIATRY 894, 907 (2007) [hereinafter AACAP PRACTICE PARAMETER].

65 See, e.g., Hoagwood K. et al., Treatment Services for Children with ADHD: A National Perspective, 39 J. AM. ACAD. CHILD ADOLESCENT PSYCHIATRY 198-206 (2000) (noting that “major shifts have occurred in stimulant prescriptions since 1989, with prescriptions now comprising three-fourths of all visits to physicians by children with ADHD.”).

66 See JACKSON, supra note 1, at 267-99.

67 See id.; see also Burton, supra note 43, at 462-63.

68 Whittaker, supra note 47, at 227 (citing P. Jensen, 3-Year Follow-Up of the NIMH MTA-Study, 46 J. AM. ACAD. OF CHILD & ADOLESC. PSYCHIATRY 989, 989-1002 (2007)).

69 See, e.g., B. Molina, Delinquent Behavior and Emerging Substance Abuse in the MTA at 36 Months, 46 J. AM. ACAD. OF CHILD & ADOLESC. PSYCHIATRY, 1028-39 (2007) (stating that relative to normative comparative group, MTA children had significantly higher rates of delinquency); see also B. Molina, MTA at 8 years, 48 J. AM. ACAD. OF CHILD & ADOLESC. PSYCHIATRY 484-98 (2009); Whittaker, supra note 47, at 227.
According to their advocates, nothing “works” as effectively for inattention or hyperactivity as stimulant medications. The overwhelming majority of articles appearing in medical textbooks and journals on the subject of ADHD present stimulants as the gold standard of treatment, with a reported efficacy rate of 70-90%. By efficacy (favorable short term response) it is suggested that children become less impulsive, less fidgety, and more focused. However, it is important to appreciate the quality of the studies, which have been responsible for the construction of this opinion. A meta-analysis of sixty-two randomized controlled trials (RCTs) involving almost 3000 subjects with a primary diagnosis of ADHD demonstrated weak findings for short acting Ritalin. Thirty-nine percent of published trials were of low quality, 26% of the trials reported results of Ritalin along with additional drugs or interventions; and at least eight trials suppressed teacher data, which showed poorer Ritalin effects. Moreover, all trials noted significant adverse effects. Based upon these findings, the [meta-analysis] authors concluded that ‘broad generalizations about the usefulness of Ritalin should probably be avoided, particularly due to the lack of long term trial evidence.’ However, long-term studies have been conducted, and these investigations reinforce the opinion that stimulant utility is limited.

Even medication advocates who had once sought to establish the superiority of medication have conceded that “stimulants do not produce lasting improvements in aggressivity, conduct disorder, criminality, education achievement, job functioning, marital relationships, or long-term adjustment.” In short, stimulant medication to treat ADHD is hardly the panacea it was originally touted to be, and many researchers and physicians are now arriving at the conclusion that such medication may do significantly more harm to ADHD patients than good in the long-term.

Given this growing body of evidence undermining the mainstream mental health community’s position on stimulant medication as a safe and

70 Jackson, supra note 1, at 273; see Burton, supra note 43, at 462-63 (discussing a 2010 study which indicated that children diagnosed with ADHD who had been treated with stimulants were found to be ten and a half times more likely to have been identified by a classroom teacher as performing below age-level, and had significantly greater diastolic blood pressure than ADHD-diagnosed children who had never received medication); Whittaker, supra note 47, at 227.

71 Breggin, supra note 45, at 28 (discussing numerous studies establishing the high risk and/or low effectiveness of ADHD medications).

72 See, e.g., Jackson, supra note 1, at 267-97 (long-term effects may include permanent negative changes to brain chemistry, heart disease, growth retardation, addiction to other recreational drugs, and psychosis).
effective form of treatment for ADHD-associated behaviors, it is no surprise that many ADHD patients and/or their legal surrogates want to know about alternative treatment options to such medication.\(^{73}\) However, studies have shown that patients and physicians have differing views on how much information needs to be disclosed, with patients wanting significantly more information regarding alternative treatments than their physicians seem willing to provide.\(^{74}\) Reasons for this growing divide between what patients want to know and what physicians disclose to them are undoubtedly manifold. Physicians may be affected by managed care concerns or other time pressures, or may be genuinely uncomfortable with recommending available treatments outside of their areas of medical expertise.\(^{75}\) Others, however, do not provide such material information regarding alternative treatments to their patients because they insist that alternatives simply do not exist, even with available scientific literature to the contrary.\(^{76}\)

**B. The ADHD-Diet Studies: Is Diet a Viable Alternative Treatment Option?**

ADHD – it’s just a couple of symptoms. It’s not a disease. There is a paradigm shift needed. If a child is diagnosed with

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\(^{73}\) See, e.g., Debbie Schacter & Irwin Kleinman, *Informed Consent and Disclosure of Information for Stimulant Medication: An Exploratory Study of Teenagers*, Parents’ and Physicians’ Preferences for Information Disclosure, 5 JOURNAL OF ETHICS IN MENTAL HEALTH 1, 4 (2011); see also Jackson, supra note 1, at 5 (noting that “multiple contemporary surveys around the world reflect a public preference for the non-drug treatment of psychiatric conditions. Consumers convey significant doubt about the effectiveness of psychotropic medications, and substantial concern about their potential to harm the body or cause maladaptive changes (addiction).”).

\(^{74}\) Schacter, supra at 4; Jackson, supra note 1, at 5; see Alexander G. Fiks et al., Contrasting Parents’ and Pediatricians’ Perspectives on Shared Decision-Making in ADHD, 127 Pediatrics e188, e190 (2011) (“Parents emphasized the importance of clinicians providing information regarding all treatment options. They reacted negatively to doctors who ‘pushed’ medication without offering a balanced presentation of alternatives.”).

\(^{75}\) See generally Lakhan supra note 52, at 5 (“There is tremendous resistance to using [nutritional] supplements as treatments from clinicians, mostly due to their lack of knowledge on the subject. Others would rather use prescription drugs that the drug companies and the FDA researches, monitors, and recalls if necessary.”); Gerald F. Tietz, Informed Consent in the Prescription Drug Context: The Special Case, 6 WASH. L. REV. 367, 392 (1986) (noting that physicians often do not inform patients about non-drug or nutritional alternatives because they simply do not know enough about these alternatives themselves); see also Morris, supra note 13, at 347-48 (noting that physicians can no longer be trusted to place the individual patient’s medical interest above all other interests. Managed care imposes upon them a requirement that they divide their loyalties).

\(^{76}\) See, e.g., Carl Sherman, Nutrition, Diet and Non-Drug ADHD Treatments, ADDitude Magazine (Jan. 29, 2011), http://adhdinvasion.blogspot.com/2011/01/nutrition-diet-and-non-drug-adhd.html (“ADHD isn’t caused by an allergic reaction to food or anything in food, including additives. The evidence to support elimination diets or tests for food sensitivities simply doesn’t exist.”); but see Jackson, supra note 1, at 190 (“Just as political and cultural institutions have failed the mentally ill, so too have professional opinions about the kinds of interventions which appear to be most helpful.”).
ADHD, we should say, ‘ok, we have got those symptoms, now let’s start looking for a cause.’ In all children, we should start with diet research. If a child’s behavior doesn’t change, then drugs may still be necessary. But now we are giving them all drugs, and I think that is a huge mistake.\(^\text{77}\)

In contrast to the developing body of evidence showing that stimulant medication is neither as safe nor as effective as originally proclaimed, the evidence suggesting an alternative treatment option through diet-based protocols is steadily increasing.\(^\text{78}\)

In the early 1970’s, Dr. Benjamin Feingold was one of the first physicians to suggest a causal connection between dietary factors and the behavioral symptoms now associated with the ADHD diagnosis.\(^\text{79}\) His “Feingold Elimination Diet” was based upon his belief that hyperactive behavior in most children was primarily caused by certain artificial food colors, flavors, and preservatives found in the children’s diets.\(^\text{80}\) Feingold maintained that such hyperactive behavior could be effectively addressed without psychotropic medication simply by removing such food-based irritants from these children’s diets.\(^\text{81}\) Although many parents reported success with their own children on the Feingold elimination diet protocol, early scientific studies testing the Feingold treatment protocol produced mixed results.\(^\text{82}\) Later, the results of most of these early studies were deemed inconclusive due to their small study size or allegedly unscientific methodologies, but studies on the connection between diet and ADHD-identified behaviors continued.\(^\text{83}\)


\(^{79}\) See, e.g., articles, supra note 52.

\(^{80}\) Id.

\(^{81}\) Id. (noting that “studies from the 1970’s and 1980’s cautiously supporting the behavioral benefits of diets free from synthetic food dyes and additives were counteracted by negative ones.”); see Schnoll, supra note 54, at 64-66.

\(^{82}\) In essence, ADHD-diet studies can generally be classified into one of two theoretical approaches: a “nutritional deficiency” theory, which posits that ADHD symptoms are generally caused by a lack, or low concentration of, certain vital nutrients deemed essential to healthy brain development and functioning, or an “allergic reaction theory,” which posits that ADHD-like symptoms are actually caused by allergic reactions to certain foods or non-foods in the child’s food supply. See, e.g., articles, supra note 52. The major criticism of earlier ADHD-diet studies was the failure to put into place scientifically-recognized control mechanisms, such as double-blinded, placebo controls. See, e.g., Ronald E. Kleinman et al., *A Research Model for Investigating the Effects of Artificial Food Colorings on Children with ADHD*, 127 PEDIATRICS e1575, e1580 (2011) (“because most existing controlled studies of [artificial food coloring] and ADHD were conducted in the 1970’s and 1980’s, outcomes are not consistent with the current standards
Recently, a number of Randomized Controlled Trials (RCT’s) have given serious weight to the ADHD-diet connection, and have presumably addressed the scientific community’s criticism of earlier methodologies.

1. The Southampton Study

In 2007, the U.K. government, through its British Food Services Agency, sponsored the Southampton Study. In this study, researchers built upon a previous 2004 double-blind placebo-controlled study of preschool children that revealed that children who were initially put on a diet free of artificial dyes and benzoate preservatives subsequently exhibited increased hyperactivity when given a drink containing such preservatives and dyes. The Southampton Study expanded upon this 2004 study to include 153 three-year-olds and 144 eight and nine-year-olds who were representative of the general population. The study, which was published in the U.K. scientific periodical The Lancet, showed a statistically significant increase in negative ADHD-associated behaviors when children were given drinks with the identified dyes and preservatives. Although the researchers did not go so far as to claim that food additives “cause clinically defined ADHD,” the researchers nevertheless concluded that their results “strongly support[ed] a relationship between food additives and [ADHD-associated] behaviors.” After reviewing these results, the British Food Services Agency asked U.K. food manufacturers to voluntarily remove such colorings and preservatives from their food products. Encouraged by the British Food Services Agency’s proactive actions, health advocates in the United States lobbied the Food and Drug Administration to take similar actions with respect to the use of such colorings and preservatives in U.S. food supplies. The FDA declined to take such action.

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85 Id.; see Julie R. Barrett, Hyperactive Ingredients?, 115 ENVTL. HEALTH PERSPECTIVES A578, A578 (Dec. 2007).
86 Burka, supra note 79, at e55.
87 See Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children, U.S. FOOD & DRUG ADMIN. (Mar. 30-31, 2011), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM248549.pdf (“Based on our review of the data from published literature, FDA concludes that a causal relationship between exposure to color additives and hyperactivity in children in the general population has not been established.”).
2. The SAD Study

In 2010, another study was conducted in Australia by the Telethon Institute for Child Health Research, known as the SAD study.88 The study, which was published in the *Journal of Attention Disorders*, looked at the dietary patterns of 1,800 adolescents from the long-term Raine Study and classified diets as having “healthy” or “western” patterns.89 The “healthy” diet was characterized by a high intake of fresh fruit and vegetables, whole grains and fish, and tended to be higher in omega-3 fatty acids, folate, and fiber.90 The “western” diet was characterized by a tendency towards take-out foods, confectionary, processed, fried, and refined foods, and tended to be higher in total fat, saturated fat, refined sugar, and sodium.91 The SAD study results showed that the diet high in the western pattern of foods was associated with more than double the risk of having an ADHD diagnosis compared with a healthy diet pattern, after adjusting for other social and family influences. Although the researchers did not conclude that ADHD was “caused” by the diet-based factors, the researchers did conclude that more studies were needed to uncover what was behind the clearly observed link.92

3. The INCA Study

Finally, in 2011, the ADHD Centre in the Netherlands conducted the INCA study, a five-week, double-blind study with 100 children enrolled between the ages of four to eight who had been identified as having ADHD.93 During this five week period, children were assigned to either a restricted diet group or a control group. Remarkably, in the restricted diet group, when the identified food irritants were removed from the children’s diets, 64% of these ADHD-identified children ceased behaviors associated

88 See Amber L. Howard, et al., *ADHD Is Associated with a Western Dietary Pattern in Adolescents*, 15 JOURNAL OF ATTENTION DISORDERS 403-11 (2010) [hereinafter SAD STUDY] (“SAD” refers to the Standard American Diet, which is also referred to as a “Western” diet in this study).
89 Id. at 405; see *About Us, Raine Study*, http://www.rainestudy.org.au/about/what (last accessed July 31, 2013) (The Raine Study is a long-term Australian health study started in 1989 involving 2900 pregnant women and their eventual offspring. The women were assessed at various stages of their pregnancy and during this time, information was collected on the mother and the father, such as information on each parent’s diet, exercise, work, health, etc. After the children were born, the children were assessed over the years, and information on their height, weight, eating, walking, talking, eating, behavior, any medical conditions or illness was, and continues to be, collected.).
90 SAD STUDY, supra note 88, at 404.
91 Id.
92 Id. at 409; see Jess Halliday, *ADHD Could Be Linked to Diet*, FOODNAVIGATOR.COM (July 30, 2010), www.foodnavigator.com/content/view/print/314196 (discussing SAD Study results).
93 See Pelsser, supra note 6, at 494.
with ADHD altogether. The results of this INCA study, which were also published in The Lancet in 2011, prompted the main author of the study to conclude that the majority of ADHD-identified children are more likely suffering from a hypersensitivity to certain foods than from a true "disease."

In addition to such individual high-profile studies, several recent meta-analyses of all of the available published studies on diet and ADHD in the last decade have also concluded that the weight of the evidence supports the conclusion that diet is causally connected to the behavioral symptoms associated with ADHD. Consequently, many researchers have concluded that diet should be considered as an important modifiable factor in any ADHD treatment protocol, and ideally before stimulant medication is prescribed.

Nevertheless, despite a growing call to consider and disclose diet-based alternatives to psychotropic medication, particularly outside of the United States, the mainstream prescribing physician communities within the United States appear unconvinced. Specifically, the most recent clinical guidelines of both the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatrists (AACAP) do not disclose the positive results of these RCT's or meta-analyses in their clinical guidelines at all, nor do they offer any information regarding possible diet-based treatment alternatives to the recommended stimulant medication. In fact, the AACAP Practice Parameter, without much

94 Id. at 500.
95 See NPR, supra note 77 (interviewing lead author of the INCA study, Dr. Peller, who concluded: "We’ve got good news – that food is the main cause of ADHD. We’ve got bad news – that we have to train physicians to monitor this procedure because it cannot be done by a physician who is not trained.").
96 See Burka, supra note 79, at 654 ("The authors believe there is enough evidence to consider dietary influences as a modifiable risk factor"); Curtis, supra note 52, at 79 ("[M]uch recent research has suggested that nutritional and environmental factors also play a major role in the development of autism and ADHD disorders.").
97 See, e.g., Millchap & Yee, The Diet Factor in Attention-Deficit/Hyperactivity Disorder, 129 PEDIATRICS 330, 330 (2012)("A greater attention to the education of parents and children in a healthy dietary pattern, omitting items shown to predispose to ADHD, is perhaps the most promising and practical complementary or alternative treatment of ADHD."); Schnoll, supra note 54, at 63 ("In general, diet modification plays a major role in the management of ADHD and should be considered as part of the treatment protocol."); Natalie Sinn, Nutritional and Dietary Influences on Attention Deficit Hyperactivity Disorder, International Life Sciences Institute, 66 NUTRITION REVIEWS 558, 559 (2011) ("It may be more prudent to address ADHD symptoms with a nutritional and dietary approach before prescribing medications.").
98 This author acknowledges that many individual prescribing physicians within the U.S. may indeed be disclosing available alternative treatments to psychotropic medications as part of their clinical practice. However, this article also assumes that many practitioners rely upon the clinical guidelines and practice parameters of their respective professional organizations, such as the AAP, APA, and the AACAP, to make their treatment recommendations. Accordingly, this author believes that the failure of these guidelines to disclose information regarding available alternative treatment options is significant and may suggest pervasive nondisclosure.
elaboration, suggests either that these recent RCT’s supporting non-pharmacological approaches do not exist, or do not justify any change in the drug treatment protocol. 99

Of course, a strong correlation doesn’t necessarily indicate causation, and mainstream physicians may very well reasonably conclude that such diet-based treatment alternatives have not been proven effective to their own medically trained satisfaction. However, given the availability of the published scientific literature supporting diet-based causal connections, and studies showing clear patient preference for drug-free alternatives, shouldn’t a prescribing physician disclose this available alternative treatment information to his or her ADHD patient, regardless of the physician’s own beliefs as to the alternative’s efficacy or effectiveness? And wouldn’t a patient deprived of this material information have a legal cause to complain that she or he did not give informed consent to the recommended treatment of medication?

Case law, unfortunately, does not support either supposition, which perhaps explains why many physicians continue to shirk their full disclosure obligations.

IV. COURT BASED DEFERENCE TO PHYSICIAN PREFERENCE: WHY PRESCRIBING PHYSICIANS FAIL TO DISCLOSE AVAILABLE ALTERNATIVE TREATMENT OPTIONS TO THEIR MENTAL HEALTH PATIENTS

Although there are a few cases regarding a physician’s failure to inform patients about the risks of psychotropic medication, there are virtually no published cases addressing the failure of a physician to disclose a specific alternative treatment to psychotropic medication. 100 Nevertheless, analogous case law in both medical community and

99 See AACAP PRACTICE PARAMETER, supra note 64, at 903 (opining that the 1997 AACAP practice parameter, which reviewed and rejected a variety of non-pharmacological interventions for ADHD including dietary modification, was still valid, since "no studies have appeared since then to justify [any non-pharmacological intervention's] use."); see also AAP CLINICAL GUIDELINES, supra note 63, at 1010 (indicating diet-based RCT’s not considered during AAP’s evidence review process). Notably, although the pharmaceutical companies and CHADD are represented on the respective committee/clinical boards making these pharmacological treatment recommendations, nutritional experts are not. CHADD, or Children and Adults with Attention Deficit/Hyperactivity Disorder, is a national non-profit organization founded in 1987, allegedly for the purposes of education, advocacy and support. However, despite CHADD’s claim to be a “support group,” CHADD has been repeatedly criticized by the World Health Organization and others for serving as a conduit for pharmaceutical company advertising and lobbying, in violation of the 1971 Psychotropic Drugs Convention. See JACKSON, supra note 1, at 262; see also Whittaker, supra note 47, at 220-21 (discussing the pro-drug lobbying efforts of CHADD).

100 See Lenz, supra note 50, at 77-84 for a discussion of cases discussing a physician’s failure to disclose the risks of the psychotropic medication.
reasonable patient jurisdictions illustrates why mental health patients will be unlikely to establish a viable informed consent claim against their physicians for failing to disclose unrecognized drug-free alternatives to medication — and thus why mainstream prescribing physicians may continue to recommend psychotropic medications despite patient preference and evidence that alternative treatments are indeed available.

A. Alternative Treatment Disclosures Under the Medical-Community Standard

Because the medical community standard only requires that a physician disclose those treatment alternatives that a reasonable physician in his or her particular medical community would ordinarily disclose, it is hard to imagine a physician disclosing any alternative treatments unrecognized by his or her own conventional medical community. Indeed, the limits of the medical-community standard are aptly illustrated in the case of Moore v. Baker.101

In Moore, a patient sued her surgeon for recommending a neurosurgical procedure known as a carotid endarterectomy to fix a blockage that was impeding the flow of oxygen to her brain, without disclosing the availability of an unconventional alternative treatment known as EDTA therapy.102 Blood clot complications arose following the recommended surgery, and the patient suffered permanent and severe brain damage. In her complaint against the surgeon, the patient alleged that the surgeon violated Georgia's physician-oriented informed consent law because he failed to tell the patient about a known alternative, EDTA therapy, which the patient claimed was not only as effective as the recommended surgery, but also did not entail the same high risks. In support of her claim, the patient produced two affidavits from medical practitioners: one an osteopathic doctor (D.O.), and one a traditional allopathic doctor (M.D.).103 Both experts opined that the EDTA therapy should be considered by the mainstream medical community as a viable alternative to surgery. The surgeon moved for summary judgment in response, and produced evidence suggesting that EDTA therapy was not recognized by the mainstream medical community.

101 989 F.2d 1129 (11th Cir. 1993).
102 Id. at 1130 (EDTA therapy stands for ethylene diamine tetra acetic chelation therapy).
103 Id. at 1133; see What is Osteopathic Medicine?, AM. ASSN OF COLL. OF OSTEOPATHIC MED. (AACOM), http://www.aacom.org/about/osteomed/Pages/default.aspx (last accessed Nov. 26, 2013) ("Osteopathic physicians, also known as DO's, work in partnership with their patients. They consider the impact that lifestyle and community have on the health of each individual, and they work to break down barriers to good health.").
Rather than simply allowing the claim to go forward for a jury to decide, the lower district court granted the surgeon’s motion for summary judgment, and the Eleventh Circuit affirmed, reasoning that the mainstream medical community did not recognize or accept EDTA as an alternative to the recommended surgery, that the physician had not received medical training in EDTA therapy, and that no one at the Medical College of Georgia had either taught the alternative therapy or recognized it as a practical alternative.\textsuperscript{104}

Yet, the patient was not insisting that the physician or even anyone else within the mainstream medical community perform the EDTA alternative, but merely that the physician should have disclosed the known available alternative to the patient, so that the patient could have made her own treatment decisions. Nonetheless, the Eleventh Circuit stated, “Georgia’s informed consent law does not require physicians to inform patients of all alternatives to surgery or even all the alternatives that the medical profession should accept. The law requires only disclosure of those alternatives that are generally recognized and accepted by reasonably prudent physicians.”\textsuperscript{105}

As illustrated by Moore, a patient seeking relief for a physician’s failure to disclose available but unrecognized alternative treatment options in a medical-community jurisdiction will likely be unable to sustain a cause of action for a lack of informed consent to a recommended treatment, even if the patient is able to produce evidence that viable but undisclosed alternatives exist, and that at least some practitioners would have disclosed this information to them. The medical community standard clearly places “low value on patient’s informational needs and decision-making autonomy...[reinforcing] society’s high regard for the medical profession while reifying well-entrenched paternalism.”\textsuperscript{106}

## B. Alternative Treatment Disclosures under The Reasonable Patient Standard

The “reasonable patient standard” purportedly requires physician disclosure of information that a reasonable patient would find material to a treatment decision. Thus, under this standard, the focus is supposed to be on what a reasonable person objectively needs to hear from his or her physician to allow the patient to make an informed, intelligent decision.

\textsuperscript{104} Moore, 989 F.2d at 1130.
\textsuperscript{105} Id. at 1133.
\textsuperscript{106} Bulen, supra note 20, at 337 (noting that the physician-oriented standard, in effect, “defers to the medical community to impose its own disclosure standard.”).
regarding proposed medical treatment. Presumably, this would also include information on all available alternatives to any recommended treatment or any “alternative schools of thought” within the same medical community as to the best course of treatment. Unfortunately, case law in reasonable patient jurisdictions actually provides very little assurance that courts will require disclosure of any alternative treatments outside of the mainstream medical community’s recognized treatments—or even require disclosure of alternative schools of thought or debates within the very same medical community about the best modes of treatment.

First, in many reasonable patient jurisdictions, the courts limit disclosure of alternatives to those that are “medically reasonable,” either without clearly establishing who would determine such medical reasonableness, or else by explicitly deferring to the mainstream medical community for such a reasonableness determination.\(^{107}\) Clearly, however, by deferring to the mainstream medical community to define what is and is not “medically reasonable,” there is virtually no distinction between the reasonable patient standard and the medical community standard.

Second, while the availability of alternatives recognized by at least some members of the same physician community should theoretically trigger a disclosure obligation, case law within reasonable patient jurisdictions conflicts as to just how much “debate” or “consensus” is needed within such a community before an alternative treatment approach would merit physician disclosure. While some courts suggest that some “debate” over treatment options within the relevant mainstream physician community would trigger a physician’s disclosure obligation, other courts have refused to recognize such a disclosure obligation, even in the face of significant debate or recognized “alternative schools of thought” over treatment options.\(^{108}\) For example, in the California case of *Parris v. Sands*, a patient who had her spleen removed thirteen years prior due to having Hodgkin’s disease, visited an emergency care clinic due to a

\(^{107}\) *See*, e.g., *Stover v. Ass’n of Thoracic & Cardiovascular Surgeons*, 635 A.2d 1047, 1051 (Pa. Super. Ct. 1994) (“Under our view of the doctrine of informed consent, a physician would need to discuss alternate prostheses and their relative merits only when the other prostheses represent medically recognized alternatives.”); *see also* *Ray v. Kapiolani Med. Specialists*, 259 P.3d 569, 584 (Haw. 2011) (noting that “healthcare providers will not be overwhelmed by our holding because the plaintiff will need to show that the medical community recognizes the different dosage as an alternative treatment.”).

presumed upper respiratory infection.\textsuperscript{109} Although the patient’s history of Hodgkin’s Disease suggested that she might still be immunocompromised and might need antibiotics with upper respiratory treatment, the physician on duty concluded that the patient was suffering from a viral infection and thus did not recommend antibiotics. At the time of the physician’s decision, there was substantial debate within the mainstream medical community itself regarding the length of time an asplenic patient remains immunocompromised following a splenectomy. Several days after her initial emergency care visit, the patient had to return, due to life-threatening bacterial pneumonia. Because she had not received antibiotics during the initial visit, the plaintiff consequently suffered permanent lung damage, and sued the emergency care physician for medical negligence and for failing to disclose the fact that there was an “alternative school of thought” within the relevant medical community regarding whether antibiotics were always necessary with asplenic patients.

Although expert testimony conflicted on whether the physician’s actions in failing to prescribe antibiotics fell within the allowable standard of care, the lower court refused to grant the plaintiff’s request for a jury instruction on the physician’s duty to disclose a “contrary recognized school of thought within the medical community.”\textsuperscript{110} Ignoring the fact that a reasonable patient would likely have found such an alternative school of thought material to a treatment decision, the Court of Appeals affirmed, reasoning that physicians generally do not have a duty of disclosure concerning an alternative treatment or procedure he does not recommend, and that “only in the unusual case would such duty be appropriate.”\textsuperscript{111}

Given such a puzzling outcome in a reasonable patient jurisdiction, it should come as no surprise that courts are even more deferential to the recommending physician where an alternative treatment is only recognized outside of the mainstream community. This was certainly the case in the California case of \textit{Schiff v. Prados}.\textsuperscript{112} In \textit{Schiff}, the plaintiffs’ four-year-old daughter, Crystin, was diagnosed with a malignant brain tumor. After removal of the tumor, defendant Dr. Prados, head of the board recommending treatment options, recommended two options for treatment: (1) intensive chemotherapy and radiation, or (2) taking Crystin home and

\textsuperscript{109} Parris, 21 Cal. App. 4th at 187.
\textsuperscript{110} Parris, 21 Cal. App. 4th at 192.
\textsuperscript{111} \textit{Id.} at 193 (The court then indicated, in dicta, that such an unusual disclosure circumstance, where unrecognized treatments or procedures should be disclosed, “would likely need to involve surgery, cancer diagnosis or cancer treatment, or other serious, life threatening procedures.”).
Letting her die. The parents, wary about using radiation and chemotherapy on their young daughter, repeatedly asked about alternative treatment options from the various physicians, including Dr. Prados, but were repeatedly told there were no other available alternatives. As a result, the parents chose the recommended chemotherapy and radiation for Crystin. However, even after the initial bouts of recommended treatment, some residual tumor remained. Not wanting to put their daughter through more chemo and radiation, the Schiffs began researching alternative therapies on their own. They came across a medical doctor in Texas who had been experimenting with a new type of cancer treatment using antineoplastons and queried Dr. Prados about this alternative treatment option. Although familiar with this treatment option himself, Dr. Prados was adamantly opposed to this alternative treatment option and tried to steer the Schiffs towards other mainstream alternatives. The Schiffs nevertheless elected to try the alternative antineoplaston treatment, and traveled to Texas to do so. The alternative treatment appeared to be working, and after her initial treatments with the alternative therapy, Crystin became cancer free.

However, six months after her successful antineoplaston treatment, Crystin died. The cause of death was deemed due to the initial aggressive radiation and chemotherapy treatments she had received prior to finding out about the alternative antineoplastons treatments on their own. The Schiffs consequently sued Dr. Prados, alleging that Dr. Prados had not obtained their informed consent to the treatment with radiation and chemotherapy because he had failed to advise them of the alternative available antineoplaston treatment in Texas. Dr. Prados moved for summary judgment on the basis that the alternative treatment option was not “available” in California because it had not been approved by the FDA when the Schiffs had consented to the chemotherapy and radiation therapy, and California law required FDA approval before a physician could perform such treatment in California. Dr. Prados further argued that he had no duty to inform the Schiffs about an alternative treatment that he did not recommend. The court granted the defendant’s motion and the Court of Appeal affirmed, first on the basis that there was no general duty to inform patients of “unrecommended” treatments, and second, that in this particular case, treatment in California with antineoplastons was

113 Schiff, 92 Cal. App. 4th at 695.
114 Id. at 696 n.1 (Antineoplastons are substances derived from human urine. According to the doctor practicing this alternative cancer treatment, when injected into the body, antineoplastons ‘reprogram’ cancer cells to function normally).
115 Schiff, 92 Cal. App. 4th at 696 n.1.
considered illegal by California statute because it had not yet been given FDA approval. The court thus reasoned that because the treatment was not legally “available” in California, the physician was not legally required to disclose it.

The Schiff court’s reliance on the California statute to justify physician nondisclosure of the available alternative treatment information is perplexing, since the duty to disclose alternatives does not require that the physician actually perform the alternative treatment option. Moreover, the court’s failure to recognize any disclosure duty is particularly troubling, considering that the parents specifically and repeatedly asked about alternatives to the recommended treatments prior to “choosing” the recommended treatments that ultimately killed their young daughter -- and were told there were none.

Both the Parris and Schiff decisions suggest that courts in purportedly reasonable patient jurisdictions may in reality require nothing more of physicians than the medical community standard would require – compliance with a physician’s duty of due care. Indeed, the Schiff court makes it plain that it does not understand the distinction between the physician’s duty of due care and the physician’s duty to disclose all material information that a reasonable patient would find material to a treatment decision at all:

With respect to alternative treatments, under the doctrine of informed consent there is no general duty of disclosure with respect to non-recommended procedures. Instead, the failure to recommend a procedure must be addressed under ordinary medical negligence standards. That is, a physician must disclose alternative treatments only to the extent that it is required for competent medical practice within the medical community.

By failing to recognize that the duty to disclose information that would be material to a patient is an independent and more expansive duty than the duty of due care, these reasonable patient courts ignore the essential reasoning of both Cobb and Canterbury, both of which declared that:

To bind the disclosure obligation to medical usage is to arrogate the decision to the physician alone. Respect for a patient’s right of self-determination on a particular therapy demands a standard

116 Id. at 701, 703-05.
117 Id. at 706-07.
118 Id. at 701.
set by law for physicians rather than one which physicians may or may not impose upon themselves.\textsuperscript{119}

As the case law illustrates, courts thus far have been extremely reluctant to require a physician to disclose material information regarding alternative treatments residing outside of the medical community’s recognized treatments or even alternative schools of thought within the same medical community, even in purportedly “reasonable patient” jurisdictions. But how can such paternalistic deference be reconciled with the stated purpose behind “informed consent” – i.e., to allow patients greater autonomy and self-determination regarding their own physical and mental health? And what if an entire medical community is wrong regarding a course of treatment or slow to accept a beneficial treatment that might decrease or eliminate unwanted side effects or better align with a patient’s own healthcare preferences? Under the current reality, it will be the under-informed patients, and not the non-disclosing physicians, who will suffer the ultimate consequences.

C. Why Disclosure of Unrecognized Alternatives is Critical in the Experimental Mental Health Context

Although a failure to disclose information regarding unrecognized but available alternative treatment options in any context robs a patient of true autonomy and self-determination, there are additional reasons why disclosure of available alternative treatment options to psychotropic medication is particularly urgent.

First, as earlier described, unlike many proven successful medical treatments, compelling evidence now suggests that psychotropic medication is not only of limited effectiveness, could do more harm to the mental health patient than good.\textsuperscript{120} Consequently, for a prescribing physician to recommend psychotropic medication without being required to disclose existing safer alternatives is an extremely troubling aspect of current single modality mental health care treatment.\textsuperscript{121}

Second, unless a mental health patient is a serious threat of harm to either himself or others, the use of psychotropic medication can always be

\begin{footnotes}
\textsuperscript{119} Canterbury, 464 F.2d at 784 (“both the patient’s right to know and the physician’s correlative obligation to tell him are diluted to the extent that its compass is dictated by the medical profession.”).
\textsuperscript{120} See generally JACKSON, supra note 1.
\textsuperscript{121} See Matthies, 733 A.2d at 463 (N.J. 1999) (physicians have duty to disclose both less hazardous and more hazardous alternatives to the recommended treatment and “may neither impose their values on their patients or substitute their level of risk aversion for that of the patients...[b]y not telling the patient of all medically reasonable alternatives, the physician breaches the patient’s right to make an informed choice.”).
\end{footnotes}
selected later, in the event that the non-medication alternatives prove unsatisfactory to the patient or the patient’s legal surrogate. This is unlike a traditional medical treatment situation involving a life-threatening illness or one requiring immediate surgical attention.\textsuperscript{122}

Third, the scientific literature suggesting viable alternative treatment options to psychotropic medication is abundant, and should be given no less consideration than the literature suggesting the effectiveness of psychotropic medication.\textsuperscript{123} Indeed, while some pro-medication advocates may argue that the studies for alternatives, such as diet-based alternatives, do not satisfy the rigorous standards for evidence-based medicine, the same arguments, and more, have been advanced with respect to studies on the safety and effectiveness of psychotropic medications.\textsuperscript{124}

Fourth, evidence overwhelmingly reveals that patients and legal surrogates want to know about safer alternatives to psychotropic medications, and have often queried their physicians about the availability of such alternatives. The reported failures of the mainstream prescribing physician communities to respond to patient-initiated queries on alternative treatments is another troubling aspect of current mental health care treatment.

Finally, negligence-based informed consent laws present a uniquely difficult burden for mental health patients who are put on psychotropic medication without being informed of available safer alternatives. That is, due to the still unknown extent of the harm caused by psychotropic medications and the nature of mental illness itself, in many instances, any “harm” caused by the medications may go undetected for years, or may be attributed to the alleged progression of the mental illness itself.\textsuperscript{125}

Accordingly, mental health plaintiffs will often be at a unique

\begin{enumerate}
\item \textsuperscript{122} See Parris, 21 Cal. App. 4th at 193 (Of course, the Parris court’s dicta notes that in cases of cancer or other potentially life-threatening procedures, a physician may have a duty to inform the patient of unrecognized alternatives).
\item \textsuperscript{123} See, e.g., JACKSON, supra note 1, at 300-01 (noting numerous studies that have shown that non-pharmacological treatments for various mental health disorders often significantly outperform pharmacological treatments).
\item \textsuperscript{124} See JACKSON, supra note 1, at 17-40 (noting glaring problems with various RCT’s for psychotropic medications, including selection bias, non-equivalent dosing, concomitant medications used to compensate for side-effects of the study drug, omission of negative effects data, biased assessments, industry sponsorship of the studies, and publication bias or suppression of any negative results); see also Michael Weir, Legal Issues for Medical Doctors in the Provision of Complementary and Alternative Medicine, 26 MED. & LAW 817, 820 (2007) (“Even in the modern context there is no clear consensus on the extent to which [orthodox medicine] is based upon solid scientific evidence. At the extreme edge of opinion one source states that because of the poor quality of scientific research that only about 15% of medical interventions are supported by solid scientific evidence.”).
\item \textsuperscript{125} See JACKSON, supra note 1, at 235 (discussing the tendency to “blame the victim” by attributing any harm to the progression of the illness itself and not to any effects of the medications).
\end{enumerate}
disadvantage when compared to traditional medical plaintiffs in trying to establish the elements of both causation and harm. Because such negligence-based laws would therefore almost always fail to provide an adequate remedy for such patients, even assuming they could establish a breach of a duty to inform them of the available alternatives, they should be supplemented or replaced by a dignitary-based cause of action, where patients are provided with a remedy for being deprived of their informational rights alone.\textsuperscript{126}

There is, of course, a pragmatic reason why prescribing physicians should be routinely disclosing alternatives to psychotropic medication: to restore credibility to a now suspect profession and industry.\textsuperscript{127} Specifically, as increasing numbers of children and adults are diagnosed or labeled with newly created mental health disorders, and as evidence continues to emerge of the often symbiotic relationship between the pharmaceutical industry and the relevant prescribing physician/psychiatric communities, more and more patients are likely to turn away from the mainstream mental health care system.\textsuperscript{128} A renewed, legally enforced commitment to one’s ethical obligations to disclose all risks, benefits, and viable alternatives, including safer drug-free alternatives, may convince mental health patients and/or their surrogates that their physicians are following their Hippocratic Oaths to keep patients from harm.\textsuperscript{129}

\textsuperscript{126} A dignitary or informational-based model would recognize that depriving a patient of information alone does indeed result in an actual loss: the loss of individual autonomy and the right to determine what should be done to one’s own body. See Morris, supra note 13, at 330 (noting that a patient deprived of information alone does have a complaint: the patient has been deprived of the right to decide); Kristen Ann Curran, \textit{Informed Consent: A Right Without A Remedy Examined Through The Lens of Maternity Care}, 21 \textsc{Am. U. J. Gender Soc. Pol’y \\& L.} 133, 158 (2012) (“informational standing is a possible mechanism to remedying violations of informed consent that do not result in any injury other than the denial of information and, consequently, infringe upon the private right of bodily integrity.”).

\textsuperscript{127} See, e.g., \textsc{Jackson}, supra note 1, at 16 (“it would be difficult to overstate the ethical crisis which has emerged in the field of psychiatry, due to conflicts of interest, and the intentional manipulation of [psychotropic medication] trial designs.”); \textsc{Whittaker}, supra note 47, at 54-66 (noting the “unholy alliance” between the pharmaceutical industry and the psychiatric and medical communities).

\textsuperscript{128} See, e.g., Fay Karpouzis & Rod Bonello, \textit{Nutritional Complementary and Alternative Medicine for Pediatric Attention-Deficit/Hyperactivity Disorder}, 14 \textsc{Ethical Human Psychology \\& Psychiatry} 41, 41 (2012) (“increasing prevalence rates of pediatric and adolescent attention-deficit/hyperactivity disorder, concerns over safety and efficacy of psychostimulants, and fears about long-term use of psychostimulants have lead many parents to seek alternative therapies for their children.”).

\textsuperscript{129} For the original, as well as a modern, version of the Hippocratic Oath see Peter Tyson, \textit{The Hippocratic Oath Today}, PBS.ORG (May 27, 2001), http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html (Interestingly, the original version provides the following: “I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice. I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect.”).
V. A LEGISLATIVE PROPOSAL TO ENSURE DISCLOSURE OF SAFER ALTERNATIVES

While the relevant mainstream physician communities involved in prescribing psychotropic medications may eventually acknowledge the available scientific literature supporting alternative treatment options to psychotropic medication, these prescribing physician communities have an ethical obligation to disclose this alternative treatment information now. Yet, with studies showing continued physician resistance to their disclosure obligations, the parameters of these disclosure obligations must be set and enforced by law.

Unfortunately, it is clear that courts have failed patients seeking redress for physician nondisclosure of unrecognized but available alternative treatment options thus far. Moreover, in the mental health context, general informed consent laws will never ensure physician disclosure because they often fail to provide a remedy to patients entirely. Accordingly, legislatures should adopt dignitary-based informed consent provisions that would better ensure adequate disclosure of alternative treatment options and provide a mental health patient with an actual cause of action in the event that a physician fails to disclose the material information regarding these alternatives to psychotropic medications.

Admittedly, there must be a balance between a patient's reasonable informational needs and a physician's liability concerns. As case law already recognizes, physicians should not have to provide a “disquisition” or a “short medical education” or disclose information that is already common knowledge.\(^{130}\) Nor should physicians be required to disclose any illegal or unsafe alternative treatment options that lack data-driven evidence supporting their safety and effectiveness. At the same time, however, physicians should not fail to disclose alternative treatments options simply because they lie outside of their own medical community’s practice area or because they do not like or offer the alternative treatments themselves.\(^{131}\)

While there is no obvious “tipping point” for mandatory disclosure of an alternative treatment option, a number of scholars and practitioners addressing physician disclosure of Complementary and Alternative (CAM) therapies have offered a number of useful factors that could be easily

\(^{130}\) See Canterbury, 464 F.2d at 782 n.27.

\(^{131}\) See Lakhan supra note 52, at 5; see also Pauline W. Chen, Teaching Doctors About Nutrition and Diet, N.Y. TIMES, Sept. 16, 2010, available at http://www.nytimes.com/2010/09/16/health/16chen.html?_r=0 (noting that “you can’t just keep writing out script after script after script of new medications when diet is just as important as drugs or any other treatment a patient may be using.”).
utilized in any statutory scheme to regulate the disclosure of alternatives to psychotropic medication.\footnote{132 See generally Michael Weir, Obligation to Advise of Options for Treatment: Medical Doctors and Complementary and Alternative Medicine Practitioners, 10 JOURNAL OF LAW & MED. 296 (2003); Gilmour, supra note 21, at 190; Bulen, supra note 20, at 354.}

\section*{A. Risk-Benefit Assessment}

First, in order to exercise the right of self-determination effectively, patients must be able to compare reasonable treatment alternatives and the risks attendant to each. For example, a reasonable alternative to a recommended treatment or procedure may improve the patient's condition less, but virtually eliminate serious risks, which may be of more concern to that particular patient.\footnote{133 Bulen, supra note 20, at 341.} If the physician fails to disclose the less effective, but safer alternative to the patient, then the patient cannot perform the individualized risk assessment inherent in the very purpose behind meaningful "informed consent."\footnote{134 Id.} Thus, for all of the reasons this article discusses, in the case of a choice between a pharmacological treatment versus an alternative non-pharmacological treatment, prescribing physicians should always be required to also disclose to patients any available safer non-pharmacological treatments in addition to the recommended treatment with psychotropic medication.\footnote{135 See, e.g., P. Hill & E. Taylor, An Auditable Protocol for Treating Attention Deficit/Hyperactivity Disorder, 84 ARCHIVES OF DISEASE IN CHILDHOOD 404, 405 (2001) (see for an example of how this might work in practice: incorporating diet-based treatments prior to resorting to medication).} This should be particularly the case where the patient is not a serious risk to himself or others and can always later choose the riskier alternative of medication, if the non-pharmacological alternative treatment recommendation proves ineffective or unsatisfactory to the patient.\footnote{136 See Matthies, 733 A.2d at 463.}

\section*{B. Clinical Trials and Published Literature}

Second, physicians should be required to disclose alternative treatment options where there is published scientific literature supporting the viability of such alternative treatment options.\footnote{137 Bulen, supra note 20, at 354-55.} While not often readily acknowledged by mainstream medicine, there is an abundance of scientific studies and published literature establishing the efficacy and effectiveness of many alternative treatments to traditional recommended treatments. For example, the Cochrane Collaboration, an international

132 See generally Michael Weir, Obligation to Advise of Options for Treatment: Medical Doctors and Complementary and Alternative Medicine Practitioners, 10 JOURNAL OF LAW & MED. 296 (2003); Gilmour, supra note 21, at 190; Bulen, supra note 20, at 354.

133 Bulen, supra note 20, at 341.

134 Id.

135 See, e.g., P. Hill & E. Taylor, An Auditable Protocol for Treating Attention Deficit/Hyperactivity Disorder, 84 ARCHIVES OF DISEASE IN CHILDHOOD 404, 405 (2001) (see for an example of how this might work in practice: incorporating diet-based treatments prior to resorting to medication).

136 See Matthies, 733 A.2d at 463.

137 Bulen, supra note 20, at 354-55.
network developed to collect, review, and promote evidence-based research about many medical and mental health treatments, lists more than 4,000 RCT's related to Complementary and Alternative Medicine (CAM) treatments in its database, with many of the RCT's revealing that various CAM modalities may be viable effective alternative treatments for a number of medical and mental health ailments.\textsuperscript{138} Thus, in the case of the disclosure of diet-based alternatives to stimulant medication, because numerous RCT's and meta-analyses already provide evidentiary support for alternatives to psychotropic medication, prescribing physicians should also be required to disclose this option to patients when recommending psychotropic medication.

Although some prescribing physicians might argue that they can't be expected to know about all the published scientific literature on relevant CAM modalities or all treatment alternatives beyond his or her mainstream medical or mental health training, a number of CAM scholars and at least one court disagree.\textsuperscript{139} Instead, like any professional in a particular practice area, physicians in the vast informational age of today should be expected, at the very least, to be up-to-date and familiar with the scientific literature regarding treatments outside of their range of medical expertise when those alternative treatments are relevant to the very disorders the physicians are being relied upon, and remunerated, to treat. As the \textit{Canterbury} court noted:

\begin{quote}
The patient's reliance upon a physician is a trust of the kind which traditionally has exacted obligations beyond those associated with arms-length transactions. His dependence on the physician for information affecting his well-being, in terms of contemplated treatment, is well-nigh abject.\textsuperscript{140}
\end{quote}

Thus, where published scientific literature is available on alternative treatment options for a particular disorder, it seems inherently reasonable to expect a prescribing physician treating patients who presumably have that disorder to know about the evidence suggesting that alternative

\begin{footnotes}
\item[138] Id.; see About Us, \textsc{The Cochrane Collaboration}, http://www.cochrane.org/about-us (last accessed Sept. 15, 2013).
\item[139] See, e.g., Harbeson v. Parke Davis, Inc., 746 F.2d 517, 519 (9th Cir. 1984) (holding doctors liable for failing to respond to plaintiffs' inquiries about risks of anticonvulsant medication on unborn children, and particularly finding that: "a literature search would have revealed several articles regarding the correlation of Dilantin and birth defects, including a 'hallmark' article...published in The Lancet"); see also Weir, \textit{supra} note 132, at 301 ("In essence, we could ask ourselves whether a reasonable doctor practicing medicine in the 21\textsuperscript{st} century, in light of increasing knowledge regarding patient behavior and alternative medicines, should be aware of, and advise patients of, the presence of alternative approaches.").
\item[140] Canterbury, 464 F.2d at 782.
\end{footnotes}
treatments are available, and to convey that information to their patients when making treatment recommendations.141

C. Supplementing Patient Queries

Third, although patients should not be expected to ask for information before receiving it, where patients or their legal surrogates have specifically queried about alternative treatment options, physicians should be required to provide patients with this information, even if the physician himself does not agree that such alternatives are effective.142 At the very least, a query certainly alerts the physician to an individual patient's particular medical or mental health needs and concerns.143 As many scholars and medical practitioners have already acknowledged, patients today have greater access to information about their medical and mental health care options than ever before. Because of the widespread availability of information about complementary and alternative treatments, as well as information about the high risks of psychotropic medications, many mental health patients and/or their legal surrogates have already expressed a preference for non-invasive and non-pharmacological treatment options. While physicians may not necessarily agree with the preference for such non-invasive alternative treatment options, they "may neither impose their values on their patients or substitute their level of risk aversion for that of their patients."144 Instead, the physician, as the person in the position of greater medical knowledge, must simply communicate all known risks and benefits of the alternative treatment options, helping the patient to sort through any complicated areas of uncertainty, and allowing the patient to make the ultimate decision regarding his or her own mental health care. Only if this dialogue and exchange of all material information occurs can a mental health patient or their surrogate truly consent to a recommended course of treatment involving psychotropic medication.

141 See, e.g., Weir, supra note 132, at 301; see also Bulen, supra note 20, at 355 (noting that "Because these RCT's suggest that some CAM treatments may be safe and effective, a reasonable patient could conclude that their availability is material to decisions to undergo medical treatment. Moreover, upon comparison of the risks and benefits of CAM versus conventional treatments, a reasonable patient could elect CAM. If physicians are to respect patient autonomy and give the patient-oriented standard its full meaning, then they must disclose reasonable, safe, and effective CAM.").
142 But see Canterbury, 464 F.2d at 783 n.36 ("We discard the thought that the patient should ask for information before the physician is required to disclose. Caveat emptor is not the norm for the consumer of medical services. Duty to disclose is more than a call to speak merely on the patient's request; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision.").
143 See Matthies, 733 A.2d at 463 ("A physician may select a method of treatment that is medically reasonable, but not the one the patient would have selected if informed of alternative methods.").
144 Id.
VI. CONCLUSION

In the experimental context of mental health treatment, failing to disclose the availability of safer, non-invasive alternatives to psychotropic medication can prove tragic to the mental health patient, who may never recover from the harms caused by the medication. When evidence suggests that alternatives are not only available but may also be more effective in the long run, physicians, courts, and legislatures have the collective obligation to ensure that mental health patients and their legal surrogates are provided with this material alternative treatment information. Indeed, patients who are not provided with this material information regarding available alternatives by their treating physicians are not giving true informed consent to treatment with psychotropic medication.

Unfortunately, without better informed consent laws that ensure physician disclosure of nontraditional alternative treatment options and an actual dignitary-based remedy for patients who are deprived of this material information, mental health patients will continue to be funneled to dangerous, and perhaps wholly unnecessary, mind-altering medication. Legislatures should instead enact dignitary-based informed consent provisions that specifically address the need to disclose all available alternatives to psychotropic medications and provide a cause of action to plaintiffs for the informational breach alone. By enumerating specific factors to help guide both physicians and courts in determining whether disclosure of an existing alternative treatment option is or was warranted, legislatures can strike a balance between ensuring that physicians will be protected against unlimited liability for failing to disclose unsafe, unsubstantiated, or illegal treatments, and ensuring that patients will receive all of the material information they need in order to participate meaningfully in their own mental health treatment decisions.