Rethinking the Civil Protection of Patients from Misleading Pharmaceutical Marketing Under Saudi Law

Muflih Saud Almughyirah

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RETHINKING THE CIVIL PROTECTION OF PATIENTS FROM MISLEADING PHARMACEUTICAL MARKETING UNDER SAUDI LAW

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Submitted to the faculty of Indiana University Maurer School of Law in partial fulfillment of the requirements for the degree of Doctor of Juridical Science

May 2023
Accepted by the faculty, Indiana University Maurer School of Law, in partial fulfillment of the requirements for the degree of Doctor of Juridical Science.

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May 19, 2023
Abstract

The effect of pharmaceutical marketing on individuals is a universal concern. It can influence patients’ health and wealth. Patients, as well as their prescribing medical doctors, have been targeted by such marketing through different means. Many patients are unaware of their position as the most vulnerable party in this context and how these promotional strategies affect their physicians’ decisions. When pharmaceutical marketing includes false, misleading, or otherwise negligent statements, patients become potential victims. This research addresses patients’ civil protection from misleading pharmaceutical marketing under Saudi law. The study addresses four crucial aspects of patient protection: (i) ex-ante government regulations, (ii) civil liability, (iii) compensatory damages, and (iv) access to justice. The study will also explore and identify major challenges confronting the current legal efforts and suggest solutions to contribute to developing patients’ protection from misleading drug marketing in Saudi Arabia.
Dedication

To

My parents who I cannot thank enough for their wonderful inspirations and great influence on my life. May Allah reward them the highest level of paradise.
Acknowledgements

All the praises and thanks be to Allah (God).

During my academic journey to complete this dissertation, I have been fortunate to work with supportive people. First, I would like to express my deep appreciation to my advisor and the committee chair, Professor Christiana Ochoa, who has given me considerable time, effort, and advice to help me complete this work. I would like also to thank the member of the committee, Professor Jody Madeira, who has been supportive and helped me to understand important insights related to the subject of this research. I would like to send my warm regards to the staff of Graduate Legal Studies at Maurer School of Law. I would like to thank Dean Lesley Davis and Professor Gabrielle Godwin for their professional assistance in academic and administrative affairs.

I have been surrounded with people who have helped me with their kindness. My thanks to all who have helped me and wished me the best. I am indebted to each one and their contributions and assistance. I would like to extend my appreciations to professors and colleagues in the SJD program during 2019 – 2023, with whom I have had many discussions of many aspects that have helped me to develop this research. I would like also to extend my thanks to the Saudi Food and Drug Authority (SFDA). Special thanks to Dr. Ali Alhomaidan, who has welcomed me and answered my questions regarding the SFDA’s role in regulating pharmaceutical marketing.

I would like to send my deepest thanks to my mother who has encouraged me from the first stage to pursue my education and has been praying and wishing the best for me every single day of this long journey. Secondly, I thank my siblings who have been very supportive, sending their best wishes and encouragements. My thanks also extend to my family who chose to come all the way
from home with me to support me during these years. My wife Fatimah, my son Saud, and my daughter Lubna, who have been patient with me being busy during this research work. They have motivated me to pursue working all the time.

Finally, this dissertation and this journey would not be accomplished without the support of the Kingdom of Saudi Arabia. Special thanks to Prince Sattam bin Abdulaziz University for supporting me during this journey. My thanks extend to the faculty and staff of Prince Sattam bin Abdulaziz University who have been helpful and encouraging during these recent years.
TABLE OF CONTENTS

ACCEPTANCE PAGE...........................................................................................................I

ABSTRACT..........................................................................................................................II

DEDICATION.......................................................................................................................III

ACKNOWLEDGEMENTS.................................................................................................IV

INTRODUCTION...................................................................................................................1

CHAPTER I: FUNDAMENTALS OF THE PROTECTION OF PATIENTS FROM
MISLEADING PHARMACEUTICAL MARKETING..............................................................7
  PART I: OVERVIEW OF MISLEADING PHARMACEUTICAL MARKETING............8
  PART II: SAUDI LAW, LEGISLATION, AND SOURCES OF THE STUDY.........17
  PART III: THE RIGHT TO HEALTH AND THE RIGHT TO ACCESS MEDICINE
  UNDER SAUDI LAW.......................................................................................................20
  PART IV: SAUDI HEALTH SYSTEM AND THE PROCESS OF ACCESSING
  MEDICINE.....................................................................................................................23
  PART V: THE LEGAL PROTECTION OF PATIENTS FROM MISLEADING
  PHARMACEUTICAL MARKETING..................................................................................29
  PART VI: PHARMACEUTICAL CORPORATIONS' AND PHYSICIANS' LEGAL
  RELATIONS WITH PATIENTS........................................................................................36
# CHAPTER II: *EX-ANTE PROTECTION*

PART I: OVERVIEW

PART II: SFDA GENERAL REQUIREMENTS AND MEASURES TO ENSURE INFORMATION ACCURACY IN MARKETING

PART III: MEANS DESIGNED TO POLICE DIRECT-TO-PATIENT ADVERTISEMENTS

PART IV: MEANS DESIGNED TO POLICE DIRECT-TO-PHYSICIAN PROMOTIONS

PART V: TOWARDS MORE ENFORCEABILITY OF *EX-ANTE* REGULATIONS

---

# CHAPTER III: CIVIL LIABILITY

PART I: OVERVIEW

PART II: CIVIL LIABILITY PILLARS (ELEMENTS)

PART III: CHALLENGES PATIENTS FACE WHEN ESTABLISHING CIVIL LIABILITY AND PROPOSED SOLUTIONS

---

# CHAPTER IV: COMPENSATION

PART I: OVERVIEW

PART II: ISLAMIC ESSENTIAL PRINCIPLES OF COMPENSATION

PART III: COMPENSATION FOR DEATH AND INJURIES

PART IV: OTHER COMPENSATORY DAMAGES

PART V: CHALLENGES AND SOLUTIONS

---

# CHAPTER V: PATIENT’S ACCESS TO JUSTICE

PART I: OVERVIEW

PART II: ADMINISTRATIVE COMPLAINT SYSTEM

PART III: LITIGATION
PART IV: ALTERNATIVE DISPUTE RESOLUTIONS (ADR) AND PATIENTS

PART V: TOWARDS MORE EFFICIENT AND EFFECTIVE PATIENTS’ ACCESS TO JUSTICE

CHAPTER VI: CONCLUSION

PART I: SUMMARY

PART II: TOWARD IMPROVED PATIENTS’ CIVIL PROTECTION FROM MISLEADING PHARMACEUTICAL MARKETING
Introduction

Pharmaceutical marketing with massive spending has influenced health professionals’ and patients’ medication selections. Marketers work to increase their sales, not to educate patients or physicians, and this aim can lead to using advanced and intensive marketing tactics that may be considered misleading. With such misleading marketing, the focus has shifted to choosing or using promoted medications instead of the medications that are best for patients’ interests. Misleading marketing can cause devastating consequences for patients. It can have negative effects on patients’ rights to health, access to medicine, and access to correct information. Should patients be left alone facing enormous corporations and often suffering from unfavorable implications of marketing?

The law should protect patients in medical malpractice and consumer cases to ensure that negative consequences are limited. Protection starts before any damage occurs, through ex-ante regulations, and continues when damages occur, through assuring efficient access to justice and reasonable redress. The kingdom of Saudi Arabia has uncodified law as well as legislative tools that deal with distinct issues of pharmaceutical promotions. The law adopts means to regulate pharmaceutical marketing in the first place and to mitigate damages when they occur. This research seeks to explore these laws and contribute to identifying areas that need further development.

This research explores the marketing process before a potential harm occurs by addressing ex-ante regulations and after a harm occurs until a harmed patient is reasonably redressed by examining civil liability, compensation, and access to justice. Therefore, the dissertation answers one main question: what policies, procedures, or doctrines can be embraced by Saudi lawmakers
or considered by researchers to develop the civil protection of patients from misleading pharmaceutical marketing under Saudi law? The answer is found through examining the following four aspects: (i) *ex-ante* government regulations, (ii) civil liability, (iii) compensatory damages, and (iv) access to justice. After addressing these aspects, the research works to identify several major challenges to such protection and explore or propose solutions when possible.

Addressing the protection of patients under Saudi law is significant for three crucial reasons. First, accessing correct information can lead patients to enjoy their right to health and access to medicine. Determining the proper medication and doses relies heavily on the information available from the manufacturer. The research will present the influence of pharmaceutical marketing and how some marketing instruments have been considered a resource of information. Second, the Saudi Vision 2030 targets privatizing healthcare, and patients will have to deal more with the private health sector.\(^1\) The nature of the patient/private healthcare relationship is different than the patient/public healthcare relationship. This should increase the general importance of raising questions about patients’ protection in this era. Finally, the topic of this research has not been largely explored under Saudi law. This dissertation seeks to contribute to rethinking current Saudi law to identify possible areas of development and to suggest reforms when possible.

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\(^1\) Saudi Vision 2030 is a plan and a roadmap that the Crown Prince of Saudi Arabia His Royal Highness Mohammed bin Salman has announced. The Vision targets many aspects, such as diversifying the economy and developing the quality of life of the Saudi people. Saudi Vision 2030 29, https://www.vision2030.gov.sa/media/rc0b5oy1/saudi_vision203.pdf (last visited April 24, 2023).
A- Scope & Limitations:

The scope of this research is holistic when considering the diverse topics covered to answer the main question, such as *ex-ante* regulations, civil liability, compensatory damages, and access to justice. However, the research addresses this variety of subjects to answer a particular question regarding the civil protection of patients from misleading pharmaceutical marketing. As a result, the research does not address each topic of this study deeply and exhaustively, but instead, presents it to the extent necessary to answer the driving research question. The work mainly concentrates on protection in Saudi law. The main purpose, therefore, is to improve patients' protection in this area under Saudi law.

The research covers direct-to-patient and direct-to-physician misleading pharmaceutical marketing, so the study does mainly cover the patient/physician and the patient/drug company relations, but it only covers aspects of such relations related to the main research concerns. The research also does not address patients' relationships with others, such as pharmacists and institutional providers.

This research focuses mainly on civil aspects, as it addresses civil liability, civil remedies, and civil procedures in most portions of the study. However, some administrative and criminal aspects will be briefly discussed in Chapters II, IV, and VI since such aspects affect civil areas and are also considered part of the whole picture of consumer law. Non-civil aspects are addressed in limited instances for the purpose of understanding or evaluating the overall protection of patients. Finally, the research is not meant to focus on the particular product that patients receive, but instead focuses primarily on misleading promotions.
B. **Methodology:**

This research describes Saudi law and examines challenges and suggests reforms when possible. Though this dissertation does not expressly compare Saudi law with other laws, many of the main questions that arise in this dissertation derive from what has been already established under other legal systems. For example, compensatory damages that are presented and discussed are recognized widely in other legal systems. The comparative method will be used to provide examples of proposed reforms when applicable. This dissertation is conducted with a lack of primary sources in several areas of Saudi law, and many aspects are covered based instead on secondary sources, such as Islamic *fiqh*.

In aspects that present Islamic *fiqh*, the research raises legal questions from comparative law backgrounds. Thus, this research is meant to explore Islamic *fiqh* for the purpose of understanding Saudi law, and it is structured based on comparative understanding of laws, not based on traditional *fiqh* methods and concepts.

C. **Research questions**

To answer the main research question, there are other sub-questions that can help reach the final outcome:

- What is the current Saudi legal landscape that provides the civil protection for patients from misleading pharmaceutical marketing? What are those patient protections?

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2 Islamic *fiqh* (jurisprudence) refers to the understanding of detailed rules of Islamic law based on sources of Islam (the Qur’an and the teaching of the prophet in addition to other sources). Islamic *fiqh* has developed through various schools over centuries, such as the Hanafi, the Maliki, the Shafi’i, and the Hanbali. These schools have differences in reasoning and interpreting Islamic sources, which has resulted in distinct opinions and rich *fiqh*. The term “Islamic *fiqh*” refers to the rulings that jurists have made based on Islamic main sources, while the term “Islamic law” or “Islamic Shariah” is more general and can encompass all aspects of Islam, including legal, ethical and other aspects.
- What *ex-ante* procedures does the Saudi Food and Drug Authority (SFDA) take to protect patients from misleading marketing? How can those *ex-ante* regulations be made more effective?

- What are the rules governing civil liability in this case? What challenges can impede patients when establishing civil liability elements?

- What compensatory damages does the law recognize for injured patients? What can be further developed regarding compensatory damages?

- What proceedings are available to patients to access justice? Are such proceedings suitable and efficient for a patient’s particular situation?

**D. Roadmap:**

The research is divided into six chapters that serve the purpose of rethinking patients’ civil protection from misleading pharmaceutical marketing under Saudi law. Chapter I explores major related background and concepts. It introduces the topic of the dissertation and describes Saudi legal aspects related to this research. Chapter II addresses *ex-ante* regulations as an essential aspect of patient protection. It aims mainly to evaluate their effectiveness in protecting patients. This chapter also serves the additional purpose of presenting several health law sources that regulate pharmaceutical marketing and that provide essential background information before discussing other aspects.

Chapter III deals with aspects of civil liability of pharmaceutical marketers and physicians. The chapter examines challenges that can impede patients when establishing civil liability. Chapter IV examines compensatory damages available to patients under Saudi law. The chapter considers whether such compensatory damages are sufficient to make patients whole, and how the area of damages can be developed further. Chapter V considers the patient’s access
to justice available in the current system and discusses developments that might improve such access. Chapter VI is the conclusion and strives to answer the main question based on the information developed throughout the dissertation.
Chapter I: Fundamentals of the Protection of Patients from Misleading Pharmaceutical Marketing.

Introduction

This dissertation seeks to identify challenges that face the protection of patients from misleading pharmaceutical marketing, mostly from a civil perspective. Chapter I defines and gives an overview of misleading pharmaceutical marketing, Saudi law, the right to health, the Saudi health system, the justifications for patients' protection, and the relations between patients and pharmaceutical marketers and patients and their physicians. Addressing such topics lays the groundwork for further research in the next chapters.

This chapter consists of six parts. Part I is an overview of pharmaceutical marketing. Part II will review Saudi law. Part III will describe the right to health and the right to access medicine. Part IV will explore the Saudi health system and the process of accessing medicine. Part V will discuss justifications for the legal protection of patients. Part VI examines the legal relations between patients and pharmaceutical marketers from one side and patients and their physicians from the other.
I: Overview of Misleading Pharmaceutical Marketing:

Saudi Arabia has a growing pharmaceutical market, yet the majority of medications in Saudi Arabia are imported from international producers. These drug corporations market their products in Saudi Arabia as they usually do in other markets worldwide. This part explores pharmaceutical marketing, marketing strategies, and adverse effects of misleading pharmaceutical marketing in Saudi Arabia. The part first answers questions regarding the concept of pharmaceutical promotions. Then it states basic information about drug promotions in Saudi Arabia.

A. Misleading pharmaceutical marketing.

This section explores concepts related to misleading pharmaceutical promotions, namely, pharmaceutical marketing, direct-to-patient advertisements, direct-to-physician promotions, and misleading promotions. The goal is to construct a reasonable understanding of the crucial concepts before delving further.

The first vital concept is pharmaceutical marketing. Black's Law Dictionary defines marketing as "the act or process of promoting and selling, leasing, or licensing products or services." This research focuses mainly on promotions in general and misleading promotions in particular. The World Health Organization (WHO) defines pharmaceutical promotions as "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs." The definition

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4 Id.
5 Marketing, BLACK’S LAW DICTIONARY (11th ed. 2019).
encompasses all kinds of marketing communications, whether directed to patients or physicians, or even other parties, such as pharmacists and institutional providers. In addition, the definition includes all kinds of activities that can be in the form of advertising or influencing information sources as long as they are meant to increase consumption of the marketer's products. Therefore, regular advertisements are promotions within the meaning of this definition, as are other promotional activities include lectures, conferences, or research funds.

The other two primary concepts that are used widely are direct-to-patient or direct-to-consumer advertisements and direct-to-physician promotions. Direct-to-patient marketing is linked chiefly with ads that target the public. The International Chamber of Commerce Advertising and Marketing Communications Code defines advertisements or advertising as all kinds of media broadcasting that includes marketing interactions, that are done in exchange for economic or other benefits. Such advertisements target patients through any form of written, verbal, and visual communications. In contrast, direct-to-physician promotions are intended to influence a particular group, health professionals and physicians, in this regard. Pharmaceutical promoters use methods, such as professional events and academic publications, to promote medications to physicians. The SFDA has regulations that govern both direct-to-patient and direct-to-physician marketing.

After defining promotions and other related concepts, the concept of misleading marketing is still not covered. The law implicates criminal consequences when pharmaceutical

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7 “Advertisement is a commercial solicitation; an item of published or transmitted matter made with the intention of attracting clients or customers.” Advertisement, BLACK’S LAW DICTIONARY (11th ed. 2019). “Advertising is the action of drawing the public’s attention to something to promote its sale.” Advertising, BLACK’S LAW DICTIONARY (11th ed. 2019).

marketers use misleading information to promote or label a pharmaceutical or herbal product. However, the question remains what constitutes a misleading information? Misleading marketing can be related to other essential terms, for example, anti-fraud and false advertisements. The Saudi Anti-Commercial Fraud Law was enacted to protect consumers from commercial fraud, not limited to advertisements. The act defines fraudulent products as all products that have been changed in a way that decreases their intangible or tangible value. It likewise states that all who deceive or attempt to deceive consumers by hiding or changing specifications of a product to reflect unreal information about the quality or quantity or any other significant information commit fraud. Therefore, the anti-fraud law defines acts constituting fraud as acts conveying untruthful significant information that can affect the value of the product. Can this be applicable to misleading pharmaceutical marketing?

The law does not seem to restrict the value only to financial aspects, and the value as expressly stated comprises broadly tangible and intangible sides. Based on this understanding, if the patients or their physicians have relied on provided information to use the medication, and they discover that the “value” of the medication is not as stated to them, it is possible to define this as fraud. However, if the law is meant to restrict the concept of “the value of the product” to a particular interpretation, such as financial cost and the origin of the product, the value will not

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9 Law of Pharmaceutical Products and Facilities, Royal Decree No. M/108 Date. 22/8/1441 A.H., art. 34 (2020) (Saudi Arabia). (The criminal punishment can reach 5 million Saudi Riyal (about $1331835.95) in case of using untruthful information…)

10 The concept of altghyr or altldys [deception or omission] is to represent untruthful information or hide significant information. Deceptive information must be material in the dealing process to be effective. SECRETARIAT GENERAL OF THE GULF COOPERATIVE COUNSEL, WTHYLH ALKWYT LLNZAM (ALQANWN) ALMDNY ALMWHD LDWL ML SALT'EAWN LDWL ALKHLYJ AL'ERBYH [The Document of Kuwait for the Unified Civil Law of the Coop. Couns. for the Arab States of the Gulf] art. 185, 186 (2011). WBBH ALZHLYL, ALFOH ALESLAMY WADLTH ALTFSYLYH [ISLAMIC JURISPRUDENCE AND ITS DETAILED GROUNDING] 3069- 72(1997).


12 Id. art. 1.

13 Id. art. 2.
then become as important for pharmaceutical marketing as it is for other commodities. The pharmaceutical information displayed or marketed is itself essential to the decision to use the medication or not, especially when the product has no effective alternatives or is still in the exclusive patent period. In many cases, the critical need for the medication based on the information given can probably outweigh the cost factor. Can the value standard still be effective to protect patients when determining whether misleading pharmaceutical marketing constitutes fraud or not if the standard is restricted only to financial aspects?

Saudi law has more to offer in this regard. While the Anti-Commercial Fraud Law has stated the value standard as the main factor to determine whether misleading pharmaceutical information is within the concept of fraud in the Law or not, SFDA regulations have another stricter approach that prioritizes information itself. Health regulations in Saudi Arabia include requirements for the information presented in pharmaceutical marketing. Those will be addressed in depth later in this study,14 but some requirements are related to the kind of information that should be included. All information in the marketing of the advertised product should comply with one of the SFDA-approved material forms, such as leaflets and labels.15 In addition, there are requirements regarding other fundamental information, such as safety warnings and the name of the product.16 Therefore, according to health regulations, the SFDA should approve information included in marketing. Including non-approved information can lead SFDA to determine that the promotion is misleading and to take necessary steps to protect patients as a result.

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14 See Chapter II, infra.
B. Methods of pharmaceutical marketing in Saudi Arabia.

Businesses usually argue that they have the freedom to promote their products. Laws regulating pharmaceutical marketing worldwide vary in different jurisdictions, and thus methods should be adjusted to meet legal requirements according to applicable laws. Pharmaceutical corporations use diverse strategies and styles to promote their products in Saudi Arabia. Corporations promote their products to patients directly and to health professionals. This section outlines common marketing methods in Saudi Arabia. The section addresses direct-to-patient marketing first and then direct-to-physician marketing.

In direct-to-patient marketing, pharmaceutical advertisers use the media to target patients. Direct-to-patient advertisements are limited in Saudi law to nonprescription drugs only. Saudi Arabia lines up with most of the world in limiting direct-to-patient advertisements to only nonprescription medications. Advertisements may be in written material, radio, and video media. Advertising can be in the form of brochures, television, magazines, newspapers, billboards, posters, and on internet platforms. Social media has recently become one of the

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17 The Executive Regulation of the Law of Pharmaceutical Products and Facilities, SFDA Board Decision No. 1-26-1442 Date. 22/03/1442 A.H., art. 31. (2020) (Saudi Arabia). Saudi law allows advertising of over-the-counter drugs directly to patients, and prescription-only drugs to be promoted to health professionals in, for example, scientific journals and conferences.

18 See C. Lee Ventola, Direct-to-Consumer Pharmaceutical Advertising Therapeutic or Toxic?, 36 P&T, P EER-REV. J. FORMULARY MGMT. 669 (2011). Most countries in the world do not allow direct-to-patient advertisements, but there are a few exceptions, such as the U.S.A. and New Zealand.

19 See Sinaa AbdulMohsen Al-Aqeel et al., Analysis of Written Advertising Material Distributed through Community Pharmacies in Riyadh Saudi Arabia, 11 PHARMACY PRAC. 138 (2013). Researchers were able to find numerous brochures in random Riyadh pharmacies that were easy to access through volunteer students.

most influential marketing methods.\textsuperscript{21} As will be presented later, marketers should comply with regulations, including obtaining licenses, before being allowed to advertise directly to patients.\textsuperscript{22} Therefore, advertising methods in Saudi Arabia are not mostly different from the rest of the world.

In direct-to-physician promotions, corporations use different methods, such as providing gifts to health professionals,\textsuperscript{23} funding health professionals’ pursuit of continuing education and attendance at conferences,\textsuperscript{24} advertising in scientific journals, and sending sales agents to health professionals.\textsuperscript{25} The law allows companies to promote prescription and nonprescription medications to health professionals. However, there are many restrictions and requirements that corporations should comply with before interacting with health professionals.\textsuperscript{26} Saudi law does not permit the distribution of samples to patients, as samples are considered a way to inform only physicians about the product.\textsuperscript{27} It seems that pharmaceutical marketers can target physicians and other health professionals by all possible methods as long as they meet the requirements, such as acquiring licenses and disclosing particular information.\textsuperscript{28}

\textsuperscript{22} See Chapter II, infra.
\textsuperscript{23} Noha M. Zaki, \textit{Pharmacists’ and Physicians’ Perception and Exposure to Drug Promotion: A Saudi Study}, \textit{22 Saudi Pharm. J.} 528 (2014); Salman A. Bahammam et al., \textit{Attitudes and Behaviours of Physicians towards the Relationship with the Pharmaceutical Industry in Saudi Arabia}, \textit{26 E. Mediterranean Health J.} 323 (2020). Both studies found that most physicians and pharmacists who participate in their research have received gifts from pharmaceutical corporations in Saudi Arabia.
\textsuperscript{24} Zaki, \textit{supra} note 23, at 528. Corporations have paid for health professionals to obtain education and attend conferences.
\textsuperscript{26} See Chapter II, infra.
\textsuperscript{27} The Executive Regulation of the Law of Pharmaceutical Products and Facilities, \textit{supra} note 17, art. 13/2.
\textsuperscript{28} See Chapter II, infra.
In conclusion, businesses try to employ every possible type of promotion, whether directed to patients or physicians, for their benefit. As the research shows, most promotional means exercised worldwide are available under Saudi law. There are two fundamental methods the law expressly bans, namely, advertising prescription drugs directly to the public and distributing samples to patients. In addition, the law obligates corporations to meet particular regulatory conditions in direct-to-patient and direct-to-physician marketing. In the following section, the research will give an overview of the negative impact of misleading pharmaceutical marketing.

C. Misleading marketing and its impact on the right of patients to access medicine.

Pharmaceutical promoters have spent billions of dollars on promotions to attract as many buyers as possible. Such enormous spending would not exist if it were not profitable for corporations. The question here is whether pharmaceutical marketing is beneficial or detrimental to patients' interests. Some argue that promotions are advantageous for patients since they help educate them, whereas others believe pharmaceutical promotions are more disadvantageous. This research focuses on patient protection from misleading marketing, so it concentrates on promotions' negative aspects. This study is not meant to ignore the benefits of pharmaceutical marketing but to develop patient protection from misleading marketing.

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29 See Chapter II, infra.
31 Some statistics show that pharmaceutical corporations have spent more on marketing than on research and development within the last decades, but recently, other statistics show that for several large drug makers spending has shifted to an equal amount or more on research and development. Zachary Brennan, Do Biopharma Companies Really Spend More on Marketing Than R&D?, REG. FOCUS (July 24, 2019), https://www.raps.org/news-and-articles/news-articles/2019/7/do-biopharma-companies-really-spend-more-on-market.
There are many advantages of promotions. Both direct-to-patient and direct-to-physician promotions can contribute to the process of educating and updating health professionals and patients about medicines. Advertisements can motivate patients to visit and ask their provider about medication and help them to discuss more medicine choices instead of relying on physicians to start the conversation.\textsuperscript{33} Physicians can learn about new medications or be updated through promotional methods since corporations are presumed to know more about their own products.\textsuperscript{34} Therefore, promotions can be essential not only to introduce the brand, but also to deliver information about products. Being an information source makes promotions a key player in informing the patients and physicians about new medication and updates.

Nevertheless, including information is not necessarily always beneficial. It can be constructive only if the information is correct and accurate. Corporations are for-profit and they promote to make money. Many opponents claim that pharmaceutical corporations start to promote new products before safety information is wholly collected and released.\textsuperscript{35} They also use regular advertising strategies to increase their profits, disregarding the unique nature and risk of medications.\textsuperscript{36} For example, they use emotions and desires to motivate patients toward their products.\textsuperscript{37} Although promotions contribute to both physicians' and patients' learning, they can sometimes mislead them and negatively affect patients' healthcare.

Misleading patients and their physicians will likely lead patients to receive expensive or incorrect medicine, or to misuse medicine. It is true that corporations have the right to market

\begin{itemize}
  \item \textsuperscript{33} Ventola, \textit{supra} note 18, at 672.
  \item \textsuperscript{35} Ventola, \textit{supra} note 18, at 674.
  \item \textsuperscript{36} See Main, \textit{supra} note 32.
  \item \textsuperscript{37} Id. at 137.
\end{itemize}
their products freely. But patients have the right to be protected. Corporations in this regard practice their rights to make money, and patients practice their rights to health and well-being when accessing medicine. Healthcare and medicine are supposed to serve the human right of health first, not only increase commercial profits.

If patients need to purchase medications, they are not acting in the same capacity as when buying common consumer goods, which are generally not as risky as medications. Patients also do not choose medications based on their preferences. For example, a patient may choose to visit her physician to help mitigate her pain after having an injured hand or going through surgery. Nevertheless, she has no idea that a prescription of an opioid with a high dose, possibly as a result of inaccurate or manipulated information, can make her suffer from addiction for years. When she went to her physician, she did not visit the doctor to access the wrong medication or the wrong dose. She went to enjoy her right to healthcare, and she ends up as a victim.

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II: Saudi Law, Legislation, and Sources of the Study.

This part contains three significant sections: Saudi law and Islamic law, the hierarchy of Saudi legislation, and the sources of this study.

A. Saudi law and Islamic law:

The law of the kingdom of Saudi Arabia must comply with Islamic law. The Basic Law of Governance has asserted the Quran, and the Hadith [teachings of the prophets] are the two primary supreme sources of the legal system. These two primary sources of Islamic law are superior to all legislation, so laws shall comply with Islamic teachings. In addition to being the supreme source of law, Islamic law is the law when no written legislation exists. Islamic law also plays a role in interpreting legislation. Thus, Islamic law is essential in forming Saudi law in four vital aspects: being the highest in the legislative hierarchy, regulating uncodified areas, being a source of codified laws, and interpreting aspects of codified areas.

B. Hierarchy of Saudi legislation:

Saudi written legislation consists of different levels in a hierarchy, namely, basic laws, ordinary laws, decisions, and regulations. Basic laws are limited and govern fundamental public and constitutional matters. They are promulgated by Royal Order. The Basic Law of

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41 The scope of written laws is likely to change soon after the codification of Islamic Fiqh [Islamic jurisprudence] is complete. Islamic Fiqh has been a primary resource of Saudi law, and it will remain so. However, instead of being a direct source in many areas, it will be the source of codified laws. This will move the nature of Saudi law to be more similar to a civil-law system. See Frank E. Vogel, SAUDI BUSINESS LAW IN PRACTICE 31-34 (2019).
42 A written Saudi law, a single act, is called nzam. Id. at 29.
43 A Royal Order is a decision that the king enacts in his authority as the king of the kingdom without consulting the council of ministers or the Shura Council. Thus, it reflects the opinion and the power of the king. See Mohammad Almarzougi, AL-SULTA AL-TANDIMIYAH FEE AL-MAMLKA AL-ARABIA AL-SAUDIA [THE LEGISLATIVE AUTHORITY IN SAUDI ARABIA] 83-85, 356 (2003).
Governance and the Shura Council Law are two instances of basic laws. In contrast, most legislation becomes ordinary law, governing normal procedural or substantive matters. Ordinary laws are promulgated via Royal Decree.\textsuperscript{44} Most Saudi laws, such as media and publications laws, criminal laws, employment laws, commercial laws, and health laws, are considered ordinary. After laws, regulations come into the hierarchy.\textsuperscript{45} Regulations include binding legal rules, but neither a Royal Order nor Decree promulgates them.\textsuperscript{46} There are several types of regulations, such as administrative regulations and executive regulations.\textsuperscript{47} All laws should comply with Islamic law, and ordinary laws should not contradict basic laws. Regulations should not conflict with any law.

\textbf{C. Sources of this study:}

This study will examine the appropriate laws and regulations that address patient protection from misleading pharmaceutical promotions. In uncodified areas of law, the study will explore aspects of Islamic jurisprudence.\textsuperscript{48} This research is not designed to address a particular statute, but it is instead meant to answer research questions about patient protection. Seeking such an answer requires tracing several laws and regulations. In written laws, the research will rely on laws such as Basic Law of Governance (1992),\textsuperscript{49} Health Law (2002),\textsuperscript{50} Law of Pharmaceutical

\begin{footnotesize}
\begin{enumerate}
\item A Royal Decree is a decision signed by the king in his authority as the president of the state in a certain matter that has been discussed with both the council of ministers and the Shura Council. \textit{Id.} at 85-87, 362.
\item What is mentioned here is just an overview of Saudi legislative tools. There are other tools and details, which will not be important for the purpose of this research.
\item See Almarzougi, \textit{supra} note 43, at 88-92.
\item \textit{Id.}
\item Court judgments are not a primary source of law in Saudi Arabia but are a secondary source that can assist in understanding the law in practice.
\item Basic Law of Governance, \textit{supra} note 40.
\end{enumerate}
\end{footnotesize}

In terms of regulations, the SFDA regulates pharmaceutical marketing in Saudi Arabia. Within recent years, the SFDA has issued regulations, codes, and guidelines that are vital to this study. For instance, the SFDA issued the Regulations and Procedures for Approving Advertisements for Non-Prescription Medications (2014), the Transparency and Payments Disclosure Guidance for Medical Companies (2016), and Saudi Code of Pharmaceutical Promotional Practices in the Kingdom of Saudi Arabia (2018).

In addition, the research will rely on other legal and Islamic fiqh sources to answer many essential questions in uncodified areas of law. Some aspects of the research, such as civil liability and civil remedies, rely heavily on Islamic law as the main source. Moreover, international legislative tools, codes, and models will be used as additional sources of definitions and to clarify points when needed. Therefore, the research explores secondary sources to address questions in certain areas, and understanding Saudi law is significantly linked to the understanding of Islamic law.

55 Regulations and Procedures for Approving Advertisements for Non-Prescription Medications, supra note 16.
56 Transparency and Payments Disclosure Guidance for Medical Companies, the Saudi Food & Drug Authority (2016).

The right to health is the most essential right that needs to be protected from misleading marketing. The right to health is a fundamental human right, and the law should employ patient and consumer protection legislation to ensure access to accurate information that leads patients to enjoy the right of health and wellbeing properly. This part gives an overview of the right to health and access to medicine.

A. The right to health.

Saudi legislation has acknowledged the right to health. Healthcare is a subject explicitly addressed in the previous constitutional act, the Basic Instructions for the Hijazi Kingdom of 1926. The current constitutional act, the Saudi Basic Law of Governance, also states that the government should guarantee healthcare for every citizen. It recognizes the right to healthcare and public health separately from other human rights, such as social rights, the right to own and enjoy a secure shelter, environmental rights, and other economic and human rights. Moreover, the law defines healthcare as "preventive, treatment and rehabilitative services concerned with the health of the individual and the community at the primary, secondary and specialist levels." The law also emphasizes and clarifies the government's commitment to securing healthcare, promising to "insure availability of health care, without necessarily being directly provided or funded by the State, except as stipulated by the provisions of this Law."
Like Saudi law, fundamental international treaties have recognized and protected the right to health.\textsuperscript{63} The Universal Declaration of Human Rights (UDHR) broadly acknowledges the right to health. It mentions the right to health to include access to healthcare, and other necessary related rights, such as social services, food, clothes, and shelter.\textsuperscript{64} The World Health Organization (WHO) Constitution asserts that the right to health is not only the right to be free from illnesses but also the right to "\textit{the enjoyment of the highest attainable standard of health}" in the body and soul without discrimination.\textsuperscript{65}

Furthermore, the International Covenant on Economic, Social, and Cultural Rights (ICESCR) affirms likewise that the right to health is "\textit{the enjoyment of the highest attainable standard of physical and mental health.}" The ICESCR expands on how the enjoyment of health is achievable. It lists such enjoyment as improving child health, protecting the environment, preventing diseases, and preparing healthcare needs and equipment.\textsuperscript{66} International legal instruments have emphasized the right to health repeatedly, and the emphasis can extend to more details as it is in the ICESCR.

The concept of the right to health under Saudi law tends not to be as broad as the UDHR's and WHO's, but it is more focused on direct health rights.\textsuperscript{67} The right to health under Saudi law consists of public health and the right to healthcare. Also, Saudi law does not ignore other related fundamental social and economic rights but recognizes them independently.

\footnotetext[63]{International law compacts and treaties have been presented in this dissertation only to provide examples and help analyze Saudi law regardless of whether they are signed or ratified by the Kingdom of Saudi Arabia or not.}
\footnotetext[67]{See John Tobin, \textit{The Right to Health in International Law} 122 (2011).}
B- The right to access medication.

The right to access medicine is an essential part of the right to health in Saudi law and international law. This section focuses on this right because it is the most relevant part of the right to health to the subject of this research. If this dissertation is meant to protect the right to health, it is mainly for the protection of the right to access medicine. This section supports the idea that access to medicine is a crucial element of the right to health. It exhibits the right to access medicine under Saudi law and then international law.

Saudi law recognizes the right to access medicine as a part of the right to health. The Saudi Health Law includes fundamental provisions to ensure convenient access to medicine. The act underlines that the state should endeavor to provide healthcare and ensure public health, including the safety of medications and their uses. The state should undertake to supply medicine and ensure ideal use. The Ministry of Health (MOH) is responsible for regulating and controlling the drug market to assure availability, appropriate usage, and affordability. The MOH is responsible for ensuring the accessibility of health and medicine in Saudi Arabia. The law also recognizes that the availability of essential medications is within the meaning of primary healthcare. Therefore, Saudi health law guarantees the right of patients to access effective, safe, and affordable medicine. The law also distinguishes essential medicines and considers them as part of primary healthcare.

These international treaties have recognized the right to health, and humans cannot enjoy good health without appropriate medicines. The ICESCR has mentioned that medical treatment

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68 Health Law, supra note 50, at art. 3/4.
69 Id., at art. 17/4.
70 Id., at art. 5/7.
71 Id., at art. 4.5.
72 Id., at art. 1/3.
is necessary for people to obtain the right to health.\textsuperscript{73} The United Nations' General Assembly has asserted that access to medicine is a crucial element to accomplish the best possible level of human health.\textsuperscript{74} The assembly articulates that proper access to medications can be provided when affordability, effectiveness, safety, and quality are assured.\textsuperscript{75} Therefore, the right to access medicine is deemed a substantial part of the right to health.

**IV: Saudi Health System and the Process of Accessing Medicine.**

Understanding the nature and the structure of the health system is necessary to the comprehension of basic aspects of patients’ protection when accessing medicine. Patients cannot access prescription medicine without going through the health system processes. In this part, the research will give an overview of the Saudi health system and the process of accessing medicine.

**A. Saudi health system.**

The Saudi health system is divided into three levels; primary health care, secondary health care, and specialized health care.\textsuperscript{76} Primary healthcare units, general hospitals, and specialized hospitals are distributed all over the country. The government has predominantly funded and operated the healthcare system.\textsuperscript{77} In 2020, there were 504 hospitals in Saudi Arabia, 337 of which were public.\textsuperscript{78} The Ministry of Health has been the primary provider along with other

\textsuperscript{73} See the International Covenant on Economic, Social and Cultural Rights (1966) at art. 12.
\textsuperscript{74} G.A. Res. 12/24, (1) (Oct. 12, 2009).
\textsuperscript{75} G.A. Res. 12/24, (2) (Oct. 12, 2009).
\textsuperscript{76} Health Law, supra note 50, at art. 1.
\textsuperscript{77} See Alrasheedy et al., supra note 3, at 330.
governmental entities, such as university hospitals and military health services.\textsuperscript{79} The Saudi health system has been primarily public, but the private sector also operated 167 hospitals in that same year.\textsuperscript{80}

The private sector has increasingly played a greater role in providing healthcare in the last two decades. In 1999, the government established the Council of Cooperative Health Insurance,\textsuperscript{81} which has enforced a plan to require all private employers to provide health insurance for their employees and their families.\textsuperscript{82} This new requirement has contributed to expanding private healthcare that, in turn, encouraged considerable investment in private healthcare. In 2009, the Ministry of Health operated 244 hospitals.\textsuperscript{83} By 2012, they operated 259 hospitals, about 6\% more.\textsuperscript{84} In 2020, there were 287 Ministry of Health hospitals, an increase of approximately 11\%.\textsuperscript{85} However, there were 113 private hospitals in 2008.\textsuperscript{86} They had increased by around 22\% to 137 in 2012,\textsuperscript{87} and by another 22\% to 167 in 2020. The growth of private hospitals indicates how the private sector has expanded more than twice compared with the public sector in the last decade.

\textsuperscript{80} \textit{Key Health Indicators 2020}, supra note 78.
\textsuperscript{82} \textit{Id.}
\textsuperscript{85} It was stated that there were 337 public hospitals in 2020. This number includes hospitals operated by university and military branches. Only 287 out of 337 are operated by the Ministry of Health for that same year. \textit{Key Health Indicators 2020}, supra note 78.
\textsuperscript{86} Albejaidi, supra note 83, at 803-804.
The Saudi Vision 2030 has corroborated the private sector's growing role in the health system.\textsuperscript{88} The vision aims to privatize various public sectors, including healthcare.\textsuperscript{89} The plan relies on private health providers and insurance corporations as funders.\textsuperscript{90} Such privatization of public healthcare would be added to the massive recent investments in the private sector. The increasing shift to privatization, especially for essential services, heightens the significance of improved protection for patients. The profit factor can change many aspects of the patient health provider relationships, such as the quality of healthcare, the access to healthcare, and possible conflicts of interests. The 2030 Vision asserts the need for deliberate reconsideration of legislation to ensure their coherence with the new developments,\textsuperscript{91} and this study is to contribute to identifying several possible areas of developments.

Whereas most of the Saudi health system has been operated by the Ministry of Health and other governmental agencies, the face of the system will likely change as the 2030 Vision is implemented. The private sector will play a more significant role within the next decade. Such a shift will affect legislation, and rethinking consumer and patient protection is essential at this time.

\textsuperscript{88} Saudi Vision 2030, \textit{supra} note 1, at 29.
\textsuperscript{89} \textit{Id.} at 45.
\textsuperscript{91} Saudi Vision 2030, \textit{supra} note 1, at 81.
B. The process of accessing medicine.

Patients cannot access medicine autonomously. Most health systems in the world require specific procedures before approving pharmaceutical products, to ensure their safety and effectiveness. Additionally, patients cannot access many medications without medical prescriptions. In this section, the research will review how the approval and the prescription requirements interact with the patient's right to access medicine. This part briefly presents the Saudi Food and Drug Authority's (SFDA) and prescribing physicians' roles to answer several questions.

1. The SFDA role in regulating drugs.

The SFDA law was promulgated in 2007. One of the fundamental purposes of the SFDA is ensuring the safety of drugs for humans and animals. The SFDA has the authority to require specific standards for drugs and inspect them to assure such standards are met to determine their eligibility for approval. In the pharmaceutical area, the SFDA's role extends to include other aspects, not only approving drugs. It contributes to consumer protection in terms of drug safety.

The SFDA's role in this regard is meant to ensure that patients access effective and safe medication. Such procedures have a significant impact since they change how patients access medicine. These procedures are vital to protect patients from improper pharmaceutical products.

92 See Gail A. Van Norman, Drugs and Devices: Comparison of European and U.S Approval Process, 1 JACC BASIC TRANSL. SCI. 399 (2016).
93 SFDA Law, supra note 53, art. 1.
94 Id. art. 2.
95 Id. art. 5.
96 Id.
97 Id.
It is the front line of patient protection and a preventative strategy in the interest of patients. However, some argue that such a process can be a double-edged sword when slow procedures impede access to proper medicine. Critics think that such regulatory requirements can cause loss of patients' lives if approval is late or not given. Ensuring medication safety is necessary, but necessity should be measured proportionately with its cause.

As a result, many regulatory authorities have started to consider exceptional circumstances when authorizing medicines. Saudi law has granted SFDA the authority to allow non-banned medications for personal use in exceptional cases. This article has been mainly to help patients who have been treated abroad and have medications that are not registered in Saudi Arabia. As long as these medications are not banned, SFDA can issue a special permission based on a medical record. Moreover, the SFDA has adopted special procedures to authorize pharmaceutical products in a time of emergency. Accordingly, requiring authorization before using drugs can be seen as a restriction on patients' right to access medicine and as an assurance of safe and effective medicine at the same time.

2. The prescribing physician's role.

Even after the SFDA approval, patients cannot access all kinds of medications directly. The Saudi health system is not different, in that regard, from many health systems worldwide. Patients can directly access over-the-counter medications, but they need a prescription to access

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99 The Executive Regulation of the Law of Pharmaceutical Products and Facilities, supra note 17, at art. 25.
100 Id.
101 Id.
other medications. This is meant to ensure patients use the right treatment and the right doses depending on their health condition. This prescription requirement can also be controversial for many opponents, who call it medical paternalism.\textsuperscript{103} It can impede patient access to medicine if access to healthcare is expensive or impossible.

In Saudi Arabia, the Ministry of Health is responsible to ensure access to healthcare. The Ministry of Health has launched an application through which people can contact a physician for free and get necessary prescriptions immediately through email.\textsuperscript{104} If necessary, patients can schedule an appointment to meet a physician in the nearest primary care unit to continue treatment or do medical exams. This investment in technology is a remarkable step toward limiting obstructions that the requirement for prescriptions can cause.\textsuperscript{105} Patients can get prescriptions for free while they are going to the pharmacy.

There are concerns raised by the fact that the private healthcare sector will have a more significant role in the future, and the public sector role is likely to diminish. Whether this quick free access to healthcare and medicine will remain at the same level or not will be apparent in the future. The Ministry of Health has constantly confirmed that health insurance will be guaranteed to all citizens.\textsuperscript{106} Therefore, the kingdom will privatize healthcare and provide insurance to all citizens, which suggests that Saudi patients will likely access healthcare for free even in the future.

\textsuperscript{103} See FLANIGAN, supra note 98.
\textsuperscript{105} Id.
V: The Legal Protection of Patients from Misleading Pharmaceutical Marketing.

As patient protection is a necessity to help patients access their right to health, businesses consider marketing one of their rights. This part reviews patient protection history and developments and how consumer protection is related to patient protection. Moreover, the part explores justifications for patients' protection.

A. Overview.

The enormous growth of commercial activities worldwide has led to the increasing influence of businesses. The globalized drug sector is not an exception. As companies have become even more powerful, patients and consumers have become more vulnerable. Facing such challenges with traditional law or outdated consumer policies can be devastating to patients and consumers. There has been an international trend to develop the protection of consumers, including patients. There have been calls to deem consumer law itself as a human right. Consumer law is an effective tool in protecting fundamental human rights and economic human rights in particular. The United Nations and the World Health Organization have published guidelines to encourage policies for protecting consumers and patients among states.

Individuals have limited resources and capacities to deal with corporations through avenues of conventional laws. Since the industrial era began, the law has been continuously

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109 Id. at 21-22.
reformed to meet dramatic changes in the world. The industrial movement has had an enormous impact on human history. It has been built upon centralizing capital and production in immense entities, not only national or regional centralization but global. Such developments require updating policies and legislation to serve the purpose of justice.

Legal systems internationally have adopted policies that change as consumer interests develop. Some have seen consumer protection not only as a protection method but as a contributor to efficient economic functioning. Consumer law has focused on creating a systemic protection process to consolidate fair business practices. Such processes aim to accomplish several goals, such as balancing consumer-business relations, decreasing the costs of access to justice, protecting consumer safety, assuring availability of essential goods, and organizing consumers. One of the fundamental consumer rights is access to information. Consumers cannot decide independently if they are unable to obtain sufficient information about products. Misleading marketing can be an obstacle that can affect consumers’ awareness negatively. Consumer protection has played a role in regulating commercial marketing process to protect the public.

Legal systems vary in justifications for such protection as well as the nature of legal tools. Most systems, however, agree that conventional civil law cannot keep up its justice role with high efficiency because most consumer rights are based on small claims. Such limited claims in the long-complicated process of traditional litigation are highly ineffective for consumers. Another trend is that the law should not only be limited to remedial strategies when

\[111\text{ See generally Howells, supra note 107, at 145-175.}\]
\[112\text{ See HOWELLS ET. AL., supra note 108, at 10-11.}\]
\[113\text{ See UNITED NATIONS, GUIDELINES, supra note 110.}\]
\[114\text{ Id.}\]
\[115\text{ See HOWELLS ET. AL., supra note 108, at 2.}\]
protecting consumers. Preventative means should also be considered.\textsuperscript{116} As a result, lawmakers have embraced effective claims systems, and also enhanced means of controlling safety, quality, and accuracy of products and advertisements. Legal reforms in this regard have not been restricted only to civil law. They have extended to criminal and administrative aspects.\textsuperscript{117} Legal systems worldwide have considered adjusting procedural and substantive methods in private and public laws to improve proper protection for consumers. Such policies fit the historical developments that humankind have taken in managing economy and production.

Healthcare is one of the areas that has been privatized in many parts of the world.\textsuperscript{118} Health has been under the concern of consumer protection with other essential privatized services, such as water, power, and education.\textsuperscript{119} Countries that transform their service systems to depend on the private sector need to reconsider legislation after repositioning patients' relations with service providers. Drug production has relied more on the private sector.\textsuperscript{120} Medication production is not distinct from commercial production of other goods. Therefore, many consumer protection laws apply to patients as mass consumers who are recipients of mass production.

Patients must deal with businesses to access appropriate healthcare. Even if patients can benefit from general consumer protection, the World Health Organization has been eager to encourage countries to enact policies that secure safe access to information for patients.\textsuperscript{121} In

\begin{flushleft}
\textsuperscript{116} Id.
\textsuperscript{117} Id.
\textsuperscript{119} See HOWELLS ET. AL., supra note 108, at 7.
\textsuperscript{121} See WHO, ETHICAL CRITERIA, supra note 6.
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addition to the risks that patients and consumers face from businesses, patients experience higher challenges when accessing drugs due to the special nature of health information. The next section goes further to explain significant justifications of patient protection.

**B. Justification for Patient Protection from Misleading Pharmaceutical Marketing.**

Patients usually seek medicine to enjoy their health. Pharmaceutical corporations play a significant role in assuring the availability of medications for patients. Their role can start from supporting or conducting research through the distribution of medications. Pharmaceutical corporations operate as businesses, so they do their best to make money. Patients, on the other hand, seek to enjoy their health. If conflicts of interests exist between powerful corporations and individual patients, the law should assure a reasonable balance. Such balance should enhance a healthy and just economic atmosphere for patients and corporations. There are three substantial reasons for legal protection of patients from misleading pharmaceutical marketing: patients can face normal consumer problems, health information is more sensitive, and the role of prescribing physicians can be devastating.

One crucial explanation of why patients' protection is necessary is exactly the same argument in support of consumer protection from misleading advertising, such as protecting the right to health as a basic right and balancing consumers and corporations' bargaining positions. Protecting consumer basic rights, such as education and access to essential services, can also fit the right to health in the situation of patients. Misleading pharmaceutical marketing can cause healthcare to be meaningless or harmful when it leads patients to use the wrong medication or misuse the right one. For example, the opioid crisis in the U.S.A and other parts of the world has
demonstrated the role of marketing in causing misusage of medications\textsuperscript{122} and thus bringing devastating consequences on patients.\textsuperscript{123} Marketing of drugs can cause patients not only to spend more but also, more importantly, to suffer more and to die more. It can possibly be described as an act of corruption that turns the benefit of healthcare to serve someone's pocket instead of serving patients. As a result, the law should regulate pharmaceutical marketing to ensure fair access to the right to health.

Another typical consumer and patient rationale is that patients and corporations are not in comparable bargaining power. There are gaps between patients and corporations in financial and organizational capacities. Corporations, in general, have more economic capacity than patients. They can hire the best professionals and workers to fight for their interests, control drug supplies, and monopolize medications in certain cases.\textsuperscript{124} On the other hand, patients are separate individuals, usually with limited monetary resources and no ability to file expensive lawsuits. Thus, the law should adopt appropriate methods that fit patients' situations when advocating their rights, such as class actions, and create active consumer protection entities. In addition, if corporations do not expect penalties and compensations in proportion to their profits when violating patients' rights, the level of deterrence is probably not sufficient. The law should be designed to provide justice, so businesses will operate without negatively impacting patients' fundamental rights.

\textsuperscript{122} Opioids are a set of pain relievers that are widely prescribed to patients, and then have been proven to cause addiction. Some victims have ended up losing their lives. Scott E. Hadland, et al., \textit{supra} note 39. \textit{See also} Nguyen, et al., \textit{supra} note 39.

\textsuperscript{123} \textit{See} Nguyen, \textit{supra} note 39, at 1051-59 (demonstrating that physicians who receive payments were motivated to prescribe higher doses of opioids). \textit{See} Hadland et al., \textit{supra} note 39.

\textsuperscript{124} Here, the research is not opposing patent rights or patent protection. It is only to explain that patients face these circumstances as reality, and they should have stronger tools to protect their interests or at least make their voice be heard.
In addition to consumers’ common arguments, health information is sensitive. Patients do not use medications for its main purpose because they think it is delicious or looks good! They either use it because they think it is beneficial for their medical condition or their physicians think so. Patients' and physicians' decisions are supposed to be built on research. Short-term and long-term side effects of medications are generally based on research.\(^{125}\) Major trends in determining the best treatment protocols depend on latest research findings. However, both patients and physicians either depend on or are influenced by what pharmaceutical corporations select from research findings to appear on their products or advertisements. Most physicians consider marketing methods, such as sales representatives, as an information resource.\(^{126}\) Even if pharmaceutical corporations are obligated to update health professionals about their products, it is unclear, when a pharmaceutical representative is talking with a physician about a product, whether the representative is doing a legal duty to deliver scientific facts or just marketing. Patients are the final target of marketing, and they are mostly dependent on their physicians’ decisions. They are highly vulnerable, and the law should minimize marketing adverse effects in this regard.

Finally, patients are mostly dependent when accessing medications. All patient drug choices are conditional on proper authorization from the SFDA in Saudi Arabia. Most of their choices require prescriptions and, without a prescription, patients can only access over the counter medication. Such protective requirements are meant to assure safety, quality, and effectiveness for patients. Nevertheless, many unscrupulous pharmaceutical corporations have taken advantage of such requirements. They worked intensively to influence physicians – even the most ethical


\(^{126}\) Ibrahim & Bélanger, supra note 25, at 76.
ones. Physicians rely on pharmaceutical producers to inform them about new updates to their products, contributing to this problem.\textsuperscript{127} Physicians have power over patients, and this power has safety and quality justifications, but it should be measured. The law should assure that this power cannot be misused to harm patients.

In conclusion, protection of patients is substantial. Lawmakers have had to embrace various legal avenues to meet the new challenges, including general consumer policies. Patients cannot enjoy the right to health if they are in unfair bargaining positions and exposed with their physicians to misleading information sources. Legal protection of patients is necessary to ensure proper access to the right to health. The law should specifically support patient organizing efforts, take measures to ensure independence of information sources, and deter corporations via proportionate remedies and penalties.

\textsuperscript{127} Id. About 56\% of physicians believe that regular agent visits affect their medication selection. See Zaki, supra note 23, at 528. The study found that interactions between health professionals and pharmaceutical corporations affect the drug prescriptions.
VI: Pharmaceutical Corporations' and Physicians' Legal Relations with Patients.

Patients are the core of this research, and their legal relations with pharmaceutical corporations and physicians are important in determining future legal implications when damages occur. This part aims to build understanding of the nature of each relationship and then outlines challenges that will be addressed in this research. For example, patients have the right to access sufficient information about their treatment, and they also have the right of loyalty when dealing with physicians. Although these rights are recognizable under Saudi law, several challenges exist when establishing liability or seeking redress. First, this part presents pharmaceutical corporations' legal relations with patients. Second, it explores physicians' legal relations with patients. Finally, it previews areas to develop the protection of patients.

A. Patients' legal relation with pharmaceutical corporations (marketers).

Patients may find themselves in a situation where they need to use pharmaceutical products. They may have to obtain medications via a direct contractual relation with distributors or by other contracting forms. Sometimes, patients have only one or two drug choices, and at other times, patients may have many options, possibly including generic affordable medications. Patients or their physicians are supposed to base their decisions to use medications on scientific grounds. The decision to prescribe or to use a nonprescription medication depends on accessing adequate product information. Lack of access to correct information can result in many negative consequences to individual patients and communities.\(^\text{128}\) Therefore, the information that

\(^{128}\text{See Ashish Chandra & Gary A. Holt, Pharmaceutical Advertisements: How They Deceive Patients, 18 J. BUS. ETHICS 365 (1999). (Once the product has become familiar to the community, it is difficult to correct the general misunderstanding after the spread of incorrect or vague information.)\]
pharmaceutical producers present is crucial in determining the correct use, safety, and effectiveness of the medication for the patient’s particular medical needs.

The protection of patients from misleading information and misleading pharmaceutical marketing in particular is supposed to be statutory, not contractual. Consumer legislation usually assures the right of information and correct advertisements. Statutory protection can likewise extend to persons other than patients who are in a contractual relationship with marketers. Marketers intend to induce patients or their physicians to use or prescribe their medications. All audiences of such marketing efforts deserve protection since they are invited to contract. Consumers' and patients' protection from misleading marketing should not be limited to the parties in an enforceable contractual relationship. They also protect individuals in the community. This fact is significant to consider, especially with the absence of a comprehensive consumer law in Saudi law.

Pharmaceutical corporations as producers are obligated to provide precise facts about their products under Saudi law. They have a duty under general rules of civil law to be honest and transparent and avoid altghyryr or altdyys [deception or omission]. Access to sufficient

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129 Islamic fiqh ponders offers that are targeted to the public under the condition that the advertiser expresses his/her intention to formulate a contract. For example, saying that whoever wants to buy a named medication for $50 is welcomed. Consequently, listing a product in a website with its price and availability can reflect that the seller is intending to contract, and this can formulate an offer. However, in most cases, media advertisements do not include material facts of the product, and thus, they can be mere invitations to contract. Invitation to contract is a stage before a valid offer is formulated. The consumer would have the choice to offer to buy the advertised product, and the advertiser has the right to accept or not. The Saudi E-commerce Law has considered the electronic advertisement as a contractual document that is complementary to contracts and binding for all parties. The law does not state clearly that advertisements are offers, but it takes into consideration that what a normal consumer understands from advertisements can build their decision to enter into contractual relations. It is similar to pre-contracting negotiations when an offer and acceptance are not established yet, but such negotiations are still significant to interpreting the contract, and what the parties intend to achieve. MUHAMMAD TAQI USMANI, FIQH ALBYWE [JURISPRUDENCE OF SALES] 1/35-38 (2015). See M'EYD ALTWALBH, MS'EWLYH ALM'ELN 'EN AL'ELAN ALMDL Fy ALMAQ'E WALASWAQ ALELKRWNYG [RESPONSIBILITY OF ADVERTISER FOR MISLEADING ADVERTISING ON WEBSITES AND ELECTRONIC MARKETPLACES] 14 (2021). See MOSTAFA ALZARQA', ALMDKHL ALFQHY AL'EAM [THE GENERAL JURISPRUDENTIAL INTRODUCTION] 405 (2004). E-Commerce Law, Royal Decree No. M/126 Date. 7/11/1440 A.H., art. 10 (2019) (Saudi Arabia).
accurate information has also been a basic right of consumers.\textsuperscript{130} Furthermore, pharmaceutical corporations have specific duties, as drug producers.\textsuperscript{131} The law requires them to provide adequate information about their medications to health professionals.\textsuperscript{132} They are also required to update public content about their medications, such as label and leaflet information.\textsuperscript{133} As will be presented in the next chapter, advertising information should be based on certain approved publications that the law requires corporations to update with recent developments. The law mandates that the pharmaceutical industry provide and update information about their products to patients and physicians. Noncompliance with such duties can result in administrative, civil, or/criminal consequences.\textsuperscript{134}

\textbf{B. Patients' legal relation with physicians.}

The patient/physician relationship is totally distinct from relations with manufacturing corporations. Medicine has been historically regarded as a humane profession.\textsuperscript{135} It is grounded on trust and high ethical standards. Patients are supposed to have a sort of a contractual relationship with physicians. However, most violations of patient protection from misleading pharmaceutical marketing are violations of statutory legal rights. Physicians have legislative obligations, such as loyalty to and transparency with their patients, and these duties cannot be

\begin{flushleft}
\textsuperscript{130} See UNITED NATIONS, GUIDELINES, supra note 110, at 5.
\textsuperscript{131} The law includes requirements for ensuring accuracy of information. See The Executive Regulation of the Law of Pharmaceutical Products and Facilities, supra note 17, at art. 6/6, 34/5.
\textsuperscript{132} Id.
\textsuperscript{133} Id.
\textsuperscript{134} The law is meant to obligate pharmaceutical corporations to perform these duties. Thus, violations of such duties can result in civil remedies and criminal penalties. Violations of the Pharmaceutical Products and Facilities Law can result in financial penalties that reach SR 5000000 (about $1,333,333.33), closure of facilities for no more than 180 days, and/or revocation of facility licenses. In addition, liability can be established, and civil remedies can be sought under the general civil law, which will be discussed in chapters III and IV. Law of Pharmaceutical Products and Facilities, supra note 9, art. 35.
\textsuperscript{135} SAUDI COMMISSION FOR HEALTH SPECIALTIES, CODE OF ETHICS FOR HEALTHCARE PRACTITIONERS 10 (2014).
\end{flushleft}
waived by any mutual agreement.\textsuperscript{136} Patient protection policies are mostly legislative and enforced regardless of the details of the contract.\textsuperscript{137}

Patients rely on their physicians to determine the risks and benefits of using most medications. With such prescribing power, physicians are required by law to respect patients' rights and interests.\textsuperscript{138} One duty related to protection from misleading marketing is the duty to inform patients of accurate information. Physicians are obliged to obtain and develop their knowledge with the latest developments.\textsuperscript{139} Physicians' resources should be scientific and independent to serve their patients properly. In addition, physicians have to inform patients about the diagnosis and treatment, including the possible advantages and disadvantages of each treatment.\textsuperscript{140} The latter side of the duty cannot be accomplished without the first side, so physicians who lack access to facts from reliable sources cannot help their patients appropriately and cannot deliver accurate information to their patients.

Another substantial duty is loyalty. The medical professional highly relies on confidence. Even patients with knowledge still need to trust in their physicians' judgment and knowledge. Physicians have a fiduciary duty to do whatever is necessary for their patients' interests. The law has reinforced such duties, which have been basic standards in medicine. The law has asserted that physicians are obligated to practice medicine in the best interests of their patients.\textsuperscript{141} The law has been even clearer when stating that a health practitioner may not ask, accept, or take any

\begin{itemize}
\item \textsuperscript{136} Legal rules accompanied by criminal punishments are meant to be mandatory and imperative, not supplementary, so agreements in violation of imperative provisions are void.
\item \textsuperscript{137} Patients’ protections are based on statutory or judicial patient rights. Patient rights as consumers are ensured in legislation or respected by courts as judicial principles. The bases of patients’ protection are presented later in chapter III when dealing with establishing civil liability.
\item \textsuperscript{138} Law of Practicing Healthcare Professions, \textit{supra} note 52, at art. 5, 12.
\item \textsuperscript{139} \textit{id.} at art.7.
\item \textsuperscript{140} \textit{id.} at art.18.
\item \textsuperscript{141} \textit{id.}, at art. 9.
\end{itemize}
benefit in exchange for prescribing certain drugs or equipment.\textsuperscript{142} Therefore, physicians should select a medication because it fits their patients' needs. If a prescription is written to fulfill a physician's interests, it can violate the loyalty duty and result in several legal consequences. Violation of such legal duties can lead to professional, civil, or/criminal consequences.\textsuperscript{143}

C. Areas of development of the protection of patients.

As it has been presented in this part, Saudi law has the foundation to build up patients’ protection under general rules of law. Saudi law has statutes that assure patients’ protection in the patient/marketer relationship in several aspects, but a comprehensive consumer law does not exist yet. Consequently, many basic consumer protections from misleading marketing, such as the basic general consumer right to access information, have not been expressly mentioned in primary sources. In patient/physician relations, health laws have played a more effective role in assuring many related rights, such as the loyalty right. This research will expand later to present examples of challenges that can result from a lack of codification in consumer law.

Patients can face other challenges before or after any damage occurs. In terms of \textit{ex-ante} regulations, patients may be not effectively protected by existing procedures, such as disclosures and licensing. Lack of such protections can complicate other substantive rights, such as evidence when proving liability as chapter III presents. Also, patients may find compensatory damages restricted under Saudi law. Chapter IV addresses key challenges in this regard and raises

\begin{flushright}
\begin{itemize}
\item \textsuperscript{142} \textit{Id.}, at art. 12.
\item \textsuperscript{143} The law imposes civil, criminal, and disciplinary (professional) consequences when violations of such duties occur. In addition to the possible applicable civil compensation, the law states that health professionals can be punished by jail and/or financial penalties, or only financial penalties depending on the type of violation. Professional punishments can include a warning, a financial penalty, and/or revoking the license to practice medicine. \textit{Law of Practicing Healthcare Professions, supra} note 52, at art. 28-32.
\end{itemize}
\end{flushright}
questions of compensation under Saudi law. Sometimes, patients’ choices to pursue their claims are limited to expensive means, making the cost of accessing justice significant. The next chapters will present the law in these areas and raise the related challenges, hopefully to contribute to improving the protection of patients under Saudi law.

**Conclusion**

Chapter I has provided an overview of the fundamental aspects of this research into the protection of patients from misleading pharmaceutical marketing. Chapter I has introduced pharmaceutical marketing and related concepts. It has also summarized vital Saudi law. It links this research with the right to health, as the central right that this patient protection serves. There has also been an exploration of the structure and developments of the Saudi legal system. The legal protection has been established in the chapter to present leading consumers' and patients' protection trends. Finally, the research has explored legal duties of drug corporations and physicians that have connection with pharmaceutical marketing. The chapter laid the groundwork for further expansion in next chapters.

Misleading pharmaceutical marketing can be a serious challenge to patients' right to health, which is recognized under Saudi and International law. The U.N. and the WHO guidelines have encouraged states to adopt policies to protect patients from misleading marketing. Saudi Arabia has several laws that regulate pharmaceutical marketing and meet such challenges. The law in this regard aims to protect patients from various adverse implications of misleading marketing, such as spreading inaccurate health information and harming the patient-physician relationship. Such protection derives from the law and is not affected by the contractual status under Saudi law. Even if protection exists under Saudi law, several questions
can arise about areas that need more development for a better protection of patients. In the next chapters, the research will answer many fundamental questions about patient protection under Saudi law before identifying areas that need more development.
Chapter II: Ex-ante Protection (Government Regulations).

Introduction

This chapter presents substantial ex-ante regulations that can contribute to protecting patients from misleading pharmaceutical marketing. The Saudi Food and Drug Authority (SFDA) is the primary player in implementing laws and regulating this marketing. Exploring the laws and regulations of pharmaceutical marketing within SFDA's jurisdiction will lead to an understanding of the SFDA's role in pharmaceutical marketing and its responsibility to protect patients from misleading marketing.

SFDA’s regulations include preventative procedures that can reduce patients' harms from misleading marketing in the first place. These procedures can also play a role in establishing corporations' or physicians' liability toward damaged patients. Understanding the role of the SFDA and the laws & regulations that it enforces can answer key questions in this study. It can illustrate the distinct methods that Saudi lawmakers employ to enhance patient protection and lead to a comprehensive understanding of the Saudi legislation that interacts in one way or another with patient protection.

The chapter starts with an overview in Part I and then Part II addresses general rules that can apply to direct-to-patient and direct-to-physician marketing. Part III focuses on SFDA regulations specifically applicable to direct-to-patient advertisements. Part IV presents SFDA regulations applicable to direct-to-physician promotions. Part V raises the enforceability challenge for aspects of ex-ante regulations.
I: Overview.

The UN consumer protection guidelines encourage countries to adopt policies that can protect consumers from misleading marketing.\textsuperscript{144} The WHO Ethical Criteria for Medicinal Drug Promotion also states that countries should regulate pharmaceutical promotions with proper measures to ensure reasonable medication use.\textsuperscript{145} Legal systems have adopted different policies to regulate pharmaceutical marketing, such as traditional and/or self-regulatory policies.\textsuperscript{146} Every legal system chooses tools that are consistent with its general structure.

Businesses work to market their products, and they have incentives to increase their revenues rather than to assure accuracy. Their focus is on how advertising can attract patients or consumers.\textsuperscript{147} Protection of patients from misleading marketing cannot always work with conventional expensive legal tools, such as litigation.\textsuperscript{148} Therefore, laws tend to foster suitable procedures and appropriate punishments to protect patients through preventing and/or deterring violations of patients’ rights.

\textit{Ex-ante} safeguards work more efficiently to protect patients, especially in the case of limited damages when an individual patient may be seeking small claims. Lawmakers, as a result, tend to adopt policies that can help to control marketing, requiring it to be constructive and truthful, to restrict possibilities of harm to patients. In this chapter, the focus is on how SFDA procedures help promotional practices to be more accurate, and what are the impacts of such SFDA procedures on the protection of patients.

\textsuperscript{144} See UNITED NATIONS, GUIDELINES, supra note 110, at 14.
\textsuperscript{145} WHO, ETHICAL CRITERIA, supra note 6, at 5.
\textsuperscript{146} See HOWELLS ET. AL., supra note 108, at 19-46.
\textsuperscript{147} Id. at 108.
\textsuperscript{148} Id. at 2.
The SFDA is responsible for regulating the pharmaceutical industry in Saudi Arabia. Its role includes ensuring product safety, quality, and effectiveness, so it has a vital part in ensuring proper access to medications. SFDA’s role is not only in licensing pharmaceutical products but also in ensuring that the products remain safe and effective during their license period. The law grants the SFDA the authority to take the necessary steps to assess the risks and suggest restraints, such as suspending the license and withdrawing the product from the market if necessary.

The SFDA’s role extends to ensuring adequate and accurate access to information as well. Knowledge about medications is complex and involves high risks. Patients and their physicians rely fully or in part on drug producers to provide information about products. For example, the kind of information provided about uses, doses, and side effects can have a significant effect on patients’ lives and well-being, either positively or negatively. This information can also increase or decrease sales of pharmaceutical products depending on the approved uses and doses. Corporations may try to claim more uses and doses to increase sales. Thus, medication information is sensitive because it can affect patients’ health and producers’ financial records at the same time. The SFDA’s role is important to ensure such information is credible.

The SFDA has a crucial role in setting standards that assure the accuracy of information provided to patients. For instance, the SFDA requires licensing of advertisements and disclosure of essential information about payments and contractual relations between corporations and

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149 SFDA Law, supra note 53, art. 3.
150 See Law of Pharmaceutical Products and Facilities, supra note 9, art. 24, 33.
151 SFDA Law, supra note 53, art. 3. See also Templates for Labeling Information, SPC and PIL, SAUDI FOOD & DRUG AUTHORITY (2020). The SFDA is responsible for investigating medications and ensuring compliance with safety, quality, and effectiveness standards, including information resources such as labels, leaflets, and summary characteristics.
health professionals.\footnote{See Part III, section B, and Part IV, section B, \textit{infra}.} The SFDA requires pharmaceutical advertisers or promoters to use SFDA-approved information in marketing.\footnote{See Part II, section A-A, \textit{infra}.} This chapter will address such requirements, and the effectiveness of these requirements in protecting patients from misleading marketing will be examined later in this study.

This chapter will include government policies to protect patients from misleading pharmaceutical marketing based mainly on the Pharmaceutical Products and Facilities Law and its Executive Regulation and other SFDA regulations.\footnote{See Chapter I, part II, section B, \textit{supra}, for overview of the hierarchy of legislative tools of Saudi Law.} Guidelines and regulations that the SFDA and the Ministry of Health have enacted are considered administrative decisions.\footnote{See HMDY MHMD AL’EIMY, ALQANWN ALEDARY FY ALMMLKH AL’ERBYH AL’ED ‘EWDYH DRASH MQARNH [ADMINISTRATIVE LAW IN THE KINGDOM OF SAUDI ARABIA: A COMPARATIVE STUDY] 295 (2010). If the administration publishes a rule that is meant to regulate comprehensively and not to deal with a specific matter, it is still an administrative decision and equal in authority to other decisions that are meant to deal with individual cases.} The Saudi Administrative Court has defined administrative decisions as the disclosure of the administration’s binding directive that is within its legal authority and with the purpose of creating legitimate and possible legal consequences.\footnote{The Saudi Appellate Administrative Case No. 36/T/6 1423H Case No. 165/3/Q 1422H.} Even if guidelines are not meant to be equal to traditional executive regulations, they are still a representation of the administration’s will and deemed as administrative decisions.

Administrative decisions cannot themselves create criminal sanctions in Saudi law,\footnote{Basic Law of Governance, \textit{supra} note 40, art. 38 (stating that crimes and punishment shall only be imposed based on a Shariah or a statute provision.)} but the administration has power to enforce regulations and guidelines via other methods. For instance, businesses which deal with government authorities usually have long-term deals, so they adhere to the instructions from such government authorities to keep a good relationship with the
administration. In addition, authorities always have the right to take further administrative steps, such as officially cautioning businesses. Consequently, regulations can play a role in governing pharmaceutical marketing, but they cannot impose criminal punishments, as will be discussed later in Part V.

The SFDA has worked in the last two decades to develop its policies to ensure the safety, effectiveness, and quality of drugs in Saudi Arabia. The SFDA aims to set standards for information distributed by pharmaceutical producers to reduce negative effects of pharmaceutical marketing. In the next parts, the chapter addresses policies and tools that the SFDA adopts to prevent negative impacts of pharmaceutical marketing.

II: SFDA General Requirements and Measures to Ensure Information Accuracy in Marketing.

Saudi law has surrounded pharmaceutical promotions with certain requirements. Several of these requirements, assumed in all sorts of pharmaceutical marketing, are in compliance with general conditions, such as public order and registration of the promoted product. Nevertheless, there are other requirements specifically for particular kinds of marketing, such as requiring direct-to-patient advertisements to be for only non-prescription medication and requiring disclosure of payments between physicians and corporations. This part explores the common general requirements and measures that are applicable to both direct-to-patient and direct-to-physician marketing. The part addresses the requirements in section A, and then section B describes the measures that are taken to ensure enforcement of such requirements.
A. General Requirements for Promotional Materials and Activities.

The SFDA requires pharmaceutical marketers to fulfill a set of criteria that is based on principled reasons. Promotional materials and activities should meet minimum standards to ensure accuracy due to their possible effect on patients' and physicians' medication choices. Saudi law requires promotions to: 1) comply with morality and the public order; 2) promote an SFDA registered product; 3) include correct facts and clear language; 4) contain SFDA approved information; and 5) state the medication's generic name.

1. Compliance with morality and the public order.

This requirement that promotional material be based on the acceptable cultural and religious norms is to protect the community at the time of the action. Every society has its principles and values that are based on religious and cultural standards. The ideas of public order and public morality are relative, and they can be different from one society to another. Even if several legal systems agree to comply with a certain cultural or religious principle, they are likely to interpret such principles differently. Even a single society can have different interpretations of the same principle from one time to another.

SFDA regulations emphasize that pharmaceutical marketing should respect Islamic law, society values, and public decency, and this emphasis applies to direct-to-patient and direct-to-physician marketing. Saudi media laws have banned publishing what violates Islamic Shariah,  

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and that includes advertising. The law adds a standard that advertisements should not contain content that can harm families or embarrass parents in front of their children. Also, illegal activities, such as crimes, should not be presented positively in advertisements. Advertisements should not include improper words. Media laws and SFDA regulations have affirmed this presumption of protecting society and religious norms.

Islamic Shariah as stated here, is broader than its transactional parts, and it extends to other devotional and ethical aspects. According to the general practice of promotions in Saudi Arabia, it is hard to define exactly what the doctrine of Islamic Shariah is here. An SFDA document that regulates advertising of medical devices states that advertisements shall comply with norms and customs of the community and shall not violate the public decency. The SFDA has the discretion to determine what satisfies this requirement. Decisions to approve or not approve advertisements are inaccessible to researchers, so it is difficult to build a comprehensive understanding of the general practice.

2. SFDA registration of the product.

The law presumes that the promoted product should be registered with the SFDA. A registration process is required to permit sales and usage of a pharmaceutical product in Saudi
Promoting a product before registration has no point if the targeted patients and physicians cannot access the products in Saudi regions. Also, the SFDA should ensure the safety and effectiveness of products before marketing. This is one of the primary purposes of establishing the SFDA. This requirement is to assure that no pharmaceutical product is promoted in Saudi Arabia without going through the SFDA process of proving the products’ safety and effectiveness and becoming available in the market.

3. Marketing should be apparent and not deceptive.

Marketers use many methods and styles to attract patients to their products, and sometimes, they go far beyond reasonable marketing into areas that constitute acts of deception. It is a common sense that deception counteracts justice for patients, and thus it is fundamental for legal and ethical schools to express objection to deceptive acts. Islamic law adopts well-rooted anti-fraud doctrines. Saudi legislation has also addressed fraud, deception, or misleading information in consumer cases in many laws and regulations, such as Anti-Fraud law, Law of Printed Materials and Publication, and Law of Pharmaceutical Products and Facilities. SFDA’s regulations have also confirmed this trend by requiring clarity and adherence to certain standards to avoid deception in both direct-to-patient and direct-to-physician marketing.

167 Law of Pharmaceutical Products and Facilities, supra note 9, art. 17.
168 SFDA Law, supra note 53.
169 See Chandra & Holt, supra note 128.
In direct-to-physician promotions, interactions between pharmaceutical marketers and physicians can be in several forms. The law has confirmed that information should be accurate in all situations.\textsuperscript{174} The law states that pharmaceutical corporations and manufacturers are responsible for ensuring that health professionals have access to updated correct information about prescribing medicines.\textsuperscript{175} Studies or quotations of opinions that are used to support the medication should reflect facts and should not be confusing or misleading.\textsuperscript{176} Comparisons between products should not diminish other products and mislead health professionals.\textsuperscript{177} The law prohibits doubts about the effectiveness and safety of other registered products or claiming, with no scientific basis, that certain products do not have safety concerns.\textsuperscript{178} Funded symposia, meetings, and lectures should deliver accurate information about medications.\textsuperscript{179} Sales representatives should have sufficient knowledge that enables them to deliver complete and accurate information.\textsuperscript{180} Saudi law states the general requirements of precise drug information in direct-to-physician promotions and confirms such requirements when regulating most promoting methods.

In direct-to-patient advertisements, the law confirms that pharmaceutical corporations, manufacturers, and health professionals are responsible for delivering updated, accurate, unbiased information about medications to patients.\textsuperscript{181} When communicating with patients directly, marketers should inform patients about drugs, diseases, and other related information.

\textsuperscript{174} Law of Pharmaceutical Products and Facilities, \textit{supra} note 9, art. 34.
\textsuperscript{176} Saudi Code of Pharmaceutical Promotional Practices, \textit{supra} note 15, at art. 2 (5, 8) & art. 4.
\textsuperscript{177} \textit{Id.} at art. 2 (10).
\textsuperscript{178} \textit{Id.} at art. 2 (14, 15).
\textsuperscript{179} \textit{Id.} at art. 7 & 9.
\textsuperscript{180} \textit{Id.} at art. 10.
\textsuperscript{181} \textit{Id.} at 7.
with high transparency and neutrality.\textsuperscript{182} Advertisements should not mislead consumers through comparisons with other products and containing phrases that can be interpreted unreasonably.\textsuperscript{183} Reasonableness is probably linked to SFDA approved information. SFDA has required approved information in all forms of marketing as will be presented in the next section, and this can be a basis for what SFDA considers reasonable information. It is notable that SFDA regulations restrict direct-to-patient advertisements more than direct-to-physician promotions. While comparison is allowed if done objectively in direct-to-physician marketing, it is not allowed at all in direct-to-patient marketing. This is just an example of how the regulations deal with the gap between the normal lay person and the expert person.

4. SFDA Approval of the Information.

The SFDA should approve all information before marketing. Pharmaceutical marketing can significantly affect patients' and health professionals' awareness and medication choices, so the SFDA is not tolerant of many kinds of claims spread when promoting medications. Requiring only SFDA-approved information in marketing materials can help minimize the spread of misleading information. Such a requirement is also presumed in direct-to-patient and direct-to-physician promotions.

In direct-to-patient advertisements, advertising materials should be consistent with the information provided in one of the following: the approved patient leaflet, the approved summary of product characteristics, the approved product's external label, or the approved

\textsuperscript{182} Id. at art. 3.
product's external packaging. These four sources have been reviewed previously when the product was registered. In direct-to-physician promotions, the SFDA still requires the SFDA approved uses, doses, administration, precautions, contraindications, and side effects. Such requirements help minimize the risk of including inaccurate information in advertisements, which can enhance patients' protection.

5. Stating the generic name of the medication.

Saudi law has stipulated including the generic name of medications next to the brand name. Pharmaceutical marketers always try to focus on the product’s brand name. However, this stipulation of the generic name is significant because it links the medication with its scientific origins. It can tell that this brand name means this type of medication, which probably has or will have affordable generic alternatives. The law requires mention of the generic names of medications in direct-to-patient and direct-to-physician promotions.

In direct-to-patient advertisements, the law requires including the active ingredient name if possible and the medication's generic name. The size of the generic name should be no less than one third of the brand name size. In direct-to-physician promotions, all marketing materials directed to health professionals should include the generic name. Including the generic name in marketing gifts, such as calendars, is optional and constitutes an exception to the

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189 Id.
general rule. The law aims to link medications to their generic names so that patients and their physicians learn or remember facts instead of commercial names. Focusing on facts rather than brands and made-up presumptions makes medication access more efficient for patients.

B. Measures.

SFDA adopts requirements to prevent or limit negative effects of misleading information and measures to ensure that pharmaceutical corporations and health professionals comply with such requirements. The SFDA uses disclosures, licenses, and the Scientific Office (SO) of each pharmaceutical manufacturer to assure compliance with regulatory and statutory requirements. The SO is a department within individual pharmaceutical companies, which has supervisory duties to ensure corporations work in a more scrupulous way. This part addresses only the Scientific Office because it engages in both direct-to-patient and direct-to-physician marketing. Part III of this chapter presents the licensing since it is required for direct-to-patient advertisements, and Part IV addresses the disclosure requirement because it is required in related direct-to-physician promotions.

Every pharmaceutical corporation that has a registered manufacturer in Saudi Arabia is obligated to have a Scientific Office (SO). The law requires that the office manager be a Saudi licensed pharmacist who works fully in this position. The SO is responsible for implementing the regulations and instructions of the SFDA. The SO should review promotional materials

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191 Id. at art. 2-18. The Saudi Food & Drug Authority, Regulation for Promoting Memorial Items 2 (2011). See Part IV of this chapter that addresses gifts.
192 See Alghasham, supra note 187, at 24.
193 Law of Pharmaceutical Products and Facilities, supra note 9, art. 6. See also The Registration Rules of Pharmaceutical, Herbal and Health Product Manufacturers and their Products Guidelines, supra note 185.
194 The Executive Regulation of the Law of Pharmaceutical Products and Facilities, supra note 17, art. 6/4.
195 Id. at art. 6/5.
before publication. The SO is the information provider for pharmaceutical products and the reviewer of marketing content to ensure compliance with SFDA-approved information.

The SO is supposed to interact with health professionals and researchers to provide information, fund scientific activities, and fund continuing education programs. The SO can contribute to other research and scientific activities. Free samples can only be distributed through the SO. The SO is responsible for updating the SFDA on information regarding the quality and effectiveness of medications.

The SO is supposed to conduct its business with adherence to ethical and scientific bases and the Saudi Code of Pharmaceutical Promotions Practices. When exploring the SO’s role in law, it can seem that it is an independent entity for scientific matters. However, the SO cannot be totally independent from the interests of pharmaceutical corporations. It is difficult to imagine that the SO can be an effective player in assuring compliance with the law while it is fully funded and employed via drug producers.

196 Id. at art. 6/6.
197 Id.
198 Id.
199 Id.
200 Id.
201 Id.
III: Means Designed to Police Direct-to-patient Advertisements.

This kind of marketing is directed at the public and requires regulatory work that is designed to protect the public. This part will focus on requirements and measures that the SFDA takes to regulate direct-to-patient advertisements.

A. Requirements.

1. The medication should be nonprescription.

Marketers can apply to obtain SFDA approval of direct-to-patient advertising only to advertise nonprescription medications.\(^{203}\) Saudi law does not allow prescription medicines to be advertised directly to patients.\(^{204}\) Patients cannot access prescription drugs directly, so it appears that the Saudi regulator does not see a justification for allowing such medications to be advertised straight to patients. Instead, the law allows promoting prescription medication to health professionals, such as physicians, since they are mostly responsible for selecting the proper medication for their patients. As a result, this can be seen as a crucial step to reduce patients' risk to access risky medications or misuse them.

2. Including safety and education statements.

The law requires advertisers to include warnings or educational statements about significant facts.\(^{205}\) Audible advertisements should state that “this product has several side effects. To know more about them, consult your doctor or pharmacist and read product


\(^{204}\) The Executive Regulation of the Law of Pharmaceutical Products and Facilities, supra note 17, art. 31/1.

When advertising painkillers, the regulation requires the inclusion of the following language: "if symptoms persist for more than 48 hours, please consult a doctor." Advertisers should append awareness statements to other pharmaceutical products as well. These statements can play a helpful role in informing or reminding patients of facts that can decrease advertisement harms to patients. In addition, the law requires pharmaceutical producers to write the statement "not for sale" on samples. This is required because the law does not allow samples to be sold but only to be distributed for free in limited cases. Statements can be effective and instrumental in warning or informing patients of vital related facts about medications.

3. Comparison with other products is not allowed.

In direct-to-patient advertisements, comparing advertised products with other products is not allowed. This contrasts with direct-to-physician promotions, in which comparing products is acceptable with certain conditions. The law here aims to distinguish between experts and lay persons when receiving promotional content. Advertisements usually tend to include a reasonable level of exaggerations about advertised products or services. While health professionals have adequate knowledge to evaluate information in advertisements, patients may be at higher risk of being misled. The Saudi law bans all comparisons in direct-to-patient advertisements to limit risks.

206 Id.
207 Id.
209 The Executive Regulation of the Law of Pharmaceutical Products and Facilities, supra note 17, art.13.
212 HOWELLS ET. AL., supra note 108, at 108.
4. Internet advertising requirements.

Recently internet advertisements have been on the rise and businesses have been motivated to advertise on many popular platforms, such as Twitter and Snapchat. The law requires online advertisements to comply with all other regular requirements. Moreover, the law has added other requirements that online advertisements should not link to other medical or pharmaceutical information sources unless SFDA approves that. Also, information intended to be for health professionals should not be published or advertised on a public website. Online advertisements are still required to comply with general promoting requirements, and in addition, they should ensure their content does not violate SFDA approved information.

However, in practice, control of online advertisements is more challenging than traditional advertisements. The Saudi Central Commission for Audiovisual Media has recently required social media figures (influencers) who use their popularity to advertise for businesses to obtain a license called *mawthoq*. Advertising with lack of such license can have consequences not only for influencers but for business marketers (owners of advertised products). Online advertisements can be more complicated to regulate since they are decentralized, more personalized and can raise privacy issues, and difficult to track. Regulation of these requires non-traditional methods that aim to protect the audience with effective enforcement.

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213 See generally Ben Said et al., *supra* note 21, at 9.
215 *Id.*
216 *Id.*
B. Measures.

Approval request (Licensing):

SFDA enforces its requirements through licensing. Marketers are required to file an application and state basic and other information, such as whether the advertisements are audible, visual, or written and the target audience of the advertisement.\(^{219}\) SFDA reviews applications after submission and either approves or returns them with comments.\(^{220}\) The applicant has 90 days to correct the application based on SFDA's comments.\(^{221}\) Applicants can petition to SFDA within 60 days of the decision date\(^{222}\) and then seek judicial review in the administrative court. In case of approval, the license is valid for a year, and renewal is required to continue distributing or broadcasting the advertisements.\(^{223}\) After approval, the advertiser is not allowed to make any change without SFDA approval.\(^{224}\)

Licensing is a process that can help considerably in preventing violations of the law. Licensing includes all types of direct-to-patient advertising. SFDA's role is to ensure that the general and specific requirements of advertisements are fulfilled and that advertisements are not published before approval and remain in compliance for a year. This continued oversight can be beneficial to patients' protection. There is a judicial review to assure that SFDA does not violate

\(^{220}\) Id.
\(^{221}\) Id.
\(^{222}\) Id.
\(^{223}\) Id.
\(^{224}\) Id.
businesses’ rights. However, it is still unclear what steps are taken by the SFDA when violations of such requirements occur, and many standards are still ambiguous.

IV: Means Designed to Police Direct-to-physician Promotions.

Promotors target physicians through distinct kinds of promotions that have special characteristics and certain requirements. Unlike direct-to-patient advertising, direct-to-physician promotions can be for prescription and nonprescription medications. This part addresses the requirements and measures that are meant specifically to regulate direct-to-physician marketing. Such requirements are meant to increase transparency and reduce the influence of misleading marketing on physicians.

A. Requirements for each type of direct-to-physician promotions.

1. Payments.

Direct payments are illegal under Saudi law. The law prohibits health professionals from obtaining any monetary or in-kind benefits from pharmaceutical corporations when they promote or direct patients to use or buy a particular product or service. Pharmaceutical corporations are banned from paying health professionals directly to encourage them to prescribe their products. This ban affirms the general duty of physicians to work for their patients’ best interests.

225 See Law of Procedure before the Board of Grievances, Royal Decree No. (M/3) Date. 22/06/1435H, art. 13 (2019) (Saudi Arabia).
226 Law of Practicing Healthcare Professions, supra note 52, at art.12.
227 Id.
229 See Law of Practicing Healthcare Professions, supra note 52, at art. 5.
2. Funds and Gifts.

Although corporations cannot make direct payments, they can fund other physicians' and health institutions' activities and grant certain kinds of gifts and resources. SFDA regulations have restricted financial funds and gifts by requiring reasonableness and certain limits. This section addresses these types of allowed support and overview related restrictions.

First: Reasonable funds and compensations.

The law mentions three main kinds of funds: institutional funds; fund for symposia, meetings, and continuing health education; and individual funds.

- Institutional fund.

The law allows hospitals among all health institutions to accept funds from pharmaceutical corporations.\(^{230}\) Saudi law defines hospitals as every place prepared to receive patients, examine them, treat them, and admit them.\(^{231}\) Funds can be directed to private and public hospitals in the form of furniture or equipment.\(^{232}\) It seems that listing furniture and equipment is to indicate that the fund should be in-kind, not monetary. In addition, when the regulation presents these examples, it states, "in the form of assistance to furnish a department or to purchase a device."\(^{233}\) The regulation states clearly the purpose of such fund to be related to hospital operations. By restricting in-kind funds, the law probably intends to exclude the possibility that corporations may fund doctors’ clinics. However, some private hospitals have partnerships to operate physicians' clinics.


\(^{231}\) Law of Private Health Institutions, Royal Decree No. M/40 Date. 03/11/1423H, art. 1 (2003) (Saudi Arabia).


\(^{233}\) Id.
within a hospital. It can be unclear, in those cases, if the funds are directed to a hospital or a doctor’s clinic. It is unclear also why funds can be justified for hospitals, especially private hospitals, if they have even a possibility to affect physician’s medication selections in any way.

- Symposia, meetings, and continuing health education.

Pharmaceutical corporations can organize or fund scientific events.\textsuperscript{234} SFDA regulations state that all professional, marketing, or scientific events should comply with all laws and instructions.\textsuperscript{235} The regulations state that the main purpose of these events should be to educate, to enhance the audience's scientific knowledge objectively, and to promote healthy discussions.\textsuperscript{236} Funds for individuals and the hospitality level at these events will be discussed next under individual funds.

- Individual funds.

The law allows pharmaceutical corporations to support scientific activities and continuing education programs, and allows health professionals to attend scientific conferences.\textsuperscript{237} These events are supposed to develop the knowledge of health professionals.\textsuperscript{238} The support to individuals to attend scientific events should include only actual costs, such as travel tickets, registration fees, and staying fees.\textsuperscript{239} Reimbursement should be based on actual receipts.\textsuperscript{240} Corporations should not pay health professionals

\textsuperscript{234} The Executive Regulation of the Law of Pharmaceutical Products and Facilities, \textit{supra} note 17, art. 6/6.
\textsuperscript{236} \textit{Id.}
\textsuperscript{237} The Executive Regulation of the Law of Pharmaceutical Products and Facilities, \textit{supra} note 17, art. 6/6.
\textsuperscript{239} \textit{Id.}
\textsuperscript{240} \textit{Id.}
for any kind of entertainment directly or indirectly.\textsuperscript{241} Parties not participating in the event, such as family members and companions, should not be reimbursed.\textsuperscript{242}

The law requires reimbursement to be reasonable.\textsuperscript{243} The standard for reasonableness here is to pay what health professionals would usually pay for themselves.\textsuperscript{244} The law also requires the event to be within a proportionate period to its scientific substance.\textsuperscript{245} The law does not ban corporations from taking social responsibility. Still, it has restricted the kind and scope of funds to ensure that corporations do not use them for non-scientific purposes.

Although corporations are legally restricted when dealing with health professionals financially, they still influence health professionals. Such funds can probably cause some health professionals to be biased toward a brand, even unconsciously. Corporations’ funds here can help health professionals to avoid paying cash for their expenses, and these savings can be equal to the value of expensive gifts or direct payments. So, these funds can affect physicians’ ability to make neutral decisions about patient health and medication selections.\textsuperscript{246} It is crucial to consider policies that can help professionals focus on conducting their professional duties and benefit from such fund. This can probably be achieved through limiting direct interactions between corporations and physicians involving a third party, such as a non-profit organization to manage such fund and opportunities.

\textsuperscript{241} Id.  
\textsuperscript{242} Id.  
\textsuperscript{243} Id.  
\textsuperscript{244} Id.  
\textsuperscript{245} Id.  
\textsuperscript{246} See Ibrahim & Bélanger, supra note 25, at 76.
Second: Gifts and educational materials.

The regulations and guidelines permit certain types of gifts to be given to health professionals. They distinguish between educational materials and gifts.

- Educational materials.

Corporations can provide physicians with educational materials. Informational materials include books, and scientific references. The law requires that these materials should be within a reasonable price range.

- Gifts.

The regulations have allowed pharmaceutical corporations to give gifts to health professionals. The SFDA has required gifts to be related to the office and professional use and state examples of gifts, such as pens, notes, and calendars. Gifts should include the product's name, and marketers have the choice to include the commercial or generic name. Gifts have to be in-kind and should not exceed 50 Saudi Riyals for each gift [about $13.33]. The total gifts amount for a year should not exceed 500 Saudi Riyals [about $133.33]. The law has expressly stated that the amount should reflect the value, but it is unclear how the value would be measured. The law does not specify if the cost will be measured according to the market value or the actual cost.

248 Id.
249 Id.
252 Id. at art. 2-17.
253 Id.
3. Sales representatives.

The law does not allow anyone other than professional pharmacists to work on promoting and introducing pharmaceutical products.\textsuperscript{254} The law encourages the creation of pharmaceutical marketing where science and professionalism are superior to commercial interests. SFDA regulations have placed significant obligations on pharmaceutical marketers.\textsuperscript{255} Marketers should ensure that their sales representatives are informed of their legal and ethical duties, trained well, and adequately educated about the corporations' promoted products.\textsuperscript{256} Sales representatives are required to provide a summary of the promoted product's characteristics.\textsuperscript{257} Sales representatives must inform their corporations of any additional information that is related to the products, such as side effects.\textsuperscript{258} They should not use unacceptable ways to meet physicians.\textsuperscript{259}

As stated earlier in this chapter, the law requires the scientific office (SO) of each company to ensure that all marketing materials, such as the Summary of Product Characteristics (SPC) are precise. Such qualifications and constraints can enhance the best practices of those agents’ work. The question remaining is, even if the information is precise on paper, what about the conversations? According to many studies, sales representatives are the top source of information for physicians in Saudi Arabia.\textsuperscript{260} It is unclear if representatives focus on delivering facts or achieving commercial targets when meeting health professionals.

\textsuperscript{254} Law of Pharmaceutical Products and Facilities, \textit{supra} note 9, art. 11.
\textsuperscript{256} \textit{Id.} at art.10-1.
\textsuperscript{257} \textit{Id.} at art.10-2.
\textsuperscript{258} \textit{Id.} at art.10-3.
\textsuperscript{259} \textit{Id.} at art.10-5.
\textsuperscript{260} \textit{See} Chapter I Part V Section B, \textit{supra}.
4. **Providing samples.**

Samples should be distributed to introduce the product to health professionals, and they should not be sold, prescribed, distributed, or kept in pharmacies.\(^{261}\) The law does allow health professionals to distribute samples to patients, as needed, in exceptional situations.\(^{262}\) Free samples should not exceed 1% of the total imported or locally manufactured quantities.\(^{263}\) As mentioned earlier in this chapter, the statement "Free samples" is required to be written on all samples.\(^{264}\) Samples have been a way to lead both patients and prescribing physicians to a particular brand. The law has restricted distribution of sample medications to minimize the risks of unscrupulous practices, such as selling samples or not informing patients of their medication choices.

5. **Advisors and Lecturers.**

The SFDA regulates pharmaceutical corporations’ contracts with advisors and lecturers to obtain consulting services and organize lectures.\(^{265}\) These contracts have been covered in the regulation because they can justify direct payments to physicians and other health professionals. The regulation states that these payments should be reasonable, to cover actual costs incurred by the advisor and the lecturer when performing the services or giving the lecture.\(^{266}\) In the case of advisors, the law states expressly that corporations can compensate them for their time.\(^{267}\)

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\(^{261}\) The Executive Regulation of the Law of Pharmaceutical Products and Facilities, _supra_ note 17, art.13.


\(^{263}\) The Executive Regulation of the Law of Pharmaceutical Products and Facilities, _supra_ note 17, art. 13-4.

\(^{264}\) _Id._ at art. 13-1.


\(^{266}\) _Id._ at art. 8, 9-4.

\(^{267}\) _Id._ at art. 8-1.
There is no express prohibition of payments to lecturers, but the law requires pharmaceutical corporations to disclose their relationship with the lecturer.\textsuperscript{268} Advising contracts should also be submitted to an SFDA website and advisors should disclose their free and paid advising services.\textsuperscript{269} Information presented in the lecture should be scientific, medical, and pharmaceutical information.\textsuperscript{270} Information that the advisor provides to marketers should be used appropriately.\textsuperscript{271}

As noted, the law aims to regulate contracts and payments between health professionals and pharmaceutical corporations so that those relationships are transparent and serve its main purpose. Regulating such relationships can help to limit questionable payments between professionals and corporations. It also can let the audience for lectures and presentations know the nature of the relationship between lecturers and funders only if such information is publicly accessible or disclosed before the lecture. The audience can then consider that when evaluating the credibility of the information from the lecture.

B. Measures.

One of the most common influences on health professionals is money. Some pharmaceutical marketers have used indirect payments to health professionals for marketing purposes unscrupulously. Humans can be influenced by gifts and scholarships even if they are given in good faith. Certainly, there are cases where possibilities of corrupt practices and direct payments exist. Since money can be a key factor in inducing unscientific and sometimes even

\textsuperscript{268} Id. at art. 9-3.
\textsuperscript{269} Id. at art. 8-G.
\textsuperscript{270} Id. at art. 9-2.
\textsuperscript{271} Id. at art. 8-E.
unscrupulous practices, the law measures compliance with these obligations by requiring financial disclosure.

The law requires pharmaceutical corporations and physicians to disclose all kinds of funds or payments if they exceed 50 Saudi Riyals [$13.33] each time and 500 [$133.33] Saudi Riyals in total during a year.\textsuperscript{272} The law lists examples of payments, such as advising fees, lecture fees, course fees, support for attendance of educational events, support for research and educational scholarships, support for attendance at symposia and conferences, hospitality payments, and provision of scientific books and tools.\textsuperscript{273} Corporations are required to inform health professionals of their duty to disclose payment information to the SFDA.\textsuperscript{274}

Requiring disclosure is a way to make physicians and corporations accountable. Physicians and corporations cannot, under law, use any of the legally permitted funds and reimbursements to hide illegitimate payments that can harm patients' interests. Since this dissertation seeks to evaluate patients' protection, the main concern here is what happens if a corporation or a health professional fails to meet the disclosure requirements. The protection of patients can depend greatly on the answer to this question.

\textsuperscript{272} Id. at art.11.  
\textsuperscript{273} Id.  
\textsuperscript{274} Id.
V: Towards More Enforceability of Ex-Ante Regulations.

Protection of patients from deceptive pharmaceutical marketing starts with effective ex-ante means. As presented previously in this chapter, Saudi law has adopted several significant methods to regulate such marketing. This includes, for example, regulating information in direct-to-consumer advertisements when the law requires advertisements to comply with SFDA approved information. The law has also regulated direct-to-physicians marketing to prevent conflicts of interests and minimize unethical interactions between health professionals and pharmaceutical corporations. The law has adopted two important measures, licenses and disclosures, to enhance objectives such as transparency and accountability. These ex-ante requirements can play a role in minimizing the occurrence of possible violations of patient rights and subsequently avoid the risk of high cost of access to justice, substantively and procedurally.

Although Saudi statutory law and administrative regulations have regulated marketing to patients and physicians, those provisions should be reviewed to assess the effectiveness of such procedures and measures in protecting patients. These ex-ante regulations play a role in governing marketing to prevent patient damages and in interpreting general laws and rights regarding patient’s protection. Such assessment should fit within the general goal of rethinking the protection of patients from misleading pharmaceutical marketing as whole, so the scope should be reasonably measured to serve such purpose and should not extend further.

Saudi law has adopted several policies and mechanisms that are similar to many comparative laws. Regardless of what should be done to develop such policies, this research argues that enforceability should be dealt with before any other specific concern. Lack of enforceability can decrease the effectiveness of even the most developed ex-ante policies.
Developing the enforceability of laws can be achieved through various methods and strategies, such as assuring the proper funds and resources for the competent executive authority, SFDA in this case, to meet enforceability demands. From a legal point of view, the level of enforceability is linked to many vital aspects, such as the power of the legislative instrument that has required such obligation. The other is the implications that can result when such an obligation is violated.

As for the power of legislative instruments, obligations can be stated in any legislative tool, including normal laws or regulations in the case of ex-ante procedures. However, the type of legislative tool can affect the implications significantly. The consequences of violating such ex-ante procedures can be only administrative, such as warnings if required in administrative regulations. If such ex-ante procedures are imposed in a normal law, the implications can extend to criminal punishments. Under Saudi law, a number of ex-ante policies and procedures have been expressly mentioned in ordinary laws (statutes), but other significant requirements and measures are regulated by administrative regulations, which raises questions regarding whether they are backed by criminal sanctions or not. Such concerns are fundamental to determining the level of enforceability of such regulations.

Saudi statutes have extended some policies and procedures that are meant to protect patients from misleading pharmaceutical marketing, such as article 13 of the Pharmaceutical Products and Facilities Law which states a principle regarding distribution of samples. However, other rules as significant as requiring disclosures from health professionals and pharmaceutical corporations regarding mutual contracts and payments have not been established based on statutes but through administrative regulations. This can be an essential cause of lack of

\[275\] See Law of Pharmaceutical Products and Facilities, supra note 9, art. 13.
enforceability. Under Saudi law, the basic law of governance states that crimes and criminal punishments shall only be enacted by a law.\footnote{Basic Law of Governance, supra note 40, art. 38.} Regulations, such as the one requiring disclosures, are not considered laws but administrative decisions. Laws shall be promulgated by a Royal Order or a Royal Decree depending on the nature and type of such law.\footnote{See chapter I Part II.} Since disclosures rules are not imposed via either a Royal Order or decree, noncompliance with these rules do not result in criminal punishments.

Understanding relations between pharmaceutical corporations and health professionals can be vital in reducing illegal activities of pharmaceutical marketing that are linked to considerable money. How can an administrative decision that is not backed by proportionate penalties motivate involved parties to report mutual payments and contracts? In the U.S, the law requires disclosures of payments to physicians of any sort such as cash, consulting fees, and educational funds.\footnote{Affordable Care Act, Pub. L. 111-148, Section 6002 (2010), \url{https://www.congress.gov/bill/111th-congress/house-bill/3590/text}.} Failure to comply with such legal requirements can result in financial penalties that can reach a million dollars.\footnote{Id.} Such a requirement is meant to achieve a level of transparency and promote ethical standards in pharmaceutical marketing.\footnote{Tim K. Mackey & Bryan A. Liang, Physicians Payments Disclosure Under Healthcare Reform: Will the Sun Shine?, 26 J. AM. BD. FAM. MED. 327-331 (2013).} Therefore, Saudi lawmakers should reconsider many of the \textit{ex-ante} policies, such as disclosures, to ensure that potential penalties can deter violators appropriately.
Conclusion

The aim of this chapter was to provide an overview of *ex-ante* policies and procedures that are part of the SFDA’s role as the main player in regulating and implementing laws related to pharmaceutical marketing in Saudi Arabia. The chapter explored general SFDA requirements to approve direct-to-consumer advertising as well as conditions that are required in direct-to-physician marketing. The chapter presented three important measures, such as the scientific office, licenses, and disclosures. The focus then shifted to raise the challenge of enforceability as the primary impediment that causes such policies and procedures to be less effective or ineffective in protecting patients from such deceptive or misleading marketing. In Part V, this chapter argued that the enforceability challenge has been fundamental and should be considered before anything else. The part suggested that disclosure requirements should be imposed in laws that are promulgated by a Royal Decree to be backed by deterring criminal means.
Chapter III: Civil Liability

Introduction

This chapter addresses civil liability under Saudi law when misleading pharmaceutical marketing causes damage to patients. It answers essential civil liability questions to understand how patients can establish liability in direct-to-patient and direct-to-physician marketing. Then, the chapter raises fundamental challenges and explores possible solutions. Establishing civil liability is the first step that patients must deal with when seeking proper compensations. Part I gives an overview of civil liability fundamentals under Saudi law. Part II addresses civil liability elements. Part III raises challenges and proposes solutions to improve patients’ protection when seeking to establish liability.
I: Overview.

The idea of patients’ protection as explored earlier in this study has been to assure and enforce the basic rights to health and access to medicine and other related rights, such as the right to access information.\textsuperscript{281} As it was presented, lawmakers work to enforce these legal rights either through administrative, criminal, and/or civil means.\textsuperscript{282} This research concerns mostly the civil aspects of patient protection, and this chapter discusses civil liability, which is the first recourse when damaged patients seek redress for their sufferings. Subsequently, chapter IV will address compensatory damages that are considered under the law, and that patients can seek after establishing liability.

Saudi civil law has been generally uncodified. The main direct source of this law has been Islamic \textit{fiqh} so far.\textsuperscript{283} This chapter presents primary aspects of civil liability that patients experience if trying to establish marketers’ and/or physicians’ liability. Saudi law lacks a comprehensive civil code and a codification process is still ongoing.\textsuperscript{284} This chapter addresses two aspects – liability of marketers and liability of physicians. Although there is no specific legislation that addresses marketer’s liability, the Law of Practicing Healthcare Professions includes articles that regulate the liability of health professionals.\textsuperscript{285} Islamic \textit{fiqh} is the only source in the absence of a codified law and the explanatory source in presence of a codified law.\textsuperscript{286} As a result, addressing the civil liability of pharmaceutical marketers and physicians

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\textsuperscript{281} See Chapter I, Part VI.
\textsuperscript{282} See Chapter I, Part V.
\textsuperscript{283} See Chapter I, Part II.
\textsuperscript{284} Lawmakers have been working to codify civil law in the Kingdom of Saudi Arabia. See Part III of this chapter.
\textsuperscript{285} See Law of Practicing Healthcare Professions, supra note 52, at art. 26-27.
\textsuperscript{286} See Chapter I part II.
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cannot be conducted without addressing aspects of Islamic *fiqh* and Saudi legislation, if exists in the concerned subject matter.

There is no codified Saudi law that can be deemed a comprehensive product liability or marketing liability statute. Several duties can be inferred from general rules and certain statutes can help in building a general understanding of marketer’s liability, such as aspects of the Commercial Anti-fraud Law and the Law of Printed Materials and Publication.287 In contrast, health legislation includes more expressions of patients’ rights that can contribute to patients’ protection significantly. The Law of Pharmaceutical Products and Facilities and the Law of Practicing Healthcare Professions have stated important express duties that fundamentally protect patients’ rights, such as requiring licensing of advertisements and requiring physicians to refrain from practicing medicine for their own personal interests.288 This chapter starts from general rules in Islamic *fiqh* since a general codification does not exist yet and draws on particular statutes if applicable.

In Islamic *fiqh*, the civil liability question is answered under what is called *aldman*. The scope of *aldman* theory is not limited to civil liability, but it certainly includes civil liability as it is known in comparative law.289 *Aldman* is translated literally as assurance, and Islamic jurists have been defining several approaches. One definition is the obligation to compensate damaged persons for the financial and personal injuries they have suffered.290 It aims to preserve people themselves and their financial interests and to deter violators, causing them to take necessary

289 Although questions of civil liability are answered under *aldman* in Islamic *fiqh*, the concept of *aldman* extends to aspects of criminal liability.
290 WHBH ALZHYLY, NZRJT ALDMN FY ALFQH ALESLAMY [*ASSURANCE THEORY IN ISLAMIC FIQH*] 21-22 (2012).
care to respect other’s rights.  

Aldman is divided into distinct types, such as *algshb* (usurpation of property), *al’eqd* (contract), and *aletlaf* (destruction).

The type of Aldman most applicable to this study is *aletlaf*, assuring recovery from wrongful conduct that causes harm to others. The perpetrator in this case violates a right that is respected by law. Codified laws have assured many but not all patient’s rights, and others are recognized in Islamic *fiqh*. For example, the right of truthfulness in dealings and the right to access information are not stated in a general consumer law, but they are still recognized under the general rules of Islamic law. In contrast, there are other statutory rights, such as the right of loyalty, and the right to respect patients’ lives and wellbeing and refrain from harming them. These legal rights are based on the law, not the contract and can be protected by criminal penalties. Contract provisions that mention these rights only confirm them, not to

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291 Although the idea of deterrence can exist in compensation, deterrence here is not probably meant to be only the aim of civil compensations but also criminal punishments since aldaman rules are not restricted to civil aspects. See Id. at 22.

292 *Algshb* is the act of taking over the property of others. See Vogel supra note 41, at 225.

293 *Dman al’eqd* or the contractual assurance in Islamic *fiqh* is different from the concept of contractual liability in other legal systems. While other legal systems compensate financially for breach of contractual obligations, Islamic *fiqh* allows financial compensations for only financial destructions, not all contractual breaches. Other non-financial remedies can be considered in case of breach that does not result in actual financial loss. See Vogel supra note 41, at 225.

294 *Aletlaf* classically tends to discuss recovery from destruction of property in the Hanbali school. This chapter defines destruction to include personal liability in addition to liability in case of destruction of property. This classification has also been adopted by several jurists when discussing aldaman as a general theory. See Id. at 240; Alzhyly, supra note 290, at 24-26; Mostafa Alzarqa’, Alfel Aldar wa Aldman FY [The Harmful Act and Its Guarantee] 63-66 (1988).


296 Islamic law requires honesty and transparency in transactions that are backed by civil, criminal, and religious means. Alslmy, supra note 171, at. 51-60. (2004). In addition, Saudi legislation considers commercial deception a crime. See The Executive Regulation of the Law of Pharmaceutical Products and Facilities, supra note 11; Law of Pharmaceutical Products and Facilities, supra note 9, art. 34.

297 See The Executive Regulation of the Law of Pharmaceutical Products and Facilities, supra note 17, art. 6/6. (The law requires drug corporations to inform patients and their physicians with updated product information).

298 Law of Practicing Healthcare Professions, supra note 52, at. 5, 12. Physicians have the duty to protect safety, dignity, and lives of their patients and refrain from taking advantage of their patients.

299 Id., supra note 5, art. 27. The law lists several reasons that can be a basis to raise the civil liability of a health professional that includes failure to meet considered medical practices.

300 E.g. Id., supra note 5, art. 28-30. The law imposes criminal penalties when patient rights are violated, including the right to take medical decisions based on the particular patient interest and the right to obtaining patients’ consent
impose them. These rights are ensured either by legislation or well-established fiqh principles, and they play a significant role in the protection of patients even if other rights are not mentioned in primary sources. This chapter will discuss what statutes mention and what they do not, and what key developments are needed to ensure better statutory protection.

Although civil liability in issues of patient protection can mostly be grounded on non-contractual bases, consequences can affect contracts. When patients are damaged because of misleading information, they are likely to be in a contractual relationship. That is certainly the case if they have misused the medication due to such information. If patients, for example, have been able to prove deception, this can result in considering the contract voidable or revocable (khyar alfskh). In some cases, the economic value of medication is not significant for an individual damaged patient. However, in the case of class actions, expensive medications, and medical malpractice, the value can be great and can even affect the defendant considerably. Still, for most individual patients’ mere restitution of the medication’s value cannot be as effective as compensation that results from the damage itself. Later, this research will address compensation and class actions, and the next part of this chapter will discuss the civil liability elements that are considered under Saudi law.

301 Islamic fiqh grants contractors the right to either pursue or revoke a contract in certain cases, such as when a defect exists in a product and in case of deception. See ALZHYLY, supra note 10, at 3103-4.
II: Civil Liability Pillars (elements).

After exploring the general background, it is time to address each element of civil liability under current Saudi law. These rules rely heavily on Islamic fiqh, which refers to elements as alrkn or pillars.302 The Saudi judiciary has varied their ways of dealing with elements of civil liability. Some judgments have expressly mentioned such elements,303 and other judgments have implied them.304 Patients have to establish the three elements of civil liability that are similar to other legal systems as well, namely, al't'edy (wrongful conduct), aldlrr (damage), and alefda' (causation),305 and they have to prove such elements either when seeking to establish marketers’ or physicians’ liability. The aim of this part is to describe liability elements under Saudi law, to understand patients’ position when establishing such liability, to examine if primary statutory sources protect patients expressly in medical malpractices and consumer cases, and to pave the way for the following third part that highlights major areas of development.

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302 Alrkn in Islamic Fiqh is a part of something that cannot exist without it. See EYAD BN NAMY ALSLMY, ASWL ALFQH ALDY LAYS'E ALFQYH JHLH [THE PRINCIPLES OF JURISPRUDENCE THAT A JURIST CANNOT ACCOMMODATE TO IGNORE] (2005).

303 Some court judgments mention liability elements explicitly. E.g., The Saudi Administrative Case No. 2591 1438H. E.g., The commercial Court Case No. 239 1441A.H. Appellate Court decision No. 2239 1443A.H. (2022) Published online https://sjp.moj.gov.sa/Filter/AhkamDetails/39956, See also E.g., The commercial Court Case No. 1938 1442A.H. Appellate Court decision No. 1739 1443A.H. (2022), https://sjp.moj.gov.sa/Filter/AhkamDetails/41001.

304 Implying elements is also common in almhknh al'eambh (the general court) and the Sharia Health Panel decisions. E.g., The Sharia Health Panel Case No. 7/436 & Date. 25/02/1436H.

305 See ALZHYLY, supra note 290, at 24-26. See also VOGEL supra note 41, at 240-48.
A. Alt'edy (harmful conduct).

Islamic jurists use the word alt'edy to refer to the act of transgressing or violating one’s legal obligations. Persons who commit alt'edy overstep what is legally permissible for them to do and, as a result, transgress the respected rights of others. Islamic fiqh obligates the wrongdoer (almt'edy) to compensate victims for the destruction the wrongdoers cause under Aldman rules. Whether this wrongdoer is a minor or an adult and commits the tort intentionally or unintentionally does not affect his obligation to compensate. Both pharmaceutical marketers and physicians have a general duty to refrain from harming others. This section discusses establishing wrongful conduct particularly in direct-to-patient and direct-to-physician marketing and provides examples for each type of marketing.

1. The harmful conduct in direct-to-patient advertisements.

Wrongful conduct in the case of direct-to-consumer advertisements can be established when patients are harmed because of misleading information in advertisements. Advertising is considered misleading if it includes deceptive or untruthful information that can directly or indirectly deceive patients or misguide them. Misleading can be through including untruthful

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307 Id.
308 The legal guardian will certainly be responsible to compensate on behalf of incapacitated persons in this case. See AHMD 'EBDALLH ALQARY, MLH ALAHKAM ALSHR'EYH [SHARIAH RULINGS JOURNAL] 443 (Ebdalwhab Abwslyman & Mhmd 'Ely eds., 2005).
309 If Islamic Fiqh has tended to protect the victims by not requiring the intent and the legal capacity as requirements for civil compensations, it has certainly given the intent and the legal capacity significance in case of criminal aspects, especially in cases of personal harms. In addition, the applicability of compensation in personal injuries can be affected by the applicability of criminal punishments in several circumstances. See ALZHYLY, supra note 290, at 25. See also Ch IV, Part III.
310 The E-commerce law, supra note 129, at art. 11; see also SECRETARIAT GENERAL OF THE GULF COOPERATIVE COUNSEL, MSHRWE ALNZAM (ALQANWN) ALMUWHD LHMAYH ALMSTHLK LDWL MMLS ALTEAWN LDWL ALKHLYJ AL'ERBYH [Draft of the Unified Consumer Protection Law for the Countries of the Cooperation Council for the Arab States of the Gulf] art. 2, 9 (2016); see also WHO, ETHICAL CRITERIA, supra note 6, at 5-9.
information or presenting selective facts and omitting others to lead patients to inaccurate beliefs about the product.\textsuperscript{311} The general rule here is the perpetrator of conduct that causes harm to others must compensate for the harm they have caused.\textsuperscript{312} However, general rules are broad and can be interpreted and applied differently. The best protection for patients as consumers is by expressly governing consumer rights in a precise practical manner that is comprehensible, especially for patients and merchants.

The first step for patients seeking to establish wrongful conduct due to misleading advertisements is to prove that their rights have been violated according to a general principle, such as deception or the right to access accurate information as consumers. Their grounding can be based on Islamic \textit{fiqh} or proper legislation when applicable. The information that patients claim to be misleading should be material in leading the patient to contract and then misuse the product.\textsuperscript{313} Patients have the general right to access truthful information about the product.\textsuperscript{314} If the deceptive information is about usage, doses, effectiveness, or ingredients of the product being promoted, this can at least be a violation of a patient’s right to access truthful information. The existence of misleading information in advertisements can satisfy the element of harmful conduct (\textit{al't'edy}). Here, advertisers, by spreading such untruthful information, can be violators of patients’ rights to access correct information about the product. The right to access correct information is not settled as a general principle in a primary source due to lack of comprehensive

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\textsuperscript{311} See ALTWA?BH, \textit{supra} note 129, at 20-21. \\
\textsuperscript{312} The Document of Kuwait for the Unified Civil Law of the Coop. Couns. for the Arab States of the Gulf, \textit{supra} note 10, at art. 261. \\
\textsuperscript{313} See ALZHLY, \textit{supra} note 10, at 3069-72. \\
\textsuperscript{314} See Unified Consumer Protection Law for the Countries of the Cooperation Council for the Arab States of the Gulf, \textit{supra} note 310, art. 2.
\end{flushright}
consumer laws. Statutes that indicate such rights are usually regarding specialized areas of law, such as advertising in E-commerce Law.  

Patients can also rely on the SFDA regulations in establishing the harmful conduct. The SFDA requires direct-to-consumer advertisements to comply with one of the following: the approved patient leaflet, the approved summary of product characteristics, the approved product's external label, or the approved product's external packaging. For example, if an advertiser includes information that violates laws and regulations, such as promoting non-approved use, patients may establish the wrongful conduct and prove the medication is misleading based on that. Here, patients may presume from the advertisement that the marketed use is safe, but in fact, it has not been examined and approved. Another example is when advertisers market prescription medications to the public, while the law prohibits such advertising.

Patients can rely on these violations to establish the harmful conduct. Nevertheless, the question that may arise here is whether courts consider SFDA regulations enforceable. It is likely to be deemed enforceable in civil matters since the law authorizes SFDA to regulate pharmaceutical marketing. Though, it is not optimal to open the door to challenge enforceability, at least from the patients’ side. Another concern is whether SFDA procedural

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315 The E-commerce law, supra note 129, at art. 11.
317 The Executive Regulation of the Law of Pharmaceutical Products and Facilities, supra note 17, art. 31/2.
318 Id. art. 31/3. See also Regulations and Procedures for Approving Advertisements for Non-Prescription Medications, supra note 16, at 6.
319 This research has raised the issue of enforceability when the regulations require obligations that are not backed by criminal sanctions in chapter II. Even if SFDA regulations are enacted with legislative instruments that are not sufficient to justify criminal sanctions, this does not mean that these regulations cannot be enforceable in civil matters. The Basic Law of Governance has required criminal punishment to be in laws, not regulations, to protect people from arbitrary criminal punishments but not to waive other rights of different natures that can be based on such regulations. Basic Law of Governance, supra note 40, art. 38.
requirements can reflect actual safety and effectiveness concerns or only presumed concerns. It is not clear if courts would consider damages due to non-approved use as a reason for a damage even if the marketer can approve such use is safe and effective in courts. The question that remains open here is whether courts may find non-compliance with SFDA procedural requirements to be wrongful conduct with no substantive examination of actual reasons.

2. **Harmful conduct in direct-to-physician promotions.**

Harmful conduct in the case of direct-to-physician promotions can be established when patients are harmed due to the involvement of physicians in disseminating misleading information. A key question to determine physicians’ liability in general is whether the physician has done his/her job with reasonable care and according to medical practices. If the answer is yes, the patient cannot properly establish the first element of liability. If the answer is no, the first element can probably be fulfilled. Patients must prove a certain duty that they claim the physician has violated either by intention or by negligence. Patients in this case can establish violations under the general duty of reasonable care according to health legislations, and they can also establish harmful conduct based on more specific legislative rights.

Health legislation has also mentioned other rights that can be suitable to protect patients when harmed due to involvement in pharmaceutical marketing. Physicians’ involvement can be intentional or unintentional and based on that this section presents examples of both involvement types. First, in cases of negligence, physicians are influenced by marketing with no intention to gain personal interests. Law of Practicing Healthcare Professions requires physicians to independently develop their knowledge of their profession to be informed about new
developments and inventions.\textsuperscript{320} In addition, physicians have a duty to inform their patients about medications and explain the necessity and consequences of treatment.\textsuperscript{321} If a physician fails to build an independent perspective about a medication or to inform patients about fundamental facts or instructions, the physician can be found to be negligent.

Second, physicians may be involved in pharmaceutical marketing deliberately to further personal interests. In this case, they can be found in breach of their general duty to practice medicine in the interests of their patients and their communities to help them enjoy their health and well-being.\textsuperscript{322} More specifically, the law has expressly banned physicians from taking advantage of patients or gaining any benefits from a third party to promote a medication or a product.\textsuperscript{323} Such involvement can have criminal aspects that are beyond the scope of this research. These statutory legal obligations can be the bases of patients’ claims in case of intentional involvement in pharmaceutical marketing. Although intentional involvement is possible, many barriers can arise when establishing liability, such as the need to prove intentional involvement.\textsuperscript{324}

The wrongful conduct as established can be grounded in general principles of law that have been established under Islamic law. In addition, several statutes can play roles in consumer and medical practices cases. Patients in consumer cases confront more challenges than in medical malpractice cases due to the lack of a comprehensive consumer law along with the

\begin{footnotes}
\footnotetext{320}{Law of Practicing Healthcare Professions, \textit{supra} note 53, at art. 7.}
\footnotetext{321}{\textit{Id.}, at art. 18.}
\footnotetext{322}{\textit{Id.}, at art. 5, 9.}
\footnotetext{323}{\textit{Id.}, at art. 12.}
\footnotetext{324}{It will be discussed in section D of this part, \textit{infra}.}
\end{footnotes}
relative limited predictability in civil general rules. This chapter will discuss these issues and others in Part III.

B. *Aldrr* (harm).

Harm is the main element that motivates patients to establish liability since it is the devastating result that has caused them to suffer. *Aldrr*, or the harm, is defined in Islamic *fiqh* as "every harm that causes suffering to a person in their wealth, body, emotions, and/or dignity."\(^{325}\) The concept of harm is limited to damages that are real and certain (*Muhaqaq*). Damage must be actual and proven in existence and amount to be established. This has restricted considered damages under Islamic *fiqh* and thus Saudi law compared to other legal systems.\(^{326}\) While actual physical or tangible damages are compensable in Islamic *fiqh*, it is not always the case for non-physical and future damages.\(^{327}\) Chapter IV will discuss compensatory damages in more detail.

C. *Alefda’* (causation).

The word *alefda’* means here that the harmful conduct has led to the damage.\(^{328}\) Causation (*tasbub*) can be found when “doing a conduct that causes a harm normally and no other factor is in between.”\(^{329}\) Islamic *fiqh* distinguishes between direct wrongdoing (*mubashr*) and causation (*tasbub*). Indirect wrongdoers can be responsible only if there is negligence.\(^{330}\)

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\(^{325}\) ALZHYLY, supra note 290, at 29. See ALKAFEEF, supra note 293, at 25. See MAHMASANY, supra note 306, at 169-72.

\(^{326}\) See VOGEL, supra note 41, at 241-244.

\(^{327}\) Id.

\(^{328}\) MUHAMAD FWZY FYD ALLH, NZRYH ALDMAN FY ALFIQH ALESLAMY AL'EAM [THE GUARANTEE THEORY IN GENERAL ISLAMIC JURISPRUDENCE] 96 (1983)

\(^{329}\) ALQARY, supra note 308, at 430. See ALZHYLY, supra note 290, at 32.

\(^{330}\) See MOHAMAD BIN ALMADANY BWSAQ, ALTEWYD 'EN ALDRR FYALFIQH ALESLAMY [COMPENSATION FOR DAMAGES IN ISLAMIC JURISPRUDENCE] 66 (1999).
causation, and no other factor made by choice in between the conduct and the damage.\(^{331}\) Direct harmful conduct can be established when the wrongdoer has committed the wrongful conduct directly with an object that causes the harm.\(^{332}\) Direct wrongdoers are responsible directly and absolutely when a plaintiff is able to prove such wrongdoing unless the conduct falls under certain exceptions.\(^{333}\) Thus, in case of causative wrongdoing, there are certain conditions that must be met to establish liability, but in case of physical direct wrongdoing, direct wrongdoers are responsible as long as their wrongdoing is proven.

There may be more than one direct and/or causative wrongdoer. Direct or causative wrongdoers who have equal roles when causing damage to others are responsible to compensate separately in equal amounts.\(^{334}\) In case one or more of them are direct wrongdoers and others are causative wrongdoers, the direct wrongdoer/s will bear responsibility.\(^{335}\) However, if there are direct wrongdoers or causative wrongdoers with distinct roles in causing the damage, Saudi courts have been dividing responsibility by percentages and then dividing compensation based on the same percentages.\(^{336}\) Medical experts on the Shariah Health Panel estimate such percentages in medical malpractices cases.\(^{337}\) In addition, there are exceptional situations when a causative wrongdoer can be responsible even if there is a direct wrongdoer.\(^{338}\) A key question

\(^{331}\) Id., at 65-68.

\(^{332}\) ALZARQA', supra note 294, at 74.

\(^{333}\) See ALQARY, supra note 308, at 443.

\(^{334}\) See MAHMASANY, supra note 306, at 187-89.

\(^{335}\) Id. at 189-90.

\(^{336}\) E.g., The Saudi Administrative Case No. 644/10/g 1434H. In this case, the court has found a hospital responsible for 95% and the midwife (the nurse) responsible for 5% of the damage based on the Shariah Health Panel’s expert’s assessment of the situation. The compensation then has been divided based on that. The court in this case has jurisdiction to only grant 95% of the damage against the public hospital and the rest should be sought through the Shariah Health Panel directly as it has jurisdiction in cases against private parties. See also BWSAQ, supra note 330, at 84-85.

\(^{337}\) Id.

\(^{338}\) To illustrate, if a judge made a judgment based on witnesses’ testimony, and the witnesses have confessed that their testimony has been untruthful after the judgment has been implemented, they are liable. The judge here is the direct wrongdoer, but the indirect wrongdoer bears responsibility in this case. Moreover, there are cases when the
that helps identify whether the causative wrongdoer is liable in a case where a direct wrongdoer exists is whether the conduct of the causative wrongdoer alone caused the damage? The next two sections focus on causation in direct-to-patient and direct-to-physician marketing.

1. Causation in direct-to-consumer advertisements.

Patients must prove that the damage has been the result of the claimed wrongful conduct. A patient who has been harmed because of relying on advertisements has to prove that the misleading advertising information caused the harm. If the advertiser has claimed a non-approved use of a medication, for example, to establish civil liability, the patient must prove that the damage was because of the advertiser’s wrongful conduct. The patient must demonstrate that if the advertiser had not promoted the product for this non-approved use, the patient would not have used the product, and thus would not have been harmed. When patients use a medication based on advertisements, the advertiser is not considered a direct wrongdoer since the patient administers the medication themselves.

As previously discussed, patients must fulfill three conditions to prove that the advertiser has caused the damage. First, there must be negligence. In this example, the advertiser has promoted a non-approved use of the medication, and this can establish negligence. Second, there must be causation. The patient must prove that promoting such misleading information can normally lead to the damage. Since the use is non-approved, the patient can argue that the

339 Id. at 45-47.
340 See ABDAIRHMAN AL’ETHMAN, ALTGHYR BALMRYD - AHKAMH ALFQHYH WEJRA’ATH ALNZAMYH [DECEPTION OF PATIENTS – ITS JURISPRUDENTIAL RULINGS AND LEGAL PROCEDURES] 17-19 (2021); see also FYD ALLH, supra note 328.
341 BWSAQ, supra note 330, at 65-68.
advertised use has not been checked for safety and effectiveness by the SFDA. That can at least create a presumption that it leads to the damage. Third, they must prove that no other factor has been made by choice in between. If the patient has reasonably understood the risks, that can be deemed another factor that helps the advertiser to escape liability or share liability.

2. **Causation in Direct-to-physician Promotions.**

Patients must establish that the claimed harmful conduct of the physician has been the cause of their damage. Patients should prove that the physician’s breach of their duty of care or their duty of loyalty has caused of the damage. If the physician has not breached such a duty, the patient would not have been harmed. If a physician has prescribed a medication based on a sales representative’s advice, and has not reasonably ensured the credibility of such advice, the physician can be found negligent if the patient has been harmed. If the patient administered the medication herself, the physician would be considered a causative wrongdoer, not a direct.342

If a physician has prescribed a medication, he can be liable when three conditions are fulfilled. First, the physician must be found to have breached a right of the patient, such as the right of loyalty. Second, the patient must prove that the physician’s breach can normally lead to damage. If a physician has a personal interest in prescribing a medication, the patient can argue that this can normally lead to bias and conflicts of interests. Prescribing medication based on personal gains, not patients’ interests, can normally lead to serious damage. Third, the patient must prove that no other factor has led to this damage. For example, if a patient knows the risk of the medication and continues using it, the patient is the direct wrongdoer in this case and is

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342 See AL’ETHMAN, supra note 340.
responsible for his own damage instead of the physician, since the patient’s action has been done directly and by choice.\textsuperscript{343}

In some cases, other factors can contribute to determining liability. If a physician causes harm to patients based on the effects of misleading pharmaceutical information, the level of involvement may affect liability. For example, the marketer may have provided a journal or scientific reference, which a physician has reasonably relied on routinely in practice.\textsuperscript{344} This can shift responsibility to the marketer. Nevertheless, relying on sales representatives’ briefs can raise questions about whether the physician has made reasonable efforts to obtain credible information or ensure their procedures fit what has been set in considered medical practice. Thus, sharing the liability with or shifting the liability to the marketer can be possible.

Patients must establish causation in direct-to-consumer and direct-to-physician marketing. Causation can be established by demonstrating that if a duty of marketers or physicians not been breached, the damage would not have existed. The three conditions to establish causation along with other rules stated in these causation sections are derived from jurisprudence and not stated in a primary source of law. In the two types of marketing, costly expertise and scientific analysis will certainly be part of the determination of whether or not the damage has really been caused by the conduct of the physician or the marketer. Patients may find

\textsuperscript{343} As established earlier in this chapter, when there is a direct wrongdoer, the rule is that he is going to be considered responsible. In this case, the patient cannot build a solid argument that he has been deceived, or his doctor has violated his duty and causes the damage. The patient himself has been the direct cause of the damage by knowing that a medication is risky for his situation but continuing regardless of that or knowing that the physician is really marketing such medication and prescribing it for personal interests. \textit{See} AL'ETHMAN, supra note 340.

\textsuperscript{344} \textit{See} BEN GOLDACRE, BAD PHARMA: HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS 267-68 (2013). Pharmaceutical marketers have influenced scientific references in many ways, such as paying writers and academics and promoting selective positive research that serves their interest.
it difficult to prove that a relationship between a physician and a corporation exists. Evidence costs and disclosures and can play a role in a patient’s right to access justice.

D. Evidence to Prove Civil Liability Elements.

Evidence is essential to establish civil liability. Patients must demonstrate each element by a recognized evidentiary instrument. The general rules of evidence are applicable in this case. Under Saudi law, the plaintiff who is making a claim must show adequate evidence. It is the patient’s burden to demonstrate wrongful conduct, damage, and causation. Evidence under Saudi law is not restricted, and patients can establish their case by any method.345 It can be in the form of witnesses, oaths, official or non-official documents, experts, or any other clues that lead the court to draw inferences. Certainly, the court will weigh each type of evidence, but as a rule, evidence is whatever can lead to the truth.346 Patients may need to rely on specially conducted scientific research, tests, or/and expertise to prove claims regarding the safety and effectiveness of medication when needed. There is also a concern regarding whether patients must bear the cost of evidence in medical malpractices and consumer cases or not. Such concern will be raised as a challenge in the following part.

345 Saudi Arabia has legislation that regulates evidence. It states that there is no specific legal form to prove any right unless stated in law or agreement. Therefore, the general rule is that evidence is non-restricted under Saudi law. Law of Evidence, Royal Decree No. M/43 Date. 26/5/1443, art. 5 (2021) (Saudi Arabia).

346 Id.
III: Challenges Patients Face when Establishing Civil Liability and Proposed Solutions.

As presented in this chapter, civil liability in this subject area is established through the general rules of Islamic fiqh. Patients should present the elements and prove the existence of such elements according to the general rules. The aim of this study is to holistically address patients’ protection from misleading pharmaceutical marketing, so this chapter raises only the major challenges of civil liability in this area. First, this part presents the uncertainty challenge and explores solutions by presenting aspects of the ongoing legislative process. Then, the part raises the evidence challenge, disuses barriers that can impede demonstrating liability elements, and proposes solutions.

A. The Uncertainty Challenge & Solution.

The uncertainty of civil law in Saudi Arabia has been a controversial issue. Saudi law has reached a reasonable level of predictability since the law derives from traditions and practices of rich Islamic fiqh. The level of predictability has not satisfied many who think it can be even more predictable by codification. Whether to codify Saudi civil law or not has been a major argument within the last several decades. While supporters think that the law cannot develop and be consistent anymore without codification,347 others think codification restricts judges who are supposed to independently decide cases based on legal and religious reasons.348 Such arguments have resulted from a general perception that something should be done to develop the

predictability of the law. This has been synchronous with an increase in publishing of court judgments, enacting statutes in different areas, and finally working toward promulgating a general civil code. This section will first address the challenge and explore the current codification process of civil law and whether it can be effective in enhancing patients’ protection or not.

1. The uncertainty challenge.

As presented, patients need to base their claims on different principles of fiqh or statutes depending on whether they seek to establish liability of physicians or pharmaceutical corporations. Major principles that can serve in cases of patient protection are well established under Islamic fiqh, such as requiring dealing with high honesty. Other principles are even stated in statutes, such as the Anti-Commercial Fraud Law and Law of Practicing Healthcare Professions. While some principles and statutes can play a direct role in protecting patients, others can be interpreted differently since they can be broad and vague. Such broad concepts can leave even basic consumer rights ambiguous and arguable. Should the law leave patients’ rights as consumers to different interpretations based on general rules?

Patients face uncertainty in two aspects: the uncertain general rule and the uncertain consumer laws. Generally, Islamic fiqh consists of many rules that can be solutions to many medical practices and consumer issues. The fiqh is rich to the extent that there are several main doctrines of fiqh, and these schools of fiqh have different opinions and theories. The Saudi judiciary has fostered certain doctrines in certain areas. Still, this is not as predictable as a body of judicial precedents would be. Thus, it is better for patients to have unified rules regarding liability to avoid confusion and discrepancies in findings. For consumer law, the lack of a
comprehensive law means that even essential consumer rights are not written in a primary source. This contrasts with the patient-physician rights in medical malpractices cases. The Law of Practicing Healthcare Professions has expressly stated aspects of patient rights, which are effective in determining liability as presented earlier in this chapter.349

In addition to lack of codification, cases regarding consumer and patient rights are rarely published. Within the last two decades, the Saudi Ministry of Justice, as well as the Board of Grievances, have been publishing cases in different areas of law. Medical malpractice cases and cases of patients as consumers are rarely published. Published cases would provide predictability that can help patients, their representatives, and researchers to understand and discuss the law in this area. Saudi law can achieve more effective protection of patients by considering new legal methods or strategies, and this is discussed in the next section.

2. Solutions to the uncertainty.

Uncertainty in Saudi law has been at the center of lawmakers’ focus in recent years. Efforts started with increasing publications of judicial principles and court judgements, codifying special statutes in particular areas, and codifying statutes that regulate broader areas, such as Family Law.350 The first section presents the ongoing process of codifying Saudi law. Second, the section examines how this development can affect patients’ cases in terms of liability.

349 See Part II, Section A-2 of this chapter.
- **The ongoing process of codification.**

  The codification process aims to codify most major areas of law, including civil law. The Crown Prince of Saudi Arabia His Royal Highness Mohammed bin Salman has announced that four significant pieces of legislations will be gradually enacted.\(^{351}\) The legislation includes a codification of the law of civil transactions.\(^{352}\) It is likely that civil liability will be codified in this law. If so, this law can increase the predictability of civil liability under Saudi law. However, the remaining question is how the codification process can impact patients’ protection. The next section predicts the possible effect of codifying civil law on patients’ protection.

- **The expected impact of this process on patients’ protection.**

  From a patient’s perspective, the law of civil transactions can help in providing a general ground to interpret statutes and contracts that regulate their affairs. For example, the concepts of deception and duress and their impact will be expressly drafted instead of being found in various references of Islamic *fiqh*. In addition, the elements of liability will be enumerated and defined instead of trying to predict what the court may or may not adopt in any particular case. However, protection of patients in medical malpractice and in consumer cases should not only depend on general rules of law. Patients and consumers need protection that fits their legal statuses. Even if general rules can broadly serve to protect aspects of their rights, an advanced level of patient and consumer protection cannot only be achieved through general rules of civil law. Justifications of


\(^{352}\) *Id.*
special protection of patients and consumers rights have been discussed earlier in chapter I.

Saudi law already has health statutes, so medical malpractice cases have reached a more predictable level for patients. However, for consumer rights, no primary source states general consumer rights that can be applicable in all transactions. Vision 2030 has stated that legislation in the kingdom of Saudi Arabia should be reviewed to fit new developments.³⁵³ Privatization has been one of the major programs of the vision, and this highlights the importance of developing consumer laws.³⁵⁴ Furthermore, Saudi law has been shifting gradually to be completely codified, so codifications will be the main source of law. With such a trend, it is unsuitable for the codified legal system not to have a comprehensive consumer statute. Therefore, codifying Saudi transactional laws can decrease ambiguity and patients can be better protected if consumer laws are also codified.

In addition to codification of civil and consumer law, consumers’ and patients’ cases should be published, and the opinions should be available to the public. To better understand the challenges of consumer protection, including consumers of medical services and medication, it is desirable to establish a policy center that traces consumer and patient cases, collects relevant statistics, and does research to understand barriers and find solutions. Also, patients should be able to understand their rights easily. Several consumer guidelines are published online in Saudi Arabia.³⁵⁵ However, none of these guidelines discuss what procedures patients can take to

³⁵³ Saudi Vision 2030, supra note 1, at 81.
³⁵⁴ Id. at 45.
protect their rights in consumer and medical malpractice cases. It is important to have detailed guidelines to present this information specifically for patients. The guidelines should summarize all relevant steps, from identifying a legal issue, to the complaint process, to the form of the final outcome.

B. The Burden of Proof as a Challenge.

Each element of liability must be proven by sufficient evidence. The burden of proof is on the plaintiff. This burden is applicable even in consumer and malpractices cases. It is not easy for patients to demonstrate liability when sophisticated high-cost scientific evidence is required. This section presents barriers that patients may face and then proposes and highlights solutions to help facilitate patients’ burdens when proof is needed.

1. The Challenge.

Patients bear the burden of proof in their individual capacity in most cases.356 If the other party is an entity, it certainly has more resources and expertise to deal with cases. For example, in medical malpractice cases, medical records are in the hands of the other party and not the patient. The Saudi judicial system is based on neutrality between parties in civil matters, as in other legal systems.357 As a result, patients must raise claims that state their positions and also defend claims the opposing party raises. In some cases, they are left to work individually on their own to prove their suffering by showing scientifically that their suffering exists.358 They must prove that the claimed wrongful conduct caused their suffering. The other party will probably claim that the harm was caused by another factor that happened concurrently.

356 Class action is not common in Saudi law practice. See Ch V, infra.
357 See VOGEL supra note 41, at 57-59.
358 See Ch V, infra.
Patients’ roles in these cases entail presenting sometimes complicated scientific evidence. Sometimes, access to scientific data is impossible or expensive. In other cases, dealing with such data, if obtained, requires expertise. In cases involving pharmaceutical producers, examinations should be done to prove the reason behind such damage and link that to the claimed conduct. In medical malpractice cases, mere evidence of an incorrect prescription is not enough. The patient must demonstrate that the damage was caused by the claimed wrongful conduct. The patient must eliminate other possibilities that can be the cause of the damage and demonstrate with no doubt that wrongful conduct is the reason for such damage. A number of questions can arise, such as whether patients in their position as plaintiff can be empowered to prove their claims, and whether they can access information reasonably and bear the costs to prove liability, especially causation.

Published medical malpractice cases have shown that the Health Shariah Panel has a significant role in proving negligence of health professionals.\textsuperscript{359} Whether this role will remain after the establishment of medical courts is questionable. The new Saudi Evidence law has stated that in case of the need to consult experts, the court decides who bears the expert fees or cost.\textsuperscript{360} It has been the case in Saudi courts that expertise is provided within the court on various topics, including assessing damages to the body.\textsuperscript{361} It is not clear if patients have to bear costs to demonstrate their claims, or if the Ministry of Justice will keep the expertise service after the

\textsuperscript{359} See Ch IV, Part III, Section B – 2 – Second, and notes 418 & 419 infra.
\textsuperscript{360} Law of Evidence, supra note 345, art. 112.
\textsuperscript{361} The Saudi Law of Civil Procedures created departments in courts called the Department of Experts, but the new Evidence Law has voided this article. Therefore, it seems that the relationship between experts and courts would likely be reorganized in administrative and financial matters. Law of Civil Procedures, supra note 54, at art. 128. (Saudi Arabia). Law of Evidence, supra note 345, art. 128.
new Evidence Law is completely enforced. The new rules regulating expertise costs are general and do not state exceptions.\textsuperscript{362}

Patients also face special challenges when they seek to establish liability of physicians, especially if trying to prove a physician’s intentional involvement in pharmaceutical marketing. In some cases, proving the existence of a relationship between physicians and corporations is complicated since not all physicians disclose their relationships due to the lack of enforceability that has been discussed in chapter II. It is also unclear if the SFDA allows the public to access disclosure information, if available. In other cases, even if such a relationship is provable, it is still challenging to demonstrate that it caused the damage to patients’ interests. Physicians and corporations can have many forms of relationships that can result in bias and affect patients’ rights indirectly, including, as an example, all sorts of educational funds. As a result, it is challenging to know about that in the first place and then prove its negative effect on patients’ rights.

2. Solutions.

Patients are confronted with many obstacles when seeking to prove liability. Based on the current Saudi law, there are reasonable steps that can be taken to facilitate access to justice for patients. Empowerment of patients in medical malpractice and consumer cases can be achieved in various ways. Four important steps can be accomplished through ensuring access to SFDA research regarding medications, access to SFDA information regarding licensing and disclosures.

\textsuperscript{362}See Law of Evidence, supra note 345, art. 112, 122.
excepting patients and consumers from costs of expertise, and ensuring sufficient funds to consumers. Each of these can play a critical role in developing patients’ access to justice.

- Access to SFDA research regarding medications.

One solution is to require the Saudi Food and Drug Authority (SFDA) to allow access to their materials. The SFDA has a continuous research effort that supports its decision-making. Saudi law does not require SFDA to allow the public access to its research. If the SFDA concludes that a specific medication has negative effects that require immediate withdrawal from the market to prevent future damage, little recourse is available to people who have already been damaged. The least that can be done in this situation is to allow access to the studies by which the SFDA has determined the product should be withdrawn. Access to such studies can help patients to realize what happened to them and enable them to have a potential piece of evidence if they choose to make a claim.

Allowing access based on legal grounds can be achieved through various approaches. One, lawmakers can consider regulating what information should be disclosed and be made available to the public. This has happened worldwide. For example, the U.S Food and Drug Administration has rules regulating what can be publicly available. These rules state that information submitted in the process of approving drugs, including information regarding safety and effectiveness, should be available to the public unless it falls under an exception, such as in the case of trade

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363 See SFDA Law, supra note 53, art.5.
secrets. Considering such rules can help the SFDA itself and patients to determine the kind of information that should be available to the public and not leave that to the mere discretion of the SFDA.

Second, information that cannot be made available publicly can be accessed in exceptional circumstances by recognizing the right of patients to access data upon request. For example, in the U.S, a federal statute grants individuals the right to access information from federal agencies upon request.\(^\text{365}\) This right can also increase transparency regarding SFDA decisions and help understand their effects on the public and patients in particular.

In addition, consumer organizations should have access to such information to play a role in developing consumer awareness or to take legal action on behalf of consumers. Consumer organizations can then publish reports letting patients know about the existence of such risks and claims and their outcomes. If this gap in access to SFDA information had been regulated, many claims would have arisen, and others would have been resolved. SFDA may take steps mandated by its authorizing legislation, but the law should maximize the benefits of SFDA research to serve harmed patients.

- Access to SFDA information regarding licensing and disclosures.

Patients should be allowed to access updated and accurate information regarding licensing advertisements and disclosures of physician-corporations relationships. The SFDA requires advertisements to be licensed and checked for certain requirements before

being published.\textsuperscript{366} The SFDA licensing number must be included in the advertisement, but there should be an independent method provided to verify that the license is still valid.\textsuperscript{367} In addition, SFDA requires health professionals to disclose contracts and payments with pharmaceutical corporations. Disclosure can be even more effective if it is accessible to the public.\textsuperscript{368} These two steps can give patients and the public important information that can help them understand various aspects of their claims and help prove their claims, serving their right to access justice.

- Patients and Consumers & Costs of Expertise in the new Evidence Law.

The new Saudi Evidence Law has regulated expertise costs, and the necessity to deposit such costs when the court requires it. The court has the authority to not pursue the case if such deposit requirement has not been fulfilled. What happens if a patient who has had to be in court to recover from a loss cannot pay such costs? The law does not state any exceptions in this regard. It is important to consider consumer and patient cases and find suitable solutions to ensure reasonable access to justice that is best for their situations. Patients and consumers who file a lawsuit to recover damages may be unable to bear such costs. It is also possible that they could lose such cases due to the lack of funding or experience.

\textsuperscript{366} See Chapter II, supra.
\textsuperscript{368} See Chapter II, supra.
Ensuring sufficient funding to consumers.

Patients and other consumers may find themselves unable to access justice because of lack of funds. There should be programs and policies that aim to minimize the cost and fund access to justice in certain cases. Part of such funding should be to encourage group actions instead of individual cases. Working in groups can help to make spending on costs, including evidence, more efficient. Class actions, as an example, allow damaged patients to collectively hire lawyers and experts to help in their case, which may minimize the financial burden on individual patients. Class actions and other access to justice issues under Saudi law will be addressed in Chapter V.

Conclusion

Civil liability under Saudi law can be established when demonstrating three elements: wrongful conduct, harm, and causation. Saudi law requires plaintiffs to bear the burden of proof. Thus, patients have to present adequate evidence to establish each element based on the general rules of civil law. Evidence in drug-related cases sometimes involves scientific grounding. Patients may lack the resources and expertise to access and deal with such evidence. Saudi law should adopt policies that enhance patients’ positions in such cases. These policies can include obligating government entities to publish, or allow access to, studies that support their decisions on issues regarding consumer health. Also, patients should be allowed to independently access information regarding licensing of pharmaceutical advertisements and disclosures of dealings between pharmaceutical corporations and health professionals. It can also be helpful to minimize evidence costs by legislation or by funding or encouraging organized and collective consumer efforts to advocate for patients’ rights. The next chapter will address compensatory damages that patients can seek after establishing civil liability.
Chapter IV: Compensation

Introduction

Damaged patients seek to establish liability to end their unjust situation. They may seek to recover from physical, financial, or emotional damages. The law provides remedies that aim to achieve a more just result for damaged patients. Financial compensation is one of the common civil remedies that legal systems have adopted to bring at least partial fairness to the damaged party. This chapter examines recognized compensatory damages for patients under Saudi law to finally approach aspects of challenges and solutions to the development of patients’ civil protection.

The main question of this chapter is what types of indemnification patients can seek after the liability of wrongdoers is established. Then, the chapter raises the question of what challenges exist in areas of compensation and addresses possible solutions. Part I is an overview of compensatory damages. Part II highlights two primary principles of compensation in Islamic fiqh. Part III explores compensation for physical injuries and death. Part IV addresses other kinds of compensatory damages. Finally, part V discusses challenges that can be encountered under Saudi law and suggests possible solutions.
I: Overview.

Saudi law has various remedies that can apply when the civil liability of wrongdoers is established. Such remedies have not been codified yet and are still regulated under Islamic fiqh.\footnote{Civil remedies are expected to be codified during the ongoing codification process that has been mentioned in Ch III, Part III.} One of the main purposes of these remedies is undoubtedly to make the harmed party’s position what it was before the damage occurred—in other words, to make the plaintiff whole—to the extent possible. Before claiming compensation, civil liability should be established.\footnote{See Chapter III, supra.}

Compensation (alt'ewyd) is defined in Islamic fiqh as “money or possessions that the court awards for damaged persons through obligating wrongdoers, who cause damages to others’ bodies or/and wealth, to recompense such loss.”\footnote{BWSAQ, supra note 330, at 155.}

Patients’ damages can be physical, emotional, and/or financial. It is possible that patients have direct suffering, such as injury and/or death, because of misleading pharmaceutical marketing. Injury can include internal and external body harm. For example, internal injuries can occur when wrongful conduct causes an illness, and external injuries can occur through harm to, for example, skin or eyes. Injuries also can be temporary or permanent. This can vary in degree and in the way the injury starts, including the possibility of lapsing, persisting, or developing over time. While misusing medications can lead to physical injuries, it can likewise cause psychological suffering, such as trauma or depression.\footnote{See Elizabeth Y. Schiller et al., OPIOID OVERDOSE (StatPearls Publishing, 2022), https://www.ncbi.nlm.nih.gov/books/NBK470415/.} Death is also possible due to development of injuries or directly as a result of medication misuse. Death has already been occurring widely because of opioid overdoses in the U.S.\footnote{See Hadland et al., supra note 39.}
Moreover, misleading pharmaceutical marketing can result in financial loss. Patients may directly lose all or part of their income depending on their work circumstances when they are damaged. This can happen, for example, if an overdosed patient reaches an advanced level of addiction. Patients may bear medical expenses to treat the medical implications of the damage. For instance, patients may bear medical costs to treat such addiction. General living expenses can significantly increase for patients if they are forced to change their lifestyle due to their injuries. In some cases, patients may need someone to rely on or with special training to pursue their lives, and this new condition of dependence can cost them financially.

Furthermore, patients can be involved in other indirect harmful situations due to the direct damage. For example, if the medication causes the patient to lose consciousness, the patient may be injured in a car accident. This car accident can result in additional financial loss and physical injuries. Additionally, if the lack of consciousness causes the patient to behave inappropriately, the patient can be at risk of being damaged further. For instance, the patient may be involved in an embarrassing situation at work. If a manager that has been under the effect of a medication has said weird words or engaged in strange conduct, such situations can result in negative effects on their reputations. It can likewise have consequences for their employment that potentially causes complete or partial loss of income.

The fact that physical, psychological, and financial harms are imaginable because of misleading pharmaceutical marketing is not adequate for courts to grant compensation. Several sorts of compensation can face challenges to their recognition in the Saudi legal system and sometimes to the ability to demonstrate the existence and the amount of the damage. First, it is

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possible patients suffer from a certain harm, but it is not necessarily compensable under the legal system. This chapter outlines the main principles necessary to understand Saudi law tendencies regarding compensatory damages. Another obstacle, the nature of the harm, can affect the evidence. Linking the damage to misleading pharmaceutical marketing can be complicated. After establishing civil liability, the focus should shift to proving the existence, the significance, and the amount of the damage. This chapter aims to raise questions regarding available compensation for patients who have suffered injuries and/or death, as well as other sorts of compensation under current Saudi law. The chapter will then suggest general trends of developments.

II: Islamic Essential Principles of Compensation.

As has been presented in the first part, compensation under Saudi law has not been codified so far, and this situation will likely shift. The major source that governs compensation in the absence of a code is Islamic fiqh. Saudi courts rely on such principles and doctrines to decide whether to recognize a certain compensatory damage or not. In this part, the aim is to explore the main principles of compensation in Islamic fiqh so that there is an understanding of the whole picture. It also helps identify justifications for tendencies that will be discussed later in this chapter. This part addresses two of the primary Islamic principles of compensation, namely, compensation should be based on certitude, and damages should be factual.

Compensation should be built on certainty.\textsuperscript{375} Property in general that includes money is one of the five necessities in Islam.\textsuperscript{376} Taking other people’s wealth is forbidden, and that means others, non-owners, are not allowed to take from such wealth unless justified. The Qur’an states, “Do not consume your property wrongfully, nor use it to bribe judges, intending sinfully and

\begin{footnote}
375 \textit{BWSAQ, supra} note 330, at 165.
376 The five necessities are faith, life, progeny, property, and mind. IBRAHIM AL-SHATIBI, ALMUFAQAT 1/31 (1997).
\end{footnote}
knowingly to consume parts of other people’s property.\footnote{377} Courts require standards that can lead to certainty to justify taking other’s respected property, including in compensation. In cases of misleading pharmaceutical marketing, patients may face difficulty proving that a deceptive pharmaceutical marketing activity has caused the damage. Failing to adequately prove the liability elements can result in the court’s considering the damage uncertain and not sufficient to justify taking the wealth of others (granting the compensation).

Another major principle is that compensation should be for actual damages.\footnote{378} Islamic \textit{fiqh} tends to consider actual losses that are estimated based on objective standards. Compensation should cover what has been lost as a result of the wrongful conduct. The idea of considering other factors that are related to the wrongdoer, such as their level of wealth or a company’s revenue, is not acceptable. The reason is that the main purpose of compensating is to repair damages, not to enrich victims. The estimation should be established on verified factors, not presumed or suggested.\footnote{379} Consequently, courts have to decide the amount of the damage to compensate based on objective standards and certain actual losses.

These principles are among the essential effective principles that have been influencing Islamic \textit{fiqh} as well as Saudi courts when dealing with compensation. Even if the bases of these principles are solid, distinct understandings and interpretations of these principles can lead to diverse doctrines among jurists and courts. In the next part, more detailed examples related to these principles will be presented.

\footnote{377} \textsc{The Qur’an} 2:188 (M.A.S. Abdel Haleem trans., Oxford University Press 2016).
\footnote{378} \textit{BWSAQ}, supra note 330, at 170.
\footnote{379} \textit{See Vogel}, supra note 41, at 242.
III: Compensation for Death and Injuries.

A. Overview.

Patients may experience several kinds of damage because of misleading pharmaceutical marketing. Common physical injuries can be internal injuries, such as lung-related, heart-related, and sense-related diseases, and/or external, such as skin-related and hair-related complications.\(^{380}\) Pain and suffering (moral damage) can also be linked to misuse of medication due to misleading marketing.\(^{381}\) Death is possible as a direct consequence or resulting from complications of injuries. While common injuries are conceivable as direct implications of misleading marketing, there is always a chance of having indirect consequences that can stem from such direct damages. Part I has already provided examples of the car accident and the manager. The ramifications of patient damage can be complex and unlimited. This part, nevertheless, focuses on compensation of physical injuries and death, and the next part addresses moral damages.\(^{382}\)

Physical damages, in Islamic fiqh, are “all types of harm that injure, disfigure, or cause incapability for a body part completely or partially that including causing the damage to be incapable of working.”\(^{383}\) Physical damages are covered under a compensation system that consists in Islamic law of two significant concepts diya and arsh.\(^{384}\) Diya is "a sum of money or

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\(^{380}\) See Schiller et al., supra note 372.

\(^{381}\) Id.

\(^{382}\) Why are moral damages not addressed in this part? First, moral damages, or pain and suffering, are addressed generally in this part since they can be under unspecified arsh. Second, it is not addressed in this part in a separate section because moral damages are still controversial in Saudi courts. The next part presents moral damages from two important aspects. Do Saudi courts recognize moral damages at all? If they recognize moral damages, do courts grant such damages when arsh and diya are applicable?

\(^{383}\) BWSAQ, supra note 330, at 295.

\(^{384}\) The nature of diya has been arguable in Islamic fiqh, and it is not settled as a compensation system. Some jurists see diya as an alternative punishment, and others see it as a civil compensation. A third doctrine has seen diya as not only punishment and not only compensation, but a combination of the two. This research addresses diya as
possessions that is paid to victims or their legal representatives due to transgressions or crimes. \(^{385}\) Arsh’s concept has encompassed compensation for injuries, not death. Arsh can be specified or unspecified. \(^{386}\) In specified arsh, the type of injury and the amount of compensation have been determined in Islamic law, but unspecified arsh has been left to the court’s discretion to decide the proper compensation. \(^{387}\) Understanding diya and arsh systems for certain specified compensation can assist in grasping possible assessments in cases of non-specified injuries. \(^{388}\)

The applicability of financial compensation in Islamic fiqh as well as the overall compensation amount can vary based on the type of wrongful conduct, whether it is intentional or non-intentional. \(^{389}\)

\(^{385}\) MOUSA AHMAD ALHAJAWY, ALEQNA’E FY FIQH ALEMAM AHMAD BIN HANBAL [PERSUASION IN THE JURISPRUDENCE OF IMAM AHMAD BIN HANBAL] 4/199.

\(^{386}\) Specified arsh is also called dyht ala'eda' walmnaf'e [diya of body parts and their functions]. ALHAJAWY, supra note 385, at 4/216.

\(^{387}\) ALZHYLY, supra note 10, at 5749.

\(^{388}\) Usually, courts’ estimations of compensation for non-specified injuries should be consistent with specified compensation. For example, it is unreasonable to grant compensation for a single injury with more than the full diya’s amount granted in case of death. It is likewise not reasonable to compensate for partial disability of a hand with half of the diya, which is meant to compensate for complete disability of it. Therefore, addressing specified compensation for death and injuries gives an insight into the whole system of compensation.

\(^{389}\) First, the diya amount in case of damages resulting from criminal intentional conduct is distinct from the diya amount in a case of non-intentional conduct. Second, in case of crimes, criminal remedies can affect civil compensation in Islamic fiqh. Victims or their families have the right to pursue or waive aspects of criminal punishment. In case they choose not to waive criminal remedies, they will directly lose their right to be financially compensated. On the other hand, they can accept financial compensation granted by the court or negotiate with the criminal’s representatives or family to reach a financial deal that can exceed the diya amount and waive their right to pursue criminal penalties. If a victim has waived his right to criminal remedy, this does not necessarily entail total waiving of criminal liability. Public prosecution usually seeks punishment to protect the public, so the family of the victim cannot waive criminal liability at all. RESEARCH CENTER OF THE MINISTRY OF JUSTICE, ALMBAD‘E W ALQARAT ALSADRHN ALHY‘EH ALQADA’EYH AL’ELYA W ALHY‘EH ALDA’EMH WMILIWS ALQDA’ ALA’ELA W ALMIKHMIH AL’ELYA [PRINCIPLES AND DECISIONS ISSUED BY THE SUPREME JUDICIAL COMMISSION, THE PERMANENT AND GENERAL COMMITTEE OF THE SUPREME JUDICIAL COUNCIL, AND THE SUPREME COURT] 234-35 (2017); see also Abdalh Muhamad Alkhnyn, Sulh B‘ed Alwraithh ‘En Alqsas Beakthr Min Aldiyh [Reconciling by Waiving Criminal Punishment for More than Diya Amount], 92 ISLAMIC STUD. J. 337-370 (2011).
Most patients’ cases regarding damages resulting from misleading pharmaceutical marketing can be classified under non-intentional harmful conduct.\textsuperscript{390} It is common in published medical malpractices cases to presume that injuries and death are accidental.\textsuperscript{391} Marketers promote their products to the public to increase their sales, and physicians prescribe medications to treat patients. Advertising is part of marketers’ business, and prescribing is part of physicians’ job. Whenever a mistake exists during a normal business or a professional activity, it is more likely to be accidental and be attached to the general purpose unless proven otherwise.\textsuperscript{392} In addition, patients usually visit a doctor voluntarily and give their consent.\textsuperscript{393} They have a choice to refuse to use a prescribed medication. They also have the choice to select and use a medication in the first place if it is non-prescription. This can complicate proving if the intention exists. Therefore, the possibility of intentional harm from misleading marketing is highly infrequent, and patients would face challenges to prove the intention when it exists.

\textsuperscript{390} A transgression can be deemed intentional under Islamic fiqh when three conditions are met; the committer; 1) has intended to commit such a transgression, 2) has done the conduct with aggression, and 3) has used a tool that leads to the purpose of the crime. Ebdalslam Alshwy’er, \textit{shrwt almsa’lh ‘en alkhfa altby wb’ed almba’d e alqda’eyh fy: blth fghy tbyqy ‘ela alahkam alqda’eyh fy almmlkh al’erbyh als’ewdyh [Conditions of Responsibility for Medical Malpractices with Some Judicial Principles: an Applied Jurisprudence Research on Judicial Rulings in the Kingdom of Saudi Arabia]}, The Scientific Record of the Second Islamic Fiqh Conference for Contemporary Medical Issues 5073 (2010).

\textsuperscript{391} \textit{E.g.} The Saudi Administrative Case No. 14/40/D/46 1434H. This is also coherent with the fatwa (opinion) of the former Head of the Judges of Saudi Arabia that criminal liability is waived if a physician is qualified, has conducted his work according to medical practices, and has obtained valid consent from the damaged patient. \textit{MUHAMAD BN ABDUALRAHMAN BN QASM, FITWA WRSA’EL SMAHH ALSHEIKH MUHAMMAD BN IBRAHIM [FITWAS AND MESSAGES OF HIS Eminence Sheikh Muhammad bin Ibrahim]} 8/103-107 (1978).

\textsuperscript{392} \textit{See} Ebrahim Muhammad Alhwsny, \textit{Tbyqat Hkwmh Al’edl fy Aljnayh ‘ela Madwn Alnfs fy Alfiqh Aleslamy [the Applications of Discretionary Compensation of Injuries In Islamic Jurisprudence]} 45 (2012).

\textsuperscript{393} The former Head of the Judges of Saudi Arabia has stated that it is hard to establish intentional conduct of a physician when patient’s consent is valid. Alshway’er has justified that the aggression condition that is required to prove the intent would be not constituted since an act of aggression is supposed to be without consent. \textit{BN QASM, supra} note 391, at 8/103-107. Alshwy’er, \textit{supra} note 390, at 5088.
B. Compensatory Remedies for Patient’s Death and Injuries (*diya, arsh*).

The *diya* amount that is granted in several cases of death, including wrongful death, is the core of the compensation system in Islamic *fiqh*. In case of injuries, the specified *diya* for loss of primary parts and senses are determined based on the full amount given in case of applicable death. For example, a complete loss of sight is compensated with the full *diya*. Nevertheless, partial loss of sight is recompensed with *arsh* that is proportionate with the percentage of loss, which experts determine. In other body parts, the compensation granted is also proportional to the *diya*, such as a half, a quarter, and a tenth of the *diya* as will be addressed in the next sections. As a result, the death *diya* amount is the basis of body parts’ *diya* (specified *arsh*), and it is fundamental to determine the compensation even when a court has to decide based on its discretion to evaluate partial damage of a specified *arsh* or compensation in unspecified *arsh*. This section explores first the *diya* in death and then the *arsh* amounts in case of injuries.


The *diya* is measured in the value of essential commodities and gold and silver in *fiqh* resources since it was paid this way before modern currencies.\(^{394}\) The value is reflected in modern currencies and updated from time to time.\(^{395}\) The Saudi Supreme Court has determined the value of the *diya* in modern currency.\(^{396}\) The highest applicable amount of *diya* for wrongful death is 300,000 Saudi Riyal (SR) (about $80,000).\(^{397}\) The highest amount of *diya* for intentional

\(^{394}\) The *diya* is determined by the value of a hundred camels, two hundred cows, or two thousand sheep, and it is also measured in a certain amount of gold and silver. Under Saudi law, camels are the original method to estimate *diya*’s amount. ALHAJAWY, supra note 385, at 4/206. See RESEARCH CENTER OF THE MINISTRY OF JUSTICE, supra note 389, at 303.

\(^{395}\) Id.

\(^{396}\) Id.

\(^{397}\) Id.
or semi-intentional injuries reaches 400,000 SR (about $106,000).\textsuperscript{398} Mostly, malpractice is considered non-intentional as stated earlier in this part. An example of applying diya in medical malpractice cases is the following: the Shariah Health Panel has found a physician, two midwives, and a hospital responsible for 90\% of the death in a case.\textsuperscript{399} The amount of SAR 270,000 was divided between them based on their roles, and 10\% has not been awarded.\textsuperscript{400} This case is just one of many published cases where decisions presume that medical malpractice is non-intentional and thus granting diya for non-intentional murder.

2. Compensation for Patient’s Injuries (arsh).

Arsh includes all injuries that do not result in death.\textsuperscript{401} Arsh is divided into two main parts. One is specified compensation (alarsh almuqdr) that has been determined in amount for specific injuries. The other is unspecified and left for the judge to determine, called discretionary compensation (hkwmh al’edl).\textsuperscript{402} Misleading marketing can cause several types of physical harm to patients. This section concentrates on examples of common physical harms that can directly result from misleading pharmaceutical marketing. To illustrate, it is more possible to imagine cardiovascular damage and pulmonary damage as common direct damages of misleading pharmaceutical marketing more than wounds, fractures, and other damages to limbs. This section addresses first specified compensation and then second the court’s discretionary role to evaluate partial damage in specified compensation and decide the proper unspecified compensation.

\textsuperscript{398} Id.
\textsuperscript{399} The Saudi Administrative Case No. 14/40/D/46 1434H.
\textsuperscript{400} The panel did not state expressly why 10\% was left. It seems from the facts in the case showing that the family has been responsible for 10\% because they were allowed to leave the hospital for a certain time, but they did not come back on time, which can be a factor in causing the death. Id.
\textsuperscript{401} See ALKAFEF, supra note 293, at 333.
\textsuperscript{402} ALZHYLY, supra note 10, at 5749.
First, Specified Compensation (*alarsh almuqdr*).

The focus in this section is on injuries that result in damage to the body parts physically or functionally. Such injuries and their compensation have been determined in Islamic law. Physical harm to parts is harm that can be noticed in the body part itself, such as broken hands. Functional harm incapacitates the purpose of the particular body part with no noticeable physical injury, such as loss of smell with no external harm to the nose. Specified compensation amounts are determined based on the significance of the body part. The rule in Islamic *fiqh* regarding physical or functional damage of body parts is if the damaged body part or sense is only one-of-a-kind, such as the nose or the sense of smell, it results in awarding full amount of the *diya*. Parts that are more than one of a kind can be divided according their numbers, so, for example, the court divides the *diya* by two if the damaged part is one of the two eyes and divides by ten if the damaged part is one of the ten fingers or toes.

Common patient injuries due to misuse of medication can cause damage to specified or non-specified parts. It is probable that a patient may lose the ability to smell, hear, or see partly or completely because of medication misuse. If a patient has lost a sense completely and permanently because of a prescription or misleading information, the court is likely to grant him a full *diya*. If the sight is lost in one eye or the hearing is lost in one ear, half of the *diya* will be granted. Partial loss of sense would result in partial evaluation of *diya* based on the

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404 *Id.*
percentage determined by experts, and temporarily loss of senses would be under the discretion of the court.

In some cases, medications have caused a patient to suffer damage in an internal body part, such as heart, lungs, and liver. According to the rule presented above, courts should recompense patients with full or part of the diya depending on the significance of the particular body part.\footnote{Muhamad S’aeed Alqhtany, Ahkam Aljnayh ‘Ala Tuhal Aladamy [Provisions of Damage to the Human Spleen], 9 AL’EDL J. 16 (2001).} For example, loss of one of the two lungs can be compensated with half of the diya. The court is supposed also to base the discretionary compensation on this fact, so if the medication causes a partial damage of the heart function, the court is supposed to grant a compensation based on the expert assessment of the damage from the full diya amount. However, this is not settled in Islamic fiqh. Some jurists have argued that internal parts are not specified, so the court has discretion to determine the appropriate compensation amount.\footnote{Id. at 15.} The fact that it is not settled can open the door to many possibilities, but it is known for certain that the patient has the right to be compensated and the disagreement is on the basis of such compensation.

Another example of possible damage due to medication is hair loss.\footnote{E.g., Hair Loss, Harvard Health Publishing, \url{https://www.health.harvard.edu/a_to_z/hair-loss-a-to-z#:--text=While%20hair%20on%20some%20parts,Atamet%20%20Larodopa%20%20Sinemet)\), (last visited Feb. 21, 2023).} Patients may lose their beard, eyelash, eyebrow, or/and head hair. Complete loss of beard, loss of all eyelashes, loss of both eyebrows, or total loss of head hair can result in full diya for each of them.\footnote{ALHAJAWY, supra note 385, at 4/219.} If a patient has lost one set of eyelashes, the compensation is a quarter of the diya.\footnote{Id. at 15.} Losing one of
the two eyebrows can result in half of the *diya*. In the case of partial hair loss, as an example, the court usually depends on experts to determine the percentage of the loss and grant the patient part of the *diya* based on this evaluation.

Patients may be granted full *diya* or a specified part of the *diya* if the court considers that the injury meets the criteria of specified compensation. Although courts are likely to compensate patients for internal body parts if damaged, the basis of such compensation can vary to be as specified or unspecified compensation based on the court’s determination. The next section addresses the court’s role in evaluating partial damage in specified compensation and unspecified compensation.

**Second, the Role of the Court to Evaluate and Determine Compensation.**

There are many cases when patients’ injuries, such as inability to breastfeed, are not specified with a particular compensation amount (*alarsh ghyr almugdr*). The court has the discretion, called (*hkwmh al’edl*), to assess the compensation. In other cases, the patients’ injuries are specified, but the damage has not met the criteria to grant the *diya*. For example, loss of part of the hair or part of the sight should be evaluated and determined by a court depending on the extent of the damage. In these two cases, the court has the discretion to either assess the compensation or determine how much of the specified compensation the damaged patient should be granted for their partial damage. Saudi courts have tended to rely on the Health Shariah

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413 *Id.*
414 *See* next section, *infra.*
416 *Id.* at 87. ALHAJAWY, *supra* note 385, at 4/219.
417 *See* ALZHYLY, *supra* note 10, at 5702.
Panel as experts in many cases. In other situations, there are experts in civil courts used to estimate and to determine the kind of injury and the degree.

The court should take into account many aspects before determining or evaluating the injury. First, if the injury and the compensation is specified, the court cannot use its discretion. The court should determine that it has the discretion when the injury is unspecified, or the injury is specified but does not meet the defined standards. Another important aspect is the court should not decide before the full extent of the injury is known and definite. If the injury can develop or can result in death, the court should wait until the situation becomes clear. Also, the court should determine based on medical experts’ opinions.

In addition, courts shall not grant the entire specified *arsh* when the injury is partial. Maximum specified compensation (specified *arsh*) is applicable in case of the complete loss of the specified part or function. However, patients may be partly harmed, resulting in partial loss of the body part or partial lack of function. Experts have a role in such cases to assess the percentage of damage in the body part, such percentage reflects the part of the specified *arsh* that is supposed to be granted by the court. For example, in one case, the Shariah Health Panel estimated the level of incapacity of a victim of medical malpractice to be 28% in the left hand and 25% in the right lower leg. As a result, the court granted the patient what is equal to 28%

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418 E.g., The Saudi Administrative Case No. 2143/2/G 1435H.
419 E.g., The Saudi Administrative Case No. 103/1/G 1436H (relying on a committee of experts in a civil court to estimate compensation amounts).
420 ALHWSNY supra note 392, at 59.
421 Id.
422 Id.
423 Id.
424 Id.
425 The Shariah Health Panel Case No. 3/29 Date. 1429 A.H.
of one hand’s and 25% of one leg’s specified compensation.\textsuperscript{426} The court cannot grant the full specified compensation if the injury is only partial.

Courts also shall not grant more than the amount of one \textit{diya} for each injury. If a patient has more than one injury of distinct kinds, the maximum should be one \textit{diya} for each injury of a kind. In the previous example, the panel granted separate compensation for the hand and another one for the foot. If the victim has lost both hands and feet, the court is supposed to grant two full amounts of \textit{diya}.\textsuperscript{427} However, the panel also has other limits than the full \textit{diya} limit, such as the fact that the damage was in one hand has reduced the maximum to be half of the full \textit{diya} because a hand is two of a kind. Another limit is the fact that the damage is not complete but partial. This has resulted in granting only the percentage that experts have estimated. Thus, persons who have several injuries can be compensated with no more than one \textit{diya} for each injury of a kind.

Saudi courts have been applying a compensation system that relies on Islamic \textit{fiqh}. However, this system will not likely continue to be the primary direct source as civil codes are expected to be enacted in the near future. This compensation system is based on the amount of compensation granted in death as maximum for each body part injury. Some body part injuries are specified in amount. The rule in specified body part injuries is that losing a body part that is one of a kind is compensated with full \textit{diya}, and losing a body part that is two of a kind is compensated with half of the \textit{diya}. Thus, the specified compensation is based on the importance

\textsuperscript{426} \textit{Id.}

\textsuperscript{427} \textit{E.g.}, a Saudi Court has found a hospital and a nurse liable for causing complete paralysis of a child, based on the Health Shariah Panel decision. The court granted a full \textit{diya} for paralysis of upper extremities, full \textit{diya} for paralysis of lower extremities, full \textit{diya} for loss of the mind, full \textit{diya} for loss of urinary ability, and full \textit{diya} for loss of excrement ability. The total was five \textit{diyats}. The court found the public hospital responsible for 95% of the damages, and the nurse for 5%. The Saudi Administrative Case No. 644/10/g Date. 1434H.
of the body part, and the *diya* can be divided based on the number of the particular body parts. Courts have discretion to determine the compensation in partial damage of specified injuries and in unspecified injuries. It is not settled whether injuries to visceral organs fit under specified compensation (applying the rule of full *diya* to them as one or two of a kind) or unspecified compensation (left to the discretion of the court).

**IV: Other Compensatory Damages.**

**Overview.**

In addition to physical injuries and death, patients can raise the question of whether they can seek compensation for their financial losses, emotional suffering, medical expenses, and income loss. Patients may suffer financial costs as a result of being victims of misleading marketing that can lead to medication misuse. They may bear medical costs and/or be unemployed.\(^{428}\) They may also bear other indirect costs if the impact is severe.\(^{429}\) Moreover, patients may suffer from various psychic consequences due to misuse of medications linked to misleading pharmaceutical marketing.\(^{430}\) This part explores several sorts of compensation that are expected to be at the center of damaged patients’ concerns. Since a codified law has not yet been enacted, Islamic *fiqh* remains a direct source of compensation under Saudi law.\(^{431}\) This part presents doctrines of Islamic *fiqh* and other factual backgrounds to understand the Saudi judiciary’s general trends in the area of compensation.

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\(^{428}\) See Rhee & Rosenheck, *supra* note 374. See Part I of this chapter, *supra.*

\(^{429}\) See Part I of this chapter, *supra.*

\(^{430}\) *Id.* See Schiller et al., *supra* note 372.

\(^{431}\) See Ch III, part III, *supra.*
Several principles affect compensation. Two of the critical principles have already been explored, namely respecting people’s property by requiring compensation to be based on solid justifications and granting compensation for actual damages only.\textsuperscript{432} In addition to these two principles, there is a significant common principle that has impacted the Saudi judiciary trend regarding adopting additional compensation. That is the principle of not accepting other kinds of compensation when \textit{diya} or \textit{arsh} is applicable.\textsuperscript{433} This principle is grounded on the idea that the right of \textit{diya} is determined with no restrictions, and the majority of jurists hold that it is not acceptable to add more than what has been already specified.\textsuperscript{434} This principle seems to be predominant in the Saudi judiciary.\textsuperscript{435}

Jurists have agreed that considering additional compensation for the exact injuries and death that are meant to be compensated via \textit{diya} and \textit{arsh} is not acceptable at all, and they have different opinions when considering compensating other damages, such as medical expenses. Some jurists have accepted one type of compensation, such as medical expenses, but stick to the majority perspective and have not completely agreed to accept all other kinds of compensation.\textsuperscript{436} Other jurists have argued that even if texts of main Islamic sources should be superior, interpretations of early jurists in certain aspects have been made according to the

\textsuperscript{432} See Part II of this chapter.
\textsuperscript{433} \textsc{Ministry of Justice, Tqryrat Mahkamht Altmyyz Khial Khmsyn 'Eama [Court of Cassation Decisions during Fifty Years]}, Dec. No. 283/G3/B Date. 23/5/1427 A.H. “The plaintiff of the private right shall not be granted other than what has been determined in fiqh of \textit{diya} and \textit{arsh}.”
\textsuperscript{434} Abduallh Muhamad Almutlaq, \textsc{Ms'ewlyh Aljany 'En 'Elaj Almjny 'Elyh Wdman Tetuleh 'En Al'eml [Responsibility of the Offender to Compensate the Victim for Medical Expenses and Work Disruption]}, 70 \textsc{Islamic Stud. J.} 316 (2003).
\textsuperscript{435} \textit{Id.} \textit{E.g.,} The Shariah Health Panel Decision No. 183/4/434 Date. 16/7/1434 A.H. The Shariah Health Panel Decision No. 1217 Date. 5/7/1429 A.H. In the two cases, plaintiffs have claimed other kinds of compensation, but the panel as well as the court have not addressed such compensation claims at all. They instead focused on the question whether to grant \textit{arsh} or \textit{diya} or not. \textit{E.g.}, The Saudi Administrative Case No. 2220/2 Date. 1431 A.H. In this case, a Saudi court has granted the plaintiff compensation for moral damage, and such judgement does not include granting a \textit{diya} or \textit{arsh}.
\textsuperscript{436} \textit{E.g.} \textsc{Alzarqa', supra} note 294, at 136-39.
circumstances they have lived in and circumstances today are not as in the past. They have added that interpretations should be reconsidered for some kinds of compensation, such income loss. This principle affects additional compensation when arsh and diya are applicable, and this part would present specific aspects of it when addressing each type of compensation separately. The next sections address several kinds of compensation separately.

A. Financial loss.

There is a possibility that patients may bear many costs, such as medical costs, because of their sufferings. As a rule, Islamic fiqh accepts recovery of financial damages as long as they are actual losses. This principle has been widely embraced by Saudi judiciary as well. Based on this rule, a patient who has made any payment due to the claimed damage is supposed to be compensated as long as such a payment can be proven. Any necessary payments patients have had to pay because of their medical damages should be recovered, including medical expenses. However, when diya or arsh is applicable, the principle presented earlier can significantly restrict or at least cause the court to hesitate to grant even actual financial loss. An important result here, patients who are not granted arsh or diya are more likely to recover from actual financial loss if proven.

B. Medical expenses.

According to the general rule addressed in section A, restitution of medical expenses is supposed to be awarded when patients can prove such costs. However, this has not often been the

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437 E.g. ALKAEEF, supra note 293, at 311.
438 Id.
440 See RESEARCH CENTER OF THE MINISTRY OF JUSTICE, supra note 389, at 472.
case, and it is challenging to find published court judgements mentioning compensation for medical expenses.\textsuperscript{441} The healthcare system in Saudi Arabia has been mostly public,\textsuperscript{442} and many patients have been insured by their employers even if they are treated in private hospitals.\textsuperscript{443} This can probably provide a factual explanation why medical expenses have not been widely claimed in courts. The healthcare system in Saudi Arabia has been transforming, and privatization will be predominant. It will become even more important to raise this question now and in the future as such a change is forthcoming.

In Islamic fiqh, the majority of jurists tend to not grant medical expenses.\textsuperscript{444} This has been prevalent in Saudi judiciary, and the former Head of Judges and Mufti has adopted this opinion.\textsuperscript{445} The majority opinion is based on the principle of not accepting other compensation when diya or arsh is granted.\textsuperscript{446} On the other hand, the idea of compensating for medical expenses has existed in Islamic classical fiqh.\textsuperscript{447} Some jurists have strongly supported the right of restitution of medical expenses even with fostering the principle of not accepting additional compensation other than the specified diya as a rule.\textsuperscript{448}

One of the jurists has raised a question; what if the arsh or diya barely covers medical expenses or is not sufficient to cover such expenses at all?\textsuperscript{449} What is left for the injured or their

\textsuperscript{441} Not mentioning such compensation expressly does not mean necessarily it is not considered. This can mean three possibilities: 1) medical expenses and other financial losses are considered, but no sufficient cases are published; 2) medical expenses and other financial losses are considered when estimating compensation, and because estimation grounding is not clarified in most judgments, it is not clear if such expenses are deemed within the estimation; or 3) medical expenses are not considered at all because of the principle that other kinds of compensation should not be applicable when diya or arsh is applicable.

\textsuperscript{442} See Ch I, part IV, supra.
\textsuperscript{443} Ch I, part IV, A, supra.
\textsuperscript{444} See Almutlaq, supra note 434, at 290.
\textsuperscript{445} BN QASM, supra note 391, 11/342.
\textsuperscript{446} Almutlaq, supra note 434, at 290-291.
\textsuperscript{447} BWSAQ, supra note 330, at 358-59.
\textsuperscript{448} Id. ALZARQA', supra note 294, at 136-39.
\textsuperscript{449} Id., at 138.
families in case of death?\textsuperscript{450} Another jurist has justified such medical expenses by stating that it is not only for the benefit of the patient, but it is also for the benefit of the wrongdoers who would choose to treat patients rather than leave them to die and bear maximum expenses and possibly criminal consequences.\textsuperscript{451} Although Saudi courts grant compensation for actual financial damages, medical expenses are not mentioned expressly in court judgments. Islamic fiqh accepts the idea of compensating medical expenses, but yet the Saudi judiciary seems to adopt the majority view of not granting medical expenses when diya or arsh is applicable.

C. Loss of income.

Patients may lose part or all their income temporarily or permanently as victims of certain violations. First, it is important to distinguish between loss of income and loss of the capacity to earn. Loss of income refers to past loss of income during a period in which a patient is unable to work and has not received usually confirmed payments as a result. Loss of the capacity to earn money in the future means patients are expected to lose their income for a period of time or their whole life because of the injury. It is more acceptable for the former be deemed as actual financial loss, but the latter seems to fit more with loss of future earnings, which is another category that is highly controversial under Islamic fiqh. As a general rule, the Saudi judiciary has adopted the principle that expected damages should not be considered and estimated before it happens.\textsuperscript{452}

Second, it is crucial to recall employment, social insurance, and civil service laws. In many cases and within the scope of these laws, it is possible that patients would receive some

\textsuperscript{450} Id.
\textsuperscript{451} Almutlaq, supra note 434, at 312-13.
\textsuperscript{452} RESEARCH CENTER OF THE MINISTRY OF JUSTICE, supra note 389, at 451.
payment from their employers or the Saudi General Organization for Social Insurance, if applicable. Consequently, several applicable laws can help patients during their injury even if a court has not granted such loss of income. This is not the case for all patients, but it is still applicable and should be mentioned here.

Third, courts have tended to deal with income loss as they have dealt with medical expenses. After reviewing several published Shariah Health Panel decisions, it appears that the question of compensating the loss of income has not been commonly mentioned. When examining Islamic *fiqh* references, compensating the loss of income is not a settled issue. Most jurists have found that compensation for lost income should not be granted when *diya* or *arsh* is granted. The main argument is that no more than one compensation should be granted for the same damage. Some jurists have added that injured people who are in danger of poverty should be supported by the government.

From another perspective, Ali Alkfeef has stated that *diya* and *arsh* are meant to compensate for physical injuries, but other financial damages should be taken into consideration. He argued that people in the past had simple lives, based on local agricultural products and self-employment, and what results from such injuries is limited economic losses for such a non-complex society. What is noticeable in Alkfeef’s view is that he expresses that *arsh* and *diya* are meant to compensate for injuries, and he distinguishes that from other financial

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454 See note 441.
455 BWSAQ, supra note 330, at 359-63.
456 Id.
457 Id. at 363.
458 ALKAFFEED, supra note 293, at 311.
459 Id.
damages, such as loss of income.\textsuperscript{460} This view can probably lead to reconsideration of the particular purpose for \textit{diya} and \textit{arsh}, possibly resulting in a final determination of whether granting compensation for certain financial losses can contradict or supplement a fair compensation for patients.

\textbf{D. Moral damages.}

The term moral damages means intangible damages, emotional damages, and pain and suffering. Moral damages are, “all harms that affect a person in their dignity, emotions, and feelings.”\textsuperscript{461} There has been a distinction made between moral damages that do not result in financial loss, and moral damages that result in financial loss.\textsuperscript{462} If the reputation of someone has been harmed, it is pure moral damage unless it has caused any financial loss as a consequence, such as losing a job.\textsuperscript{463} It appears that the moral damage in this context can be seen as moral wrongful conduct for such financial damages. The financial loss of the job would be considered as financial damage not moral.\textsuperscript{464} It has been well-established among jurists that financial losses that result from moral harms should be compensated,\textsuperscript{465} and this is consistent with what has been stated in section A of this part.

Islamic jurists have not agreed on considering financial compensation for moral damages.\textsuperscript{466} Most jurists consider that financial compensation does not apply to moral damages.

\begin{footnotesize}
\textsuperscript{460} Id.
\textsuperscript{461} BWSAQ, supra note 330, at 29.
\textsuperscript{462} Abdulmalik Al'eskr, \textit{Alt'ewyd 'en Aldrr Alm'enwy [Compensation for Moral Damage]}, 27 QADHA J. 184 (2022).
\textsuperscript{463} Id.
\textsuperscript{464} Id.
\textsuperscript{465} ABDALLH MUHAMAD ALKHNYN, DAMAN ALADRAR ALM'ENWYH BALMAL [GUARANTEEING MORAL DAMAGES IN MONEY] 15.
\textsuperscript{466} EBDAL'EZZY BN S'ED ALDGHYTHR, ALAKHTYAR FY MSA'EL ALT'EWYD 'EN ALADRAR [THE CHOICE IN MATTERS OF COMPENSATION FOR DAMAGES] 2-6 (2017).
\end{footnotesize}
damages.\textsuperscript{467} The majority view is based on the presumption that moral damage is a recovery from criminal aggression.\textsuperscript{468} For example, they have mentioned repeatedly that Shariah resources have specified some criminal punishments as the only remedy in case of verbal aggression.\textsuperscript{469} In the case of verbal abuses that do not satisfy elements of specified crimes, jurists have considered other moral remedies, such as an apology if the verbal abuse is slight.\textsuperscript{470} However, moral damage can result from non-criminal conduct, such as medical malpractice, and criminal liability in such cases may not arise at all.

Patients may have short-term or long-term mental health complications because of misusing a medication when a physician prescribes a high dose.\textsuperscript{471} In addition, it is possible that misusing medications can lead patients to be unconscious and possibly behave or talk improperly.\textsuperscript{472} In such cases, jurists mention other reasons not to consider moral damages that can be related to moral damage caused by malpractice. For example, moral damages do not include a financial loss and a physical loss.\textsuperscript{473} Furthermore, intangible damages cannot be assessed as accurately as tangible damages.\textsuperscript{474} Finally, adding financial compensation in addition to the \textit{diya} and \textit{arsh} is not accepted.\textsuperscript{475} In contrast, other jurists think that intangible damages are compensable financially.\textsuperscript{476} Jurists who have adopted this opinion include moral damages within the concept of harm that Islamic resources have recognized as compensable.\textsuperscript{477}

\textsuperscript{467} E.g. The Council of the International Islamic Fiqh Academy Resolution No. 109 (3/12), \textit{supra} note 439. See also \textit{ALDGHYTHR}, \textit{supra} note 466, at 3; \textit{ALZARQA'}, \textit{supra} note 294, at 124.
\textsuperscript{468} Al'eskr, \textit{supra} note 462, at 186-88.
\textsuperscript{469} \textit{Id.}, at 187.
\textsuperscript{470} \textit{ALKHNYN}, \textit{supra} note 465, at 15.
\textsuperscript{471} See Part I, \textit{supra}.
\textsuperscript{472} \textit{Id.}
\textsuperscript{473} \textit{BWSAQ}, \textit{supra} note 330, at 34-35.
\textsuperscript{474} \textit{Id.} Al'eskr, \textit{supra} note 462, at 187-88.
\textsuperscript{475} ALZARQA'. \textit{supra} note 294, at 126.
\textsuperscript{476} ALZHYLY, \textit{supra} note 290, at 53; Al'eskr, \textit{supra} note 462, at 190; \textit{ALKHNYN}, \textit{supra} note 465, at 17.
\textsuperscript{477} \textit{ALKHNYN}, \textit{supra} note 465, at 17; Al'eskr, \textit{supra} note 462, at 189.
Saudi courts are also varied in their consideration of moral damages. First, it is challenging to find a published case granted compensation for moral damages when *diya* or *arsh* is applicable.\(^{478}\) This suggests that the principle of not accepting other compensation when granting *diya* or *arsh* applies in cases of moral damage. This also has been seen as a justification for not accepting moral damages at all.\(^{479}\) While it has been known for decades that Saudi courts have adopted the majority opinion in Islamic *fiqh*, the minority view in Islamic *fiqh* exists noticeably in Saudi administrative court judgments\(^{480}\) that have tended to compensate financially for moral damages.\(^{481}\) Therefore, the majority and minority doctrines of Islamic *fiqh* regarding compensation exist in the Saudi judiciary,\(^{482}\) but it seems that recognizing moral damages, as a principle, would not result in granting compensation for moral damages when *arsh* or *diya* is applicable.

\(^{478}\) See note 441.

\(^{479}\) Alzarqa', *supra* note 294, at 126.

\(^{480}\) Medical malpractice cases against public hospitals are under the jurisdiction of the administrative courts. In addition, administrative courts have the authority to review Shariah Health Panel decisions as an administrative panel.

\(^{481}\) Al'eskr, *supra* note 462, at 198.

\(^{482}\) E.g., Case No. 3551928 Date. 1435H. Published in: MINISTRY OF JUSTICE, MJMW’EH ALAHKAM ALQDA’EYH L’EAM 1435H [A COLLECTION OF JUDGMENTS FOR THE YEAR 1435H], 2/103 (2017). Contra, Administrative Case No. 2220/2/g 1431H.
V: Challenges and Solutions.

A. Challenges.

The compensation system in Saudi Arabia has been seen as the area where development is needed the most. Harmed patients go to courts to obtain justice and to recover from their sufferings. As mentioned earlier, Islamic fiqh as the main source of Saudi law has been striving to balance two main respected interests when imposing compensation. On the one hand, the fiqh aims to mitigate a victim’s damage. On the other hand, the fiqh seeks to ensure that the court’s judgement is based on proper justifications before taking money from another person to grant it to the victim. The fiqh has carefully required restrictive standards to achieve such aims. The influence of Islamic fiqh references as direct sources in courts will not remain once codified laws are enacted, and certainly, this would have many implications, such as uniting courts’ views on many major matters and settling many undecided matters. Consequently, challenges that have arisen in this part may or may not remain after codified laws are enacted.

First, the compensation system under Saudi law relies heavily on the amount of diya. The amount of diya can significantly affect most types of patients’ compensation. Although the amount of diya is settled in confirmed texts of main sources of Islam, it is not clear how often the Saudi judiciary would re-estimate this amount in modern currency. Reviewing the evaluation of diya on a regular basis can allow courts to account for economic changes as accurately as possible. It is also important to have the justifications and the estimation methods available for experts and researchers to understand the process and work on studying it and developing it. The
amount of *diya* is central to determining patients’ compensation, and it is significant to reconsider its amount to ensure that it reflects the purposes of imposing *diya* in Islam.

Another significant challenge is the idea of not accepting additional compensation when *diya* or *arsh* is applicable. It has arisen against the applicability of any claimed damages. Medical expenses, for example, can be controversial due to this principle. Moral damages and loss of income are two other deep controversies to reconsider and settle. The question is; if the new code recognizes moral damages, for example, will the court consider them when *arsh* or *diya* is applicable? The question remains open then, and it is possible that patients would not be granted moral damages based on the new civil code when they are granted *arsh* or *diya*.

Second, other compensation should not be presumed to be insured or covered by any other plans. When considering types of compensation other than *diya* and *arsh*, it should be remembered that patients today do not face the same circumstances that existed a decade or decades ago. Many developments have been ongoing. Regarding medical expenses, patients have been enjoying public healthcare as a choice and this has worked as an important factor. Public healthcare will be privatized, and privatization can bring other factors that have implications for the law. This requires more attention to compensation for medical expenses. In case of loss of income, certainly with new laws, such as regulation of freelancing, in addition to the existence of productive families’ programs and other commercial activities, patients may find themselves not covered by any government or private insurance plans and unable to work for a period. This is certainly concerning and should be considered to ensure sufficient and just recovery from damages.
B. Solutions.

It is predicted that Saudi law will not remain the same regarding compensation. The ongoing process to codify Saudi law would considerably change the role of Islamic fiqh in the Saudi judiciary.484 The code is expected to choose a doctrine of Islamic fiqh instead of leaving this to courts. Thus, whatever is embraced by lawmakers will be the choice, and courts will have less authority to select the proper rule from Islamic fiqh. This would certainly overcome some challenges, and it is also possible that new challenges will arise. Legislation can contribute to decreasing uncertainty and increasing predictability of Saudi law. This section will discuss possible trends of solutions from two perspectives.

First, new research in Islamic fiqh should be done to answer many open questions in compensation. In terms of estimating diya and arsh, it seems reasonable to have a yearly review of amounts, since prices of essential commodities change from time to time, and diya’s value is probably affected. The principle of not accepting compensation if diya or arsh applies should probably be reconsidered. The following questions should be answered. Are diya and arsh to compensate or to punish? If diya or arsh is to punish, why should it prevent other kinds of compensation? If diya or arsh is meant to compensate, is it to compensate for all damages or particular damages?

Furthermore, actual financial losses should be settled and compensated even if arsh or diya is applicable, especially in the case of medical expenses. Loss of income should be studied and classified. In some cases, income loss can possibly satisfy actual financial loss, but in other cases, it seems further research is needed. Moral damage should not be seen as verbal abuse, but

484 See Ch III, part III, supra.
it should be discussed as if it is within the concept of harm or not before discussing other details. In addition, it seems developing methods to estimate compensation can change the general view of moral damages. Research should be done to examine new accounting and financial methods that can help with more accurate assessment of compensation.

**Conclusion**

Compensation under Saudi law has been based on Islamic *fiqh*. Islamic *fiqh* recognizes the right of compensation for physical injuries and death with specified and discretionary amounts. Islamic *fiqh* compensates for certain financial damages. Medical expenses are supposed to be compensated as actual financial loss, but moral damages and income loss are still controversial. Although compensation for physical injuries is mostly settled, other compensation is still not expressly regulated. Compensation claims of all sorts can be ignored by courts if *diya* or *arsh* is applicable, and courts would not grant medical expenses, income loss, or even moral damages according to the majority of jurists in *fiqh*.

Saudi law is about to enter a new era when newly codified laws are enacted. This can transform many civil law principles, including compensation. Meanwhile, more research should be done to consider the following: the purpose of *diya* and *arsh*, and whether it is acceptable to grant patients additional compensation or not. Legislation should settle the question of adopting moral damages or not. In addition, medical expenses should be expressly dealt with in court judgments upon the request of plaintiffs. Loss of income should be regulated in a way that does not leave people who are not insured according to employment and social insurance laws with no protection.
Chapter V: Patient’s Access to Justice.

Introduction

After addressing the main substantive rights, such as civil liability and compensation, it is vital to examine available procedural methods that facilitate accessibility to such rights. This chapter addresses procedural civil aspects of access to justice. The main question is what proceedings are available to patients to access justice in medical malpractice and consumer cases. The question extends to whether the available proceedings assure efficient and effective access to justice. This chapter describes current available means to access justice, presents challenges, and finally suggests trends of developments.

Part I introduces access to justice by presenting conceptual and theoretical grounds. Part II briefly explores administrative claims and reporting systems to understand their roles in protecting patients. Part III describes various accessible dispute resolution methods under Saudi law, such as conventional forms of litigation including individual, group, and organized representations. Part IV presents alternative dispute resolution (ADR), and how it can function to serve patients’ access to justice. Part V finally raises challenges and explores possible solutions.
I: Overview.

Access to justice can include substantive and procedural aspects, and it has been common to use this term to refer to procedural methods that can lead to justice as the fruit of law, especially in the context of consumer protection. The Saudi Basic law of Governance has assured that everyone has the right to litigate and has confirmed the right of just and equal treatment. Under Saudi law, the main right to access justice is recognized, however, the concern in this chapter is whether the access to justice that is provided to patients is appropriate and sufficient. Patients in medical malpractice and consumer cases can face access to justice challenges if such process does not fit their situations. The U.N consumer guidelines have mentioned the necessity to have suitable dispute resolution systems for consumers. Efficient and effective access to justice starts from important questions, such as the cost, the time, and the outcome and concludes with providing means that are apt to a patients’ particular situations.

One of the main questions that studies raise when considering consumer access to justice is: is it effective for a consumer to go through prolonged litigation to redress small claims? The answer has commonly been no, especially when it comes to very small claims or risky litigation. Patients may feel lost or incapable of seeking their rights because access to justice comes at such a high cost. If patients or consumers must go through a long costly litigation to seek possibly uncertain and/or limited results, even meritorious claimants may not seek remedies, and the wrongdoer can escape liability. Many consumer and patient claims would be left unaddressed.

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486 Basic Law of Governance, supra note 40, art. 47.
487 See UNITED NATIONS, GUIDELINES, supra note 110, at 11.
488 HOWELLS ET. AL., supra note 108, at 484.
with such inefficient access to justice. These realities have led legal systems worldwide to design adaptive strategies to further develop the efficiency and the efficacy of access to justice.

Such strategies start with policies and procedures to avoid damage and litigation in the first place by imposing *ex-ante* regulations. The amount of damage and number of claims would certainly decrease as a result, but they still exist, and thus inefficiency in *post-ante* means is still concerning. Reforms have improved many aspects for consumers, such as providing legal assistance and reconsidering court fees. In addition, reforms have extended to embrace other methods of litigating and alternative dispute resolutions (ADR), such as class actions and arbitration or other ADR. Reevaluating the challenges and cost of access to justice has been concerning legal bodies worldwide, and many remarkable developments have emerged over time.

Patients can possibly be involved in medical malpractice and/or consumer cases depending on who they seek to establish liability against. Each type of these cases has distinct characteristics. It cannot be assumed that a health professional can serve as many patients as the considerable consumers of a pharmaceutical product. For example, it is more likely for a manufacturer to have a defect in a product or a mistake in the information provided since they work to produce many of the same products. In contrast, a physician usually serves patients individually, and each patient has different health circumstances. Malpractice that occurs to one patient does not necessarily occur to another. Consequently, class actions in consumer product cases are more common than in medical malpractice cases since consumer cases usually concern

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489 *Id.*
490 *WRBKA, supra* note 485, at 53-60, 78.
491 *Id.* at 83-96.
small and similar damages for a large number of consumers, while medical malpractice typically refers to unique damages usually for one or a small group of patients.\textsuperscript{492} Next, this chapter presents the current Saudi law regarding several access to justice main aspects and raises the efficiency challenge in the last part and proposes or explores solutions.

\textbf{II: Administrative complaint system.}

Complaint and reporting systems can play crucial roles in protecting consumers. Several Saudi government authorities have reporting and settlement systems. These systems have been considered effective in either preventing damages or helping consumers to recover with no need to go through traditional litigation.\textsuperscript{493} The outcomes of such systems vary. Whereas some systems can result in taking public policy actions, others manage to reach settlements that solve the consumer concerned transaction.\textsuperscript{494} The existence and the contributions of such complaint and reporting systems depend on the goals of the authorities, the legal powers granted by law, and the way such complaint or reporting system is employed. It is possible that patients may misunderstand the role of such systems, and this can cause a false sense of security that may cost them their sought-after right.

The Saudi Food and Drug Authority (SFDA) has a system that receives reports from patients as well as health professionals regarding safety of drugs and food.\textsuperscript{495} The expected outcome of the SFDA system is to take appropriate procedures that can lead to public policy

\textsuperscript{493} See WRBKA, supra note 485, at 40.
\textsuperscript{494} Some Saudi authorities have a settlement system. For example, the Saudi Communication, Space & Technology Commission has an electronic settlement system that starts with receiving complaints from customers and concludes with a settlement for the private right of the customer. Service Link: https://mutasilind.citc.gov.sa/Services/Details/2 (last visited Feb. 25, 2023).
actions to prevent future cases. This is to serve the main purpose of the SFDA, which is to ensure food and drug safety and drug effectiveness. The SFDA has the authority to require manufacturers to meet certain standards, examine and analyze products, and take proper steps to ensure enforcement. The SFDA does not have authority to enforce patients’ private rights. Thus, SFDA’s role in this regard is mostly ex-ante. Even if a patient or a health professional reports an issue to the SFDA regarding the safety or effectiveness of a certain drug, it would only record this and take proper public action, such as warning the public or withdrawing a defective product.

Private damages of patients that have already happened are not expected to be addressed through SFDA reporting process. SFDA’s role when dealing with reports from patients is to protect the collective interest of patients, but it is not to protect the interest of an individual patient. Therefore, the individual interest of a patient that is harmed due to misleading pharmaceutical marketing can only be sought through traditional civil law instruments. This can raise several questions. The reporting system allows SFDA to know information about the existing medication issues that are reported by health professionals and patients. Then, SFDA is responsible to take public actions to protect the collective interests of patients based on this information, but what about the private interests of patients? Is there a process to ensure that damaged patients are informed of possible damages? Is there a requirement to disclose information about the damage and the possible risks to damaged patients? Are there systems to track affected individuals and guide them to seek their rights? Is the scope of SFDA’s legal

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496 SFDA Law, supra note 53, art.3.
497 Id., art.5.
498 E.g., Law of Pharmaceutical Products and Facilities, supra note 9, art. 24, 33.
obligation to inform consumers clear and precise to determine what exactly SFDA’s responsibilities are in this regard and what is left for other authorities and entities?

III: Litigation.

The traditional court system has the original duty to resolve disputes in the Saudi legal system. Litigation can be used to seek the rights of an individual or a group of individuals in the case of class actions. This part’s goal is to address the current situation of the Saudi law regarding litigation. In addition to exploring individual and group litigation, this part examines another type of litigation, that is, lawsuits that are filed by entities and organizations, such as the Saudi Consumer Association, to protect the collective interests of patients. The aim is to investigate the key questions of the current law before raising any challenges and proposing solutions later in this chapter. Section A presents individual cases, section B examines class actions, and section C explores the role of the Saudi Consumer Association.

A. Individual Litigation.

Patients have the right to litigate individually. They can be a party in a medical malpractice case against their physicians or in a consumer case against pharmaceutical corporations. The individual patient may seek justice individually through filing a conventional lawsuit. It is possible that the individual patient has sufficient economic resources to file such a suit, but many would avoid litigation due to the high cost. The Saudi judiciary has made

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499 SFDA Law, supra note 53, art. 5.

Certainly, patients are supposed to experience a tremendous improvement in litigation, but are such changes adequate for patients in all situations? Can Saudi procedural law be more effective for patients’ access to justice?

It is important first to distinguish between medical malpractice cases and consumer cases from two aspects. One is the jurisdiction can vary based on the type of patient case. Medical malpractice cases are under the jurisdiction of the Shariah Health Panel currently, and it has been transforming to medical courts gradually.\footnote{502 The Shariah Health Panel has been established as a semi-judicial panel that has the jurisdiction to hear medical malpractice. Recently, medical courts have been planned to take such responsibility soon, and all medical malpractice will be under the jurisdiction of medical courts. Law of Practicing Healthcare Professions, supra note 53, at art. 34. (Saudi Arabia). Jurisdiction Of Medical Dispute Panels Transferred To The Ministry Of Justice, Saudi Gazette, https://saudigazette.com.sa/article/627663/SAUDI-ARABIA/Jurisdiction-of-medical-dispute-panels-transferred-to-the-Ministry-of-Justice (last visited Jan. 28, 2023).} Consumer cases, on the other hand, can fit under more than one court’s jurisdiction, including general courts and commercial courts.\footnote{503 For consumer cases, cases against pharmaceutical corporations can possibly be under the jurisdiction of general courts or commercial courts. The Law of Civil Procedures states that general courts have the authority to hear cases that are not within the jurisdiction of other courts. The Commercial Courts law states that commercial courts have the authority to hear cases against merchants under two conditions; one it should be regarding a commercial contract, and there is a minimum amount for the claim. Thus, patients may have the choice to either file a lawsuit against pharmaceutical corporations in general courts or commercial courts if the case fulfills criteria of kind and amount. Law of Civil Procedures, supra note 54, at art. 31. Law of Commercial Courts, Royal Decree No. M/93 Date. 15/8/1441 A.H., art. 16 (2020). (Saudi Arabia).} Second, medical malpractice cases are different in nature from consumer cases. While consumer cases are usually a result of a violation that can harm many consumers with similar damages, medical malpractice can be a patient-physician case with unique damages. Therefore, one is more likely to find more class actions in consumer cases when the other party is a massive manufacturer that targets and deals with more customers than a single health professional.
In both medical malpractice and consumer cases, patients may face many risks that can complicate their access to justice when filing individual cases. Small claims will not likely be the best economic choice for individual cases. In other claims that can work with the individual choice, patients can bear various costs, such as financial costs, including attorney fees, court fees, and evidence costs. The patient may not eventually bear all or part of these costs, but it is still a factor that can discourage patients from accessing justice. Patients cannot be certain of winning the case, so the risk of losing exists since accepting the evidence and establishing the required elements are within the court’s discretion in many cases. Patients do not always find litigation the best way to leave them in a better position, especially when it comes to litigation with limited claim amounts, high costs, and lengthy processes. Therefore, individual cases are not the best tool to access justice in limited claim cases, and the next sections explore the current condition of other possible sorts of litigation that can be a better fit for patients.

B. Class action.

A class action is “a lawsuit in which the court authorizes a single person or a small group of people to represent the interests of a larger group.” It is the common tool that legal systems worldwide have recognized as a solution when individual suits are impractical. It has been effective in case of small claims. Instead of leaving small claims unresolved, many claims can be combined in one case and heard in one court. It is not only more efficient for patients and allows sharing of costs, but it is also effective in encouraging corporations to avoid consumer

504 See WRBKA, supra note 485, at 78.  
505 Class Action, BLACK’S LAW DICTIONARY (11th ed. 2019).  
506 See HOWELLS ET. AL., supra note 108, at 515-17.  
507 Id. at 516.
right violations, such as spreading misleading information about medications.\textsuperscript{508} Consequently, class actions can reconfigure discrete minor patient claims in consumer cases to be one larger aggregate, not only to restore patients’ private interests but also to serve the interests of all patients as a group.

Under Saudi law, the idea of class actions is generally accepted. The Saudi Civil procedural law does not expressly regulate class actions.\textsuperscript{509} However, the idea of group cases exists in practice since the law does not require litigation to be only for individuals, but it instead allows litigants to join ongoing litigation under certain conditions.\textsuperscript{510} Class actions have been expressly regulated in other specialized statutes, such as the Law of Commercial Courts.\textsuperscript{511} Consumer cases can be under the jurisdiction of commercial courts if certain requirements are met.\textsuperscript{512} Class actions should be a common practice in Saudi law, and it should be adopted and encouraged widely.

In practice, it is hard to assess consumer class action cases. No public information or statistics are available about the amount and the kind of existing class actions, and whether it is related to patient cases or not. However, Saudi general civil procedural law does not expressly either regulate class actions or prevent the idea of such cases, so the existence of class actions is possible and practical. Having no consumer class actions, publicly announced or reported, does not necessarily mean class actions are impermissible. Even if there is a lack of express

\textsuperscript{508} \textit{Id.}
\textsuperscript{509} ABDUALRHMN ALSALAMH, ALD'EW A ALIMA'EYH WTTBYQATHA FY ALANZMH ALSA'UDIYH [CLASS ACTION LAWSUIT AND ITS APPLICATIONS IN SAUDI LAWS] 15 (2020).
\textsuperscript{510} \textit{Id.}
\textsuperscript{511} Law of Commercial Courts, \textit{supra} note 503, at art.8.
\textsuperscript{512} See HOWELLS ET. AL., \textit{supra} note 108, at 484.
recognition in civil procedural law, rarity of class action can be linked to the lack of awareness. That issue will be explored more in part V.

C. The Role of the Saudi Consumer Protection Association in Representing Patients in Court.

Patient protection litigation can involve various interests, namely, public interest, individual interest, and collective interest. Each of these interests should be represented and sought in court, and the law should determine the representatives of such interests and their powers. Is the role of the Saudi Consumer Protection Association (SCPA) to protect the public interests, the collective interests, or the private interest of patients? The SCPA’s duties include receiving consumer complaints, contacting government authorities regarding violations of consumer rights, and keeping track of the efforts to resolve such issues. Since the process relies on public authorities, it is likely to result in administrative actions, such as injunctions meant to protect consumers as a whole, not a particular person. Therefore, it seems that the SCPA is meant to protect the collective interests of patients. The SCPA does not have the power to protect the public interest in criminal cases. That is left to the prosecution. The SCPA does not also have the power to enforce the private right of an individual consumer. This can indicate that the legal representation power of the SCPA, if

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513 The public interest portion is related to the protection of society from crimes, and it is within the job of public prosecution to charge criminals of consumer fraud as an example. Private interest is related to the private right of an individual, and it can be sought through the individual or a group of individuals in class actions to seek redress. The collective interest is related to the rights of a group of people as a whole, consumers in this case, and it can be sought by different parties, such as public authorities and consumer associations. See Ali Alldydy, alslf y alda'e 'en almslhh aljma'eyh walslhh al'eamh [Legal Standing in Defending the Collective Interest and the Public Interest], 1 SEC. & LEGAL J. 308-65 (2004). See Siham Alqshtwl, Almslhh Aljma'eyh Ljm'eyat Hmayh Almslhhk [The Collective Interest of Consumer Protection Associations], 2 MOROCCAN J. LEGAL STUD. & CONSULTATIONS 211-21 (2016).

514 The Consumer Association Regulation, Ministry Council Decision No. 120 Date. 23/2/1436 A.H., art. 5 (2014). (Saudi Arabia).

515 This is generally consistent with the role of consumer associations. See Alqshtwl, supra note 513.
granted, should not be seen as an alternative to any legal action to seek the private interests of a patient or patients.

Saudi law does not grant the SCPA the right to file lawsuits against violators of consumer law on behalf of consumers, such as in the case of misleading marketing.⁵¹⁶ The current role of the SCPA is limited to administrative representation locally and internationally.⁵¹⁷ Even if the law has granted the SCPA such litigating power, it cannot be considered a substitute for individual and class action litigation that aims to seek the private right of a person or persons. Unless the law grants the SCPA the power to seek the private interest in the future, the circumstances will not change. Many cases that are supposed to be under the SCPA’s authority, such as seeking judicial injunctions to prevent violations of consumer rights in misleading marketing, cannot be brought otherwise in court. The SCPA does not have the power to litigate on behalf of consumers in court, and it is useful to consider granting this power to protect patients’ interests.

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⁵¹⁶ See Consumer Association Regulation, supra note 514.
⁵¹⁷ Id.
IV: Alternative Dispute Resolutions (ADR) and Patients.

ADR is defined as, “Any procedure for settling a dispute by means other than litigation, as by arbitration or mediation.” ADR is a set of tools that solve claims, including those of patients and consumers, with less costs and time. The U.N Consumer Guidelines have mentioned ADR among tools that can help consumers access justice efficiently. ADR can also be an effective choice to settle medical malpractice cases. Although ADR has been seen as a positive choice to settle consumer and patient cases outside of conventional litigation, it can be also seen as impediment to consumer access to justice when it is managed by the powerful party to protect its interests and block access to court. In such a case, legal systems have aimed to protect consumer choice to the court of law by restricting arbitration clauses in adhesion contracts. Therefore, ADR can be used as a barrier to access to justice or a solution for more efficient access to justice. In both cases, the law should regulate ADR to ensure consumer substantive rights are not affected by waiving the right to go to court.

Saudi law has recognized settlement practices to solve several consumer issues, but the law does not have an official ADR or settlement system that serves patients in malpractice and consumer cases. For arbitration, it is possible to have medical malpractice and consumer cases solved through arbitration, but there is not a special framework for that as well. According to

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519 WRBKA, supra note 485, at 83.
520 See United Nations, Guidelines, supra note 110, at 15.
521 See KHALED ALKHAREF, A COMPARATIVE APPROACH TO MEDICAL MALPRACTICE LAW IN SAUDI ARABIA 28-31 (2021).
523 Id.
524 See note 494.
525 ALKHAREF, supra note 521, at 28.
general principles of arbitration under Saudi law, arbitrating financial cases is acceptable, and thus patients can seek compensation through arbitration. For other ADR, such as negotiation and mediation, reaching a deal regarding financial matters in consumer and medical malpractice cases is possible and supported under Saudi law. If such an agreement is notarized properly according to notarization law, authorities must enforce it as much as a confirmed arbitration award or a court judgement, as long as it complies with applicable laws and Islamic Shariah principles. Despite this, ADR in consumer and medical malpractice has not been widely utilized. This is probably due in part to lack of a framework that offers ADR options to facilitate patients’ access to justice.


The main access to justice concern is inefficiency. The patient or the consumer often lacks the ability to access reasonable redress when damaged. The idea of using expensive and time-consuming means to recover from damage is injurious from human and economic perspectives. It is not fair to complicate damaged patients’ ways to adequate and just redress, and it is important to reassess their situations to develop the available means to access justice. This part raises the inefficiency challenge and then addresses possible reforms to advance patients’ access to justice. Section A of this part presents the main challenge - inefficient access to justice. Section B explores main trends of reforms that can be adopted.

A. The Inefficient Access to Justice Challenge.

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526 The Arbitration Law, Royal Decree No. M/34 Date. 24/5/1433 A.H., art. 2 (2012) (Saudi Arabia). The arbitration law shall not be applicable to personal status laws, and disputes in which reconciliation is not acceptable. Financial cases, including diya and arsh, are among those that accept reconciliation.

527 See Notarization Law, Royal Decree No. M/164 Date. 19/11/1441 A.H., art. 41 (2020) (Saudi Arabia).

528 ALKHAREF, supra note 521, at 30.
Patient’s access to justice should be efficient and fit the patient’s particular situation. The main challenge for patients is that the traditional litigation choice is still predominant. Patients are mostly left with only the option of litigation, and courts cannot always be the best way to help consumers or patients access their rights, especially when the cost-benefit analysis is not feasible for their situations. Many factors can determine whether litigation fits the patient’s particular situation or not, such as the amount of the claimed right compared to the financial cost and the time length of the process. Damaged patients consider whether the expected outcome is worth the time and cost of the claim before taking any step.

In many cases, it is risky to litigate and bear those costs for a low probability of return. When ambiguity exists in legal rulings and in outcomes of such proceedings to the extent that the outcome becomes unpredictable, patients may avoid taking any further steps to claim their right. Even if many patient and consumer cases under Saudi law cannot be considered totally unpredictable, such cases involve risks certainly higher than if a general code and specific statutes existed. The risk involved in substantive issues regarding rights and amount of available remedies can significantly affect the decision to pursue litigation or not. It is possible evaluations of risks can result in avoidance of litigation and restrain access to justice completely in many instances, especially when alternatives do not exist.

From another perspective, patients may consider how time-consuming such risky litigation will be compared with its expected outcomes. It is probable that the outcome is predictable in some cases, but litigation is lengthy compared with small-scale financial outcomes. Such laborious and prolonged processes can discourage patients from seeking redress, especially when other factors are involved. For example, in a system where each specialized court has specific subject-matter jurisdiction, patients may be at risk of filing a lawsuit in the wrong court, and
even correcting such an error can result in long delays that can complicate the case. Litigation is time-consuming and cannot fit patients’ situations in all matters, but still, patients have to deal with litigation as the only choice to mitigate their sufferings in numerous cases.

In addition to the time and risk feasibility, patients may have to bear significant financial costs to access justice. Access to justice can be expensive in many cases. Patients will bear costs, such as attorney fees, court fees, and experts’ fees. Even if courts may require the losing party to bear all or some of such costs, patients are not guaranteed to win the case. Patients may bear other costs, such as travelling to the defendant’s court to file a lawsuit. Patients may fail to secure funds at the beginning and decide not to litigate. For patients with limited income, it is risky to bear costs of long, inefficient, costly litigation only to be left worse off if they do not prevail.

Patients may choose not to claim their rights if the legal system has failed to provide efficient access to judicial proceedings. Such efficiency should be reflected in the overall cost compared with the outcome of the process. Patients’ or consumers’ procedural access to justice can affect substantive rights significantly. Ambiguity in substantive outcomes can be discouraging, causing patients to refrain from seeking redress. Such inefficiency creates an unhealthy market when businesses think that they can get away with injuring patients, especially when the damages are small. The inefficiency can cause the number of victims to increase. Thus,

529 In many instances, patients’ cases may not be economically efficient for attorneys to take due to limited claimed amounts. An attorney may ask for a set amount or a down payment in addition to a contingency fee, so the possibility of having several forms of agreement exists.

530 A lawsuit should be filed in the defendant’s court as a general rule. Law of Civil Procedures, supra note 54, at art. 36.
it is rational for any legal system, including the Saudi legal system, to reconsider the access to justice situation and work on improving it.

**B. Towards More Efficient Patient Access to Justice.**

Many policies and procedures can be considered to improve patients’ access to justice significantly. The aim of considering such policies and procedures is to minimize the cost and the time involved. Some access to justice means can better fit patients’ situations in both medical malpractice and consumer cases, but others can be more suitable for one type of case than the other. This section outlines reforms that can develop patients’ protection in various aspects. First, the section addresses improvements in the litigation process. Second, the section presents class actions as an alternative to individual litigation. Third, the concentration shifts to the role of consumer or patient organizations to represent patients judicially. Fourth, the section examines alternative dispute resolution as an effective replacement of traditional litigation in group and individual cases.

1. Litigation:

This research has stated earlier that the litigation option, including in individual cases, can be risky and expensive, and reform should start with reconsidering litigation to ensure that it reaches a reasonable level of efficiency. The Saudi Ministry of Justice has already begun the reform by establishing specialized medical courts instead of relying on administrative committees to settle medical malpractice cases. This can minimize litigation time frames. The decision of the Health Shariah Panel cannot be enforced as a court judgement directly. It is considered an administrative decision that is subject to the primary
administrative court review in addition to review by the appellate administrative court as any administrative decision. The patient, when dealing with the panel, can obtain a decision, not a court judgement. However, new medical courts’ judgements can only be subject to appellate court review directly and the supreme court in exceptional cases. The medical court’s judgement is not considered an administrative decision that even the primary court can review. This can save time and can result in enforced adjudications of patients’ rights in a shorter time.

Courts, including medical or other general courts, on the other hand, still offer traditional litigation even with such developments. Several aspects of litigation should be reconsidered to better protect patients. Different approaches can be deemed to increase the efficiency of such cases for patients. First, it is helpful to assure limited applicability or inapplicability of court fees in patients’ cases. Second, the idea of ensuring legal assistance for patients in litigation can facilitate access to justice. Third, it is important to consider the jurisdiction of patients’ cases. If medical courts accept all patients’ cases, including consumer cases, this can be a significant way to not confuse patients with different jurisdictions. Finally, patients should also be provided with guidelines of procedures in easy language for common cases in which they could be involved. As there are steps that can help to improve efficiency of all patients’ cases, avoiding individual lawsuits or avoiding all lawsuits, when possible, can be positive for patients’ interests if such avoidance results in fair and just situations for patients. Next, other access to justice choices will be explored.
2. Class Actions:

Class actions are a way to use litigation wisely. Combining many small claims in one case can help minimize the cost and impose larger impacts on corporations. At the same time, class action is a mere procedural technique that targets the same outcome total that individual may seek separately, which preserves justice, minimizes costs, and maximizes the impact by combining claims. Class actions also send a message to corporations that patients would not leave even a small claim with no action. This can lead to more respect for patients’ rights. Saudi lawmakers should consider encouraging class actions in different ways since it has many advantages for individuals and the society. Encouragement should not only be limited to legislative efforts, but it should extend to educational efforts since the issue includes lack of legal awareness.

There are significant steps that can help in developing consumer access to justice. One is announcing expressly and publicly whether courts accept class actions or not according to general civil procedures law, especially with the absence of express recognition of class actions in such law. Second, considering express recognition of class actions in the Saudi Civil Procedures law. Third, launching a campaign to develop awareness of the importance of class actions among consumers or patients. Fourth, the Saudi Bar Association should consider lawyers’ opportunities to accept and manage class actions. Class action is not only a tool to access legal redress, but it has been a tool that corporations try to avoid for financial and reputational reasons. It plays a significant role in empowering patients. There should be a strategy to ensure this tool is used effectively.
3. The Saudi Consumer Protection Association (SCPA) Litigating Power:

As has been presented earlier, there is always room for consumer or patient organizations to represent the whole group of consumers or patients even if class actions exist. The distinction between public, private, and collective interests has been made previously, and as such a distinction exists, the significance of having independent representatives for every interest certainly arises. Such power can impact patients’ rights in several ways. Since Saudi law relies heavily on administrative actions in protecting patients, the Saudi Food and Drug Authority (SFDA) can take distinct actions to ensure the safety of medications, including banning an advertisement or withdrawing a product. While such actions are subject to judicial review if the marketer files an administrative lawsuit to counter SFDA actions, patients and consumers on the other side cannot counter non-action of SFDA. Patients should have the power to seek injunctions in court through consumer entities. This should include requesting that the SFDA and other authorities to take appropriate actions required by law. The law should consider measures to ensure that the SCPA’s granted power is truly used for the interests of consumers.

The idea of granting SCPA or other consumer entity the power to litigate on behalf of consumers is adopted worldwide. In Arab laws, Egyptian and Kuwaiti laws grant consumer associations the authority to represent patients in court in certain cases.\textsuperscript{531} In addition, the U.S. Federal Trade Commission has the power to seek redress for consumers.\textsuperscript{532} Saudi lawmakers should ponder how such power to litigate could be provided to one or more

entities to serve the interests of consumers and patients in all cases. Individual consumers may not legally be able to seek such injunctions since they have to establish legitimate interests in court.\textsuperscript{533} It is crucial to have patients’ interests represented via an independent party, such as SCPA, to seek injunctions when legally applicable. It can be constructive also to have an entity that specializes in tracking violations of patients’ rights, helping to defend such rights in medical malpractice cases as well.

4. Alternative Dispute Resolution (ADR):

ADR can have a favorable impact on patients’ cases. Having alternatives to litigation that provide access to justice with less cost is constructive for patients’ rights. The EU has adopted ADR to solve consumer disputes, and it has stated that such ADR shall be free or with minimum charge.\textsuperscript{534} Saudi law can adopt ADR processes for patients and consumer cases, but such processes should be operated under two crucial conditions. First, ADR must not affect the patient’s choice to go to court and must not entail forcing patients to choose substantive and procedural rules that are unfair to them. The other condition is the ADR process should be managed and operated under a neutral party, and it should be in full consideration of patient and consumer substantive rights. Therefore, ADR can be supportive of patients’ access to justice if it does not affect patients’ choice to file a lawsuit and it respects patients’ and consumers’ substantive rights.

ADR can be beneficial for patients in consumer and medical malpractice cases. To some extent, encouraging class actions can lead to more effective ADR when representatives of

\textsuperscript{533} Law of Civil Procedures, \textit{supra} note 54, at art. 3. “A claim is not accepted unless the claimant establishes legitimate interest, and a potential interest is accepted only in exceptional circumstances.”

\textsuperscript{534} \textit{WRBKA}, \textit{supra} note 485, at 90-97.
patients have the option to settle or negotiate with corporations to avoid litigation. Also, empowering consumer organizations representation in courts can result in enhancing the possible role of ADR, since such organizations can likewise have the power to settle or negotiate. For individual patient cases, ADR can be an essential choice, especially in medical malpractice cases since class actions, as a solution, are not common in such cases.\textsuperscript{535} The Ministry of Justice or other government or non-profit entities can play a role in enforcing systematic ADR methods before trials start.\textsuperscript{536} It can be feasible as well to establish a center for patient or consumer claims that can provide alternative dispute resolutions.

**Conclusion**

Patients should have efficient access to justice in medical malpractice and consumer cases. Not all patient cases survive the cost-benefit analysis since many consist of small-claims cases. Traditional civil law litigation does not always match patients’ needs. Patients have limited alternatives in medical malpractice and consumer cases. One option is reporting to the SFDA. However, such reporting, if applicable, would usually result in public policy action. Class actions are not observed widely in Saudi Arabia, and the Saudi Consumer Association does not have the power to file lawsuits on behalf of consumers. Saudi law should consider adding alternatives that can help patients access justice effectively, such as developing ADR to fit

\textsuperscript{535} See Part I.

\textsuperscript{536} The Ministry of Justice has been providing reconciliation service that is called TARADHI. Parties of the conflict can agree to try to reach a settlement through this service where experts play the role of mediators. At other times, courts may determine to refer parties to this center before litigations. Service link: https://taradhi.moj.gov.sa/ (last visited Sept. 14, 2021). This research has not conducted specific review to determine whether this ADR process is effective for patients or not. It is still unclear, especially with the fact that medical courts have been established recently after medical malpractices cases were under the jurisdiction of administrative panels.
patients’ situations, encouraging class actions, and authorizing the Saudi Consumer Protection Association or other consumer entity to represent patients and consumers in court certain cases.
Chapter VI: Conclusion.

This chapter summarizes the key findings of this dissertation, recapitulates reforms that have been presented in this dissertation, and enumerates questions for future research. Part I provides an overview of the dissertation and summarizes it chapter by chapter. Part II presents a comprehensive approach of the reforms suggested in this dissertation and questions for future research.

I: Summary.

The main question of this research is what policies and procedures Saudi lawmakers should consider to develop patients’ civil protection from misleading pharmaceutical marketing under Saudi law, particularly in *ex-ante* regulations, civil liability, compensation, and access to justice. After addressing the current law in each topic, the research raises a major challenge that can impede the protection of patients and suggests possible solutions. The research has explored *ex-ante* and *ex-post* protection in case of direct-to-patient and direct-to-physician marketing. The research has been mostly focused on the civil protection of patients. However, the examination has occasionally extended to other administrative and criminal aspects when necessary, since a comprehensive treatment of the protection of patients cannot be seen only from one perspective.

The significance of this study derives from the importance of the rights i) to health, ii) to access medicine, and iii) to access correct information. Patients seek healthcare because they need it. At this time of need and suffering, it is unacceptable to leave patients lacking the proper protection, subject to careless or possibly corrupt practices. Patients can be damaged due to the negligence of their physicians or of the pharmaceutical producer or marketer. Both physicians
and producers have advantages over patients. Physicians have control of prescription selection, and corporations have the products and the knowledge about the uses and the risks. As a result, patients are vulnerable and can be intentionally or unintentionally damaged. Saudi law has established substantial principles either as legislation or as Islamic *fiqh* principles, and these efforts should be reconsidered to be enforced effectively. This dissertation has addressed the current state of Saudi law, and each of its chapters has focused on an aspect of the protection of patients and suggested possible reforms.

The first chapter discussed fundamental aspects that are related to the protection of patients from misleading pharmaceutical marketing. The aim of this chapter was to establish a framework for this research and to clarify basic concepts and Saudi law. The chapter explored the right to health and the right to access medicine as two essential relevant elements. The chapter presented aspects of Saudi law, including primary features of legislation and sources of this study. Aspects of the Saudi health system were addressed in this chapter, such as the process of accessing medicine and the Saudi Food and Drug Authority’s role in approving medications. The focus then shifted to justifying the protection of patients and clarifying fundamental components of the nature of the marketer-patient and physician-patient relationships.

The second chapter focused on *ex-ante* policies and measures, particularly the role of Saudi Food and Drug Authority (SFDA) in regulating pharmaceutical marketing. The chapter presented general requirements for marketing materials and activities, requirements and measures of direct-to-consumer advertising, and requirements and measures of direct-to-physician promoting. The chapter raised challenges in enforcing *ex-ante* policies to examine the efficacy of patients’ protection under Saudi law. Several essential duties to protect patients are stated in administrative regulations. The chapter has found that to ensure *ex-ante* protection is
effective, Saudi lawmakers should impose duties, such as required disclosures, in ordinary laws that are promulgated via a Royal Decree. Royal Decrees can be backed with appropriate criminal sanctions, which cannot be the case for administrative regulations. Ensuring that essential policies and measures are backed by appropriate deterrents can increase the effectiveness of such policies, and thus maximizing the benefits of patients’ preventative protection.

The third chapter addressed the question of civil liability. Patients must establish civil liability of corporations and physicians by fulfilling the usual elements of civil liability. The chapter propounded the possible ramifications of the new forthcoming Saudi code regarding civil transactions, as it is expected to define general rules of civil liability. Then, the chapter concentrated on specific statutes that relate precisely to patients’ protection in medical malpractice and consumer cases. The chapter found that numerous patients’ rights are stated in health legislation, but Saudi law lacks a comprehensive consumer statute, which leaves many substantial consumer rights not stated in primary legal sources. In addition, patients face a critical challenge when seeking to prove elements of civil liability. Patients lack resources and expertise to demonstrate scientific aspects. The chapter suggested reforms to improve patients’ protection in this regard, such as codifying a comprehensive consumer law, allowing patients to access SFDA research and documents regarding the defects of medications, permitting access to health professionals’ disclosures, providing independent sources for licensing information, and assuring no financial obstacles can complicate patient’s burden of proof.

The fourth chapter focused on the compensatory damages that can be available to patients under Saudi law. The chapter presented the current compensation for death and injuries. The chapter likewise discussed other types of damage which patients may suffer, namely, financial damages, such as medical expenses, loss of income, and moral damages. The chapter raised the
issue of the lack of consideration of most damages when compensation for death and injuries is applicable. As a result, a conclusion was drawn about the compensation that is more likely to be granted to patients, such as compensation for injuries and death. At the same time, the chapter discussed the types of compensation that may be unavailable if compensation for injuries and death is applicable, such as financial damages, medical expenses, loss of income, and moral damages. The chapter concluded with the suggestion to reconsider the compensation available to patients under Saudi law.

The fifth chapter examined patient access to justice. The chapter presented procedural access to justice in medical malpractice and consumer cases. Under Saudi law, patients have been left with traditional individual litigation in most cases. Being left with such a limited option increases the cost of access to justice significantly, especially in the case of small claims and risky litigation. The chapter concluded with suggestions, such as i) incentivizing class actions through legislative, financial, and educational methods; ii) empowering consumer organizations to represent collective interests in court; and iii) considering a fair alternative dispute resolution system for patients and consumers. These steps can improve the patient’s access to justice, which can stimulate a healthy market by assuring that there is a fair resolution for each violation.

Whereas each of the previous chapters has covered a background or a specific aspect of this research, this chapter provides a summary and a comprehensive view of the general findings of the dissertation in its entirety. The next part concentrates on the reforms that can improve the protection of patients under Saudi law and highlights questions for future research.
II: Toward Improved Patients’ Civil Protection from Misleading Pharmaceutical Marketing.

Rethinking and contributing to developing the protection of patients from misleading pharmaceutical marketing has been the key concern of this dissertation. Improving the protection of patients from misleading pharmaceutical marketing is significant from the perspective of justice, human rights, and economic efficiency and integrity. Empowering patients can facilitate access to basic rights of health, medicine, and information. Such empowerment is necessary to balance positions and achieve the best possible justice for patients. It can also reflect on patients’ trust in the healthcare system. Even if considerable efforts have been ongoing to improve patients’ protection in the Kingdom of Saudi Arabia, there should be continuous improvement for better quality and accessibility of justice. Developing patient protection is not a mere legal concern, but it relies heavily on other factors to be effective, such as the awareness of patients. This research has focused mainly on the legal sides of patient protection and raised challenges and solutions to develop the civil protection of patients.

There is no lesson in this study clearer and more significant than the fact that patient protection from misleading pharmaceutical marketing cannot be effective using only conventional civil law methods. The protection should consist of solutions that apply before and after a harm occurs (preventative and remedial). The protection should not be limited only to civil aspects but should additionally extend to administrative and criminal aspects. Having the most developed early-stage protection policies cannot totally substitute for remedial methods. Also, having advanced avenues to obtain fair civil redress does not completely remove the need for administrative and criminal remedies. Accordingly, patients deserve efficacious methods to prevent and recover damages because of misleading pharmaceutical marketing. Effective patient
protection can be sought by comprehensively employing appropriate civil, criminal, and administrative instruments. However, this study does not cover all these aspects. It explores mostly civil aspects of patient protection with limited exceptions, such as in presenting several aspects of administrative policies.

This part attempts to outline reforms that can play a part in enhancing patients’ protection. The part will also raise fundamental questions for future research. Section A addresses trends and reforms that can contribute to improving the protection of patients under Saudi law, and section B raises questions for future research.

A. Main Trends and Reforms.

This section highlights the main points of developments and reforms that were discussed throughout the research.

1. The Probable Impact of Forthcoming Legislative Developments.

It is important to remember that this dissertation was written during a time of sustained changes. There is a major trend of codification of Saudi law that includes a code of civil transactions that will likely lead to major effects on patients’ protection. The result is that many unanswered questions and ambiguous areas of civil liability and compensation will then have more predictable and stable answers. These answers from the civil code of transactions will likely concern general rules of civil liability. This research has found that consumer rights have not been expressly stated in a comprehensive primary source of law yet. Therefore, patients would have more protection if a comprehensive consumer law is enacted in addition to this code of civil transactions.
In addition, it is important to increase public access, through publication, to official explanatory sources and court judgements along with the codification process, to provide additional guidance and examples when applying the code. It is also helpful for patients to have guidelines that are prepared in simple language to help them understand their rights. Ambiguity and unpredictability will be diminished within the coming years due to expected and ongoing legislative developments, especially with respect to civil liability, compensation, and consumer aspects. This will also advance the predictability of outcomes under Saudi law, which can further assist in determining the suitability of a patient’s case.

2. **Stronger Legislative Enforcement of Ex-ante Protection.**

The optimal solution is to prevent or reduce the possibility of patient damage in the beginning. Saudi law has policies that are meant to be preventative, but consequences of violating such policies are not clear. Having policies with vague ramifications reduces their effectiveness. This research suggests two important reforms that can lead to more enforceability of preventative means.

**First, ensure that violations of ex-ante policies and procedures have deterring ramifications.**

Several essential *ex-ante* policies are imposed by administrative decisions. For example, the SFDA has required physicians and pharmaceutical corporations to disclose mutual contractual relationships and payments. Violations of such administrative requirements are likely to result only in administrative consequences, such as warnings, because these requirements are imposed by administrative regulations, not ordinary laws. Enforcing such protective means requires deterring instruments not limited to
administrative actions. There should be criminal penalties and appropriate compensation. The Saudi Basic Law of Governance states that crimes and criminal punishments shall only be imposed in law. Thus, to be effective in deterring violations of patient rights and prevent more damages initially, the enforceability of such policies should be considered from a legislative perspective.

Second, grant the Saudi Consumer Protection Association (SCPA) the authority to seek injunctions in court.

*Ex-ante* protections are usually linked to government authorities. For instance, preventing a misleading advertisement from being broadcast should be through an administrative injunction. If the authority has the power to take administrative actions to protect patients, and corporations have the right to counter such actions in court, patients have no official representative that can seek such actions or counter them when no action is taken. Patients’ collective interests should be protected through organized legal representation. The law should authorize a consumer association or an organization, such as the SCPA, to challenge lack of administrative actions in court. This can be helpful in ensuring appropriate enforcement. Enabling organized representation to take court actions to represent the collective interests of patients can significantly improve fairness in the legal system.

3. **Support Patients’ Evidentiary Burdens.**

There is room to adopt policies that can support patients when they seek to fulfill the burden of proof. Proving the civil liability of marketers and physicians may involve scientific evidence to prove damages and analyze exact cause of the damage. Evidence in such cases is either not in the hands of or not within the expertise of patients.
Consequently, two steps can possibly contribute to support patients when fulfilling the burden of proof.

**First, patients need legal support to access what is not in their hands.** Patients should be able to access information and documents from the SFDA to support their claims and petitions. SFDA has documents that support decision-making, for instance, to warn or withdraw hazardous medications from the market. If such decisions can serve the collective interests of patients, what about the private interests of patients? Why can’t they independently access information regarding the danger and effects of such medications?

In addition, health providers have control of medical records. This can raise questions regarding whether providers can be neutral and present all the facts in those records when the health providers are at risk of losing a case against a patient. Conflicts of interest can exist and can result in devastating consequences for the patient’s legal positions. Are changes to medical records tracked by a neutral party? If not, can they be tracked to assure that medical records reflect accurate information about the patient’s situation?

**Second, it should be assured that financial costs do not impede patients’ access to justice.** The law should also ensure that cost of evidence, such as expertise, should not be an obstacle to patient justice. In addition, ensuring adequate financial resources and legal assistance for patients to seek their individual rights can contribute to deterring violators from violating the collective interests of patients.
4. **Patients should be awarded proportionate compensation.**

   One central objective of compensation is to restore the damaged patient to the pre-damage position. Compensation can also play a role in deterring corporations and physicians from violating patients’ rights. It is important to have a settled advanced compensation system to assure patients’ fair recovery, to enhance physicians’ and corporations’ accountability, to develop the predictability of the law, and facilitate the judicial process. It is a concern that patients’ claims to seek medical expenses, loss of income, and mental suffering are not considered in many instances. In cases where compensation for injuries and death (diya and arsh) apply, what if such medical expenses and loss of income are significantly more than the amount of such compensation for injuries and death?

5. **Patient access to justice must be more efficient.**

   Traditional litigation cannot fit patients in all cases. The cost of litigation and the level of outcome predictability can dissuade patients from pursuing legitimate claims and result in injustice. In consumer cases when claims are limited, patients may be discouraged from taking any action unless proper means are embraced, such as class actions. Class actions should be encouraged and expressly regulated in the Saudi Civil Procedural Law. In medical malpractice cases, other solutions, such as Alternative Dispute Resolution (ADR), can be effectively utilized to meet patients’ needs. ADR can operate online through a process that provides a fair solution for patients in medical malpractice and consumer cases. There should be a framework to employ ADR to better serve justice in medical malpractice and consumer cases. Patients’ access to justice can
be developed through ensuring the efficiency of litigation, encouraging class actions, and employing ADR. These are in addition to empowering the Saudi Consumer Association to represent the collective interests of patients as discussed earlier in this part.

B. Unanswered Questions.

The object of this research is to rethink the protection of patients from four diverse aspects – *ex-ante* regulations, civil liability, compensation, and access to justice. The research focuses on describing the current law in each aspect and finding major challenges that can affect patient protection. Frequently, the research has had to respect the boundaries and leave many matters unaddressed. These matters can be the focus of future research. This section presents several examples of important unexamined matters.

1. **More research should be done in compensatory damages.**

   Compensation is the topic that needs the most further research, especially from Islamic *fiqh* experts. Concerns about the compensation issues can extend to substantive issues as well as methods used to calculate compensation. Research is needed to reconsider the types of compensation that patients may claim and consider how those can possibly fit within the compensation system.

2. **More research needed regarding evidence in patient cases.**

   The evidence challenge has been addressed in this research from the patient perspective, and the solutions provided are procedural and related to the role of the SFDA. The new evidence law’s implications for patients and consumers should be explored in depth. In addition, if this research has suggested that patients should at least have the power to request access to SFDA documents, what about information from other
agencies regarding patients? What about patients’ medical files and reports? Can the burden of proof be shifted in some circumstances to enhance the patient’s position in medical malpractice and consumer cases? All these concerns regarding evidence need further consideration.

3. **Research required on the development of ex-ante regulations.**

   This research has addressed *ex-ante* regulations to examine their impact on patient rights and introduce main principles of pharmaceutical marketing under Saudi law. The dissertation has not explored the best possible protective methods, or whether Saudi law can foster more advanced methods or not. The research focused on the lack of enforceability as a factor that has a fundamental impact on patients’ protection. Thus, there is a gap in this area, and researchers can contribute to developing preventive means, drawing on comparative law as a source of alternative enforcement mechanisms.

4. **Research needed on developing the role of the Saudi Consumer Association.**

   The role of the Saudi Consumer Association and similar entities should be examined. This study has only concentrated on the Association’s power to represent patients. However, it is also important to draw a clear line between the role of the Association and other authorities and ministries in consumer protection. The Association should have a more advanced and effective role in the future to seek the collective interests of patients and play a role in informing patients about their right to seek their own interests.

   This dissertation has aimed to improve the civil protection of patients from misleading pharmaceutical marketing in Saudi law. This research is essential because it advocates the protection of fundamental rights of patients, such as the right to health, the right to access
medicine, as well as the right to access information. Such protection should be built on both *ex-ante* and remedial means of protection. Saudi law can be advanced through various mechanisms that improve the predictability, effectiveness, enforceability, and accessibility of patients’ rights in medical malpractice and consumer cases. This dissertation has explored aspects of patient’s protection that should be considered by lawmakers and researchers.
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