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TRUST IN THE BALANCE: PRESCRIPTION DRUG RISKS, PATIENT PERSPECTIVES, AND LEGAL (RE)CONSIDERATIONS

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ABSTRACT

Issues surrounding disclosure of pharmaceutical side effects are complicated. The literature abounds with pragmatic concerns regarding limited time or pharmacologic expertise in the clinic, patient nonadherence, and unintended placebo effects, as well as philosophical arguments over the limits of autonomy, importance of shared decision-making, and the legal mandate to garner informed consent. Yet the actual thoughts and feelings of patients are largely missing from the literature. To investigate in greater depth and expand the debate to capture patients' perspectives, we conducted a national survey exploring the gap between what patients want to be told about prescription drug risk and what they are actually told. Results from our research study indicate that many patients report having been "blind-sided" by previously undisclosed drug side effects and that a doctor's failure to warn can result in considerable harm to both patient health and the doctor-patient relationship. Of real concern – and heretofore under-emphasized import – is the potential for erosion of the patient's trust, which we argue offers a fresh evidentiary rationale to revisit the

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legal standard for what constitutes adequate patient consent and the importance of securing it.

I. INTRODUCTION

Prescription drug use among adults in the United States is at an all-time high. Nearly sixty percent of the overall adult population is using a prescription drug, with fifteen percent taking five or more medications each week.¹ In some populations over the age of sixty five, usage rates can spike to over eighty percent, with between twenty-five and fifty percent of seniors using five or more prescription drugs.² Moreover, for nearly two decades, it has been well understood that adverse drug reactions are an important clinical issue with implications for hospital admission and grave patient consequences, even when properly prescribed and monitored.³ One study of adverse drug events using data from the Food & Drug Administration (“FDA”) estimated that prescription drugs were responsible for two to four million cases of serious or disabling injury, including 128,000 patient deaths.⁴ Relying on data from the Kaiser Family Foundation, another study estimated that if milder adverse reactions are included, “about 81 million side effects are currently experienced every year by the 170 million Americans who use pharmaceuticals.”⁵

Against this troubling backdrop of real patient risk, one might assume that physicians are concomitantly diligent in their presentation of all the information patients might need to make a fully-informed decision whether and how to take prescribed medication, but several studies suggest otherwise.⁶ Research published in the last quarter of the 20th century showed physicians offering no verbal instructions for seventeen percent of prescribed medications and

1. Elizabeth D. Kantor et al., *Trends in Prescription Drug Use Among Adults in the United States from 1999–2012*, 314 JAMA 1818, 1825 (2015).

2. SLONE EPIDEMIOLOGY CENTER, PATTERNS OF MEDICATION USE IN THE UNITED STATES: A REPORT FROM THE SLONE SURVEY (2006); Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey*, W5 HEALTH AFFS. 152, 152–66 (2005).

3. Jason Lazarou, Bruce H. Pomeranz & Paul N. Corey, *Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-Analysis of Prospective Studies*, 279 JAMA 1200, 1200 (1998).

4. THOMAS J. MOORE ET AL., INST. FOR SAFE MEDICATION PRACTICES, ANTICOAGULANTS THE LEADING REPORTED DRUG RISK IN 2011, QUARTERWATCH 2 (2012).

5. Donald W. Light, Joel Lexchin & Jonathan J. Darrow, *Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs*, 14 J. L. MED. & ETHICS 590, 593 (2013).

6. J.E. Stewart & J.L. Martin, *Correlates of Patients' Perceived and Real Knowledge of Prescription Directions*, 2 CONTEMP. PHARMACY PRAC. 144, 146 (1979); Louis A. Morris, *A Survey of Patients' Receipt of Prescription Drug Information*, 20 MED. CARE 596, 596–605 (1982); Louis A. Morris et al., *A Survey of Patient Sources of Prescription Drug Information*, 74 AM. J. PUB. HEALTH 1161, 1161 (1984); Louis A. Morris et al., *Counseling Patients About Prescribed Medication: 12-Year Trends*, 35 MED. CARE 996, 996, 1001, 1006 (1997); Clarence H. Braddock III et al., *Informed Decision Making in Outpatient Practice*, 282 JAMA 2313, 2313, 2317 (1999).

discussing adverse drug effects less than one third of the time.⁷ In 2006, an observational study of physician-patient communication regarding prescription medication was published in *Archives of Internal Medicine*.⁸ This study again showed that patients were still not being consistently informed by their physician about the myriad adverse effects that might accompany a new prescription medication.⁹ Specifically, these researchers found that adverse drug effects were only discussed thirty-five percent of the time and concluded that information offered by physicians is often inadequate to address patient needs and concerns.¹⁰

Justifications for non-disclosure have been proposed and defended,¹¹ with compelling and nuanced suggestions for how physicians might approach partial disclosure.¹² Such arguments necessarily involve interpreting and negotiating the bioethical principles of beneficence, nonmaleficence, and patient autonomy.¹³ Concern over the nocebo phenomenon, in which perceived or actual physical side effects may manifest based on the patient's negative expectations, helps

7. Bonnie Svarstad, *Physician-Patient Communication and Patient Conformity with Medical Advice*, in *THE GROWTH OF BUREAUCRATIC MEDICINE: AN INQUIRY INTO THE DYNAMICS OF PATIENT BEHAVIOR AND THE ORGANIZATION OF MEDICAL CARE* 220–38 (D. Mechanic ed., 1976); Gregory Makoul et al., *Health Promotion in Primary Care: Physician-Patient Communication and Decision Making About Prescription Medications*, 41 *SOC. SCI. MED.* 1241, 1249, 1251 (1995).

8. Derjung M. Tarn et al., *Physician Communication When Prescribing New Medications*, 166 *ARCHIVES INTERNAL MED.* 1855, 1855 (2006).

9. *Id.*

10. See Marie E. Gardner et al., *A Study of Patients' Perceived Importance of Medication Information Provided by Physicians in a Health Maintenance Organization*, 22 *DRUG INTELLIGENCE & CLINICAL PHARMACY* 596, 596 (1988) (highlighting that there is a low percentage of patients who are counseled about medications and the content of what is communicated is often incomplete); accord Betsy Sleath et al., *Asking Questions About Medication: Analysis of Physician-Patient Interactions and Physician Perceptions*, 37 *MED. CARE* 1169, 1172 (1999) (illustrating the importance of physician-patient question-asking about medications to detect and avoid potential medication problems as well as to improve patient compliance); accord Dewey K. Ziegler et al., *How Much Information About Adverse Effects of Medication Do Patients Want from Physicians?*, 161 *ARCHIVES INTERNAL MED.* 706, 706, 711 (2001) (explaining that patients desire all information concerning possible adverse effects of prescribed medication); accord Kalpana Nair et al., *What Patients Want to Know About Their Medications: Focus Group Study of Patient and Clinician Perspectives*, 48 *CAN. FAM. PHYSICIAN* 104, 104, 106 (2002) (describing that patients wanted basic information about the medical condition being treated and specific information about side effects, duration of treatment and treatment options); accord Derjung M. Tarn et al., *Which Providers Should Communicate Which Critical Information About a New Medication? Patient, Pharmacist, and Physician Perspectives*, 57 *J. AM. GERIATRICS SOC'Y* 462, 462 (2009) (indicating that different expectations amongst patients, pharmacists, and physicians could result in communication deficiencies when patients receive new medications).

11. John T. Fortunato et al., *When Respecting Autonomy Is Harmful: A Clinically Useful Approach to the Nocebo Effect*, 17 *AM. J. BIOETHICS* 36, 41 (2017) (explaining that a justification for non-disclosure is that the adverse effect on the patient arises from the patient's own negative expectations).

12. Mark Alfano, *Placebo Effects and Informed Consent*, 15 *AM. J. BIOETHICS* 3, 3, 4, 10 (2015) (suggesting that since more information does not always lead to better decision making, physicians may sometimes conceal information or even provide misinformation).

13. See TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 113 (8th ed. 2019) (establishing, along with justice, the four primary principles that have guided the field of bioethics for the last forty years).

explain why some physicians are reticent to disclose drug side effects for reasons rooted in best-interest-of-patient concerns.¹⁴ Indeed, a number of diverse published reports indicate that mere disclosure of a potential side effect may increase the possibility that some types of adverse side effects will manifest from a patient's negative expectations.¹⁵ Accordingly, some argue that "more information doesn't always lead to better decision making" and "concealing information or even providing misinformation" may be warranted emphasizing beneficence over autonomy, or arguably misconstruing autonomy altogether.¹⁶

Claims rooted in concerns regarding patient adherence, however, must be considered in light of many other studies contradicting the notion that patient education increases the number of adverse effects or decreases compliance with the prescribed treatment.¹⁷ In fact, many studies have simply failed to find a nocebo effect, and in the absence of consistent evidence regarding nocebo effects, an approach that unilaterally withholds side-effect information seems overly paternalistic and difficult to justify.

14. Fortunato et al., *supra* note 11, at 41.

15. Rebecca Erwin Wells & Ted J. Kaptchuk, *To Tell the Truth, the Whole Truth, May Do Patients Harm: The Problem of the Nocebo Effect for Informed Consent*, 12 AM. J. BIOETHICS 22, 23 (2012); see also Don L. Jewett et al., *A Double-Blind Study of Symptom Provocation to Determine Food Sensitivity*, 323 NEW ENG. J. MED. 429, 432 (1990) (describing that symptoms provoked by injections were placebo responses and were not responses provoked by the injected substance).

16. Alfano, *supra* note 12, at 4; Frank G. Miller & Luana Colloca, *The Placebo Phenomenon and Medical Ethics: Rethinking the Relationship Between Informed Consent and Risk-Benefit Assessment*, 32 THEORETICAL MED. & BIOETHICS 229, 240–41 (2011) (explaining that physicians should be self-conscious about discussing the risks and benefits of symptomatic treatments with the aim of promoting optimal outcomes while respecting patient autonomy).

17. J.S. Howland et al., *Does Patient Education Cause Side Effects? A Controlled Trial*, 31 J. FAM. PRAC. 62, 62–64 (1990) (illustrating that informing patients about drug side effects did not have any detectable adverse effects); Geoffrey C. Lamb et al., *Can Physicians Warn Patients of Potential Side Effects Without the Fear of Causing Those Side Effects?*, 154 ARCHIVES INTERNAL MED. 2753, 2753–56 (1994) (describing that informing patients of potential side effects prior to starting a new medication does not lead to an increased incidence of those side effects); Louis A. Morris & David E. Kanouse, *Informing Patients About Drug Side Effects*, 5 J. BEHAV. MED. 363, 371 (1982) (explaining that patients who were informed about possible side effects may have reported having experiencing them due to "attribution-labeling" rather than a "suggestion" effect); E.D. Myers & E.J. Calvert, *The Effect of Forewarning on the Occurrence of Side-Effects and Discontinuation of Medication in Patients on Amitriptyline*, 122 BRIT. J. PSYCHIATRY 461, 463 (1973) (finding that the study results fail to confirm that forewarning patients of possible side effects either causes a greater number of patients to complain of such side effects or causes less frequent discontinuance of therapy); E.D. Myers & E.J. Calvert, *The Effect of Forewarning on the Occurrence of Side-Effects and Discontinuation Of Medication In Patients on Dothiepin*, 4 J. INT'L MED. RES. 237, 237, 239 (1976) (highlighting that the study results failed to confirm the hypotheses that forewarning patients of side effects cause a greater number of patients to complain of such effects, or that where patients experience side effects, forewarning is associated with any less frequent discontinuance of therapy).

Disclosure of all drug risks would be consistent with a “patient-centered” approach.¹⁸ The movement for a patient-centered approach to medicine seeks to avoid what the Institute of Medicine in 2001 identified as patients’ widespread “frustration with their inability to participate in decision making, to obtain information they need, to be heard, and to participate in systems of care that are responsive to their needs.”¹⁹ The patient-centered approach tracks with the strong continuing shift in both law and bioethics away from the paternalistic patterns of the past toward a more robust respect for patient autonomy.

Nonetheless, in the case of prescription drugs, this approach remains far from the norm. Just two years prior to the publication of the Institute of Medicine’s findings on patient frustration, Braddock and colleagues published an in-depth, direct-observation study analyzing 1,057 audiotaped encounters between physicians and patients involving 3,552 clinical decisions.²⁰ Researchers identified medication-related decisions (new prescriptions and changes in dosage) and follow-up appointments as the most common topics of discussion and reported that none of the medication-related conversations were “complete” in terms of “informed decision making.”²¹

The Braddock study concluded that “the ethical model of informed decision making is not routinely applied,” and noted concerns about impairment to the patient-physician relationship, as well as quality-of-care concerns flowing from patients not understanding their treatment regimens.²² Previous commentary has raised similar concerns about the impact of non-disclosure and partial disclosure on patient trust.²³ In an environment with bountiful online information, direct-to-consumer advertising campaigns, printed drug information inserts, nurses, and pharmacists behind the counter at retail pharmacy chains, most patients in the U.S. have numerous sources of education about the drugs they are prescribed.²⁴ Yet in the numerous studies referenced above, it is inevitably the prescribing

18. See Joan H. Krause, *Can Health Law Truly Become Patient-Centered?*, 45 WAKE FOREST L. REV. 1489, 1491, 1489–99, 1502 (2010) (suggesting that informed consent is a shortcoming of the patient-centered legal doctrine).

19. COMM. ON QUALITY OF HEALTH CARE IN AMERICA, INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 48–49 (2001).

20. Braddock III et al., *supra* note 6, at 2313.

21. *Id.* at 2317.

22. *Id.* at 2319.

23. Gerben Meynen & Guy Widdershoven, *Dealing with Placebo Effects: A Plea to Take into Account Contextual Factors*, 15 AM. J. BIOETHICS 19, 19–20 (2015).

24. See Joshua E. Perry et al., *Direct-to-Consumer Drug Advertisements and the Informed Patient: A Legal, Ethical, and Content Analysis*, 50 AM. BUS. L.J. 729, 754–68 (2013) (providing details about and a critique of the content provided in these sources of education).

physician from whom patients first and foremost expect to receive guidance and warnings regarding the medication being prescribed.²⁵

Physicians sometimes have legal duties to share warnings about these medications.²⁶ These duties are based on the legal concept of “informed consent.”²⁷ To determine whether informed consent has been violated, courts analyze physicians’ duties and possible breaches of those duties, along with a determination of “causation.”²⁸

Previously, in examining duties, courts had applied the somewhat-paternalistic “medical community” model, where duties were determined by standard practice by the relevant medical community, i.e., what the physician would think should be disclosed.²⁹ However, as courts have moved more towards a patient-centered approach, more jurisdictions have applied a different perspective. This perspective is variously called the “lay standard,”³⁰ the “materiality of risk standard,”³¹ the “prudent patient” standard, the “objective-patient” standard, or the “reasonable-patient” standard.³² Under this approach, the physician’s duty is determined by the patient’s need for information, i.e., whether a reasonably prudent patient could reasonably be expected to decline the treatment due to the potential risk of injury.³³ Thus, decision-influencing risks are considered material, and must be disclosed in order to satisfy the informed consent standard. In court, a jury would determine whether a reasonable patient would have considered the risk significant in deciding whether to undergo treatment.³⁴ To inform such determinations, it is important to collect specific empirical data to better understand the types of risk information that are most important in patients’ decisions to accept, or not accept, a prescribed treatment. In a general sense, the study we describe below is a first step toward developing a better understanding of how patients think and feel about being informed.

25. Nair et al., *supra* note 10, at 107; Christy J.W. Ledford et al., “Practicing Medicine”: Patient Perceptions of Physician Communication and the Process of Prescription, 80 PATIENT EDUC. & COUNSELING 384, 384 (2010).

26. David E. Seidelson, *Lack of Informed Consent in Medical Malpractice and Product Liability Cases: The Burden of Presenting Evidence*, 14 HOFSTRA L. REV. 621, 621 (1986) (“In medical malpractice and product liability actions, one theory of liability often asserted is lack of informed consent.”).

27. *Id.*

28. Causation includes both actual causation and proximate causation. *See infra* Section III.A.1 (highlighting a more in-depth discussion on causation).

29. DiFilippo v. Preston, 173 A.2d 333 (1961); Haggerty v. McCarthy, 181 N.E.2d 562 (1962); Roberts v. Young, 119 N.W.2d 627 (1963); Aiken v. Clary, 396 S.W.2d 668, 675–76 (Mo. 1965).

30. Logan v. Greenwich Hosp. Ass’n, 465 A.2d 294, 300 (Conn. 1983).

31. Febus v. Barot, 616 A.2d 933, 935 (N.J. Super. 1992).

32. *Id.*

33. Logan, 465 A.2d at 301.

34. *Id.*

Despite the robust discussion of these issues in light of shifting legal and bioethical norms, as John Lantos explained in 2015 that, “[n]o good studies have been done to find out what patients actually prefer [in the context of disclosure that creates tradeoffs between beneficence and autonomy].”³⁵ Moreover, no study has explored the nuances of patient feelings when it comes to disclosure and the potential impact those patient feelings might have on the doctor-patient relationship.

Our exploratory study had two main goals: (1) To examine how much and what types of drug risk information patients would like to receive from the prescribing physician in general, and (2) To understand the direct feelings of patients about specific instances in which they were not informed by their physician about potential drug side effects. These patient voices have been missing from the philosophical, legal, and policy discussions for far too long. Their inclusion now highlights the critical importance of this issue for the maintenance of patient trust with physicians and throughout the healthcare ecosystem. Better understanding of how – from the patients’ point of view – physicians have failed to meet patient expectations is critical to understanding how physicians can better enhance the trust that is essential to maintaining the physician-patient relationship. Additionally, this understanding ensures patient adherence to the prescribed course of treatment and provides the appropriate legal standard for gauging adequate informed consent.

II. WHAT DO PATIENTS WANT TO KNOW?

A. Research Sample

A total of 508 U.S. adults ages 40-75 were recruited from the Survey Sampling International online survey panel. Respondents in this age range were used because research indicates that they were more likely to have taken a prescription medication.³⁶ The sample was 48% female, 36% non-White (including 17% African American and 11% Hispanic), and 33% reported an educational achievement of a high school diploma or less. Of the sample, 67% had taken at least one prescription drug within the past six months.

B. Research Procedures

Potential respondents were sent introductory emails by Survey Sampling International, a national web survey panel firm, and invited to participate in an online survey via a link in the email. Five hundred thirty-nine participants initially chose to participate. Two initial screening questions disqualified a total

35. John D. Lantos, *Do Patients Want to Participate In Decisions About Their Own Medical Care?*, 15 AM. J. BIOETHICS 1, 1–2 (2015).

36. HEALTH AND BEAUTY AIDS; PRESCRIPTION BRANDS USED (2015), MRI University Reporter.

of 21 participants: 14 indicated they would not answer the survey questions honestly and another 7 indicated that they were not in the correct age range. The remaining 508 qualifying participants were asked the following questions:

- “When a new prescription drug is advertised in a magazine, what information on the drug’s possible side effects and risks would you most like to see listed?” (multiple choice: all, most severe, most common, most important by the FDA, none).
- “Have you ever had a side effect from a prescription drug?” (Y/N)
- “If yes, have you ever had a side effect from a prescription drug that the person prescribing the drug did NOT tell you about?” (Y/N)
- To gain a deeper understanding, we then asked respondents who reported this experience: “How did the fact that your prescriber did not tell you about the side effects make you feel?” to which they typed in open-ended responses.

Following these inquiries, demographic questions were asked. This research methodology was approved by the Institutional Review Board at Indiana University.

In response to the question asking about patients’ feelings and providing an open-text response box, a total of 127 respondents provided a total of 237 discrete comments or thoughts (an average of 1.87 comments per respondent). These comments, often one word and occasionally much longer phrases or sentences, were then examined by the authors, who identified several distinct categories or themes into which the comments seem to coalesce.³⁷ Next, the authors recruited two graduate research assistants, who, working independently of each other and the authors, assigned each comment a code corresponding to one of the themes. The two research assistants then compared their independent coding of the comments and found an initial concordance on 79.3% of these comments. They then discussed the 20.7% of comments on which they had initially disagreed and reached consensus on those items. The results of this analysis are described below.

37. See RICHARD A. KRUGER & MARY ANNE CASEY, *FOCUS GROUPS: A PRACTICAL GUIDE FOR APPLIED RESEARCH*, 132, 132–42 (5th ed. 2015) (providing background information on analyzing focus group results).

*C. Results*³⁸

The majority (70%) of patients surveyed stated that they wanted to be informed about all of a prescription drug's potential side effects.

Slightly over half (54.1%) of respondents reported that they had experienced a side effect from a prescription drug in the past. Among these respondents, 46.2% (or 25% of the entire sample, totaling 127 respondents) stated that they had experienced a drug side effect about which the prescriber had not warned them. These respondents were then asked to report their feelings about their physician's failure to warn them about the side effects they experienced. Their responses are summarized in the next section.

1. Negative Evaluations

A total of 124 comments (52.3%) expressed negative views and emotions regarding the prescriber's failure to disclose a potential side effect. Specific themes reported by respondents and their frequency were as follows:

a. Anger

Twenty-one comments expressed anger or similar emotions toward the prescriber. These included terse one-word comments such as "angry," "annoyed," "irritated," "mad," and longer phrases such as "it pissed me off" and "this sucks and is a major flaw in our healthcare system." Longer responses included:

"I was extremely angry. . .the side effects. . .were worse than the condition that they were supposed to help. A very bad trade off!"³⁹

"Given that I was forced to go to a hospital emergency room when the 'prescriber' denied that my symptoms could be a reaction to the drug. . .and given that a blood test done at the ER revealed that I had muscle damage caused by the drug. . .I was not happy with the prescriber. . .who is now my EX doctor."⁴⁰

"I hate our medical/mafia healthcare system."⁴¹

38. All direct quotations are taken from respondents' feedback to our survey. Survey and responses are held on file with authors. For confidentiality purposes, all respondent names are kept confidential. Survey Sampling International Survey of Various Respondents, (2020) [hereinafter Survey Response].

39. *Id.*

40. *Id.*

41. *Id.*

b. Betrayal/Violation of Trust

Eighteen comments expressed a feeling that the prescriber had betrayed, violated, or undermined the patient's trust by not disclosing the drug's risk. Often these comments mentioned the corrupting influence of the pharmaceutical industry on the doctor-patient relationship. For example, one respondent stated: "I felt like I could no longer trust doctors—maybe they were paid off by the drug sales people [sic]." Another stated that the experience "makes me feel like they are just supporting the pharmaceutical industry." Others simply reported feeling "conned," "betrayed," "misled," "uncared about," "used for financial profit," or "cheated and uncared for." The loss of trust was best captured by the respondent who simply stated: "Made me worry about all drugs he would give me."

c. Inadequate Patient–Physician Interaction

Seventeen comments complained that the lack of risk disclosure was the result of a broader systemic problem: that doctors simply don't spend enough time with patients. One respondent indicated feeling "awful," like "just another number" about the clinical encounter in which risks were not disclosed. Longer comments included:

"Doctors are very busy[,] and they spend very little time with you, and they don't usually take the time to explain anything."⁴²

"It did not surprise me at all since the Dr only spent 30 seconds on me before he started writing a prescription instead of examining me to find out what could possibly be wrong. I wasted \$110 on that Dr visit and never found out anything at all about my condition because the Dr was only in the room with me for less than 2 minutes."⁴³

d. Violation of Patient's Right to Know

Fourteen respondents viewed the omission of risk information as a violation of the patient's right to know. For example: "All these things should be discussed during the visit in which the drug was prescribed."⁴⁴

e. Other Negative Comments

Many (51) of the remaining negative comments involved brief expressions of a wide variety of negative emotions, including "upset," "sad," "confused," "helpless," "horrible."

42. *Id.*

43. *Id.*

44. *Id.*

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2. Positive/Neutral Evaluations

A total of 64 comments (27%) expressed positive or neutral evaluations of the prescriber after experiencing an undisclosed side effect. Specific themes included:

a. Not the Doctor's Fault

Thirty comments specifically stated that the failure to disclose was not the doctor's fault, typically because the patient's reaction to the drug was perceived to be unforeseeable. Representative comments included: "It was a fluke"; "Every person responds different to drugs, so they can't warn about every possible side effect";

"It didn't bother me because the doctor who prescribed it. . .had to go to the PDR [Physicians' Desk Reference] and check and my symptom [tongue swelling] was at the very bottom as the very rarest of symptoms and something he had never heard of before. I just laughed and thought of course that would happen to me."

One patient also ascribed responsibility to the pharmacy rather than the physician.

b. Patient's Responsibility to Know

Six comments expressed a "caveat emptor" position, stating that it is the patient's own responsibility to learn about the risks of the drugs he or she takes. Example comments include: "I should have done the research myself"; "I could have read about it and didn't"; and "I can read the insert of side effects."

c. Side Effects Mild/Trivial

Seventeen comments indicated that the side effects were mild or trivial, and thus not a cause for concern. Example comments include: "It was a mild, nuisance type of side effect"; and "It was not significant."

d. General Neutral Reaction

Eleven comments indicated a neutral or dismissive reaction to the event, without providing further detail. Example comments include: "I'm OK with it," "no feeling," and "meh."

3. Miscellaneous/Non-evaluative Comments

The remaining 49 comments (20.6%) did not describe respondents' reactions to the side-effect non-disclosure experience, but instead contained incidental background information, such as the name of the specific drug they

had taken, the name of their healthcare provider, or the medical condition for which they were being treated.

D. Discussion of the Study Findings

One of the central tenets of the doctrine of informed consent in both law and medical ethics is the patient's right to be informed of the potential risks of medical treatments, including prescription drugs, before agreeing to undergo treatment. As stated by the American Medical Association's Council on Ethical and Judicial Affairs, "[t]ruthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy."⁴⁵ But putting this into practice introduces a vexing question with a series of practical implications. How much risk information should patients be given about prescription drugs, and how is such information best communicated given a series of complicating dynamics? As the first in-depth inquiry into patient perspectives on this issue, our study offers the medical and bioethics community an important opportunity to re-evaluate the way this question is currently being answered.

Our research points to several interesting findings. First, the responses illuminate a variety of harms that patients are experiencing and show that the ethical concerns that have been discussed in the medical community are indeed active concerns among patients as well. Of the respondents who expressed frustration, some frame it explicitly as an issue of doctors shirking their obligations to inform:

"It pissed me off. I like to know up front about drugs before I start taking them so I can make an informed decision as to whether I want to take them or not."⁴⁶

The question of responsibility also arose. While some patients expressed that they had a responsibility to research effects themselves, another respondent felt unfairly burdened:

"Had to do my own research and then stop taking the meds. Doc should have told me and saved me some time and agony. . . I was chasing ghosts trying to figure out what was wrong with me."⁴⁷

45. CODE OF MEDICAL ETHICS: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING § 2.1.1-3 (AM. MED. ASS'N 2016).

46. Survey Response, *supra* note 38.

47. *Id.*

In other words, just because many patients feel that they *need* to do their own prescription research does not mean that they feel they *ought* to have the primary responsibility. As the above quotes illustrate, patients may feel harmed by poor disclosure practices in the form of misallocated responsibility, burdens on their time and resources, inefficiency, and wasted effort.

The comments also illustrated a much broader reaction of distrust toward physicians and medicine, substantiating concerns in the literature that even well-intentioned choices not to disclose side effects can backfire by eroding patient trust.

“Made me feel the prescriber was not interested in my well being.”⁴⁸

“Mad. This doctor was a jerk. Made me feel as if [I] were a ‘Guinea Pig’ for this particular heart medication I was on for 26 years. I was not watched carefully enough for the issues the medication causes.”⁴⁹

As noted in some of the earlier commentaries on this issue, erosion of trust may lead to erosion of compliance, and thus, ultimately, positive outcomes.⁵⁰ Three respondents in our study dropped the individual doctor who they felt had failed to fully inform them. Others connected their experience with an undisclosed side effect with attitudes that evince a troubling mistrust of medical advice more broadly.

One comment provides a clear illustration of ethical betrayal compounded by a pattern of interactions with multiple providers leading the patient to develop a broad and disturbing distrust of physicians in general:

“I have never had a physician or medical provider EVER discuss side effects and that is wrong. It makes me feel like they are just supporting the pharmaceutical industry.”⁵¹

Another comment indicates a severe loss of trust and willingness to comply, but also suggests that more information could in fact have made a difference in the patient’s attitude:

48. *Id.*

49. *Id.*

50. Guy Widdershoven et al., *Dealing with the Nocebo Effect: Taking Physician-Patient Interaction Seriously*, 17 AM. J. BIOETHICS 48, 49 (2017); Hadley Bryan & Veljko Dubljević, *To Disclose or Not To Disclose: When Fear of Nocebo Effects Infringes upon Autonomy*, 17 AM. J. BIOETHICS 50, 50–51 (2017).

51. See Survey Response, *supra* note 38.

“Obviously they are treating us as experimental test subjects as if we were human Petri dishes, and the drugs don’t really cure anything. If you take them you will just prolong the condition. . .Provide alternative information AND side effect lists.”⁵²

And of course, in addition to these potential harms, the direct risks of harm from prescription medication can be quite grave. In some instances, failure to inform patients of potentially serious side effects can result in a more debilitating condition resulting in a disastrous outcome.

“At the time I had been sick for almost a full year when I found out that the drug contained an ingredient that I am allergic to. . .[W]hen I tried to talk to the prescriber, she turned it back on me and said that I should have known that I was allergic to the ingredient. I no longer go that medical office.”⁵³

“I stopped taking the drug. I would rather die because the side effects were so severe.”⁵⁴

In addition to illustrating some of the significant negative effects of non-disclosure, our results also reveal some helpful nuances in patient views. Analysis of the qualitative data suggests that patients perceive some types of risk information to be more important than others. When patients were asked to recount how they felt after experiencing side effects that had not been disclosed by their prescribing physician, they were more likely to express negative emotions toward the prescriber (e.g., anger, betrayal) when those side effects were perceived to be both severe and foreseeable. However, respondents tended to be much more forgiving of the prescriber if the side effects were either mild or so rare and idiosyncratic as to be unforeseeable even by a conscientious prescriber.⁵⁵

III. LEGAL (RE)CONSIDERATIONS

Manufacturer liability for prescription drugs has been an extremely important topic, both in the popular press and in law reviews. The opioid epidemic has led to multi-million and multi-billion-dollar lawsuits and settlements.⁵⁶ Johnson & Johnson has been the target of a \$17 billion opioid

52. *Id.*

53. *Id.*

54. *Id.*

55. *See infra* Section II.C.2.

56. *See, e.g., Purdue Pharma Announces Agreement in Principle on Landmark Opioid Litigation Settlement*, PURDUE PHARMA (Sept. 16, 2019),

lawsuit by Oklahoma,⁵⁷ and an \$8 billion jury verdict in a case over the antipsychotic Risperdal.⁵⁸

For manufacturers of prescription drugs, one of the most important limitations to their liability derives from the “Learned Intermediary Doctrine.”⁵⁹

<https://www.purduepharma.com/news/2019/09/16/purdue-pharma-announces-agreement-in-principle-on-landmark-opioid-litigation-settlement/> (announcing that Purdue Pharma, the manufacturer of OxyContin, had reached “an agreement in principle on a framework for settling the U.S. opioid litigation facing the Company with 24 state attorneys general. . . The settlement structure is estimated to provide more than \$10 billion of value to address the opioid crisis.”); *see also* Lydia Ramsey, *4 Healthcare Firms Just Agreed to a \$260 Million Deal to Settle Key Opioids Cases Ahead of a Trial*, BUS. INSIDER (Oct. 21, 2019, 12:43 PM), <https://www.businessinsider.com/teva-cardinal-amerisourcebergen-mckesson-settle-ohio-opioid-lawsuit-2019-10> (explaining settlement by manufacturer Teva and other health care companies for a combined total of \$215 million in lawsuit by two Ohio counties).

57. Nate Raymond, *Oklahoma Judge to Rule in \$17 Billion Opioid Lawsuit Against J&J*, REUTERS (Aug. 26, 2019, 5:00 AM), <https://www.reuters.com/article/usa-opioids-litigation-oklahoma/oklahoma-judge-to-rule-in-17-billion-opioid-lawsuit-against-jj-idUSL2N25J1B7>. The judgment in this case awarded \$572 million but was reduced on appeal to \$465 million. Nate Raymond & Jonathan Stempel, *Oklahoma Judge Reduces Johnson & Johnson Opioid Payout to \$465 Million*, REUTERS (Nov. 15, 2019, 2:12 PM), <https://www.reuters.com/article/us-usa-opioids-litigation-oklahoma/oklahoma-judge-reduces-johnson-johnson-opioid-payout-to-465-million-idUSKBN1XP27F>.

58. Nora Freeman Engstrom & Diana Garnet Li, *Stanford Law Experts on Johnson & Johnson’s Product Liability Exposure*, SLS BLOGS (Oct. 14, 2019), <https://law.stanford.edu/2019/10/14/stanford-law-experts-on-johnson-johnsons-product-liability-exposure/> (detailing the “tens of thousands of product liability lawsuits” against Johnson & Johnson); Peter Loftus, *Judge Slashes Damages in J&J Risperdal Case to \$6.8 Million From \$8 Billion*, WALL ST. J. (Jan. 17, 2020, 4:51 PM), <https://www.wsj.com/articles/judge-slashes-8-billion-jury-award-against-johnson-johnson-to-6-8-million-in-risperdal-case-11579291494> (explaining that the jury award was reduced by the judge to \$6.8 million).

59. The scope of the learned intermediary doctrine across the United States is disputed. *See, e.g.*, In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp 2d 795, 806–09 (E.D. Tex. 2002) (showing forty-eight states, the District of Columbia, and Puerto Rico all to have either applied or recognized the learned intermediary doctrine); *but see* Vitanza v. Upjohn Co., 778 A.2d 829 (2001) (finding only forty-four jurisdictions have adopted or recognized the learned intermediary doctrine) and *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E. 2d 899, 903–04 (W. Va. 2007) (concluding that only twenty-two states have expressly adopted the doctrine, including twenty-one supreme courts and the North Carolina state legislature). *See generally* Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185, 1232–40 (1996) (discussing the learned intermediary doctrine and concluding that only physicians should have the duty to communicate risk information to patients); Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L. J. 633, 657 (discussing the development of learned intermediary doctrine and arguing that the emergence of robust informed consent doctrine necessitates a change in the physician’s role as learned intermediary); Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 178 (1997) (“Direct advertising encourages active participation by consumers in prescribing decisions, a favorable development that courts should not ‘reward’ by expanding the tort duties of drug manufacturers, and thereby, discouraging such advertising in the future”); Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 IOWA L. REV. 1007, 1078 (1996) (noting that changes in the delivery of healthcare justify elimination of the learned intermediary doctrine); Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 835 (1991); Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 880 (1996) (discussing the durability of the learned intermediary doctrine and arguing that in the case of

Announced initially in 1966,⁶⁰ the Learned Intermediary Doctrine states that manufacturers of prescription drugs can satisfy their duty to warn about “unavoidably unsafe” prescription drugs by providing appropriate warnings to prescribing physicians: it is not necessary to warn end-users of these drugs directly.⁶¹ This is because the physician’s medical “training and experience allow the physician to translate the technical details concerning the potential therapeutic benefits and known risks of the drug into specific recommendations and instructions for use by the individual patient.”⁶² Over the past fifty years, this doctrine has been the subject of extensive literature in law reviews and court commentary.⁶³

But what about physicians’ own liability for warning their patients about the side effects of prescription drugs? Physicians’ liability derives from a combination of a duty to warn, coupled with informed consent.⁶⁴ While the term “informed consent” itself was first used in 1957,⁶⁵ these general doctrines have a long history, going back to the beginning of the twentieth century, in cases such as *Mohr v. Williams*⁶⁶ in 1905, and *Schloendorff v. Society of New York Hospital*⁶⁷ in 1914.⁶⁸ But what about the more specific case history and academic

prescription drugs, information is best directed from the drug companies to medical professionals); Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 958 (1993) (“[T]he learned intermediary doctrine is based on medical paternalism that is inconsistent with the concept of informed consent.”); Tim S. Hall, Note, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J. L. & PUB. POL’Y 449, 461 (1993); Mae Joanne Rosok, *Direct-to-Consumer Advertising of Prescription Drugs: After a Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule*, 24 SEATTLE U. L. REV. 629, 629 (2000) (recognizing the impact of DTC advertising on increased product sales).

60. *Sterling Drug Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (stating, “[i]n [a prescription drug] case the purchaser’s doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms...there is an excellent chance that injury to the patient can be avoided.”).

61. Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 199 (2004).

62. *Id.* at 203.

63. *See supra* note 59.

64. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Ct. App. 1957).

65. *See generally id.* (describing the circumstances and reasoning from which the court derived the term “informed consent”).

66. 104 N.W. 12, 15 (Minn. 1905) (stating “[i]f the physician advises his patient to submit to a particular operation, and the patient weighs the dangers and risks incident to its performance, and finally consents, he thereby, in effect, enters into a contract authorizing his physician to operate to the extent of the consent given, but no further.”).

67. 105 N.E. 92, 93 (N.Y. 1914) (stating “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages.”).

68. Valerie Gutmann Koch, *Eliminating Liability for Lack of Informed Consent to Medical Treatment*, 53 U. RICH. L. REV. 1211, 1213 (2019) (stating, “[l]ess than a century ago, courts sought to ensure patients’ autonomous medical decision making by affirming a private right of action for failure of informed consent. The tort of lack of informed consent is intended to compensate, or make whole, the

literature on physicians' liability for the side effects of prescription drugs? Given the extensive number of cases and academic literature on manufacturer's liability, and the Learned Intermediary Doctrine, we might expect the case history and academic literature on physician's liability likewise to be extensive. However, this is not the case.

In 1986, Gerald Tietz published his article, *Informed Consent in the Prescription Drug Context: the Special Case*.⁶⁹ In this article, he noted that while "patients frequently file suit against their physicians for failure to obtain an informed consent to surgery and other bodily invasive medical treatments"⁷⁰ but, "medical patients rarely bring suit against prescribing physicians on an informed consent theory in the context of prescription drug therapy."⁷¹ He estimated that the "number of reported appellate decisions, including cases involving prescription drug injections given by the treating physician and therefore involving no written prescription, is probably less than 20."⁷² Our own review of the cases available on Lexis since 1985 found only twelve cases.⁷³

Furthermore, other than Tietz's seminal piece, there is only one other article⁷⁴ that directly examines physicians' liability for side effects of prescription drugs and considers the special case "where the chance of occurrence [of a side effect] is extremely rare."⁷⁵ While there are academic literatures related to this issue, which we will discuss further below, there simply

patient who is harmed by her doctor due to a failure to disclose the risks. . . [and] this tort is now firmly entrenched in precedent or codified by state statute.").

69. Gerald F. Tietz, *Informed Consent in the Prescription Drug Context: The Special Case*, 61 WASH. L. REV. 367, 367 (1986).

70. *Id.* at 367.

71. *Id.*

72. *Id.* at n.1.

73. Niemiera v. Schneider, 555 A.2d 1112 (N.J. 1988); Robinson v. Health Midwest Dev. Group, No. WL212776, 2001 Mo. App. LEXIS 353 (Mar. 6, 2001); Walsh v. Tabby, WL1888856, 200 U.S. Dist. LEXIS 6231 (Apr. 17, 2003); Kuperstein v. Hoffman-La Roche, Inc., 457 F. Supp. 2d 467 (S.D.N.Y. 2006); Coombes v. Florio, 877 N.E.2d 567 (Mass. 2007); Koch v. Cardiology Consultants, P.A., 2008 Del. Super. LEXIS 479 (May 16, 2008); Wilhoit v. Boehringer Ingelheim Pharms., Inc., WL702007, 2009 U.S. Dist. LEXIS 21155 (Mar. 13, 2009); Velilla v. Asociación Hosp., 902 F. Supp. 2d 211 (D.P.R. 2012); Gaghan v. Hoffman-La Roche, Inc., WL3798338, 2014 N.J. Super. LEXIS 1895 (Feb. 10, 2014); Shannon v. Fusco, 89 A.3d 1156 (Md. 2014); Hanes v. Solgar, Inc., 2017 Conn. Super. LEXIS 117 (Jan. 12, 2017); and Radzik v. Conn. Children's Med. Ctr., 2017 Conn. Super. LEXIS 219 (Jan. 27, 2017). These cases were found using one of the following searches: "informed consent"/25 "prescription drug"; physician/25 "side effect"/25 "prescription drug"; and physician /10 "duty to inform"/25 "prescription drug." This search was last completed in February 2020.

74. The title of another article seems to suggest that it might examine physicians' liability, but its focus instead is on maintaining the Learned Intermediary Doctrine exception for prescription drugs manufacturers' liability: Laurie K. Marshall, Comment, *Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where it Belongs: With Their Physicians*, 26 DAYTON L. REV. 95, 97 (2000).

75. Morris Dweck, *Failing to Warn in the Context of Rare Side Effects*, 12 CARDOZO PUB. L. POL'Y & ETHICS J. 423, 425 (2014).

has not been any article examining physicians' liability for side effects of prescription drugs in general for over thirty years.

Building upon the research on patient preferences we report in this paper, it is time to revisit this issue. Two of the key considerations in Tietz's analysis – drawing themselves from *Schloendorff*⁷⁶ and *Canterbury v. Spence*⁷⁷ – were the “fundamental notion of individual autonomy. . . [and] the protection of the individual's dignitary interest.”⁷⁸ Placing these interests at the fore, our collection of data on patients' perceptions and preferences about disclosures of side effects prompts a reconsideration of Tietz's argument regarding how the law ought to determine the standard for disclosure by physicians regarding prescription drug side effects.⁷⁹

Much has changed since the 1986 publication of Tietz's article. We have significantly different circumstances with the additional contexts of managed care and technological advances such as electronic health records.⁸⁰ Furthermore, with the first-of-its-kind data presented herein, we now have fresh insights available for physicians regarding the importance of this issue for maintaining the physician-patient relationship. With these new circumstances and new findings regarding patients' perceptions, the standard of reasonableness must be revisited.

A. Reviewing the Literature

In this section, we begin with analysis of Tietz's 1986 article, including its discussion of the standard for physicians' liability for side effects of prescription drugs and its recommendations.⁸¹ We then review a number of other related literatures.

76. *Schloendorff v. Society of New York Hosp.*, 105 N.E. 92 (1914).

77. 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972) (citing *Schloendorff*, 105 N.E. at 93 (“every human being of adult years and sound mind has a right to determine what shall be done with his own body. . .”). *Canterbury* was among the first cases to recognize and articulate the necessity of “a reasonable divulgence by physician to patient [i.e., adequate disclosure] to make such a decision [i.e., informed consent] possible.” *Id.* at 779. Jurisprudence in this area developed relatively rapidly in the context of several high-profile end-of-life cases involving newly discovered life-sustaining technologies. *See generally* *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 270 (1990) (noting that before *Quinlan*, the number of right-to-refuse-treatment decisions was relatively few); *Severns v. Wilmington Med. Ctr., Inc.*, 421 A.2d 1334, 1336 (Del. 1980); *Brophy v. New England Sinai Hosp., Inc.*, 497 N.E.2d 626 (Mass. 1986); *In re Quinlan*, 355 A.2d 647, 664 (N.J. 1976).

78. Tietz, *supra* note 69, at 406.

79. *Id.* at 369–70.

80. Eta S. Berner et al., *Will the Wave Finally Break? A Brief Review of the Adoption of Electronic Medical Records in the United States*, 12 J. AM. MED. INFORMATICS ASS'N 3 (2005).

81. Tietz, *supra* note 69, at 396.

1. Physicians' Liability and Recommendations from Tietz

Tietz begins his article reviewing the two most common models that courts have used to determine informed consent: the “medical community” model and the “objective-patient/reasonable-patient” model.⁸² He then notes a number of “special factors” that are relevant in the context of “prescription drug therapy.”⁸³ In reviewing the cases on physicians’ liability based on informed consent for prescription drugs, Tietz finds that courts exhibit “deference to the medical profession, . . . [and] adopt and apply the medical-community standard of disclosure with little or no stated rationale and with rarely more than a reference to some unarticulated necessity to defer to the judgment of the medical profession.”⁸⁴ In doing so, they “fail[] to recognize the special factors inherent in the prescription of drugs.”⁸⁵

Both models:

[I]nclude[] standards for determining the three essential doctrinal elements of informed consent: whether the physician had a duty to disclose; the scope of that duty (what procedure-specific information must be disclosed); and, if the duty was breached, whether the breach proximately caused the patient’s injury (that is, whether the patient would not have consented to the procedure had adequate disclosure been made).⁸⁶

The two models differ in how these elements are applied.

In the medical-community model, the existence and scope of the duty to disclose is based on “the practice of the local community of physicians,”⁸⁷ and breach occurs when physicians “fail[] to disclose the alternatives and risks that practitioners in the medical community would have disclosed.”⁸⁸ Proximate cause is shown by “prov[ing] that the hypothetical reasonable patient would not have agreed to take the drug had the physician made the required disclosure.”⁸⁹

Under the objective-patient/reasonable-patient model, “courts have decided that the judiciary has the responsibility for determining when the duty to inform attaches, rather than allowing the community of physicians to make that determination.”⁹⁰ However, in determining this duty, the courts consider the

82. *Id.* at 370.

83. *Id.* at 384.

84. *Id.* at 396.

85. *Id.*

86. *Id.* at 371–72.

87. *Id.* at 372.

88. *Id.*

89. *Id.*

90. *Id.* at 374.

interests of an objective-patient, not a subjective individual-patient.⁹¹ Furthermore, proximate cause is determined by asking, “[w]ould a ‘reasonable’ patient have consented to the medical procedure if the physician had made an adequate disclosure of the alternatives to and the risks associated with the proposed treatment?”⁹²

Tietz then highlights several factors relevant to prescription drugs that have been significantly ignored by courts: “Factors that should limit judicial deference to the medical profession”⁹³ include “the pervasiveness of prescription drug use, the tendency of physicians to overprescribe these drugs, and the narrow limits of physicians’ pharmacological knowledge,”⁹⁴ along with the “need for constant monitoring.”⁹⁵ Tietz identifies “factors that affect patient participation and choice”⁹⁶ such as “personal idiosyncrasies...the range of treatment alternatives, and...the risks of side effects.”⁹⁷ These factors are key in the prescription drug context because they affect the willingness of patients themselves to engage in “the constant monitoring required during prescription drug therapy.”⁹⁸

Tietz finds that the “‘objective’ standard ... does not depend on meaningful communication between physician and patient, but on a nondescript process that ultimately relies completely on medical opinion in lieu of patient participation.”⁹⁹ Consequently, in order to promote “individual autonomy [and] ...protect[...the individual’s dignitary interest,”¹⁰⁰ Tietz recommends that courts should “apply a subjective, individual-patient standard of disclosure in conjunction with a presumption of proximate cause.”¹⁰¹ Tietz summarizes the elements for physicians’ liability for informed consent concerning prescription drugs thus:

To claim lack of informed consent in a prescription drug case, a plaintiff should have to establish the same elements required for other claims of lack of informed consent—duty, breach, causation (both in fact and proximate), and damages...The obligation of the physician is to communicate and not merely to disclose risks. The duty to communicate in a meaningful fashion, taking into consideration the unique aspects of prescription drug therapy, ultimately rests on the

91. *Id.*

92. *Id.*

93. *Id.* at 385.

94. *Id.*

95. *Id.* at 389.

96. *Id.* at 392.

97. *Id.* at 385.

98. *Id.*

99. *Id.* at 407.

100. *Id.* at 406.

101. *Id.* at 370.

rights of bodily integrity and self-determination of the patient as an individual, not as a reasonable or average person...A breach of the prescribing physician's duty consists of any failure to communicate with the patient in a meaningful fashion...The causation element of a plaintiff's claim has two parts: causation in fact and proximate causation. Causation in fact is in reality medical causation, established by proof that the drug in fact caused the plaintiff's injury. The proximate cause element of a plaintiff's claim relates directly to the validity of the consent. The question is whether plaintiff would have consented to the drug therapy had adequate disclosure and discussion been provided by the prescribing physician.¹⁰²

Tietz concludes that these changes are necessary to protect "patients' rights of self-determination and bodily integrity, as well as the intangible dignitary interest."¹⁰³

2. *Additional Literatures Related to Informed Consent and Prescription Drugs*

Several other pieces related to informed consent and prescription drugs are relevant to the issue of physicians' liability in these cases.¹⁰⁴ One such literature is consistent with Tietz's analysis: commentators arguing that courts should adopt a "subjective," real patient standard rather than an "objective" reasonable patient one.¹⁰⁵ As discussed earlier, the *Canterbury v. Spence* case provides an important context for this literature.¹⁰⁶ In this case, the D.C. Circuit wrote that physicians' duty to disclose "must be measured by the patient's need, and that need is the information material to the decision. . .All risks potentially affecting the decision must be unmasked."¹⁰⁷

102. *Id.* at 412–14.

103. *Id.* at 417.

104. See Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 234 (2004) (recognizing that patient autonomy is an important ethical goal in American medical practice); Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOKLYN L. REV. 839, 855 (2009) (arguing that pharmaceutical interventions must be tailored to each patients' unique circumstances); Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: an Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697, 697 (2012) (arguing that courts and legislatures should adopt a subjective patient standard for informed consent in order to account for individual preferences and priorities).

105. See, e.g., Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J. L. & MED. 429, 445 (2006) ("A subjective-based standard, however, best reflects the ethical and legal foundations of informed consent and should represent the ultimate goal of an informed consent system.").

106. 464 F.2d 772 (D.C. Cir. 1972).

107. *Id.* at 786–87.

The court here showed a concern for individual autonomy and dignity in its reasoning, with one health law and ethics scholar suggesting that this case eventually has led to the situation where “patient autonomy is now virtually universally recognized as an ethical goal—some say the primary ethical goal—of modern American medical practice.”¹⁰⁸ However, despite this concern for autonomy and dignity, the court maintained an objective patient standard for informed consent, because it was worried about making “undue demand[s] upon medical practitioners.”¹⁰⁹ For the most part, subsequent courts have followed this approach.¹¹⁰

Additionally, just as Tietz observed, idiosyncrasies across patients should not be ignored. Lars Noah notes, “[w]hen it comes to pharmaceutical interventions, one size does not fit all.”¹¹¹ He observes that the effectiveness of prescription drugs for particular patients depends on “factors such as the nature of their symptoms, progression of the underlying disease, presence of any concurrent conditions or use of other medications, and sensitivity to (or tolerance of) specific side effects.”¹¹²

These concerns have led other health law and ethics scholars, in addition to Tietz, to argue for the adoption of an “subjective/actual patient” standard rather than an “objective/reasonable” one. Grant Morris, for one, notes that using a reasonable patient standard rather than an actual patient standard is clearly unreasonable:

For converting the real patient’s interest in making an idiosyncratic judgment about what shall be done with his or her own body into the hypothetical person’s interest in making only the ‘correct’ judgment, the quotation from Humpty Dumpty seems most appropriate: “When I use a word (like autonomy or self-determination), it means just what I choose it to mean—neither more nor less.”¹¹³

108. Hall, *supra* note 104, at 234, citing TOM L. BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS, 77–80 (5th ed. 2001); see also Tenenbaum, *supra* note 104, at 718 (stating that “the right to autonomy is now ‘deeply entrenched in our culture and law’ and is a ‘preeminent bioethical value.’”).

109. *Canterbury*, 464 F.2d at 787.

110. See, e.g., *Weil v. Seltzer*, 873 F.2d 1453, 1458 (D.C. Cir. 1989) (holding that a physician failed to adequately disclose the medication or dangers of its long-term use to a patient under the objective standard articulated in *Canterbury v. Spence*).

111. Noah, *supra* note 104, at 855.

112. *Id.* at 856.

113. Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313, 368 (2002) (citing LEWIS CARROLL, ALICE’S ADVENTURES IN WONDERLAND AND THROUGH THE LOOKING-GLASS 188 (New York, Hartsdale House)).

Evelyn Tenenbaum likewise argues that “courts and state legislatures [should] abandon objective causation and choose a standard that recognizes the importance of individual preferences and priorities.”¹¹⁴ She notes that:

[T]he foundational principle behind informed consent laws is autonomy, the personal right of patients to make informed decisions concerning their medical care... The purpose of informed consent laws is to ensure that patient autonomy is respected—that the patient’s personal preferences, values, and goals are given deference and that the choice of medical care is ultimately the patient’s alone.¹¹⁵

As a result, she argues that to protect individual autonomy, courts should adopt a subjective patient standard.¹¹⁶ Doing so will both “hopefully serve as a catalyst for meaningful disclosure [and]...focus attention on individual preferences and concerns.”¹¹⁷

While a subjective standard could lead to more disclosure, more disclosure is not always better.¹¹⁸ Just as how too many warnings on a warning label may lead consumers to ignore them, too much information about prescription drugs can create problems for patients.¹¹⁹ Lars Noah observes that “[p]hysicians could not possibly disclose all information about the risks and benefits associated with different options for treating a particular condition, and, even if feasible, such comprehensive disclosures would not necessarily promote patient autonomy.”¹²⁰ In an earlier article, Noah explained that there are “substantial costs associated with the overuse of warnings, particularly the twin dangers of diluting the impact of more serious warnings and prompting counterproductive consumer behavior in response to overly alarming warnings about relatively insignificant risks.”¹²¹ He further notes that the “risk of overreaction is not limited to lay consumers. Physicians are vulnerable as well.”¹²²

One concern regarding physicians is the phenomenon of over-warning of prescription drug side effects which can lead to adverse impacts on prescribing

114. Tenenbaum, *supra* note 104, at 698.

115. *Id.* at 718.

116. *Id.* at 745.

117. *Id.*

118. *See, e.g.*, Noah, *infra* note 120 (describing the risks associated with excessive warning).

119. *See, e.g.*, Noah, *infra* note 120 (describing how excessive disclosure may dilute serious risk and emphasize insignificant risks).

120. Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J. L. & MED. 361, 367 (2002).

121. Lars Noah, *The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” about Consumer Product Hazards*, 11 YALE J. ON REG. 293, 296 (1994).

122. *Id.* at 390.

decisions.¹²³ Daniel Cantor likewise notes that “physicians are often unwilling to warn patients of the inherent risks of prescription drug use because the physicians fear that too much informed consent may frighten the patient and cause the patient to reject treatment.”¹²⁴ So the question then becomes, where do we draw the line between too little and too much information?

Another literature that clarifies physicians’ liability for prescription drugs is literature on the impact of managed care on informed consent.¹²⁵ In 1999, Joan Krause “argued that the use of health care cost containment strategies has a detrimental effect on the doctrine of informed consent, particularly on the requirement that, in order to obtain truly ‘informed’ consent, physicians must disclose the existence of alternatives to the proposed treatment.”¹²⁶ She noted that “current trends in the health care market give physicians and insurers incentives to withhold information about treatments that are not covered under the patient’s insurance policy.”¹²⁷ As a result, she argued for three different changes, including changes to informed consent law, “consumer-oriented protections, [and]...utilizing the professional regulation system.”¹²⁸

In 2002, Grant Morris argued that due to “the emergence of managed care...no longer can physicians be trusted to make treatment decisions guided solely by their fiduciary obligation to their patients’ medical well-being. Insurers will not allow them to do so. Insurers also induce physicians to withhold information about their decisions.”¹²⁹ Consequently, he suggested an alteration to physicians’ duty to inform patients, so that “[w]henver the physician’s clinical judgment of medically appropriate treatment differs from the HMO’s judgment of medically necessary treatment, the physician should inform the patient of this discrepancy.”¹³⁰

In 2004, Timothy Hall likewise noted the impact of managed care on duties to disclose and argued for a change to the Learned Intermediary rule.¹³¹ He noted several changes due to the “the twenty-first century American managed health care system.”¹³² For example, he pointed out that:

123. *Id.*

124. Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853, 1869 (1995).

125. See generally John H. Krouse, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261 (1999) (addressing the detrimental impact health care costs containment strategies has on the doctrine of informed consent).

126. *Id.* at 265.

127. *Id.*

128. *Id.* at 266.

129. Morris, *supra* note 113, at 316.

130. *Id.* at 363.

131. Hall, *supra* note 59.

132. Hall, *supra* note 61, at 196.

[P]atients receive far less personalized attention from their physicians, and are seen by a greater variety and diversity of physicians, than in the past. The average length of an office visit is shorter under aggressive managed care cost containment structures, providing less time for personal interaction and fewer opportunities for physicians to educate and inform their patients.¹³³

He further noted that “managed care organizations (“MCOs”) increasingly exert control over the doctor-patient relationship, including the choice of prescription drugs, through the use of pre-authorization requirements, formularies, and pharmacy benefit managers.”¹³⁴

IV. RECOMMENDATIONS

Our research and review of the literature lends support to the recommendations of Luana Colloca, who suggests a personalized approach to disclosure of information.¹³⁵ Our results indicate that this might align well with what patients feel they are missing. A personalized disclosure approach can be sensitive to placebo effects and nocebo effects, attempting to respectively harness and minimize them while highlighting the most significant risks of a drug and coaching a patient to think through those risks. In his argument in favor of discretionary non-disclosure for the sake of minimizing nocebo effects, Alfano advises that nondisclosure is acceptable only for symptomatic side effects.¹³⁶ Fortunato, however, points out that this distinction may not necessarily track with the distinction between severe and non-severe side effects.¹³⁷ Rebecca Erwin Wells and Ted J. Kaptchuk note that some types of side effects are “critical to reveal because they may result in more debilitating symptoms/conditions and thus may be more important for the patient’s full informed consent.”¹³⁸ For illustration, they point to the possible life-threatening side effects of lymphoma with the use of cyclosporine and nephrolithiasis with topiramate use, as well as the heightened risks for those with a history of diabetes or psychiatric illness if prescribed prednisone.¹³⁹ The responses given by patients in our study suggest that they too intuitively prioritize the importance of disclosing certain symptoms over others.

133. *Id.* at 196.

134. *Id.*

135. See generally Luana Colloca, *Tell Me the Truth and I Will Not Be Harmed: Informed Consents and Nocebo Effects*, 17 AM. J. BIOETHICS 46 (2017) (addressing the consequences of worse symptoms when patients are informed about the side effects of the treatment as a result of informed consent).

136. Alfano, *supra* note 12, at 8.

137. Fortunato et al., *supra* note 11, at 36–42.

138. Wells & Kaptchuk, *supra* note 15, at 25.

139. *Id.*

One of the pragmatic arguments against full disclosure is that doctors simply do not have enough time. For example, a majority of physicians report spending fewer than twenty minutes on average with their patients.¹⁴⁰ With such limited time in the clinic, it is reasonable to privilege diagnostic analysis and addressing a patient's questions over enumeration of potential drug side effects.¹⁴¹ Furthermore, as a practical matter, the spectrum of ways in which multiple drugs could interact in any individual patient could be beyond the ability of even the most experienced and knowledgeable prescribing physician, a reality even acknowledged by one of the respondents in our study.¹⁴² Indeed, particularly as compared to just a few decades ago, "there is an exponentially larger range of potential pharmacological therapies and an even larger, more complex and unpredictable set of potential side effects," which, when compounded with an individual patient's unique psychology, creates an "infinitely more complex medical landscape."¹⁴³ The urgency of this research is magnified by the ever-increasing number of drug combinations being prescribed to patients, especially over the age of sixty five.

These practical concerns are perhaps mitigated to some extent by access to alternative sources of information on the Internet, enclosed in the package insert, through the pharmacist, or, in some contexts, by a different member of the healthcare team. In their response to Alfano, Meynen and Widdershoven point out that the current information environment, including internet reference sources and forums, drug manufacturer information, etc., effectively renders some proposed approaches to disclosure moot.¹⁴⁴ Technological communication options have only continued to improve, offering the physician increasingly flexible options for informing patients. Indeed, technological symptom tracking via apps may greatly improve the physician's ability to manage information around symptomatic effects, improving the quality of follow-up consultations, which are proposed by Fortunato et al., as a key component of a balanced approach to disclosure, and further discussed in Widdershoven et al.'s response.¹⁴⁵ Nonetheless, the volume of information can easily overwhelm a patient, and its manner of presentation can either help or hinder their ability to interpret it, an issue fully explored in the literature of psychological "nudges" in

140. Carol Peckham, *Medscape Physician Compensation Report 2016*, MEDSCAPE (Apr. 1, 2016), https://www.medscape.com/features/slideshow/compensation/2016/public/overview?src=wnl_physrep_160401_mscpedit&uac=232148CZ&impID=1045700&faf.

141. Andreas Storm et al., *Basic Drug Information Given By Physicians Is Deficient, and Patients' Knowledge Low*, 20 J. OF DERMATOLOGICAL TREATMENT 190, 190-93 (2009).

142. Louise Mallet et al., *The Challenge of Managing Drug Interactions in Elderly People*, 370 THE LANCET 185, 185-91 (2007).

143. Fortunato et al., *supra* note 11, at 39.

144. *See generally* Meynen & Widdershoven, *supra* note 23 (discussing two points of criticism concerning the empirical presuppositions of Alfano's suggestions).

145. Fortunato et al., *supra* note 11, at 39; Widdershoven et al., *supra* note 50, at 48-50.

the medical context.¹⁴⁶ Our findings suggest that many patients expect to or are willing to do their own research, but still desire the physician to help them flag the most salient risks.

Moreover, the physician's limited time with the patient, while it presents a logistical challenge, simultaneously underscores the importance of empowering patients. In these instances, fully informing patients of significant drug-specific side effects is not merely an act that is consistent with legal and ethical standards of patient autonomy, but in fact an act that empowers a patient to evaluate the trade-offs between potential consequences of a prescribed medication and the continuing symptoms of the underlying malady. One of our respondents in this study who experienced side effects they were not warned about illustrates:

“I was extremely angry. These drugs were prescribed to control my epileptic grand mal seizures but the side effects of some were worse than the condition that they were supposed to help. A very bad trade off!”¹⁴⁷

While many bioethicists and physicians continue to exhibit paternalistic understandings of beneficence that interpret the best interests of the patient as a narrow set of “correct” medical choices, in many cases it is not realistic for a physician to make a holistic evaluation of what will best serve the patient's *overall* quality of life. Patients must balance many different health concerns and often medications at once. Some side effects may be tolerable for one patient but highly problematic for another, depending on things like their occupation, psychiatric history, family responsibilities, pain tolerance, other medical decisions, or presence or absence of a support network. Moreover, prescriptions come at a financial cost, and physicians are not able to assess the wider health implications of those costs for each patient. The decision to go on a new prescription may involve additional trade-offs for patients in terms of stress, family dynamics, employability or job performance, and other lifestyle aspects that affect their overall health, in many cases even down to the level of basic interests such as food, shelter, and access to other prescriptions or forms of care.

The significance and potential complexity of the trade-offs involved in making medical decisions require a fully enabled and supported patient autonomy. Other research has shown that properly informing patients leads to a feeling of empowerment as the patient is equipped with the information necessary to take control of her health, which can lead to improved patient adherence and overall health outcomes.¹⁴⁸ Thus, a reasonable and realistic use of

146. Alfano, *supra* note 12, at 4, 9–10.

147. Survey Response, *supra* note 38.

148. Ronald M. Epstein et al., *Communicating Evidence for Participatory Decision Making*, 291 JAMA 2359, 2361 (2004).

the physicians' limited time with the patient would be to combine: (1) "highlighting" the most potentially significant information with modeling useful framing for their decision making, (2) coaching patients on how to filter the additional information they are provided, (3) directing them to consult with pharmacists or other relevant members of the healthcare team, and (4) deploying available consumer technology to improve symptom tracking.

Furthermore, our findings and analysis of the informed consent law suggests an urgent need to balance patients' stated desire to be informed about *all* prescription drug risks with their need to fully comprehend the relatively small subset of risk information that is most important in their treatment decisions. While patients should be provided access to all risk information, there is a danger that they will be overwhelmed by exhaustive lists of every possible side effect, and that this information overload will cause patients to overlook crucial risk information which, if known, might alter their decision to undergo treatment.

An approach to disclosure that is patient-centered and premised on a desire to safeguard patient trust, i.e., responds to the information needs and desires of the patient and encourages the patient to take responsibility for his treatment, has been shown to improve health outcomes of chronically-ill patients.¹⁴⁹ Premised on prior research and our study's findings, one can imagine a doctor taking care to give a patient the choice as to whether he or she would prefer a modified choice or a more fulsome description. One can imagine the following approach, which recognizes and respects the patient's autonomy in a very particularized way: "I am going to tell you the most frequent and significant side effects to be alerted for, but if you want a larger or more thorough description, I am happy to provide that information as well."

Similarly, physicians might consider adoption of a two-tiered presentation of risk information, in which: (1) the most important risk information is presented in an understandable format, to ensure that it is noticed and comprehended before the patient consents to treatment, and (2) patients are then provided with easily accessible and more exhaustive risk information that can protect the patient from any surprise adverse reaction that might work long-term damage on her ability to trust her healthcare provider. In a doctor-patient encounter, this might involve a brief face-to-face communication in which the prescriber mentions the drug's most important risks, verifies patient comprehension of those risks, and then asks the patient if he or she would like to try the drug. Afterwards, the patient could be provided with a brochure or directed to a website enumerating all of the drug's potential side effects and encouraged to call the office with any questions. Furthermore, larger clinical practices could benefit from the employment of a

149. Sherrie Kaplan et al., *Assessing the Effects of Physician-Patient Interactions on the Outcomes of Chronic Disease*, 27 MED. CARE S110, S111 (1989); Ledford et al., *supra* note 25.

clinical pharmacist, who could be on hand to explain any questions that patients have concerning prescription drug side effects, to help make doctors' time with patients more efficient, and to protect against the potentially corrosive impact of a patient feeling blindsided or betrayed by misunderstood side effects.

As noted by Ziegler and colleagues, "nonphysician information sources may influence attitudes in a variety of ways" and correlations between information provided in the clinic and information from direct-to-consumer (DTC), Internet or other sources need further research.¹⁵⁰ For drug companies engaging in DTC advertising, the drug's most important risks could be presented (with the same clarity and prominence as the presentation of the drug's benefits) within both broadcast commercials and the main "display advertisement" portion of print advertisements.¹⁵¹ Then, a more exhaustive side effect list could be provided in the "brief summary" page of print ads, as well as a web site referenced in both broadcast and print advertisements.

From a regulatory perspective, these suggestions may be more likely to be applied if courts adopt more patient-centered approaches to informed consent in the context of prescription drugs, whether it be a "materiality of risk" or "reasonable patient" standard, or even further to a "subjective, individual-patient standard." Given the evolving contexts of managed care and technological advances, such a change may be warranted.

The use of this two-tiered risk communication approach would be furthered by adopting changes to the legal approach that were recommended by Tietz over thirty years ago.¹⁵² As noted above, many courts have already adopted a patient-centered approach for determining duties and breach, by applying the "materiality of risk" or "reasonable patient" standard.¹⁵³ However, given the paucity of cases on this issue in the past thirty years, no court also has applied the "subjective, individual-patient standard" for proving causation, as recommended by Tietz.¹⁵⁴ Adoption of this "real patient"-centered legal standard for causation would provide additional incentives for physicians to use the two-tiered risk communication approach suggested here.

V. CONCLUSION

Our study represents an important first step to better understanding – informed by the patient's perspective – of an ethical Catch-22 facing prescribing

150. Ziegler et al., *supra* note 10, at 712.

151. Perry et al., *supra* note 24, 729–78.

152. Tietz, *supra* note 69, at 406.

153. *See supra* Section III.

154. *See, e.g.*, Niemiera v. Schneider, 114 N.J. 550, 563 (stating, "Some commentators have urged a stricter subjective standard of informed consent with respect to prescription drugs, that is, one related to the particular patient. [citing Tietz]. . . We are satisfied, however, that the 'prudent patient' standard can be applied in this case").

physicians. In short, the dilemma is one of limited clinical time and finite pharmacological knowledge on the part of the prescribing physician, as well as a potentially well-intentioned but ultimately misguided pinch of paternalism, set against a patient who believes he'd like to be informed about "all side effects" – even if ultimately immaterial to his willingness to be compliant. Our qualitative data demonstrate that a patient who feels under-informed has a significant likelihood of losing trust in the physician and in medicine more broadly if he experiences an adverse side effect not previously discussed with his physician. This previously under-studied effect raises the stakes for an already tricky dilemma. In light of the risks, both direct and indirect, how should prescribers manage the disclosure of information about prescription drug risks?

Our paper has several important implications for both healthcare providers and regulators. First, our study suggests an urgent need to understand the stakes when deciding how to balance patients' stated desire to be informed about all prescription drug risks with their need to fully comprehend the relatively small subset of risk information that is most important in their treatment decisions. On the one hand, disclosing too little risk information may hamper patients' ability to make informed decisions about their own medical care, undermine patients' trust in their physicians, and potentially create legal liability exposure for prescribers and perhaps drug manufacturers. On the other hand, presenting patients with long lists of all conceivable risks of a prescription drug – even if feasible – may result in information overload, causing patients to miss the "needle in the haystack;" i.e., the truly important risk information that might alter their treatment decisions.¹⁵⁵

Additionally, considering time pressures in the clinic, it seems especially important to help physicians identify the specific risk information that is most essential to patients' informed decision making, so that it can be conveyed during a very brief encounter. This study represents an initial effort to shed some light on these issues. We strongly encourage further researchers to continue this line of inquiry, so that we can better understand the obstacles to improved doctor-communication about prescription drug risks and develop strategies to overcome these obstacles.

As is so often the case, relational dynamics provide a guide for ethical conduct, and a patient's trust in their physician – a critical component to accepting that a recommended treatment decision is the right one to follow – will either be enhanced or eroded depending on the openness and candor with which

155. KATHRYN J. AIKIN ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS—SUMMARY OF FDA SURVEY RESEARCH RESULTS (2004), <https://www.fda.gov/files/drugs/published/Patient-and-Physician-Attitudes-and-Behaviors-Associated-With-DTC-Promotion-of-Prescription-Drugs-Final-Report.pdf>.

the physician communicates to the patient.¹⁵⁶ In other words, a physician must beware of paternalistically hiding the ball out of a well-intended concern of causing the patient to be alarmed. Such an approach, as our findings illustrate, may backfire and the unpleasant surprise of an adverse drug reaction may create a level of anger and frustration that undermines any positive or persuasive effect the physician's prescribed course of therapy might have otherwise achieved.

We encourage future researchers to continue these lines of inquiry, so that we can better understand the obstacles to effective communication around prescription drug risks and develop strategies and best practices that will ultimately result in an enhanced level of trust between patient and provider. As Lantos ominously warned: “[t]rust between doctors and patients, once lost, may be impossible to regain.”¹⁵⁷

156. Meynen & Widdershoven, *supra* note 23, at 19–20; Glenn Salkeld et al., *A Matter of Trust—Patient's Views on Decision-Making in Colorectal Cancer*, 7 HEALTH EXPECTATIONS 104, 104–05 (2004).

157. Lantos, *supra* note 35, at 1–2.