

Objective Behavior Determination of the Crime of Obstructing Drug Administration

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Abstract

In order to further regulate the borderline behavior of drug crimes and protect the social public interest, the Amendment (XI) to the Criminal Law made a legislative response to this, adding a crime of interfering with drug administration after Article 142 of the Criminal Law. The appearance of this crime broke the traditional system which mainly harms human life and health and drug management order, and reconstructed the drug crime system. In the drug crime system, there are many views on the doctrinal study of the crime of interfering with drug administration, but on this basis, there are still some problems in the judicial determination of the crime of interfering with drug administration, which are also the focus of this paper. Under the background of the newly regulated drug crime system and the increase of the crime of interfering with drug administration, it is urgent to take the difficulties arising from the judicial application process as the important difficulty, which is mainly the identification of four kinds of illegal and interfering acts in its objective elements. This paper discusses the difficulty of identifying the crime in judicial practice, so as to provide some reference and guidance for the judicial practice of the crime of obstructing drug control in our country, so as to avoid the false judicature and misjudgment.

Keywords

Drug Crimes; Crime of Obstructing Drug Administration; Objective Behavior; Judicial Determination.

1. Introduction

Drugs are special commodities that concerns people's life safety, and drug crimes pose a serious threat to public health and social security. Therefore, cracking down on drug crimes has always been a process of continuous improvement in China. On December 26, 2020, the Eleventh Amendment to the Criminal Law was introduced, which added the crime of obstructing drug management in the field of drugs, in order to crack down on behaviors that endanger public life and health and disrupt drug management order.

2. Analysis of the Attributes of the Crime of Obstructing Drug Management Section Headings

The crime of obstructing drug management added in the Eleventh Amendment to the Criminal Law starts from the legislative provision of "violating drug management regulations", and it is found that this crime is based on the premise of violating administrative legal obligations in the preceding law. It is clear that this crime belongs to a typical statutory offense in terms of its nature attribution and has dual illegality, which is beyond doubt in the academic community. It is precisely because legislators have standardized the construction of this crime, clarifying the premise of "violating drug management regulations" and the four types of obstructive

behaviors of this crime, that the nature of the crime of obstructing drug management is fundamentally related to its objective behavior, which is also a key issue that is difficult to apply in judicial practice.

2.1. Statutory Offender: Using "Drug Administration Regulations" as the Precedent Law

With the development of the market economy, drug crimes have become increasingly rampant. In order to regulate this situation, the Criminal Law uses various administrative regulations as the prerequisite law, and under the principle of adhering to the unity of legal order, it has opened up the path of legal offenses.[1] The "violation of drug management regulations" stipulated in Article 142-1 of the Criminal Law is not only limited to the newly revised Drug Management Law of the People's Republic of China in 2019, but also includes the Implementation Regulations of the Drug Management Law of the People's Republic of China, the Regulations on the Administration of Anesthetic Drugs and Psychotropic Drugs, etc. Under the principle of adhering to the unity of legal order, the determination of statutory offenders should not be judged solely from the perspective of violating mandatory provisions of administrative regulations, but should be judged whether the illegal act has administrative illegality, rather than just a moral violation.[2] Administrative illegality has a warning function. When determining whether an illegal act constitutes a crime, it is also necessary to determine whether the act has criminal illegality, which requires the criminal law to play its independent value.

In the normative construction of this crime, although it is based on the premise of "violating drug management regulations", the crime separately lists four types of obstructive behaviors, and we can find that there are no fallback clauses in these four types of obstructive behaviors, indicating that the Criminal Law has imposed restrictive requirements on the requirements of the preceding law. Moreover, the addition of the restrictive condition of "enough to seriously harm human health" has limited the judicial determination of this crime, making the overlapping parts of the Drug Management Law and the Criminal Law substantially different. For example, the illegal acts listed in Article 124 of the Drug Administration Law mostly summarize typical behaviors that endanger the order of drug management in judicial practice, but in essence, there is no need to measure the legal interest of endangering human health. Only the violation of management order needs to be determined. The newly added crime of obstructing drug management in the Criminal Law involves two legal interests, and it is necessary to prove the connection between drug management order and human health rights and interests in order to be regulated by the Criminal Law. It is known that when determining whether an act constitutes this crime, it is necessary to combine the content of the preceding law and the limitations imposed by the criminal law to determine whether the act jointly has administrative and criminal illegality.[3] Therefore, the author does not question whether the crime of obstructing drug management is a statutory offense, but there are doubts about whether this charge is a pure statutory offense. In judicial practice, it is also necessary to first identify the various links involved in drug production and determine whether the administrative violations involved belong to criminal offenses. For example, this not only provides strict supplements to the drug management order at the level of administrative illegality, but also imposes strict restrictions on the judicial application at the level of criminal offenses, leaving room for discretion in the judicial practice of drug crimes in China.

2.2. Legal Benefit Certification: Constructed based on Objective Behavior and the Norm of "Serious Harm to Human Health"

Legal interests can be briefly summarized as the interests protected by law, which, as the name suggests, expresses that legal interests must be related to law and interests. In short, the legal interests protected by criminal law refer to the living interests of individuals protected by

criminal law.[4] Before the addition of this crime in the Eleventh Amendment to the Criminal Law, there was not much controversy in the criminal law community regarding the protection of legal interests involved in such crimes. It was generally believed that the protection of legal interests in the crime of producing and selling fake drugs and inferior drugs was a composite legal interest, that is, the order of drug management and the rights and interests of public life and health. After the promulgation of the Eleventh Amendment to the Criminal Law, there has been a hundred schools of thought in the academic community to protect the legal interests of this crime.

At present, there are two views in the field of criminal law on the protection of legal interests for the crime of obstructing drug management, namely single legal interest and composite legal interest. Among them, there are different views on a single legal interest. Professor Chen Xingliang pointed out that the protection legal interest of the crime of obstructing drug management is a single legal interest, that is, the order of drug management. And it is clearly stated that this crime is separated from the crime of producing and selling fake drugs, but the object of this crime is different from the object of the crime of producing and selling fake drugs, that is, the drug subject of this crime does not belong to fake drugs, so it does not have the attribute of endangering public life and health rights. Professor Dunning put forward a completely opposite view to Professor Chen, pointing out that although the legal interest in the crime of obstructing drug management is a single legal interest, it can only be the health and life rights of the drug users. He starts with the article "enough to seriously harm human health" and believes that the order of drug management is an abstract legal interest, and the violation of drug management regulations by the perpetrator is likely to only constitute administrative violations and not crimes.[6] Therefore, with "serious harm to human health" as the criterion for criminalization, it is clear that the substantive legal interests protected by the crime of obstructing drug management are the health and life rights and interests of drug users. However, scholar Xuan Dong pointed out that the protective legal interests of the crime of obstructing drug management are compound legal interests, that is, the order of drug management and the right to life and health of the public. He believes that the drug crime regulatory system before the promulgation of the Amendment to the Criminal Law (XI) only focused on the identification of fake and inferior drugs, and only imposed administrative penalties on the production behavior in the drug approval process, limiting the comprehensive protection of drug management order. After the promulgation of the Amendment to the Criminal Law (XI), it filled the loopholes in drug management order before the drug market and more comprehensively protected drug management order. And to further protect the public's right to life and health.[7]

In response to the different viewpoints mentioned above, the author adheres to the theory of compound legal interests, which means that the protection of legal interests for the crime of obstructing drug management is the order of drug management and the right to life and health of the public. In this regard, the author believes that after the promulgation of the Eleventh Amendment to the Criminal Law, the crime of obstructing drug management has become an independent charge in the entire drug crime system, no longer attached to the traditional crime of producing and selling fake (inferior) drugs. Therefore, we cannot only supplement the gaps in the two charges of fake (inferior) drugs. Starting from the normative structure of this crime, Article 142-1 of the Criminal Law lists four types of obstructive behavior. The drugs mentioned in item (1) are not counterfeit drugs under the Drug Administration Law; According to the "Lu Yong case", it can be inferred that some of the drugs involved in the production, import, or sale of drugs without obtaining relevant approval documents may not be fake or substandard drugs, but may have true efficacy and may not infringe on the public's right to life and health; And the third and fourth items only involve the management order of drugs, without specifying whether they are fake drugs, inferior drugs, or have any medicinal effects. Obviously, from the objective

obstruction behavior provisions listed in its normative structure, it is known that the protection legal interests involved in the crime of obstructing drug management include the order of drug management. In the normative construction of this crime, the restriction condition of "enough to seriously harm human health" further indicates that this crime is a specific dangerous offense, different from the actual harm offense of the crime of producing and selling fake and inferior drugs. The establishment of this specific danger enables the effective use of legal weapons to protect the public's right to life and health when the four illegal acts listed in the Criminal Law involve counterfeit or substandard drugs, or pose a threat to the public's life and health. For example, in judicial practice, it is sometimes difficult to provide evidence to prove the actual correlation between the harm to public life and health and the efficacy of drugs. However, the addition of the crime of obstructing drug management reduces the proof standard of this correlation, effectively controlling drug quality through criminal law, and protecting the safety of citizens in medication.

3. Identification of Objective Behavioral Forms of the Crime of Obstructing Drug Management

Drugs are an essential element in people's social life that concerns life, health, and safety. Drug crimes pose a serious threat to public health and social security, so cracking down on drug crimes has always been a process of continuous improvement in China. Legislators passed legislation in 2020 to add the crime of obstructing drug management, but this charge has limited applicability in judicial practice and even becomes a "zombie charge". This situation is often due to the lack of improvement in objective behavior in legislation. The criminal law has separated the four objective modes of conduct for this crime from the Drug Administration Law and separately listed four types of obstructive behavior. These four types of harmful behaviors can be summarized and classified into two categories based on their nature - unauthorized behavior and fraudulent and fabricated behavior. It should be noted that the Criminal Law does not provide a fallback clause for the specific objective behavior of this crime, which limits the determination of this crime.

3.1. Unadministrative Behavior

The drugs prohibited by the State Council's drug regulatory department and drugs that have not obtained relevant approval documents for drugs in the crime of obstructing drug management can be collectively referred to as drugs that violate administrative licenses. Before the revision of the Drug Administration Law, drugs involved in the first two acts of obstruction in this crime were always punished as "fake drugs". When such drugs involve production, sales, or import activities, they are convicted and punished for the crime of producing or selling fake drugs. For example, in 2012, Qin and Huang, among others, illegally produced and sold drugs that were legally recognized by the food and drug supervision and management department as counterfeit drugs without obtaining legal procedures for production and sales. In the end, the Shaanxi Provincial High People's Court issued a second instance judgment on this, ruling it guilty of producing and selling counterfeit drugs.[8] After the revision of the Drug Administration Law, the situation of "being punished according to fake drugs" has been removed. At this time, when producing and selling the above two drugs, the crime of producing and selling fake drugs will no longer be convicted and punished. It may be criminally regulated under the crime of illegal business operation, or only administrative penalties will be imposed.[9] Until the implementation of the Eleventh Amendment to the Criminal Law in 2021, the production, sale, and import of drugs that violate administrative licenses were regulated under the crime of obstructing drug management, and these two items were separated from the Drug Administration Law, expanding the regulatory system for cracking down on drug management and endangering public safety, in order to strictly distinguish the boundary

between administrative violations and criminal offenses, as well as the relationship between the crime of counterfeit (inferior) drugs and this crime.

3.1.1. Prohibited Drugs and Drugs that Have Not Obtained Relevant Approval Documents for Drugs

The National Medical Products Administration issued the "Announcement on Stopping the Production, Sales and Use of Furazolidone Compound Formulations" in 2019, the "Announcement on Cancelling the Registration Certificate of Hydroxybuzone Tablets" in 2020, and the "Announcement on Cancelling the Registration Certificate of Lianbizhi Injection Drugs" in 2022. All drugs in these regulations refer to drugs that are prohibited from use. At present, the production and sale of such drugs not only violates administrative regulations, but also requires punishment for such behavior, with the addition of a new charge of obstructing drug management, which also reflects that this charge is based on administrative regulations as a prerequisite law. But in fact, the "prohibited drugs" referred to in this crime are not only the drugs covered by these announcements and regulations issued by the National Medical Products Administration. The law has a lag, and there may still be many drugs that harm human health based on facts. The National Medical Products Administration has not yet issued regulations prohibiting the use of such drugs, so relying solely on the regulations issued by the National Medical Products Administration to determine whether they are prohibited drugs is not reasonable. The author believes that in judicial practice, factual judgments should be taken as the basis, and according to Article 67 of the Drug Administration Law, drugs with uncertain therapeutic effects or serious harm to human health for other reasons should be classified as prohibited drugs.

The production, sales, and import of drugs cannot be separated from the control of various approval documents required by Chinese laws and regulations. For drugs that have not obtained relevant approval documents in this crime, we can start with the Drug Administration Law. Among them, Articles 19, 20, 24, 25, 26, 32, 40, 41, 51, and 66 involve all aspects of drugs in the research and development registration stage, market production stage, and import operation stage.[10] In judicial practice, Shen bought Baijiu, Chinese herbal medicine, Baotaisong, piroxicam, and self-made medicinal liquor for illegal interests, and then promoted it through WeChat groups and WeChat friends circle, claiming that the medicinal liquor can treat gout, and sold it wholesale to Zhang and Huang. Zhang labeled the wholesale medicinal liquor with self-made "special gout medicinal liquor" and other words on the bottle for sale. Subsequently, the Market Supervision Administration identified the seized medicinal liquor as a drug without obtaining a drug approval certificate. After identification, Piroxicam components were found in the medicinal wine found at Zhang's residence; No Baotaisong or Piroxicam were detected in the medicinal wine found at Shen's residence. The final court ruled that Shen's behavior of producing and selling drugs without obtaining relevant approval documents is sufficient to seriously endanger human health and constitutes the crime of obstructing drug management.[11] It can be seen that in the newly added criminal law, according to the regulations involved in the Drug Administration Law, the crime of producing and selling drugs without obtaining relevant approval documents for drugs needs to be recognized by regulatory authorities.

3.1.2. Production, Sales, and Import Activities

The production and sales behavior in this crime is generally recognized by the same standards in practice as the behavior in the crime of producing and selling counterfeit drugs. In previous drug crime cases, sales behavior accounted for the vast majority, and after production behavior accounted for sales behavior, import behavior became very rare.[12] It can be seen from this that sales behavior is an essential behavior in the market, relatively transparent, and easy for law enforcement personnel to detect. For production activities, many pharmaceutical

companies and unscrupulous merchants can operate in a relatively covert manner, which makes it difficult for the investigating authorities to detect drugs with uncertain efficacy or other harmful effects on human health in judicial practice. As for the low incidence rate of import behavior, it is due to China's strict administrative licensing system and customs supervision. Articles 64 and 24 of the Drug Administration Law clearly stipulate that imported and listed drugs need to pass customs supervision and obtain drug registration certificates. In this case, it is difficult for suspect to muddle through the customs, so the number of cases of import behavior of this crime is relatively low.

And after the amendment of the Criminal Law in 2021, the Supreme People's Court and the Supreme People's Procuratorate issued the "Interpretation on Several Issues Concerning the Handling of Criminal Cases Involving Harmful Drug Safety" (hereinafter referred to as the "New Drug Interpretation") in 2022. Regarding production behavior, the New Drug Interpretation has removed the third item of Article 6 of the Old Drug Interpretation, and printing packaging materials, labels, and instructions are no longer considered as production behavior. Regarding sales behavior, according to Article 6 (2) of the New Drug Interpretation, paid or unpaid is the key to distinguishing between sales behavior and provision behavior. Moreover, the deletion of the phrase "purchase and storage without sale" in the "Interpretation of Old Drugs" reflects that this behavior is no longer considered a sales behavior. For those seized items, they should be considered as unsold and punished as attempted in judicial practice.

3.2. Fraudulent Styling Behavior

There are two main types of fraudulent and harmful behaviors, namely using deceptive means to register drugs and fabricating production and inspection records. In the normative construction of the crime of obstructing drug management, the behavior of defrauding and fabricating is different from the first two types of behavior. The first two modes of behavior are mainly focused on production and sales, and have legal provisions on the substantive efficacy of drugs. The fraudulent behavior of fabricating designs mainly exists in the process of drug application and registration. It does not directly target the substantive therapeutic effect of the drug itself, but it is a necessary path in the drug production process stipulated by Chinese law. Therefore, this type of behavior will directly infringe on the legal interests of drug management order and indirectly harm human life and health through the circulation of drugs.[13]

3.2.1. Using Deceptive Means to Register Drugs

In the implementation process of the "Interpretation of Old Drugs", those who apply for drug registration using false certificates, data, materials, samples or other deceptive means shall be punished with the crime of providing false certification documents in accordance with the 2017 "Interpretation on Several Issues Concerning the Application of Law in Criminal Cases of Falsification of Drug and Medical Device Registration Application Materials". However, this interpretation has now been abolished. After the release of the "New Drug Interpretation" in 2022, adopting the above-mentioned deceptive behavior will naturally be punished for the crime of obstructing drug management. When applying for drug registration, the proof documents and other materials provided are to ensure the precise efficacy of the drug, thereby playing a certain preventive role in not endangering human health and safety.[14] The deceptive methods used in this behavior are nothing more than unscrupulous drug merchants and pharmaceutical companies attempting to cross the national threshold for drug registration approval through covert means, in order to carry out a series of production, sales and other links to achieve the goal of obtaining high profits. Although this behavior does not directly affect the drug itself, deceiving drug registration through fraud not only disrupts the order of drug management, but also indirectly increases the safety hazards of drugs, seriously threatening the public's life and health. Therefore, the country must strengthen supervision through compulsory measures, and under the restriction of "serious harm to human health" stipulated

in the Criminal Law, make drugs comply with legal standards for human health from the source, so that the public can trust the safety of drugs in China, and buy and use them with peace of mind.[15]

3.2.2. Fabricate Production and Inspection Records

The legislator has stipulated that this charge originates from Changchun Changsheng Biotechnology Company's violation of pre-existing laws, fabricating production and inspection records, and arbitrarily changing process parameters. The act of fabricating records can be said to run through the entire process of drug development, registration, and circulation, and its behavior is particularly important. It is not excessive for legislators to regulate this behavior with criminal law. Whether it is fabricating production records or inspection records, it will make the production process of drugs unable to be displayed and become opaque, leading to the inability of drug supervision and management departments to truly control the research and development, production, and circulation processes of drug enterprises, increasing the possibility of endangering human health.[16] Therefore, any behavior that falsely fabricates drug production and inspection records and reaches the limit of "serious harm to human health" should be supported by criminal illegality and regulated by criminal law. For those fabricated behaviors that do not infringe upon legal interests, or those that do not substantially affect the accuracy and safety of drug efficacy in the process of drug research and development, production, and circulation, only law enforcement personnel are responsible for correcting and punishing them, and there is no need for criminal law to regulate them, in order to avoid wasting judicial resources.

4. Summary

Drug safety issues are receiving increasing attention from people. In order to implement the Party Central Committee's drug safety issues and respond to increasingly complex and severe crimes that endanger drug safety, China has started with administrative and criminal laws and continuously improved the drug safety regulatory system in legislation. Judicial authorities should crack down severely on pharmaceutical and drug sales activities that harm human health. The crime of obstructing drug management, as a newly added charge, has not yet formed a unified understanding of its charges, especially regarding the determination of objective behavior modes in the construction of this crime standard. Only the first two types of obstructing behaviors are more applicable in judicial practice, while the latter two types of fraudulent and fabricated behaviors are difficult to determine in judicial practice, mostly because they are difficult to discover from the source during the investigation stage. This work should be closely coordinated between administrative law enforcement departments and public security organs, and carried out truthfully in the process of drug supervision. Judicial organs should also cooperate with law enforcement departments when necessary to identify and form a unified chain. When judicial authorities apply the relevant provisions of this crime, it is necessary to accurately understand the relevant provisions, start from the nature of the crime, and combine the opinions of drug regulatory authorities to determine objective behavior with the strictest standards to ensure the realization of a fair trial.

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