

INSTITUTIONAL FUNCTIONS AND PATHWAYS FOR IMPROVING CRIMINAL PROCEEDINGS WITH INCIDENTAL CIVIL PUBLIC INTEREST LITIGATION IN THE FIELD OF DRUG SAFETY

Yuan Zhou¹, YuHang Li^{2*}

¹Guangzhou Maritime University, Guangzhou 510725, Guangdong, China.

²Fifth Procuratorial Department, Huangpu District People's Procuratorate of Guangzhou, Guangzhou 510530, Guangdong, China.

*Corresponding Author: YuHang Li

Abstract: Criminal proceedings with incidental civil public interest litigation provide an important mechanism for procuratorial organs to protect drug safety. With the expansion of online sales and cross-regional illegal operations, practice has revealed problems including inconsistent punitive damages standards, excessive reliance on actual harm, inadequate evidentiary coordination, and unclear liability allocation. Cases involving illegal botulinum toxin sales, online counterfeit drug sales, and multilevel counterfeit drug distribution show that public interest protection should prioritize risk prevention while adhering to statutory liability, proportionality, and procedural regularity. Thus, the legal basis and calculation of punitive damages should be clarified; drug safety risks should be properly assessed; evidence collection and examination should be improved; and liability should reflect each party's conduct, fault, and contribution to public interest harm. Legislative improvements, consistent judicial rules, and stronger interdepartmental cooperation can advance public interest litigation beyond case-specific accountability toward risk prevention and systemic governance.

Keywords: Criminal proceedings with incidental civil public interest litigation; Drug safety; Punitive damages; Harm to the public interest

1 INTRODUCTION

Drug safety is essential to public health. The expansion of online sales and cross-regional illegal operations has increased the risks posed by counterfeit and substandard drugs. Criminal proceedings with incidental civil public interest litigation provide an important mechanism for addressing these risks. However, challenges remain in applying punitive damages, establishing harm to the public interest, coordinating evidence, and allocating liability. Drawing on representative cases, this article examines these issues and proposes improvements to substantive rules, evidentiary coordination, liability allocation, and interdepartmental cooperation, with the aim of strengthening preventive protection and systemic governance in drug safety.

2 INSTITUTIONAL POSITIONING AND PRACTICAL CHALLENGES

2.1 The Institutional Need for Public Interest Protection in Drug Safety

Drug safety violations are often concealed and may cause widespread harm. Once counterfeit or substandard drugs enter circulation through distributors, medical aesthetics institutions, or online platforms, they may threaten public health even without identifiable injury. Individual consumers often lack access to transaction records and professional evidence, making private litigation alone insufficient to protect the public interest.

Criminal proceedings with incidental civil public interest litigation combine criminal prosecution with civil public interest remedies, facilitating evidence sharing, reducing duplicate investigations, and improving judicial efficiency. The 2018 joint interpretation issued by the Supreme People's Court and the Supreme People's Procuratorate established procedural rules for procuratorial organs to initiate such proceedings.

In drug safety cases, this mechanism addresses the limits of individual remedies, complements criminal and civil liability, and promotes risk governance through measures such as recalls, safe disposal, public warnings, and procuratorial recommendations [1]. However, criminal findings do not automatically establish civil liability. The latter must be independently determined under the applicable substantive law and standards of proof, preserving the distinct functions of criminal punishment and public interest remedies.

2.2 Practical Developments and Characteristics of Public Interest Litigation in the Field of Drug Safety

Recent cases mainly concern the manufacture and sale of counterfeit or substandard drugs, including unauthorized botulinum toxin and counterfeit drugs sold online. Online transactions and complex distribution networks make it difficult to trace products, establish sales volumes, identify liable parties, and determine distribution scope.

Procuratorial claims now extend beyond public apologies to include punitive damages, product recalls, safe disposal, and public risk warnings, reflecting a stronger focus on risk prevention and public interest restoration [2]. However, several challenges remain, including inconsistent standards for punitive damages, difficulties in establishing public interest harm without identifiable injury, inadequate coordination of evidence, and uncertainty in allocating liability among manufacturers, suppliers, sellers, and other participants.

These issues are closely connected. Applying punitive damages requires clear evidence of public interest harm and the identification of liable parties. Both depend on establishing drug distribution, individual involvement, and the risks created. Improving the system therefore requires coordinated reforms to substantive liability rules, evidentiary standards, and procedural mechanisms, rather than focusing solely on compensation calculations or case-handling efficiency.

3 ANALYSIS OF TYPICAL CASES AND RELATED LEGAL ISSUES

3.1 Case Sun Involving Obstruction of Drug Administration

In May 2023, Sun sold botulinum toxin products without the required approvals or business qualifications. In June 2024, the court sentenced Sun to ten months' imprisonment and a RMB 5,000 fine, and ordered a product recall, public apology, punitive damages equal to three times the sales proceeds, and safe disposal of the products [3].

The case raises questions about whether punitive damages may be imposed without proven physical injury and how they should be calculated. Unauthorized sales may threaten public health even where no specific injury has been identified. However, harm to the public interest does not automatically justify punitive damages; courts must examine the applicable legal provisions, the defendant's conduct, and the risks involved. The Consumer Rights and Interests Protection Law and the Drug Administration Law provide different rules for punitive damages, which cannot automatically be extended to procuratorial public interest litigation. Procuratorial organs must establish a clear statutory basis and determine the appropriate calculation method. Actual sales proceeds may serve as the calculation base, but unsold or seized products cannot automatically be counted as sales. The case also highlights the distinct functions of criminal and civil public interest liability: criminal fines punish offenders, while recalls and safe disposal control risks. Punitive damages may deter violations but must remain within statutory limits.

3.2 Case Ju and Others Involving the Sale of Counterfeit Drugs

In 2024, Ju and others sold counterfeit drugs marketed as "Avelox" through WeChat pharmaceutical groups and distributed them by mail. Testing found that the products contained no active pharmaceutical ingredients. The People's Procuratorate of Lianyung District, Lianyungang, initiated criminal proceedings and brought incidental civil public interest litigation, seeking punitive damages equivalent to three times the relevant amount and a public apology. The defendants admitted their guilt, expressed remorse, and voluntarily paid compensation [4].

The case highlights two challenges: establishing public interest harm without proven physical injury and reconstructing online transactions through electronic evidence. Counterfeit drugs may delay necessary treatment even without identifiable injury. However, unlawful conduct alone does not establish a public interest claim; the products, distribution, and health risks must be demonstrated. WeChat records, payment data, and logistics information can establish transaction details, financial flows, quantities, recipients, and distribution areas. These sources should be cross-verified with drug appraisal reports and other evidence. Authorities must preserve electronic evidence's authenticity and integrity by documenting lawful extraction procedures and explaining its source and relevance. Testing or expert review may also be required to assess drug composition, regulatory compliance, and safety risks.

3.3 The Case of Huang Involving the Manufacture and Sale of Counterfeit Drugs in Dongguan

Huang and others participated in manufacturing, supplying, and distributing counterfeit drugs through residential premises, physical stores, WeChat, and online shops. The procuratorial authorities initiated criminal proceedings with incidental civil public interest litigation. The court ordered certain defendants to pay punitive damages according to their respective liabilities, issue public apologies and risk warnings, and recall the products [5].

The case highlights the distinction between criminal liability and civil public interest liability. Criminal defendants do not necessarily include all parties liable for public interest harm, and a criminal conviction does not automatically establish equal civil liability. Liability must be assessed separately according to each party's conduct and the applicable legal basis. The allocation of liability also requires clear standards. Joint and several liability should apply only when its statutory conditions are met. Where individual contributions can be distinguished, liability should reflect each party's fault, causal contribution, and role in the unlawful conduct. The calculation of punitive damages must likewise be distinguished from the allocation of liability, with its legal basis and calculation method independently established to prevent disproportionate liability.

3.4 Common Issues Identified Across the Cases

Although the cases differ in their facts and the drugs involved, they reveal three common characteristics of public interest litigation in the field of drug safety. Harm to the public interest is primarily characterized by risk. Drugs entering the market may threaten public health even when no specific injury has been established. Determining such harm requires

balancing preventive risk control with evidentiary requirements: actual injury should not be the sole criterion, but neither should every unlawful act automatically constitute harm to the public interest.

Evidence in these cases is multifaceted. Establishing liability generally requires evidence concerning the nature of the drugs, transaction details, sales volume, distribution scope, and identities of the liable parties. Although criminal evidence provides an important foundation, supplementary investigation may be necessary to determine the extent of harm, allocate liability, and identify appropriate remedies. Liability must also reflect the different roles of the parties involved. Drug production and distribution may involve multiple participants with varying degrees of fault and contribution. The determination of liability should distinguish criminal from civil responsibility and ensure that each party's obligations correspond to their role in the unlawful conduct and the resulting harm.

4 PRINCIPAL CHALLENGES FACED BY THE SYSTEM

4.1 Lack of Clarity Regarding the Legal Basis for Claims for Punitive Damages and Rules for Calculation

Punitive damages are an important form of liability in drug safety public interest litigation, but their application raises questions concerning the legal basis, constituent elements, calculation base, and multiplier. Cases relying on the Consumer Rights and Interests Protection Law and the Drug Administration Law may produce inconsistent standards if the applicable provisions are not clearly identified.

Procuratorial organs must establish the statutory basis for their claims. Individual consumers' entitlement to punitive damages does not automatically authorize procuratorial organs to seek the same remedy in every public interest case, as the claimants, protected interests, and purposes differ. The 2024 judicial interpretation primarily addresses claims by individual consumers, leaving the basis for its application in procuratorial public interest litigation requiring further clarification [6]. Sales proceeds are relatively easy to establish in many cases. However, where drugs remain unsold, some transactions cannot be verified, or the drugs involved have been seized, the calculation base must be determined through an assessment of the available evidence. The applicable multiplier under different legal provisions should likewise be selected according to the specific statutory requirements, rather than solely on the basis of the severity of the harm caused by the case [7].

Besides, the relationship between criminal fines and punitive damages requires further clarification. The two differ in legal nature and function and therefore cannot simply be offset against each other. Nevertheless, when determining the overall liability imposed and assessing the defendant's subsequent remedial efforts, courts should also consider whether the resulting allocation of liability complies with the principle of proportionality.

4.2 Tension Between Determining Harm to the Public Interest and Proving the Existence of Risk

Public interest litigation in drug safety serves a preventive function. Counterfeit and substandard drugs may threaten public health before identifiable physical injury occurs. Restricting harm to the public interest to cases involving actual injury may delay intervention and weaken preventive protection [8].

However, not every regulatory violation constitutes harm to the public interest. Three situations should be distinguished: actual injury to health; a demonstrable risk to public health arising from drug quality, composition, or use; and regulatory violations unsupported by sufficient evidence of substantial risk. The first two may justify public interest remedies or preventive measures, while the third requires further assessment.

The standard of proof should reflect the nature of the alleged harm. Where injury has occurred, the relationship between the drugs and the injury should be examined. Where actual injury is absent but a real risk exists, the focus should be on the drugs' risk characteristics, distribution, and potential impact. Procuratorial organs should not have to prove a complete causal chain to physical injuries that have not yet occurred [9]. Nevertheless, establishing risk does not automatically establish liability. The existence of harm to the public interest and the defendant's liability are distinct questions; the latter requires examination of the defendant's conduct, fault, and the applicable legal basis.

4.3 Inadequate Evidentiary Coordination Between Criminal Proceedings and Civil Public Interest Litigation

Criminal investigations focus primarily on the elements of the offense, the amount involved, and individual criminal liability. Civil public interest litigation may additionally require evidence concerning drug distribution, affected populations, recall feasibility, disposal costs, and appropriate remedies. If these issues are not investigated concurrently, subsequent proceedings may face evidentiary gaps and duplicated investigations [9]. Electronic data are particularly important in cases involving online sales of counterfeit drugs. Chat records, payment information, logistics documents, and online store records may be held by different parties and are vulnerable to deletion or alteration [10]. Timely and lawful collection is therefore essential to reconstructing transactions. The source, integrity, and relevance of such evidence must also be verified; isolated screenshots or payment records cannot independently establish total sales.

Expert appraisal presents further challenges. Determining drug authenticity, ingredient composition, and potential health risks requires specialized expertise, while the necessary examinations vary between cases. Moreover, criminal proceedings and civil public interest litigation do not have identical evidentiary requirements [11]. Facts established in a criminal judgment carry significant evidentiary weight but do not necessarily prove every element of civil public interest liability. Effective coordination should therefore facilitate evidence sharing while preserving the parties' right to challenge evidence and avoiding unnecessary duplication.

4.4 The Need to Refine the Scope of Liable Parties and the Rules Governing the Allocation of Liability

Illegal drug distribution often involves multiple parties, including manufacturers, suppliers, retailers, online operators, and service providers. However, the scope of criminal prosecution does not necessarily coincide with civil public interest liability. Criminal defendants should not automatically be treated as the only liable parties, nor should every party connected with a transaction be held liable without a sufficient legal basis.

Liability should be determined according to each party's conduct, statutory obligations, knowledge, and contribution to the relevant harm. Manufacturers and sellers directly involved in unlawful drug production or sales are primary subjects of investigation. For warehousing, transportation, and online service providers, liability depends on their specific roles and whether they fulfilled their legal obligations. Under Article 62 of the Drug Administration Law, third-party trading platforms must fulfill statutory duties, including qualification verification and reporting. Their liability should be assessed by examining compliance with these duties and whether they knew or should have known of the unlawful conduct.

The allocation of liability among multiple parties also requires clear standards. Joint and several liability should apply only where the relevant legal conditions are satisfied. Where individual contributions can be distinguished, liability should reflect each party's fault, causal contribution, and applicable legal provisions. For punitive damages, the calculation base and allocation of liability must be separately established to prevent double recovery or disproportionate liability [12].

5 RECOMMENDATIONS FOR IMPROVING THE SYSTEM

5.1 Clarifying the Conditions for Applying Punitive Damages and the Methods of Calculation

The institutional purpose of punitive damages is to impose enhanced civil liability for specified unlawful conduct and strengthen the prevention and sanctioning of serious violations. Their application must be based on a clear legal foundation and take into account the nature of the conduct, the defendant's subjective fault, the risks posed by the drugs, and the harm to the public interest [13].

Procuratorial organs should identify the statutory basis and relevant elements of their claims, ensuring that the provisions invoked align with the case and the objectives of public interest protection. The Consumer Rights and Interests Protection Law and the Drug Administration Law should not be applied interchangeably. Where appropriate, specific provisions of the Drug Administration Law concerning counterfeit and substandard drugs may provide a more suitable basis.

The calculation base should generally reflect actual sales proceeds established by evidence. Unverified transactions may be assessed using transaction records, financial flows, logistics data, and other relevant evidence, while any price-based estimation must be explained. Seized but unsold drugs should not automatically be included in sales proceeds.

The selection of the punitive damages multiplier should consider the nature and duration of the violation, drug safety risks, distribution scope, subjective fault, unlawful gains, public interest harm, and remedial measures, within statutory limits. Procuratorial submissions and judgments should explain the chosen multiplier. Criminal fines and punitive damages must be determined separately. Voluntary compensation and remediation may demonstrate remorse where legally relevant, but do not automatically exempt defendants from civil liability [14].

5.2 Establishing a Risk-Oriented Framework for Determining Harm to the Public Interest

Public interest litigation concerning drug safety should adhere to the principle of preventive protection, while ensuring that risk assessments are grounded in specific facts. The below factors should be considered comprehensively during case handling. The inherent risks of the drugs should be assessed through testing results, expert opinions, and applicable legal standards, particularly where products lack active ingredients, contain harmful substances, lack required approval, or fail to meet quality requirements. Their distribution should also be established, including whether they entered the market, reached unspecified consumers, and circulated across different regions. Where products are seized before distribution, the assessment should consider whether a real risk has arisen and whether effective measures have contained it.

Actual injury must be distinguished from risk-based harm. Where injury occurs, its consequences and causal connection to the unlawful conduct should be examined. Where no injury is established, the nature of the drugs and their distribution may still demonstrate a real threat to public health, with remedies proportionate to the identified risk.

Procuratorial organs should bear the applicable burden of proving the unlawful conduct, public interest harm or real danger, and the connection between them. Courts should examine defendants' rebuttal evidence alongside the other evidence in accordance with the law.

5.3 Improving Evidentiary Coordination Between Criminal Proceedings and Civil Public Interest Litigation

Evidentiary coordination should begin at the initial stage of case investigation rather than being postponed until the conclusion of the criminal proceedings. In criminal cases involving suspected violations of drug safety laws, procuratorial organs may, in performing their statutory supervisory functions, pay attention to the distribution of drugs, sales proceeds, potentially affected populations, and subsequent disposal requirements as appropriate to the circumstances. This can facilitate the concurrent collection of evidence for criminal proceedings and public interest litigation.

Procedures for extracting and preserving electronic data should be standardized. In online drug sales cases, evidence collection plans should focus on key data, including transaction information, payment records, logistics information, and

accounts involved in the transactions. Original data and their sources should be lawfully preserved, the extraction process documented, and the correspondence between different categories of data verified.

Professional testing, inspection, and appraisal mechanisms should also be improved. Investigators should specify the facts requiring proof, select appropriately qualified institutions in accordance with the law, and standardize procedures for sample collection, sealing, submission, and storage. These measures help ensure that technical evidence is reliable and can be effectively examined in subsequent proceedings.

Coordination between criminal evidence and evidence used in civil public interest litigation should be strengthened. Evidence lawfully collected during criminal proceedings that is relevant to the issues in dispute may be used in the incidental civil public interest proceedings in accordance with the law, while safeguarding the parties' right to challenge the evidence. Where the criminal proceedings have not addressed the scope of harm, drug recalls, disposal costs, or other matters relevant to civil liability, procuratorial organs should conduct supplementary investigations in light of the claims advanced. Evidence preservation and interdepartmental cooperation are equally important. Appropriate preservation measures should be taken promptly, in accordance with existing legal provisions, for drug samples, electronic data, and other evidence that may deteriorate, disappear, or become difficult to obtain again.

5.4 Refining the Identification of Liable Parties and the Rules for Allocating Liability Among Multiple Parties

The identification of liable parties should be grounded in statutory provisions and the facts concerning their conduct. For parties directly engaged in unlawful drug production or sales, investigations should focus on their conduct, fault, and the relationship between their actions and the harm to the public interest. For upstream suppliers, warehousing and transportation providers, parties supplying business qualifications, online trading platforms, and other participants, liability should be assessed separately by examining whether they engaged in the relevant conduct, whether they were subject to statutory obligations, whether they breached those obligations, and how their conduct contributed to the harm to the public interest [15].

The allocation of liability should distinguish between the conditions for joint and several liability and those for several liability apportioned according to individual shares. Joint and several liability may be claimed where the circumstances constitute joint tortious conduct and satisfy the statutory requirements. Where the conduct, fault, and scope of responsibility of each party can be distinguished, their respective liability should be determined in accordance with the applicable legal provisions. For the principal parties who organized or planned the unlawful business operations, particular attention should be paid to their control over and organizational role in the overall scheme. For parties whose participation was limited, the scope of liability should be determined according to their specific conduct and the liability imposed by law [16].

Coordination among different forms of liability must also be considered. Punitive damages, drug recalls, safe disposal, public risk announcements, and public apologies address different legal concerns. The authorities handling a case should formulate specific claims according to the nature of the harm to the public interest and the remedial needs involved, explaining the purpose of each remedy and its relationship with the others so as to avoid duplicative relief or remedies that are insufficiently tailored to the harm.

5.5 Strengthening Interdepartmental Cooperation and Promoting Consistency in Judicial Rules

Drug safety cases involve criminal justice, administrative regulation, professional testing, and online transactions. Effective governance cannot be achieved through any single stage of case handling alone. Improving the system of criminal proceedings with incidental civil public interest litigation therefore requires stronger interdepartmental cooperation within the existing framework of statutory responsibilities, together with the gradual harmonization of legal application through guidance based on similar cases.

First, mechanisms for transferring case leads and sharing information should be improved. Where market regulation or drug regulatory authorities discover suspected criminal violations involving drugs in the course of performing their duties, they should transfer the cases to public security organs in accordance with the law and notify procuratorial organs of relevant leads through established working mechanisms.

Second, cooperation between procuratorial organs and professional institutions should be strengthened. For specialized issues involving drug composition, quality standards, risk levels, and disposal methods, procuratorial organs may seek professional opinions from qualified individuals in the relevant fields in accordance with the law.

Third, the governance function of procuratorial recommendations should be brought into fuller play. Where cases reveal problems involving drug business licensing, the regulation of online drug sales, or the tracing of drug distribution, procuratorial organs may issue procuratorial recommendations to the relevant administrative authorities in accordance with the law, urging them to perform their statutory duties.

Finally, consistency in judicial rules should be promoted. Recurring disputes concerning the legal basis for punitive damages claims, calculation bases, the determination of risk-based harm, the examination of electronic evidence, and the allocation of liability among multiple parties should be addressed through typical cases, professional guidance, and, where necessary, judicial interpretations to clarify the applicable rules.

6 CONCLUSION

Criminal proceedings with incidental civil public interest litigation provide an important avenue for protecting drug safety. Their effectiveness depends on coordination among substantive liability rules, evidentiary standards, and procedural mechanisms. To address inconsistent punitive damages standards, difficulties in proving public interest harm and risk, evidentiary coordination, and liability allocation, improvements are needed at multiple levels.

Substantively, the legal basis and conditions for procuratorial claims for punitive damages should be clarified, alongside rules for calculating damages and allocating liability. Procedurally, evidence should be collected concurrently for criminal proceedings and public interest litigation, with improved methods for examining electronic data and expert appraisals. Administratively, findings from individual cases should inform risk prevention, drug tracing, and case referral mechanisms. Institutionally, the responsibilities of procuratorial organs, courts, administrative authorities, and professional institutions should be clearly defined, ensuring cooperation within statutory powers and procedures. The value of drug safety public interest litigation lies not only in holding violators accountable but also in preventing risks. Consistent application of risk prevention, statutory liability, evidentiary sufficiency, and proportionality enables the system to punish violations, eliminate risks, and improve governance.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose.

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