

Introduction

*Carmel Shachar, I. Glenn Cohen, Holly Fernandez Lynch,
and Barbara J. Evans*

In some ways, transparency is a relatively new concept to the world of health and health care, considering that just a few decades ago we were still in the throes of a “doctor-knows-best” model. Today, however, transparency is front and center on almost every list of solutions to a variety of health policy problems, ranging from conflicts of interest to rising drug costs to promoting efficient use of health-care resources, and more. Doctors are now expected to be transparent about patient diagnoses and treatment options, hospitals are expected to be transparent about error rates, insurers about policy limitations, companies about prices, researchers about data, and policymakers about priorities and rationales for health policy intervention.

Despite the newfound popularity of transparency initiatives, a number of important legal and ethical questions remain. For example, what exactly does transparency mean in the context of health, who has a responsibility to be transparent and to whom, what legal mechanisms are there to promote transparency, and what legal protections are needed for things like privacy, intellectual property, and the like? More specifically, when can transparency improve health and health care, and when is it likely to be nothing more than platitude?

The purpose of this volume is to better articulate the role that transparency can play in the American health-care landscape. We asked our contributors to use their work to: (1) describe the routine and special ways transparency manifests itself in American health policy, and why it has emerged in these spaces; (2) understand when, where, how, and why transparency may be a useful policy tool in relation to health and health care, what it can realistically be expected to achieve, and when it is unlikely to be successful, including limits on how patients and consumers utilize information even when we have transparency; (3) assess the legal and ethical issues raised by transparency in health and health-care, including obstacles and opportunities; and (4) learn from comparative examples of transparency, both in other sectors and outside the United States. In sum, we hope that this volume allows for a better understanding of transparency in the health-care context, so that this health policy buzzword can be used as a solution to pressing health policy issues where appropriate, while recognizing its true limitations.

2 *Carmel Shachar, I. Glenn Cohen, Holly Fernandez Lynch, and Barbara J. Evans*

The first theme interwoven in this volume is an understanding that transparency for its own sake is *not* the final goal. The universe of health-care data and information has been experiencing a ‘big bang’ of sorts over the last decade. The health-care data generated by the U.S. system is now measured by yottabytes (10^{24} gigabytes).¹ By contrast, five exabytes (10^{18} gigabytes) of data would contain all the words spoken on earth. Too much information can hamper decision making by patients, providers, and other health-care entities, by creating information overload that leads to anxiety, an inability to focus on key details, and other challenges.² For example, patients are frequently inundated with information, especially if they choose to supplement their physician’s advice with internet sleuthing, and may find additional information paradoxically less helpful and more confusing for their decision making process. The risk of adopting transparency merely for its own sake is that these initiatives will only contribute flotsam and jetsam and add to the information overload that with which virtually all health-care stakeholders struggle. In this way, thoughtlessly implemented transparency initiatives may have the counterintuitive effect of muddying the waters rather than providing clarity.

The authors of this volume suggest two important considerations to prevent transparency from becoming counterproductive. The first is to be mindful of the true end goals of transparency initiatives. Time and time again, the true intent of the initiatives studied in these chapters is not transparency for its own sake. Rather, the purposes of these initiatives span the gamut of health-care policy goals. Regulation requiring pharmaceutical companies to publish their research and development costs has the immediate goal of allowing stakeholders to better understand the current pricing of drugs and the ultimate goal of bringing down pharmaceutical pricing. The purpose of the Sunshine Act is to empower patients to better understand when their health-care providers may have a conflict of interest resulting in biased advice or services. Federal and state bills requiring transparency around whether a provider is in or out of network for an insured patient express the ultimate goal of reducing or eliminating financially devastating surprise medical bills. In each of these cases transparency is a means to an end rather than an end in itself.

The second important consideration is that while overly broad transparency can often miss the mark, targeted initiatives can have positive impacts on the health-care goals they are intended to influence. For example, there are many websites and apps that list the retail drug prices from a variety of pharmacies. While these listings may increase overall transparency for drug pricing, a service that compiled all the relevant prices and presented them in a concise manner to consumers might ultimately have a greater impact on consumers’ spending choices, even if that service presented less information overall than the aggregation of the websites and

¹ Wullianallur Raghupathi and Viju Raghupathi, *Big Data Analytics in Healthcare: Promise and Potential*, 2 *Health Information Science and Systems* 3 (2014).

² David Bawden and Lyn Robinson, *The Dark Side of Information: Overload, Anxiety, and Other Paradoxes and Pathologies*, 35 *J. of Information Science* 2, 180–191 (2008).

apps currently existing. Likewise, for transparency intended to facilitate informed consent, targeted disclosure of the material facts designed to facilitate dialogue with the patient may ultimately lead to a better outcome than merely providing all the information possible, regardless of relevance. There have been attempts to embrace this idea of smarter disclosure, such as the revised Common Rule's new requirement that informed consent forms must "begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research."³ But how do we determine when we are being transparent about the right information and when selected transparency becomes too paternalistic? Moreover, *who* makes the decisions and what are the distributive consequences of favoring transparency that caters only to some information communities? Throughout this volume, the contributors illustrate examples of the ways in which transparency initiatives can become smarter, more focused, or otherwise better suited to achieve their ultimate policy goals. While there is no bright-line rule to help us distinguish between overly broad, "just right," and too narrow transparency initiatives, these explorations of transparency can help us better identify the happy medium for which to aim.

Another theme that emerges from this volume is the complicated relationship between transparency and privacy. Privacy, especially around health-care data, is another important value and buzzword in health care.⁴ At first glance, transparency and privacy seem opposed. After all, if certain data is deemed to be private or sensitive, it perhaps should not be available for transparency initiatives. In some cases, the assumption that transparency and privacy are in a zero-sum relationship is true. For example, sharing deidentified data sets may help advance science, but as technology progresses, there is also some risk that these data could be correlated with other data sets to reidentify patients. Companies are also pushed to be transparent about their clinical trial results or billing patterns, which could lead to competitors utilizing disclosed information to achieve competitive advantages or even dampen incentives for knowledge creation. In the public policy context, an overemphasis on transparency, in tandem with privacy requirements, can prevent agencies from carrying out their ultimate purposes. For example, the Environmental Protection Agency (EPA) in early 2018 proposed a policy change that would prevent it from considering scientific research unless the underlying data is made public for other scientists and industry groups to evaluate.⁵ This potential policy would prevent the EPA from being able to consider important environmental health studies that are

³ 45 C.F.R. § 46.116 (a)(5)(i) (2018).

⁴ For an exploration of privacy in the context of health care big data, see I. Glenn Cohen, Holly Fernandez Lynch, Urs Gasser, and Effy Vayena (eds.), *Big Data, Health Law, and Bioethics* (2018).

⁵ Lisa Friedman, *The E.P.A. Says It Wants Research Transparency. Scientists See an Attack on Science*, N.Y. Times (Mar. 26, 2018) www.nytimes.com/2018/03/26/climate/epa-scientific-transparency-honest-act.html.

4 *Carmel Shachar, I. Glenn Cohen, Holly Fernandez Lynch, and Barbara J. Evans*

based on personal health information, because of the heightened privacy requirements and expectations around that data. This dilemma, caused by the interaction of transparency initiatives and privacy considerations, relates directly back to our previously discussed theme that transparency must be considered within the context of broader goals rather than pursued solely for its own sake. As demonstrated by the dilemma facing the EPA, there can be a cost to transparency, and several chapters in this volume attempt to balance privacy interests of stakeholders against the potential of transparency to change the health-care landscape.

On the other hand, several contributors to this volume make the points that transparency and privacy are not mutually exclusive values, and that transparency initiatives can often support the privacy interests of health-care stakeholders. Transparency around the use of health-care data, for example, can better empower patients to understand the flow of health information and to set appropriate boundaries on the use of their own data. Increased transparency around the workings of the health-care system can allow for stakeholders to make more informed choices about the use of their information, empowering individuals to take steps that enhance privacy protection.

Altogether, this volume presents a sense of the exciting potential that transparency has to improve the American health-care system. At the same time, it cautions against an unqualified embrace of transparency. Transparency is not a panacea, and not all transparency initiatives will achieve their intended effects. The works in this volume create a framework for designing and evaluating transparency initiatives in the health-care context. In that sense, this collection should be read as an open invitation for further research, collaboration, and discourse among a broad range of stakeholders as they continue to implement transparency initiatives in diverse health-care settings.

The book is divided into six parts. Part I, introduced by Abigail R. Moncrieff, provides a big picture overview of the state of transparency initiatives in the American health-care landscape. Strikingly, all of these contributions frame health-care information as a market good, to be facilitated by transparency initiatives, rather than an intrinsic right. As a result of this framing, these chapters highlight the importance of remembering the end goals of transparency initiatives – that the information gleaned from these policies results in better-informed decisions that more closely reflect the goals of the decision makers. Additionally, these chapters remind us that transparency comes at a cost and all transparency initiatives should be assessed for their cost–benefit trade-offs.

Barry R. Furrow, in his chapter, “Smashing into Windows: The Limits of Consumer Sovereignty in Health Care,” identifies significant barriers to improving medical decision making through increased information to patients, such as physician control over the information, hospital circumvention of consent rules, and patient irrationality. Furrow suggests that there is reason to be optimistic that these challenges may be overcome by new technologies and initiatives such as social

media platforms, health coaches, and virtual tools. He does caution, however, that we must carefully consider the costs and benefits of each transparency tool as we attempt to empower consumers' medical decision making.

Barbara J. Evans, in her chapter, "The Interplay of Privacy and Transparency in Health Care: The HIPAA Privacy Rule as a Case Study," argues that transparency and privacy need not be seen as mutually exclusive. In health-care settings, transparency has many aspects that serve different goals, and some policies that promote transparency – such as granting individuals a right of access to their own data – simultaneously enhance privacy protections.

Govind Persad, in "Transparency Trade-offs: Priority Setting, Scarcity, and Health Fairness," explicitly explores the distribution of a certain type of health-care transparency, information about the benefits and burdens of health-related products, including pharmaceuticals, medical devices, and food. He argues that transparency initiatives must be designed with distributive consequences in mind because trade-offs between the benefits and burdens of these programs will vary widely between individuals.

Finally, Oliver J. Kim, in "Slightly Hazy: Transparency and the Cost of Too Much Information," focuses on the costs of transparency initiatives. Kim cautions that too much information, one of the potential results of increased transparency, may overwhelm consumers. This may lead to consumers making suboptimal medical decisions. Thus, Kim shies away from promoting transparency initiatives wholeheartedly, instead recommending a more paternalistic regulatory approach to help guide patient decisions.

Part II of this volume, introduced by Luke Gelinas, focuses on transparency and informed consent. At first glance, the relationship between transparency and informed consent is clear – in order for true informed consent to be given, researchers and health-care providers must be transparent about the purpose, method, drawbacks, and other aspects of a particular intervention. Without sufficient transparency it is impossible for individuals to provide "informed" consent to any intervention. Nevertheless, the three chapters in Part II illustrate that the relationship between transparency and informed consent is more nuanced than our initial assumptions. What is the appropriate level of disclosure necessary to meet our goal of facilitating informed consent? What must we disclose in order to achieve informed consent? How transparent must transparency be in this context? All three authors in this part conclude that broad and thoughtless disclosure will not in and of itself result in true informed consent. Rather, thought must be given to ensure that the patient is empowered to make decisions reflecting his or her values.

In the first chapter of this part, "Transparency versus Informed Consent: The Patient/Consumer Paradigms," Craig J. Konnoth distinguishes between informed consent and transparency, noting that the former is a concept typically applicable to patients, while the latter is applicable to consumers, and that use of either term is indicative (and potentially determinative) of social roles and

6 *Carmel Shachar, I. Glenn Cohen, Holly Fernandez Lynch, and Barbara J. Evans*

expectations. The chapter traces the evolution of transparency relative to informed consent, noting the ways in which the consumer model has taken hold – and where it has not. According to Konnoth, “[i]nformed consent and transparency conceive of autonomy in different ways,” with the former demanding the provision of resources and status to promote autonomy, and the latter assuming that the individual already has the necessary resources, and must only be provided with information and then have his or her decisions respected. The chapter concludes by suggesting that informed consent and transparency ought to be viewed on a spectrum, with some clinical circumstances calling for a patient role, and others that of a consumer.

Richard S. Saver, in “Transparency and Financial Conflicts: The Uncertain Case for Sunshine,” addresses a paragon of health-care transparency: the Physician Payments Sunshine Act and its associated Open Payments Database. The law is intended to deter inappropriate financial relationships and avoid bias in medical decision making through reporting, but Saver notes a number of downsides to the law’s requirement for transparency. For example, it may crowd out more substantial regulation of physician payments, result in information overload for patients, and paradoxically, lead to greater trust in physicians receiving such payments and higher payments in order to compensate for any detrimental reputational effects. Saver does note some high points, indicating that the law’s real value will be to regulators, who can utilize reported payment information to “better inform evidence-based regulation of industry’s promotional activities [and] enforce the existing health-care fraud and abuse laws by revealing unknown financial ties or outliers that warrant further scrutiny.”

Elizabeth Sepper, in “Making Religion Transparent: The Substance, Process, and Efficacy of Disclosing Religious Restrictions on Care,” scrutinizes the argument that transparency about religious restrictions will help resolve informational asymmetry and allow consumers to make informed choices in light of their health-care needs, noting that transparency is not the equivalent of access to services that have been restricted. This poses a challenge to the consumer model of care and suggests that referral – not just transparency – will be important. Sepper adds an additional rationale for transparency in this context: democratic engagement regarding mergers and acquisitions that may curtail access to care in light of the application of religious restrictions. The chapter concludes by addressing the role of transparency regarding such restrictions in the context of informed consent, asking whether mere disclosure without options or control really satisfies the goals of informed consent at all.

Part III, introduced by Kristin M. Madison, addresses transparency and economics, in particular health-care costs and billing. The chapters in this part attempt to articulate transparency’s potential to reduce health-care costs while being mindful of its limitations as a solution to the problem of rising health-care costs. Transparency has the potential to curtail wasteful medical spending and to promote competition that can lower prices on goods and services. Nevertheless, as the contributions to this

section discuss, realizing the full potential of transparency to address health-care costs is very challenging. The contributors to this part all make the argument that transparency must be smart or targeted in order to achieve its intended effect.

Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, in “Transparency on Prescription Drug Expenditures: A Lever for Restraining Pricing?” examine the impact that greater transparency may have on pharmaceutical drug pricing. Sarpatwari and his coauthors dissect the potential impact of laws requiring the disclosure of pharmaceutical companies’ research and development costs on drug pricing, arguing that these laws will likely not produce the intended benefits. The authors then propose alternative disclosure requirements that would shine better light onto the current structure of the pharmaceutical markets as being more effective at reducing drug pricing.

Marc A. Rodwin, in “Is Pharmaceutical Price Transparency an Effective Means to Reduce High Prices and Wide Price Variations?” likewise argues that transparency initiatives in the retail market for prescriptive drugs have not achieved their intended effect on drug pricing. His empirical analysis of the retail drug market demonstrates that significant price variation persists, even when drug prices are available to consumers online or via special apps. Rodwin argues that there are limitations to transparency as a means to counter high prices and price variations due to other market imperfections that allow drug firms to price discriminate.

Wendy Netter Epstein, in her chapter, “Price Transparency: A Contracts Solution,” looks at provider costs and the proper outcome when patients and providers have failed to discuss price. Epstein draws upon contract law and scholarship to suggest that a penalty default rule could help promote transparency for provider charges by encouraging courts to recognize a price of zero when providers have failed to meaningfully disclose their prices to consumers. This suggestion again reminds us of the need to promote thoughtful transparency, in ways that would empower the consumer to make better choices, rather than to simply provide information overload through an almost impenetrable hospital chargemaster, or a long list of service prices.

Mark A. Hall, with his contribution, “Solving Surprise Medical Bills,” concludes this part by examining the problem of when an insured patient discovers, after the fact, that a provider responsible for some part of his or her care was not in-network, leading to much higher payments for care. Hall posits that increased transparency could help in some, but not all, of these situations. He recognizes that for transparency to prevent this problem, the patient must not be in an emergency situation, must not be faced with an unduly complex web of provider relationships, and must have the meaningful opportunity to locate another provider. Thus, Hall also argues that only targeted or thoughtful transparency, rather than transparency for its own sake, will help address wasteful medical spending.

Part IV, introduced by Holly Fernandez Lynch, focuses on transparency and innovation. Transparency in pharmaceutical product development is especially

8 *Carmel Shachar, I. Glenn Cohen, Holly Fernandez Lynch, and Barbara J. Evans*

challenging because of the expectation that “confidential commercial information” must be protected to avoid conferring an advantage to potential competitors. Nevertheless, the contributors to this section make a strong argument that greater transparency in this area must be encouraged to help foster innovation. The authors of the chapters in this part also highlight where initial steps, however small, have been taken to encourage transparency.

Rachel E. Sachs and Thomas J. Hwang open this section with their chapter, “Increasing the Transparency of FDA Review to Enhance the Innovation Process.” They take issue with the lack of transparency in FDA communications with the sponsors of pharmaceutical research and marketing applications, arguing that the agency has greater authority than it currently uses to disclose limited information to the public regarding regulated products as they wind their way through the approval process. This secrecy has serious repercussions for patients and their caregivers, as well as research participants, and is also detrimental to innovation, preventing sponsors from learning from each other’s experiences in ways that could maximize both efficiency and safety. To address this problem, Sachs and Hwang recommend adopting at least a system of limited disclosure, in which the FDA discloses to the public “at a minimum, 1) the existence of particular events, including the sending of a complete response letter, the placement of a clinical hold, a meeting between the agency and a sponsor and 2) a general categorization of their substance.”

Barbara E. Bierer, Mark Barnes, and Rebecca Li pick up many of these threads in their chapter, “Transparency and Clinical Trial Data Sharing: Legal and Policy Issues.” Here, they provide a robust overview of the value of transparency regarding individual-level clinical trial data, highlighting efforts to promote such transparency as well as legal barriers and protections in both the United States and Europe. They acknowledge the importance of privacy interests and autonomy regarding individual-level trial data, but argue that on balance, its public health value is paramount. Thus, individuals should not be permitted to refuse the disclosure of their deidentified or anonymous data, but a number of safeguards should be implemented, including better education about the utility of the data, notice regarding how data is used, and enhanced protections against its inappropriate use.

Stefano Marino and Spyridon Drosos close Part IV with their chapter, “The European Medicines Agency’s Approach to Transparency.” They begin with a normative rationale for transparency regarding information held by the EMA, including accountability in the approval process, advancing the interests of patients and healthcare professionals, and maximizing the utility of clinical trial data. They then go on to explore both “reactive” and “proactive” transparency, i.e., how the EMA complies with EU requirements to provide information upon request and requirements to spontaneously disclose information, including clinical data submitted with applications for marketing authorization. In particular, the chapter explores the tension between legal requirements for transparency and legal

requirements for the protection of confidential commercial information and personal privacy, describing progress in the EMA's approach, and remaining areas of debate. Each chapter in this section considers the impact that the lesser or greater embrace of transparency will have on incentivizing developing and bringing to market new pharmaceutical products and applications.

Gregory Curfman introduces Part V, which focuses on the impact that transparency initiatives can have on promoting health and safety. This section acknowledges the trend to have patients become more personally involved in their own health care and the expectation that medical decision making will be shared decision making between the patient and provider. The patient can only occupy this increasingly central role to medical decision making through increased transparency and better information. As such, transparency initiatives are vital for promoting better medical decision making and improving outcomes. The chapters in this section also remind us, however, about the tension between increased transparency and patients' privacy interests.

Anthony W. Orlando and Arnold J. Rosoff open this part with their chapter, "The Role of Transparency in Promoting Healthy Behaviors: Pros, Cons, and Perils of Information Sharing to Foster Personal Responsibility in Health Care," which focuses on health information sharing in employee wellness programs. They are concerned that these programs pose a significant risk to employees' privacy because they encourage employees to participate in health risk assessments and share that information with their employers. Orlando and Rosoff's work cautions that we should not blindly embrace transparency for all aspects of health information, even when increased transparency might encourage healthier behaviors, but should remain mindful that privacy concerns also must be addressed.

Michelle M. Mello, David M. Studdert, Brahmajee K. Nallamothu, and Allen Kachalia, in their chapter, "The Role of Transparency in Patient Safety Improvement," document a wide range of initiatives intended to improve patient safety and experiences. They argue that these initiatives, while not strictly transparency focused, may reinforce transparency-focused initiatives by influencing the availability of information for patients to use to make medical decisions. Thus, this chapter encourages us to remember that transparency initiatives exist in a broader health-care ecosystem.

Sharona Hoffman, in her chapter, "Personal Health Records as a Tool for Transparency in Health Care," expresses a concern about the proper balancing between transparency and privacy. Hoffman examines the use of personal health records (PHRs), especially in the context of promoting health-care transparency. Hoffman acknowledges the benefits of PHRs, such as allowing patients to store and access their own information, while also remaining concerned about the increased risk to privacy, such as an increased risk of hacking. While Hoffman does not argue against the use of PHRs, she reminds us that more work must be done to refine these

10 *Carmel Shachar, I. Glenn Cohen, Holly Fernandez Lynch, and Barbara J. Evans*

technologies to maximize their transparency benefits while minimizing their privacy concerns. This concern echoes the worries put forth by Orlando and Rosoff earlier in Part V.

Jim Hawkins, Barbara J. Evans, and Harlan M. Krumholz, in “Nontransparency in Electronic Health Record Systems,” focus on the interaction between transparency and patient safety. They describe various nontransparent business practices – such as gag clauses that prevent frank discussion of safety incidents involving electronic health record systems – that may adversely affect patients’ physical safety. They also explore how other nontransparent business practices, such as allowing deidentified health data to be shared without informing patients, can expose patients to privacy and dignitary harms.

Dov Fox closes Part V with his chapter, “Transparency Challenges in Reproductive Health Care.” Fox is concerned that a significant information gap exists in the assisted reproductive technology (ART) field, which is generally unregulated. Fox believes there should be increased transparency for “never events,” such as mishandling, misinformation, and misconception, potentially crowd sourced from previous patients. Data about these often devastating ART events is not currently being collected, so patients cannot adequately evaluate the quality of each provider. Fox’s chapter is a good reminder that there exist many corners of the health-care industry that remain shockingly nontransparent and prevent patients from being able to determine which health-care provider will provide them with the best, safest, or most appropriate outcomes.

Part VI, “Challenges in Promoting and Measuring Transparency in Health Care,” with an introduction by I. Glenn Cohen, casts a wide net over the topic of transparency. Nevertheless, these chapters all document the challenges to successfully implementing transparency initiatives, such as financial costs, federal preemption of state programs, and noncompliance. These chapters are also concerned with the political dimensions of transparency in health care.

Erin C. Fuse Brown and Jaime S. King, in their chapter, “ERISA as a Barrier for State Health-Care Transparency Efforts,” look at how state efforts to promote consumer health-care transparency, such as adopting all-payers claim databases, have been stymied by the broad application of the federal Employee Retirement Income Security Act (ERISA). Recent Supreme Court jurisprudence, especially *Gobeille v. Liberty Mutual*, have dramatically broadened ERISA’s preemption reach to block state efforts to increase health-care price transparency. Fuse Brown and King argue that the federal government must address the newly expanded reach of ERISA to facilitate and support state efforts to use transparency to improve health-care costs.

Jennifer E. Miller, in “Transparency and Data Sharing in Clinical Research and Big Pharma,” focuses on the promotion of transparency around clinical trials and their results. Miller notes that there are no clear best practices when it comes to