

Consumer Protection of Drug in Indonesian Law: Examining the Paternalism Theory

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Abstract— Strengthening progressive civil society among Southeast Asia in consumer protection, based on a long history of consumer protection movement which was initiated by civil society. This research focuses on paternalism theory; the development; the needs and applied model in Indonesian Law. This normative legal research using secondary data which is carried out by a literature study and analyzed qualitatively. The study showed that in the consumer protection of drug in Indonesian Law, paternalism has shifted from private to public. Paternalism Theory is needed in the protection of consumer drugs due to the imbalance bargaining position between consumer and business actors. The application of the Paternalism Theory in Indonesian law should be shifted from soft to strong, pure to impure and moral to welfare paternalism.

Keywords—consumer protection, drug, Indonesian law, paternalism

I. INTRODUCTION

Developing a progressive civil society among Southeast Asia could be approached in so many ways including cultivating the law as a tool of social engineering. The consumer is not a new concept, considering the beginning of civilization there has been trading and consequently suppliers and buyers. Even though globalization has modified some of the realities, at the time of the first human right declaration, no one deemed not to include such rights. The adjustments have no longer been radical to give an explanation for this sudden want of thinking about consumer protection as a quintessential right, the legislator overprotects consumers and creates a disequilibrium in the market. Legislators begin to intervene in the market making it harder for organizations to compete or even survive[1].

Advocating consumer interests is an issue of the civil society movement to protect the people. Consumer protection has become a useful instrument for the protection of the weak and vulnerable groups in society [2]. The consumer will be called vulnerable for temporary, or even permanently. Temporary circumstances, such as illness could make a consumer vulnerable, but not necessarily always disadvantaged, while disadvantaged consumers will almost inevitably be vulnerable consumers [3].

The movement met with John Kennedy's ideas about basic consumer rights in the 1960s. These rights furnish the basic regulation for United Nations Guidelines for

Consumer Protection 1999 and many other national and international, governmental and non-governmental activities in the field of consumer policy [4]. In Indonesia, since 1999 the government had promulgated Law No. 8 of 1999 concerning Consumer Protection. The achievements of the struggle of civil society organizations must be continued by ensuring that the legal elements protect the interests of consumers.

This research is focusing the subject to the consumer of the drug because it is related to health as a basic human right which stated in the international convention such as The Universal Declaration of Human Rights 1948 and the International Covenant on Civil and Political Rights 1966. In The 1945 Constitution of the Republic of Indonesia clearly stated citizens' constitutional rights to health. Drugs are used for diagnosis, prevention, healing, recovery, improvement of health and contraception for humans.

Paternalism theory is used as a basis for criticizing because the author wants to see how various actors interact. The relations which had been discussed a lot are between the consumer of drug, doctor, and pharmacist. The position and role of the other larger actors like civil society organizations and the government regarding the protection of consumer drugs have not been widely discussed.

This paper aims to answer and analyze: (i) How does the development of the theory of paternalism; (ii) Why is the Paternalism Theory needed in analyzing the protection of consumer drugs, and (iii) How is the application of the Paternalism Theory in Indonesian law properly?

The analysis extent of the study of law in Indonesia is limited by only analyzing two main legal products. First, the Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection as an Umbrella Law that integrates various regulations related to consumer protection. Second, Law Number 36 of 2009 concerning Health which covers various regulations in the health sector.

II. METHOD

A. Type of Research

This research is categorized as normative-qualitative. Normative legal research is the subject matter of the law that is conceptualized as the norm or rule that applies in society and becomes a reference for everyone's behavior.

Normative legal research focuses on positive legal inventories, legal principles and doctrines, legal theory, legal discovery in concrete cases, systematic law, the degree of legal synchronization, comparative law and legal history [5]. Such doctrinal analyses contain efforts to understand the great balance of rights and tasks below the framework described via law. Their idea is drawn from moral, felony and political philosophy. They build their evaluation around questions of what ought to be [6].

Qualitative research because it manages data as something intrinsically meaningful. Data in qualitative research that is soft, imperfect, immaterial, sometimes blurred and a qualitative researcher will never be able to express everything perfectly [7].

Normative legal research is also called doctrinal legal research. This type of research often places the concept of law as what is written in the law in books or rules or norms that are a benchmark of human behavior that is deemed appropriate [8]. Soerjono Soekanto defines more briefly that normative legal research is "legal research conducted by examining library material or secondary data"[9].

B. Research Data

The data collected in this study are secondary data obtained from legal materials. These legal materials consist of [10]:

1) *Primary legal material, that is binding or authoritative or has the authority [11] consisting of:*

- The 1945 Constitution of the Republic of Indonesia
- Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection
- Law of The Republic of Indonesia Number 36 of 2009 concerning Health

2) *Secondary legal material that provides an explanation of primary legal materials, such as the draft law, the results of research, the work of the legal circle's Legal materials in this study are:*

- Literature books
- Journal
- Report
- Article
- Sites related to research objects

3) *Tertiary legal material, that provides instructions and clarity regarding primary and secondary legal materials, like:*

- Indonesia Dictionary
- English Dictionary

C. Data Collection Method

Data collection was conducted by documentary research. The documentary research technique is used in investigating and categorizing physical sources, most regularly written documents, whether or not in the private or public domain. This research approach is simply as proper as and an occasions even greater price

advantageous than the surveys, in-depth interview or participation observation [12].

The documentary study is conducted to collect secondary data. The technique used is a documentation study, namely by collecting data on various materials contained in the literature room, such as newspapers, magazine books, manuscripts, documents, etc. which are relevant to research. The purpose and usefulness are to show the way to solve research problems [13].

D. Data Analysis

The data analysis technique is a process of systematically searching and compiling data obtained by organizing data into categories, describing into units, synthesizing, arranging into patterns, choosing which ones are important and which will be analyzed then making conclusions.

After the data is collected, then the data will be analyzed in a qualitative descriptive way, namely a method of drawing conclusions by giving an overview or describing the data collected in the form of sentence descriptions so that eventually it can lead to conclusions [14].

The interpretation used in this study is a systematic interpretation that is to see the relationship between rules in an interrelated law. The foundation of thought systematic interpretation is the Law is a unit, and none of the provisions in the Act are stand-alone rules.

III. RESULT AND DISCUSSION

A. The Development of Paternalism Theory

Paternalism has been interestingly introduced by some experts. A simple definition of paternalism is that it is the restriction of a person's freedom, usually against his or her will, for his or her own good. This definition captures many cases that are frequently thinking to be paternalistic, such as motorbike helmet and seatbelt legislation, preventing a person from unknowingly walking across a dangerous bridge, a doctor refusing to inform his patient of her terminal illness, requiring people to undergo blood transfusions when needed despite their religious objections, and laws against drug use [15].

Paternalism is very often equated with paternalism even though both are different words because paternalism is a noun while paternalistic is an adjective. Anthony T. Kronman explains the concept of paternalism starting with first describing paternalism. In general, any legal regulation that prohibits an action on the grounds that it will conflict with the welfare of the perpetrator itself is called paternalistic. One of the main objectives is to protect someone who makes a promise by limiting his power to do what is considered by law to be in conflict with his own interests.

The legal expert who first introduced legal paternalism was Joel Feinberg from America with the legal term paternalism. German scientist Peter Cserne who is currently engaged in the subject of paternalism begins the concept of paternalism with the statement that for most Westerners today the term 'paternalism' has several

negative connotations. As a result, almost every substantial contribution in the theoretical literature regarding paternalism begins by discussing the possibility of using non-degrading and not gender-dominant words (or the need to change the term into a neologism such as 'parentalism').

Cserne uses the word 'paternalism' in a descriptive sense to classify and without involving possible gender problems at all. However, the definition of paternalism is not problematic. There are three conditions included in the definition of paternalism. Paternalism (1) deliberately limits the freedom of the subject, (2) acts outside of the virtue of the subject, and (3) ignores the contemporary preferences of the subject. Paternalism has a number of justifiable cases and some cases that cannot be justified which are both different not in definitions but in terms of their justifications (legitimacy, reasonableness, etc.). More precisely, they can be conceptually differentiated only if we introduce certain specifications for different types of paternalism [17].

Gerald Dworkin gave the definition, consists of "interference with a person's freedom of motion justified by appeals to the welfare, good, happiness, needs, interests, or values of character for that reason constrained"

Paternalism in medical action today is a problem because its application in doctor-patient relations tends to sacrifice one of the important principles in biomedical ethics, namely the principle of autonomy. This problem arises as the human consciousness of autonomy has the right to self-determination. In the doctor-patient relationship, the paternalistic attitude is expressed in the attitude of the doctor who does not provide the information needed to the patient regarding medical actions to be taken so that here there is no informed consent or informed choice let alone informed refusal. The problem is, is paternalism in the field of medical services always wrong, even though this paternalistic attitude actually originates from other biomedical ethical principles, namely the principle of beneficence? Are there certain conditions from patients that allow doctors to take a paternalistic attitude without violating the principle of autonomy? In this context, there are certain parties who tend to respect the autonomy of patients with persuasive interventions when patients choose actions that are detrimental to themselves, while others tend to protect patients from possible adverse consequences of their choices. Doctor intervention in decision making is the problem of paternalism.

The relationship between doctors and their patients who were previously paternalistic today has changed. Gradually the patient begins to realize that even if he comes to seek treatment from a doctor, he has the right to obtain information about his illness, how the treatment plan will be carried out by the doctor and whether there will be any side effects that will be suffered from the effort. Besides that, the patient also has the right to determine whether he wants to follow the treatment plan or not. Even if you think the patient needs to have the right also ask for a second opinion from another doctor. Changes from this pattern can be detected, among others, from the number of claim cases with doctors, hospitals,

and foundations that manage a hospital launched by patients. In these cases, patients who feel disadvantaged because of actions taken by doctors, try to demand accountability to doctors or providers of health facilities such as hospitals / medical centers that work. Although efforts through legal channels are not always successful, but in reality, this makes the doctors feel a little bit nervous in carrying out their work. They are always alarmed if one day they will be held accountable through law. Furthermore, paternalism has shifted with the country that carries out this role.

B. The Needs of Paternalism for Consumer Protection of Drug in Indonesian Law

Debates over whether or not and how government should regulate individuals for their own good or protection are regularly couched as debates over paternalism—what it means and when, if ever, it qualifies as a normative justification for authorities' motion [16].

I start from the recent regulation of (international and national) to draw a picture of the necessity of paternalism theory to be applied. The two main instruments as a tool are concerning consumer and health. Chapter III. General Principles point 4. UN Guidelines stated that the Member States need to develop, enhance or maintain a robust consumer protection policy, taking into account the directive set out beneath and applicable international agreements. In so doing, every Member State has to set its personal priorities for the protection of consumers in accordance with the economic, social and environmental instances of the state and the needs of its population, and bearing in mind the charges and advantages of proposed measures [17]. This international instrument was clearly setting the position of state to be the guardian by the law of consumer protection.

Based on Article 1 paragraph (1) Consumer Protection Act, consumer protection is an effort that guarantees legal certainty to provide protection to consumers [18]. The sentence which states "all efforts that guarantee legal certainty", is expected to be a fortress to eliminate arbitrary actions that harm business actors only for the sake of consumer protection, and vice versa guaranteeing legal certainty for consumers [19]. Consumer protection is based on the principles of benefit, justice, balance, security, safety and legal security of the consumer [20]. Consumer protection is part of the concept of legal protection. Legal protection can be interpreted as protection by law or protection by using institutions and legal means.

Protecting consumer of drug being a crucial issue because it is related to health. Health is one of basic right as well as a basic consumer right. The United Nations High Commissioner for Human Rights (UNHCHR) and the World Health Organization (WHO) describe the right to health is an imperative phase of our human rights and of our appreciation of existence in dignity. The right to the enjoyment of the perfect conceivable popular of bodily and mental health, to give it its full name, is not new. Internationally, it was once articulated in the 1946 Constitution of the World Health Organization (WHO). The 1948 Universal Declaration of Human Rights also referred to health as a phase of the right to a sufficient

standard of dwelling (article 25). The right to health was once again approved as a human right in the 1966 International Covenant on Economic, Social and Cultural Rights. Since then, other international human rights treaties have accepted or referred to the right to health or to elements of it, such as the right to clinical care. The right to health is relevant to all States: every State has ratified at least one international human rights treaty recognizing the right to health. Moreover, States have dedicated themselves to protecting this right via international declarations, domestic legislation and policies, and at global conferences [21].

In the context of Indonesia, the Constitution on Article 28 H paragraph (1) stipulates that "every person has the right to live in physical and spiritual prosperity, to live and obtain a good and healthy environment and the right to receive health services"[22]. Following this regulation, Article 14 paragraph 1 of the Health Act regulate, the government is responsible for planning, regulating, organizing, fostering and supervising administering equitable health efforts affordable by the community [23]. Based on those regulations basically, we found that consumer protection is one of the duties of government in terms of a representative of the state.

How about consumer protection of drugs? Actually, there is no exact definition of drug consumer. Based on general definition of consumer, drug consumer is each individual user of drug available in society, for the benefit of themselves, family members, other people, which are not for trading.

The position of consumer especially drug consumer is vulnerable and weak as we discussed before. The premise is that consumers are in particular vulnerable to detriment, and require greater protection than is supplied through the procedural standards, namely there should be much less emphasis on business self-interest and consumer self-reliance [24]. So far, consumers consider it necessary from an economic perspective not because they are considered weak and at risk of being exploited by large companies, but because they lack knowledge about the products and contracts they agree on from the company. Sometimes consumers need protection because they don't always act rationally [25]

According to David Oughton and Jhon Lowry, this weak consumer position is based on several arguments as follows:

- In modern society, businesses offer to share new types of products as a result of technological and management advancements. These items are mass produced.
- There are fundamental changes in the consumer market, where consumers often do not have a bargaining position to conduct adequate evaluations of the production of goods and/or services they receive. Consumers can hardly be expected to fully understand the use of advanced products available.

- Current advertising methods do disinformation to consumers rather than providing information objectively.
- Basically, consumers are in a bargaining position that is not balanced, due to difficulties in obtaining adequate information.

The idea of paternalism is the background for the birth of the Law on the legal protection for consumers, where there is a feeling of disbelief in the ability of consumers to protect themselves due to predictable financial risks or the risk of physical loss [26].

Based on the Paternalism approach as an extreme approach, Micklitz argues that consumers need to be protected because they are weak parties in the contract. This does not only occur when dealing with large business actors but also in business in general. In fact, business generally only seeks profit for itself, does not pay attention to the interests of consumers. Proponents of this approach believe that consumers cannot evaluate information, even when given accurate information, because they act irrationally and miscalculate the risk of a product[27].

Furthermore, the United Nations Conference on Trade and Development (UNCTAD) stated that The cause of the disparity in the relationship is bargaining power and knowledge. State intervention is justified in providing consumer protection based on a number of reasons, namely economic efficiency, individual rights, and distributive justice [28].

So, from a need-based view, paying attention to consumer vulnerabilities, a key priority of the law should be to protect consumers from loss.

Paternalism theory discusses, the problems faced by consumers continue to increase in intensity, so the government needs to take intervention policies to overcome the potential that harms consumers. The theory of Paternalism justifies government intervention. Interventions are carried out so that the balance of rights and obligations between producers and consumers can be realized. Paternalistic legal manifestations are to prevent losses suffered by consumers due to agreements that harm them. The basic principle of law that is paternalistic for example, the law contains provisions that say that goods circulated in the community must meet satisfactory quality levels and are indeed suitable for consumption by consumers. This law clearly must contain provisions that guarantee the quality of goods and regulate the existence of insurance coverage for consumers who consume goods that are not in accordance with the standards (standards) as determined. Paternalistic law is formed to protect consumers who are often harmed by business actors. Consumers must be far more aware that without such legal design they will still be potentially disadvantaged because producers or business actors tend to be arbitrary due to their superior position [29].

The Paternalism theory is accurate as of the basis for an analysis of consumer protection because basic consumer protection is a vulnerability and imbalance in the bargaining position of consumers in the presence of business actors. The state must be present based on the

theory of paternalism to protect the interests of consumers without having to ignore the interests of business actors

C. The Model for Consumer Protection of Drug in Indonesian Law

Based on an analysis of the situation of consumers in Indonesia, the application of the paternalism model in protecting consumers will be based on the study of private and public law. It appears that private law can no longer rely on drug consumers to have a good position in the presence of business actors. The context is that Indonesia as a legal state of the Indonesian Law in the 1945 Constitution of the Unitary State of the Republic of Indonesia contains the idea of a welfare state [30] Article 1 Paragraph (3) The Fourth Amendment to the 1945 Constitution of the Republic of Indonesia states the principle of Indonesia as a legal state which reads as follows: "The State of Indonesia is a Law State", which has legal objectives to create justice, certainty and people's welfare [31].

According to Sudjito, the formation of the concept of the state of Indonesian law was based on the ideals of the law or the Pancasila *Rechtsidee*. Besides being a *Rechtsidee*, Pancasila is also a way of life for the nation and state of Indonesia. Positioning and practicing the Pancasila as a way of life implies a moral and trustworthy message that for anyone who makes law or policy (decision makers) so that the process of making is always oriented towards achieving state goals. The entire legislation must pay attention to and embrace the dimensions of nationality, the integrity of the entire homeland, public welfare, efforts to educate the nation's life and contribute to the international community for the sake of orderliness, the maintenance of independence, peace and social justice. The life-building of a legal state that is physically-organically diverse should be seen as a composite system, which consists of components of the body, mind, and soul, material-spiritual, social-ecological, national-international which are interrelated and interdependent [32].

Gerald Dworkin describes with paternalism, interference with one's freedom of action can be justified by reason that refers to the welfare, goodness, happiness, needs, interests or values of people who are forced

Refer to Dworkin, paternalism is divided into five categories:

1) *Hard vs. soft paternalism*: Soft paternalism is the view that the only condition in which state paternalism can be justified is when there is determination of whether a person's actions are voluntary and have sufficient knowledge. A hard paternalist says that, at least sometimes, it may be permissible to prevent someone even if he knows of its condition.

2) *Broad vs. narrow paternalism*: A narrow paternalist is only focused on the question of nation coercion, i.e., the use of legal coercion. A broad paternalist is concerned with any paternalistic action: state, institutional (hospital policy), or individual.

3) *Weak vs. strong paternalism*: A weak paternalist is justified in interfering with someone's way of achieving the ultimate goal. If someone puts safety ahead of comfort, forcing him to use a seat belt is justified. A strong paternalist believes that people may have the wrong, confusing or irrational end goal. Interfering with their steps to achieve these goals can be justified. Facing someone who prefers the wind to rustle his hair rather than improve safety, forcing them to use a helmet when riding a motorcycle. The act of coercion is justified because the ultimate goal of hair rustling is irrational or wrong.

4) *Pure vs. impure paternalism*: Pure Paternalism will prevent people from producing cigarettes because they believe that cigarettes will endanger users. The group of people who will protect is the group of users. The reason for interfering with smoking is because it will cause harm to others. The basis of this justification is paternalist because the user knows the danger. Unlike the impure paternalism which prevents cigarette producers for reasons because it will create air pollution. Paternalism is purely based on the assumption that the protected group is identical to the group that is interfered, for example preventing people from swimming when the coast guard is not there. In impure paternalism, the interference group is wider than the protected group

5) *Moral vs. welfare paternalism*: Paternalism justifications usually refer to the interests of those who are intervened. These interests are defined in things that make one's life better; specifically their physical and psychological conditions. Sometimes, supporters of state intervention try to protect the moral well-being of that person. For example, it can be said that the practice of commercial sex workers is better prevented even if they have a decent life and their health is protected from disease. This is better because selling sexual services is a destructive moral act. Such interference is justified to support the moral well-being of that person. This is an example of moral paternalism. Welfare paternalism in its intervention produces prosperity. It is important makes people live morally but also must think about welfare in question. The Law on Consumer Protection is basically not is the beginning and end of the law governing consumer protection, Legal instruments that protect consumers are not intended to kill the business of the people business actors, but on the contrary, consumer protection can encourage the climate healthy striving that encourages the birth of a strong company in face competition through the provision of quality goods and/or services. Based on this division, the appropriate model in regulation should be shifted from soft to strong, from pure to impure and from moral to welfare paternalism (prosperity to drug consumer and business actor).

IV. CONCLUSION

The development of the theory of paternalism has shifted from private to public. Previously, paternalism is concerning the relationship between doctor and patient as a

customer. Recently, paternalism is between the state as a regulator and doctor-pharmaceutical company-and drug consumer. Paternalism Theory is needed in the protection of consumer drugs due to the imbalance bargaining position between consumer and business actors. The position of consumer especially drug consumer is vulnerable and weak. The application of the Paternalism Theory in Indonesian law should be shifted from weak to strong (drug consumer sometimes is irrational who needs to be protected), pure to impure (protecting all the actors) and moral to welfare paternalism.

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