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Corporate Liability of Pharmaceutical Companies Producing Unsafe Drugs (Lesson-Learnt from the USA)

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ABSTRACT
Since the end of 2022, Indonesia has been concerned with cases of kidney failure in children. Long before that, United States of America (USA) have experienced in handling the case of pharmaceutical company. This research aims to examine the Corporate Liability Settlement for the Pharmaceutical Industry Producing Unsafe Drugs in United States and Indonesia as well as to detail more about what Indonesia can improve reflecting from the cases in America. This is normative legal research, using comparative methodology as an approach. The research has found that Indonesia shall address the idea to settle the case with plea agreement, civil lawsuit, as well as oblige the corporation to enter in corporate integrity agreement. Furthermore, a higher amount of fine is required in order to deter the company.

Keywords: *Corporate liability; unsafe Drug; Pharmaceutical Companies;*

1. Introduction

The idea of corporate liability firstly introduced in eighteenth-century when courts and legal thinkers examined corporate liability focusing on theories of corporate personality. At first, legal scholars did not believe corporations could possess the moral blameworthiness necessary to commit crimes of intent. The doctrine of corporate liability also questionable since judges required the accused to be brought physically before the court at that time. (Khanna, 1996)

As the development of human being, crime is not only committed by person but also corporation. When business entities commit a criminal act, the discourse then arises especially about the difference of views on the concept of criminal accountability. This discourse start from the theory of legal fiction asuming that "a collection of business actors / corporations is just an abstraction or imagination that is lived in the form of an in concrete shadow."(Andriadin et al., 2021).

The crime committed by pharmaceutical industry has a long history. John Braithwaite (1984) mentioned some corporate crime in pharmaceutical industry, such as: bribery, fraud in drug testing, and negligence which led to unsafe production of the drugs.(Braithwaite, 1984a) Another source mentioned the most common crimes committed by pharmaceutical industry were illegal marketing by recommending drugs for non-approved (off-label) uses, misrepresentation of research results, hiding data on harms, and Medicaid and Medicare fraud.(BMJ, 2012)

In Indonesia, the case of fraud conducted by pharmaceutical company not much in amount. Nevertheless, there was a case draws public attention. Since the end of 2022, Indonesia has been enlivened by cases of kidney failure in children. By data, 202 children died as a result of cases of acute kidney failure after consuming a syrup drug containing ethylene glycol and diethylene glycol contamination. A number of pharmaceutical companies, raw material suppliers, and individuals have been named as suspects (Tempo, 2023)

In 2011, Merck, Sharp & Dohme has agreed to pay $950 million to resolve criminal charges and civil claims. The case is related to its promotion and marketing of the painkiller Vioxx. The drug claimed for treating rheumatoid arthritis, even if it had not been approved by the Food and Drug Administration (FDA) yet.(The United States Departement of Justice, n.d.)

The procedural law in US open the plea agreement and civil settlement to be conducted parallel. By paying such amount of money, the case of criminal charges and civil claims has been settled in which this mechanism remain absent in Indonesian procedural law. Such settlements are less to be discussed in Indonesia.

Based on the aforementioned statement above, it is interesting to elaborate more about: Corporate Liability Settlement for the Pharmaceutical Industry Producing Unsafe Drugs in United States; 2) This research will address the regulation in Indonesia, evaluate, and elaborate more about things that shall be taken into account to address corporate liability of pharmaceutical companies in Indonesia.

Previous researches have mentioned about corporate liability for Pharmaceutical Companies Producing Unsafe Drugs such as conducted by Putri and Rai (2023). The research concludes that the pharmaveutical company can be imposed using Article 196 and Article 201 para (2) and (3) Law No. 36 of 2009 concerning Health. Beside the The Indonesian Food and Drug Authority (BPOM) is criminally liable under the Article 359 and Article 360 para (1) penal code.(Putri & Panjaitan, 2023)

Widyaningrum and Wijaya (2023) stress the point that criminal liability for corporation is only stated in several regulations. Existing regulations such as the Criminal Code, Laws and government regulations are not sufficient to provide a deterrent effect for corporations. (Widyaningrum & Wijaya, 2023)

This research would fill the knowledge gap by mapping the regulation and practice in United States and Indonesia, then underline a lesson-learnt for Indonesia to enhance its future legal enforcement. The author believes that the researches explained above is different from the present research since none have specifically discussed about cases in United States and Indonesia in particular. Furthermore, the Author admit that that above-mentioned research would be referred and used to enrich the analysis.

2. Method Research

This study uses a type of normative legal research because it aims to examine legislation or legal norms relating to the central theme of research (Amrullah, 2019), in this context is related to the criminal liability for corporations. Furthermore, this research also use comparative methodology as an approach. According to Khudzaifah Dimyati, comparative method is used to find out the differences and similarities between the legal institutions or legal systems. (Dimyati, 2016). Comparative methodology as an approach is used especially to evaluate existing legal rules with other legal systems. The comparative method mostly aims to examining certain legal regulations of the same problem from two or more countries. The conclusion can be utilized as a recommendation for drafting or amending legislation.(Marzuki, 2005)

Soerjono Soekanto, comparative approach is utilized to provide knowledge related to the similarities and differences between various fields of law in order to creating legal improvement. Mark Van Hoecke also addressed which argues that the comparative approach is a tool for improving domestic law and legal doctrine.(Van Hoecke, 2016) Nevertheless, it shall be noted that importing rules and solutions from abroad may not suit, due to the different context. Hence, each comparative study requires holistic contextual approach as well.(Van Hoecke, 2016)

Furthermore, this research is conducted by using library research and obtaining the data from secondary sources. Secondary sources represent the use of existing research data in order to answer the question. Nevertheless, the analysis shall be different from the original work.(Tripathy, 2013)

This research uses two types of legal materials. Firstly, primary legal materials consist of statutes, statutory instruments and law reports.(Library University Of West London, n.d.) The primary legal materials used in this research namely: Law No. 36 of 2009 concerning Health, especially in the Article 98 paragraph (3), Article 196 as well as Article 201. Secondly, this research will use secondary legal materials. Secondary legal materials usually

contain discussion and comment on the regulation, falling in the criteria are textbooks, legal dictionaries, encyclopedias and journal articles.(Library University Of West London, n.d.)

The normative legal research or doctrinal legal researchconceptualizes law as the norm. According to Soerjono Soekanto and Sri Mamuji, normative legal research examines library materials or mere secondary data. Including in normative legal principles are research on legal principles, research on systematic law, and legal history. Johnny Ibrahim stated that normative legal research is a scientific research procedure to find truth based on legal scientific logic from the normative side. Scientific logic in normative researchers built on scientific disciplines and ways of working normative law. (Amrullah, 2019)

3. Results and Discussion

3.1. Corporate Liability Settlement for the Pharmaceutical Industry Producing Unsafe Drugs in United States

Over time, corporate criminal responsibility has begun to be adopted in the legal system, including in America. The US corporate criminal liability scope is very board, including be criminally liable for almost any crime, except acts that can only be committed by natural persons, such as rape and murder.(Khanna, 1996) The crime committed by pharmaceutical company also happens a lot in United States.

The legal enforcement of pharmaceutical company in United States of America has had a long history. Merck's Vioxx scandal is an example that pharmaceutical industry fraud. In 2004, Merck withdraws one of the company products Vioxx after number of studies pointed out that Vioxx increased risk of cardiovascular problems.(Prakash & Valentine, n.d.) It then revealed that Merck had known that potential risk prior to the launching of Vioxx in 1999. The case has long journey in courts receiving 3,000 lawsuits against the company on behalf of 23,000 plaintiffs who alleged the drug caused heart attacks and strokes.(Prakash & Valentine, n.d.) The case then settled for $4.85 billion in 2007.(Cockburn, n.d.)

Another cases, GlaxoSmithKline and Pfizer have paid out a combined total of $7.44 billion in financial penalties over the past 20 years. However, the number remain as very small considering the net profits and therefore do not provide a sufficient deterrent against further violations.(Almashat et al., 2010)

The United States actually has legal instruments to ensure drug safety. The regulation to prevent the pharmaceutical industry fraud lies in Kefauver-Harris Amendments to the Food and Drug Cosmetic Act and are codified into Title 21 Chapter 9 of the United States Code. It draws the new protocol which requires the company to conduct clinical trials in order to prove that the new drug is safe and effective. Furthermore, the regulation also mentioned that the company are required to disclose the drug's side effect.(Mccarthy, 2019) Drug products may only be marketed after obtaining approval from the Food and Drug Administration (FDA).(Rodwin, 2012)

The act also regulates about the prohibition for pharmaceuticals company to make false therapeutic claims about a product. Violations of the FDCA including illegal off-label marketing can be prosecuted as criminal or civil violations. The decision to pursue criminal charges depends on some factors, such as the seriousness of the violation and the level of threat to public safety.(Almashat et al., 2010)

Almashat, et.all examined trends from 1991-2010 in federal and state criminal and civil actions against pharmaceutical companies. The study has found that from 1991-2010, 165 civil and/or criminal settlements of $1 million or more were made between the government and pharmaceutical companies, with settlement amounts totaling $19.81 billion.(Almashat et al., 2010)

Pfizer's 2009 penalty of $2.3 billionamounted to only 14% of the $16.8 billion it earned.(Rodwin, 2015) That many large firms are repeat offenders likewise suggests that violating the law may be an economically driven business decision. Six corporations paying the highest penalties over 22 years entered into at least twelve settlements for different legal violations. several firms had more settlements, including Merck (27), GlaxosmithKline (20), Pfizer (15), Johnson and Johnson (14), and eli lilly (13).(Rodwin, 2015) The fine is a resulting part of procedure called as plea agreement, Deferred Prosecution Agreements (DPA) and Non-Prosecution Agreements (NPA) which

had been known as approaches to corporate criminal prosecution. These legal mechanisms involve a negotiated settlement whereby the organization may agree to settle the case.

The United States Department of Justice (DOJ) assigned to settle the U.S. federal criminal cases operating through prosecutors located in U.S. Attorneys' Offices and divisions. The representatives of the corporation and prosecutors are signatories' parties in each agreement.(Alexander & Cohen, 2015)

Department of Justice (doJ) also has required the involved firm to enter into corporate integrity agreements (CIAs). CIAs aims to oversee the firm's management, require reporting of corporate activities, as well as change corporate culture. However, , companies such as GlaxosmithKline, Pfizer, Purdue, and others entered into new settlement agreements for separate illegal conduct even if still under the five-year period of their Cias.(Rodwin, 2015) Thus questioning whether criminal and civil penalties create deterrent effect towards pharmaceutical company.(Wolfe, 2013)

Oher enforcement tools imposed by FDA, such as: a) injunctions compelling defendants to engage in or refrain from certain activities; b) suspension or revocation of a new drug application when the underlying data's integrity is questionable; c) detention or seizure of adulterated or misbranded products; and d) forfeiture of assets.(Rodwin, 2015)

It shall to be taken into account that beside corporations having to be responsible for their actions, the legal system in US also can proceed the executive of pharmaceutical company in criminal court. In 2011, Former executives with Synthes, Inc subsidiary Norian Corporation, namely: Thomas Higgins, Michael Huggins, and John Walsh, were each sentenced to prison for charges related to illegal clinical trials of a medical device without the authorization of the Food and Drug Administration. U.S. District Court Judge Legrome D. Davis also ordered each of the defendants to pay a fine in the amount of $100,000 as an addition to the prison term.(U.S. Department of Justice, 2011a) However, criminal prosecutions of executives leading companies engaged in these illegal activities have been extremely rare.(Almashat et al., 2018)

3.2. Analysis on The Indonesia's Regulation for the Pharmaceutical Industry Producing Unsafe Drugs and What to Improve

3.2.1. Indonesia's Regulation for the Pharmaceutical Industry Producing Unsafe Drugs

Corporations as a subject in Indonesian criminal law were first introduced since the enactment of Emergency Law no. 17 of 1951 concerning the Hoarding of Goods. Although, it does not regulate in what cases a corporation is proposed as a perpetrator of a criminal act and can be punished.Sutan Remy Sjahdeini, Pertanggungjawaban Pidana Korporasi (Jakarta: Grafitipers, 2006) p.

Along with the development of corporate criminal liability doctrine, corporations as subjects of criminal law have become widely known in various laws and regulations in Indonesia. Several laws that regulate corporate liability in Indonesia include: Law Number 8 Of 2010 Concerning Prevention and Eradication Money Laundering Crime; Law No. 31 of 1999 as revised by Law No. 20 of 2001 concerning Eradication Of Criminal Acts Of Corruption; and Law Number 35 Of 2009 Concerning Narcotics.

There are about 100 regulations concern with corporate criminal liability. That amount resulting various issues, for example: in terms of providing definitions, the scope of criminal acts, and the types of criminal sanctions against corporations. The lack of clarity regarding the regulation of corporate criminal liability in the above legislation is one of the main obstacles to law enforcement in the context of eradicating corporate criminal acts.(Suhariyanto, 2017)

The clarity of new corporate criminal regulations can be seen after the Attorney General's Regulation Number: PER-028/A/JA/2014 concerning Guidelines for Handling Criminal Cases with Corporation Subjects and Supreme Court Regulation Number 13 of 2016 concerning Procedures for Handling Criminal Cases by Corporations.

At the end of last year, Indonesia was shocked by cases of sudden death in children. There are numbers of child deaths from kidney failure linked to harmful substances found in syrup medicines. The cases of acute kidney

injury prompting subsequent ban on all liquid medicine sales. According to the test, the deaths were caused by syrups containing excessive amounts of ethylene glycol and diethylene glycol.(AFP, 2022)

The impact of the drug calls for more severe sanction which no longer talking about administrative sanctions. Criminal sanctions shall be imposed in this case to the corporation as well as Indonesia's food and drug agency (BPOM).(Putri & Panjaitan, 2023)

The legal basis to impose criminal sanction towards pharmaceutical companies producing unsafe drugs stated in Law No. 36 of 2009 concerning Health. This law was revised by Law No. 17 of 2023, yet according to the non-retroactive principle, the Law No. 36 of 2009 prevails.

As stated within Article 98 paragraph (3) Law No. 36 of 2009 concerning Health "*Provisions regarding the procurement, storage, processing, promotion, distribution of pharmaceutical stockpile and medical devices shall meet the quality standards of pharmaceutical services stipulated in the Regulations Government*," Sanction of the violation of Article 98 paragraph (3) stated in Article 196 "*Each person who intentionally produces or distributes pharmaceutical stockpile and/or medical devices which do not meet the standards and/or requirements for safety, efficacy or usefulness, and quality as intended in Article 98 paragraph (2) and paragraph (3) shall be punished by imprisonment for a maximum 10 (ten) years and a maximum fine of IDR 1,000,000,000.00 (one billion rupiah)*."

Furthermore, if such violation conducted by corporation according to Article 201, beside imprisonment and fines for its management, the fine that can be imposed is 3 three times the amount stated in Article 196. Article 201 mentioned that the corporation also subject to revocation of business license; and/or revocation of legal entity status.

3.2.2. What to improve?

There are two distinct things that can be learnt from the way United States handles cases of pharmaceutical company producing unsafe drug: 1) The use of the multidoor approach to settle the case, including civil, criminal, and compliance procedure to deter the corporation; 2) the reasonable amount of fine to settle the case.

First, the use of the multidoor approach to settle the case, including civil, criminal, and administrative measure to deter the corporation. Merck, Sharp & Dohme (2011) has agreed to pay $950 million to resolve criminal charges and civil claims.(U.S. Department of Justice, 2011b) Merck was plead guilty to a one-count information charging a single violation of the Food Drug and Cosmetic Act (FDCA) for introducing a misbranded drug, Vioxx®. Under this criminal law procedure, Merck was plead guilty to a misdemeanor for its illegal promotional activity and shall pay a $321,636,000 criminal fine. (U.S. Department of Justice, 2011b) Beside the criminal charges, Merck also faced a civil settlement agreement under which it pay $628,364,000 to resolve the case. The parallel civil settlement covers a broader range of allegedly illegal conduct by Merck, including recovers damages for allegedly false claims caused by Merck's unlawful promotion of Vioxx.(U.S. Department of Justice, 2011b) As part of the settlement, Merck has also agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services (HHS-OIG). The agreement will strengthen the system of reviews and oversight procedures imposed on the company.(U.S. Department of Justice, 2011b) In addition, Merck also have to settle the number of civil claims issued by groups of plaintiff suffered heart attacks or strokes after taking Vioxx. (Berenson, 2007)

` GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability. GSK was obliged to pay GSK will pay a total of $1 billion, including a criminal fine of $956,814,400 and forfeiture in the amount of $43,185,600 in a plea agreement. Beside that, the GSK also was obliged pay $2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states.(U.S. Department of Justice, 2012)

Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. have agreed to pay $2.3 billion, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products. The amount consist of $1.3 billion criminal resolution, $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs. Beside that, Pfizer also agreed to enter into an expansive Corporate Integrity

Agreement (CIA) with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar matter.(U.S. Department of Justice, 2009)

The three above examples explain the cases used civil, criminal, as well as compliance procedure to settle the case. Merck, GlaxoSmithKline LLC and Prizer Inc went through criminal procedure plea agreement resulting an agreement to pay some amount of money. Plea bargaining applied when the government has a strong case, the Government offer the defendant a plea deal in order to avoid trial and reduce the exposure to a lengthier sentence. The defendant admits guilty and committed to the crime and the judge will decide how the defendant will be punished. If a defendant pleads guilty, there is no trial, but directly heading to sentencing hearing.(Office of the United States Attorneys U.S. Department of Justice, n.d.) Plea bargaining results a fast criminal justice procedure since there is no hearings in court. Such plea agreement mechanism remains absent in criminal procedure law of Indonesia.

Four companies have been stated as suspects in cases of acute kidney problems. These corporate mistakes include producing drugs or distributing the drug that do not meet standards and/or requirements for safety, benefits, and quality. The corporation deliberately was not testing propylene glycol additives which turned out to contain ethylene glycol and diethylene glycol exceeding the threshold limit.(*Empat Perusahaan Jadi Tersangka Kasus Gangguan Ginjal Akut*, n.d.)

The Attorney General's Regulation Number: PER-028/A/JA/2014 concerning Guidelines for Handling Criminal Cases with Corporation Subjects and Supreme Court Regulation Number 13 of 2016 concerning Procedures for Handling Criminal Cases by Corporations regulate the handling of corporations' cases. Furthermore, the feature of sanctions still complies with the material criminal law.

Related to the civil settlement, Indonesia prosecutor open for a civil lawsuit. General attorney of Indonesia can act as the plaintiff representing of Indonesian citizen claiming Article 1365 of Civil Code concerning unlawful act. Even if it is possible, the office of general attorney has not taken an actual action to file a lawsuit against the corporation who produce an unsafe drug. The office of general attorney argues that illegal acts can only be carried out after the criminal act is proven. In short, The civil lawsuit will only be filed after the criminal case is completed and proven.(Hidayat, n.d.)

Furthermore, Indonesia also does not have a Corporate Integrity Agreement (CIA) mechanism like America has. CIA is a compliance program that must be adhered to by companies containing the guidance set forth by the department of health and human services (HHS). By following the compliance program, it aims to reduce the risk of unintentional illegal conduct or misconduct due to the actions of a few rogue individuals acting without corporate authority. Moreover, as part of settlement agreements, the department of Justice (doJ) has required firms to enter into CIA designed to oversee the firm's management, require reporting of corporate activities, and change corporate culture.(Rodwin, 2015)

Regarding to the class action, the Panel of Judges at the Central Jakarta District Court granted the request for a class action lawsuit by the families of victims of acute kidney failure. The class action lawsuit submitted was in accordance with the rules for procedures for representative lawsuits. The representative is including the families of victims whose children consumed syrup medication suspected of causing acute kidney failure.(Berenson, 2007) up until this writing, the case is still ongoing.

Indonesia actually has compensation mechanism stated in Article 98 the Criminal Procedure Code (KUHAP) through civil lawsuit within the criminal procedure. However, in practice, the use of Article 98 does not work in the criminal justice system. The obstacles are the lack of knowledge of victims about the mechanism for combining compensation claims, complicated legal procedures, the length of the legal process and the unclear legal rules regarding the lawsuit arrangements.(Nurrachman & Iksan, 2021)

Crime eradication requires an integrated criminal justice system. It also contains systemic applications from its supporting sub-systems. The criminal justice system demands harmony, harmony and synergy between the subsystems, which are not only the administration of judicial , but also involve matters of

authority between their respective institutions in implementing criminal law in an integrated criminal justice system.(Jupri et al., 2022) Thus, the effort to eradicate pharmaceutical industry producing unsafe drugs also requires a multi doors measures to establish an integrated criminal justice system.

Second, The other thing that Indonesia legal system can learn from USA is about the amount of the fine money. In Indonesia legal system ,according to Article 196 of Law No. 36 of 2009, the amount of fine that can be imposed to the pharmaceutical company is maximum Rp. 3.000.000.000 or $189,014. This amount is significantly small for a corporation since the penalty is only three times that of an individual perpetrator.

The need to impose a stronger amount of fine money is because the enjoyment obtained from this act is in the form of economic gain. For this reason, the appropriate sanction to deter the corporation is through the economic loss. Criminal sanctions in the form of fines and additional penalties in the form of administrative sanctions are the main criminal sanctions for corporations.(Supriyanto, 2020) The deterrent effect is important for controlling the crime. Law enforcement without deterrent effects creates a conducive situation for perpetrators to continue the crime.(Ilham, 2019)

Furthermore, as Braithwaite (1984) argue that the fine is the predominant sanction used against corporate crime. Fine is a cheap and efficient forrn of sanction compared with imprisonment. For a corporation, fines are widely assumed to be more appropriate to corporate than to traditional crime since corporation break the law in order to maximize the profit.(Braithwaite, 1984b)

USA	Indonesia	What to improve by Indonesia
the use of the multidoor approach to settle the case, including civil, criminal, and administrative measure called as CIAs to deter the corporation	Indonesia have criminal and civil procedures to proceed the corporate as well.	Indonesia can learn the multidoor approach to settle the case, and may adopt the DPA and NPA as well as the CIAs procedure
Impose a high amount of sanction to corporations	The number of the maximum fines that can be imposed is still considerably low.	Indonesia shall increase the maximum amount of fines for corporate.

4. Conclusion

Based on the aforementioned explanation, Indonesia shall improve its legal system which comprehensively handle the case of Pharmaceutical Companies Producing Non-Safe Drugs. Lesson from America address the idea to settle the case with plea agreement, civil lawsuit, as well as oblige the corporation to enter in such a compliance program called as Corporate Integrity Agreement. Beside that, Indonesia shall impose a higher amount of fine in order to deter the company. This amount stated in the health law is significantly small for a corporation since the penalty is only three times that of an individual perpetrator.

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