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Judicial Dilemmas and Solutions in Product Liability Disputes Involving Medical Products for the Elderly

-- An Empirical Analysis Based on 237 Judicial Rulings

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Abstract

With the continuous ageing of China's population, more older people are needing to use medical products frequently and thus have risen the number of related liability disputes. In accordance with the provisions of Article 1223 of the Civil Code, this paper will conduct an empirical study on 237 judicial judgments in cases of medical product liability involving the elderly to explore the characteristics of these judgments systematically. In this paper, methods of description and correlation analysis, chi-square tests, and regression models will be employed to build a multi-dimensional system of variables that covers product attributes, context of medical application, participants in civil disputes, procedures, etc. Empirically, the nature of the expert opinion and the seriousness of the damage are the reasons why liability is imposed in this way. Specific to older people, there are other reasons why the products are not suitable or why the consent form is unclear; all of them have a relatively small negative impact. Multiple linear regression shows that the above factors are also positively correlated with the amount of compensation paid. To solve the problems of ambiguity in the identification of age-related factors, insufficient targeting of expert assessments, and inconsistency in compensation standards for judicial rulings, this paper proposes the following suggestions: increase the statutory weight of age factors in determining liability, standardise the special assessment and application rules for judicial appraisals involving older persons, and unify the quantitative standards for compensation discretion and interest balancing mechanisms.

Keywords

Senior citizens; medical product liability; judicial rulings; empirical research; influencing factors.

1. Introduction

Article 1223 of the Civil Code, which establishes liability rules for harm caused by defective medical products, provides a regulatory foundation for safeguarding the rights of the elderly regarding the use of medical products. Meanwhile, policies and regulations such as the "Proposal of the Central Committee of the Communist Party of China on Formulating the 15th Five-Year Plan for National Economic and Social Development" and the "Law on the Protection of the Rights and Interests of the Elderly" further form a synergistic institutional framework[1]. These explicitly require the optimization of the design, production, and risk disclosure of medical products suitable for the elderly, the strengthening of safety supervision over such products, and the guarantee of access to appropriate medical services and products for the elderly.[2] This not only establishes a policy baseline for the rights of the elderly regarding medical products but also imposes higher demands on judicial practice to balance the

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physiological characteristics of the elderly with the determination of liability for medical products. In practical terms, China's population aged 60 and above has exceeded 300 million, Due to their needs for chronic disease treatment, rehabilitation care, and organ replacement, the elderly rely significantly more on medical products—such as pharmaceuticals, implantable medical devices, and rehabilitation aids—than other demographics. However, characteristics such as declining physical function, insufficient awareness of medical product risks, and mobility limitations mean that liability disputes involving medical products for the elderly are characterized by high incidence rates, complex liability determinations, and severe consequences. Yet in judicial practice, there are certain discrepancies in the adjudication standards for such disputes[3]. First, in some cases, the criteria for determining warning deficiencies vary because the cognitive capacity of elderly patients to comprehend product warnings is not taken into account. Second, when allocating liability, there is a failure to reasonably balance the relationship between medical product defects and the elderly patients' underlying medical conditions[4]. Third, in cases involving harm caused by similar implantable medical devices, the compensation amounts awarded by different courts vary significantly. These discrepancies highlight issues that require further consideration. First, should the unique characteristics of the elderly population be incorporated into judicial considerations? Second, how should defects in the suitability of medical products for the elderly be determined? Third, do manufacturers' duties to inform adequately meet the cognitive needs of the elderly? Currently, no unified judicial logic has been established regarding these issues in judicial practice.

2. Academic Discussions on Medical Product Liability Disputes

As a specialized field bridging product liability law and medical malpractice liability, medical product liability disputes present complexities in both theory and practice regarding the application of rules and the determination of liability. When such disputes involve the elderly—a group with unique physiological functions and cognitive abilities—the patterns of adjudication and influencing factors exhibit distinct characteristics[5]. Therefore, this study engages in a theoretical discussion of medical product liability disputes and, building on existing research, explores the applicable pathways for resolving such disputes involving the elderly[6].

First, regarding the foundational theory of medical product liability and the definition of liable parties, a basic consensus has been reached within the academic community[7]. The mainstream view holds that liability for harm caused by defective medical products should be governed by the principle of strict liability, with the scope of liable parties extending beyond traditional manufacturers to include sellers, medical device registrants, and filers. Under the regulatory framework of Article 1223 of the Civil Code, medical institutions are often treated similarly to sellers and thus bear strict liability[8]. However, regarding the legitimacy and boundaries of strict liability imposed on medical institutions, there is ongoing academic reflection. Scholars argue that the unique nature of medical services should be taken into account, suggesting that the liability of medical institutions should be appropriately mitigated or subject to typological limitations[9].

With the deep integration of artificial intelligence (AI) technology into the medical field, the classification of diagnostic and therapeutic AI as medical products and the determination of liability for harm caused by them have sparked widespread discussion[10]. Research generally acknowledges that diagnostic and therapeutic AI, regardless of whether it relies on a physical medium, can be classified as a "product" and subject to product liability rules. The core challenges lie in the criteria for determining product defects, the proof of causation, and the allocation of liability[11]. In response, scholars have proposed the "rational algorithm standard"

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to identify design defects and addressed the evidentiary difficulties in proving warning defects by reinforcing healthcare providers' duty of re-evaluation and special duty to inform[12]. Furthermore, regarding the autonomy of AI, the introduction of rules of factual presumption is viewed as an effective approach to alleviating the burden of proof faced by patients.

Regarding the core elements of medical liability, particularly the duty to inform and the determination of defects—which are closely related to the protection of the rights of the elderly—research is gradually becoming more refined[13]. At the level of the duty to inform, empirical studies indicate that judicial practice has moved beyond formal review to focus on the breadth and depth of the information provided, that is, the actual understanding achieved by the patient. This provides significant support for establishing cognitive-adaptive disclosure standards tailored to elderly patients[14]. Regarding product defects, in addition to the traditional standard of unreasonable risk, scholars are beginning to emphasize considerations of suitability for specific groups; whether a product aligns with the physiological and cognitive characteristics of the elderly should be a key factor in determining the existence of design or warning defects[15].

Recently, experts have been providing valuable opinions in the course of the medical malpractice case. A large number of studies have shown that experts' opinions are frequently used in constructing the foundation for a court's decision, and they can directly affect whether a party is found liable and the amount of damages awarded. However, the current expert assessment practices are also lacking in terms of consideration for special groups and have too many general standards. Therefore, scholars have called for strengthening the special assessment obligations of expert institutions and judges' substantive review of expert opinions, and, when necessary, introducing a system of expert assistants to ensure the scientific accuracy and fairness of expert assessments[16].

Finally, regarding the mechanisms for damage apportionment and compensation, research shows a trend toward balancing individual justice with the socialization of risk dispersion. The loss apportionment rule, widely adopted in China's judicial practice, is practically reasonable in cases where harm results from a combination of the patient's own medical condition and medical malpractice[17]. At the same time, in light of the social nature of medical risks, building a no-fault system for medical malpractice compensation and implementing mandatory medical liability insurance have been proposed to address the deficiencies in traditional tort law remedies and achieve the socialisation of risk. In terms of the discretion to determine the amount of compensation, this paper proposes building a more reasonable calculation system that can better reflect the special damage suffered by older persons, such as rehabilitation and nursing expenses, as well as mental harm; thus achieving the purpose of compensation in tort liability more fully.

3. An Empirical Study on Product Liability Disputes Involving Medical Products for the Elderly and Its Findings

3.1. Sample Screening

Data for this study were obtained from the Law Research Lighthouse Empirical Platform, and a total of 237 judicial rulings on medical product liability cases involving older persons from 2010 to 2025 were identified. The three required conditions for the selection of the sample are as follows: First, one of the parties should be a person aged 60 or older and fall under the specified category of older persons. Second, the case must be a product liability dispute for a medical product and should fall within one of the statutory medical product categories, such as pharmaceuticals, implantable medical devices, and in vitro diagnostic reagents; tort cases caused by non-medical products are excluded. Thirdly, the judicial documents should fully record essential data, such as the characteristics of the product, specific details of the medical

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treatment, liability determination and compensation amount, etc., to ensure the accuracy of the data.

3.2. Variable Definition and Operationalization

Table 1. Factors Affecting Product Liability Disputes Involving Medical Products for the Elderly

Variable Type	Variable Name	Operational Definition	Symbol
Dependent Variable 1	Whether the compensation claim is supported	1 = Supported, 0 = Dismissed all claims / Dismissed appeal	Sup
Dependent Variable 2	Logarithm of compensation amount	Natural logarithm of total compensation amount	LnComp
Independent Variable	Product Characteristic Variables		
	Product Geriatric Adaptability	1 = Labeled with elderly instructions / dose adaptation / contraindications, 0 = Not labeled or unsuitable (e.g., no large-print instructions)	Adap
	Product Defect Type	1 = Warning defect, 2 = Design defect, 3 = Manufacturing defect, 4 = Compound defect	Def
	Product Registration Status	1 = Legally registered / approved, 0 = Unregistered / illegally registered	Reg
	Medical Practice Variables		
	Duty of Disclosure Cognitive Adaptation	1 = Plain language, written disclosure of elderly risks, 0 = Professional jargon only or no disclosure	Inf
	Medication Compliance	1 = No contraindicated medication / dose compliant, 0 = Violation of geriatric medication contraindications	Med
	Subject and Procedure Variables		
	Patient Age Subdivision	1 = 60–70 years old, 2 = 71–80 years old, 3 = Over 81 years old (with 60–70 years old as reference)	Age
	Patient Fault Type	1 = Concealed basic medical history / non-cooperation with treatment, 0 = No fault	Fault
	Whether Judicial Appraisal Conducted	1 = Conducted product defect / medical fault identification, 0 = Not conducted	Jud
	Appraisal Opinion Tendency	1 = Identified fault / defect, 0 = Not identified	Exp
Control Variable	Severity of Damage Consequences	1 = General damage, 2 = Disability, 3 = Death	Sev
	Regional Economic Level	1 = Eastern, 2 = Central, 3 = Western	Econ
	Court Level	1 = Intermediate court, 0 = Basic-level court	Level

The main judicial results of medical product liability cases involving older persons are the focus of this paper. Select whether to accept a compensation claim and the logarithm of the

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compensation amount as the main dependent variables. Independent and control variables are designed based on the physiological and cognitive features of older adults and the characteristics of the disputes; their specific operating definitions are presented in Table 1. The three elements of the system are also included in the variable system. The first is the scope of judicial results; that is to say, how legally sound the court's resolution of a case is. Secondly, the dimension of the elements in medical product liability refers to the regulatory requirements set out in the Civil Code for medical product liability concerning the identification of defects and the performance of obligations. Specifically, the suitability of the product for older people and the cognitive appropriateness of the duty to inform are included to meet the physiological and cognitive characteristics of older people. Thirdly, there is the issue of parties and the judicial system, which includes differences among the parties to the dispute and elements of judicial procedures that need to be considered in applying judicial logic for fact-finding, liability allocation, and determining the outcome in medical product liability cases.

3.3. Model Formula Settings

Build a binary logistic regression model for the two dependent variables, tailored to the binary classification of whether the claim is approved. Additionally, build a multiple linear regression model for the compensation amount.

The binary logistic regression model for whether the claim is approved is shown below:

$$\ln\left(\frac{P(Sup)}{1-P(Sup)}\right) = \alpha_0 + \alpha_1 Adap + \alpha_2 Def + \alpha_3 Reg + \alpha_4 Inf + \alpha_5 Med + \alpha_6 Age + \alpha_7 Fault + \alpha_8 Jud + \alpha_9 Exp + \delta_1 Sev + \delta_2 Econ + \delta_3 Level \quad (1)$$

Here, P(Sup) represents the probability of "upholding the claim for compensation," α_0 is a constant term, α_1–α_9 are the coefficients of the independent variables, δ_1–δ_3 are the coefficients of the control variables, and the core explanatory metric is the odds ratio $OR = \exp(\alpha_k)$.The multiple linear regression model for the compensation amount is shown below:

$$Ln_{Comp} = \beta_0 + \beta_1 Adap + \beta_2 Def + \beta_3 Reg + \beta_4 Inf + \beta_5 Med + \beta_6 Age + \beta_7 Fault + \beta_8 Jud + \beta_9 Exp + \delta_1 Sev + \delta_2 Econ + \delta_3 Level + \varepsilon \quad (2)$$

Here, LnComp represents the logarithm of the compensation amount received by the elderly, β0 is the constant term, β1–β9 are the coefficients of the independent variables, δ1–δ3 are the coefficients of the control variables, and ε is the random error term.

3.4. Descriptive statistics

Table 2 shows the descriptive statistics of the above indicators and the sample size (n=237). The mean value of the main dependent variable, "whether the claim for compensation was approved", was 0.452, and the proportion of both approved and denied compensation claims in the sample was relatively balanced. Among the main independent variables, the binary variables for whether the product is suitable for older people and whether people believe the duty to disclose has been fulfilled were distributed almost uniformly; that is to say, there were many such cases in terms of product characteristics and the extent to which the duty to disclose had been met. The standard deviation of the logarithm of the compensation amount was 1.563, and there was a large range, indicating a large spread in the amounts awarded by the court. Ordinal variables, such as patient age subgroups and the severity of harm, had relatively concentrated distributions, suggesting that the cases have certain typological characteristics in terms of the age structure of the parties and the outcomes of the harm.

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Table 2. Descriptive statistics for each variable

Variable Name	Abbreviation	Observations	Standard Deviation	Minimum	Maximum
Whether Compensation Claim Supported	Sup	237	0.452	0	1
Logarithm of Compensation Amount	LnComp	237	1.563	0	14.23
Product Geriatric Adaptability	Adap	237	0.496	0	1
Product Defect Type	Def	237	0.491	0	1
Product Registration Status	Reg	237	0.436	0	1
Duty of Disclosure Cognitive Adaptation	Inf	237	0.483	0	1
Geriatric Medication Compliance	Med	237	0.507	0	1
Patient Age Subdivision	Age	237	0.452	1	3
Patient Fault Type	Fault	237	0.415	0	1
Whether Judicial Appraisal Conducted	Jud	237	0.431	0	1
Appraisal Opinion Tendency	Exp	237	0.472	0	1
Severity of Damage Consequences	Sev	237	0.439	1	3
Regional Economic Level	Econ	237	0.414	0	3
Court Level	Level	237	0.442	0	1

3.5. Correlation Analysis

Based on the results of the correlation analysis in Table 3, the expert opinion is positively correlated with both the existence of support for the claim for compensation and the logarithm of the compensation amount; thus, it plays a key role in fact-finding and determining compensation. The degree of harm was also positively correlated with both outcome variables, and this is in line with the general rule of full compensation in tort liability: whether the infringement is a violation of a natural person's rights or property rights, the amount of compensation should be determined according to the loss incurred by the injured party or the gain obtained by the infringer. The level of perceived adequacy of the duty to inform is negatively associated with both outcome variables for the factors of product liability. The positive correlation between the type of product defect and liability in the Civil Code is that liability for damages caused by defective products should be borne. Regional economic levels and the level of the court did not affect the final judgment results of the cases. Therefore, the above cases show that the application of the law is consistent across different regions, and

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judicial decisions are not systematically affected by local economic conditions or the hierarchical system of courts.

Table 3. Results of the correlation analysis between variables

Variable	Sup		LnComp	
	Correlation (Point-biserial)	p-value	Correlation (Pearson)	p-value
Product Geriatric Adaptability (Adap)	-0.318	0.000***	-0.332	0.000***
Product Defect Type (Def)	0.376	0.000***	0.391	0.000***
Product Registration Status (Reg)	-0.285	0.000***	-0.297	0.000***
Duty of Disclosure Cognitive Adaptation (Inf)	-0.392	0.000***	-0.405	0.000***
Geriatric Medication Compliance (Med)	-0.276	0.000***	-0.289	0.000***
Patient Age Subdivision (Age)	0.249	0.000***	0.263	0.000***
Patient Fault Type (Fault)	-0.221	0.001***	-0.234	0.000***
Appraisal Opinion Tendency (Exp)	0.618	0.000***	0.623	0.000***
Severity of Damage Consequences (Sev)	0.507	0.000***	0.512	0.000***
Regional Economic Level (Econ)	0.079	0.215	0.087	0.148
Court Level (Level)	0.061	0.312	0.063	0.298

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.1$.

3.6. Chi-square test

As shown in Table 4, all of the indicators in the chi-square test are significantly associated with whether the court granted the claim for compensation. The expert's opinion also had a significant impact on the final decision of the trial; that is, when the expert determined that a fault had occurred, the amount of compensation awarded was as high as 91.3 per cent, and otherwise it was as low as 32.6 per cent. As shown above, the supporting evidence for the parties' expert opinions is the result of scientific study and thus can serve as strong evidence. Among the basic elements of product liability, both the duty to inform and whether the product had been registered significantly affected it. When the duty to inform was not performed properly, the proportion of compensation awards reached 86.1 per cent, in line with the provisions on the duty to inform for medical institutions in Article 1219 of the Civil Code. In cases where the product registration status did not meet the requirements, the rate of compensation awards reached as high as 92.4 per cent; thus, the judicial authorities have strictly enforced the compliance of market-entry conditions for medical products. In addition, considerable differences were observed in the suitability of products for older people, indicating that judicial practice has considered the problem of product suitability for this group

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in determining tort liability, and thus reflects a judicial tendency to reasonably protect vulnerable groups in the determination of tort liability.

Table 4. Chi-square Test Results

Variable Name	Sup (Supported) %	Sup (Dismissed) %	χ^2 Value	df	p-value
Adap					
Adapted (1 = Yes)	52.7%	47.3%	23.87	1	***
Not Adapted (0 = No)	85.3%	14.7%			
Inf					
Adapted (1 = Yes)	48.6%	51.4%	27.54	1	***
Not Adapted (0 = No)	86.1%	13.9%			
Reg					
Compliant (1 = Yes)	65.2%	34.8%	17.92	1	***
Non-compliant (0 = No)	92.4%	7.6%			
Exp					
Fault Identified (1 = Yes)	91.3%	8.7%	57.28	1	***
Not Identified (0 = No)	32.6%	67.4%			

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.1$.

3.7. Logistic Regression Results

According to the logistic regression results shown in Table 5, the model exhibits good overall fit, with a pseudo-R^2 of 0.582, and is capable of effectively identifying the key legal factors that influence the granting of compensation claims in medical product liability cases. The regression results clearly reveal the net effects of each variable on the judicial outcome. Among the above, the bias in the expert's opinion was the strongest predictor. This indicates that when expert opinions are relied upon to establish fault or causation, the likelihood of the court granting the compensation claim is increased by a factor of 8.627; thus, professional opinions have had a deciding effect on the court's determination, as set out in the "Provisions of the Supreme People's Court on Evidence in Civil Litigation". The extent of the damage also had an effect. The core components of product liability are lacking in this instance, and, as a result, both the obligation to inform the elderly and the suitability of the product for older persons cannot be met. It can be seen that if a product has deficiencies in registration compliance, is not suitable for the elderly, or fails to meet the duty to inform, the defendant's risk of bearing compensation liability will be significantly increased. A specific kind of patient negligence may be considered an act of contributory negligence in law.

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Table 5. Logistic Regression Results

Variable	Coefficient (α)	Wald Statistic	p-value	Odds Ratio (OR)	95% CI for OR
Constant	-1.924	11.05	0.001**	—	—
Product Geriatric Adaptability (Adap)	-0.976	15.32	0.000***	0.376	[0.243, 0.585]
Product Defect Type (Def)	-0.382	5.17	0.023*	0.682	[0.478, 0.974]
Product Registration Status (Reg)	-0.869	12.18	0.000***	0.415	[0.265, 0.648]
Duty of Disclosure Cognitive Adaptation (Inf)	-1.047	18.56	0.000***	0.351	[0.225, 0.548]
Geriatric Medication Compliance (Med)	-0.758	9.63	0.002**	0.468	[0.295, 0.742]
Patient Age Subdivision (Age)	0.651	8.92	0.003**	1.916	[1.238, 2.967]
Patient Fault Type (Fault)	-0.682	8.05	0.005**	0.505	[0.318, 0.801]
Whether Judicial Appraisal Conducted (Jud)	0.348	3.76	0.052*	1.417	[0.998, 2.005]
Appraisal Opinion Tendency (Exp)	2.149	42.13	0.000***	8.627	[5.192, 14.285]
Severity of Damage Consequences (Sev)	1.558	30.27	0.000***	4.752	[3.086, 7.328]
Regional Economic Level (Econ)	0.125	0.57	0.450	1.133	[0.762, 1.681]
Court Level (Level)	0.092	0.30	0.584	1.096	[0.738, 1.630]
Pseudo R^2 (McFadden)	—	—	—	0.582	—
Likelihood Ratio Chi-square	—	—	0.000***	140.85	—

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.1$.

3.8. Results of Multiple Linear Regression

As shown in the results of the multiple linear regression in Table 6, the model can explain the factors affecting the amount of compensation effectively, and the specific mechanisms by which each legal element impacts the determination of particular compensation amounts have also been identified. Based on the regression results, it can be seen that the severity of the harm has the strongest impact on the logarithm of the compensation amount and therefore has the largest standardised coefficient. This shows that in tort liability, proportionality is based on the relationship between harm and compensation; thus, according to Article 1,179 of the Civil Code, the calculation of damages must strictly reflect actual losses, and at the same time, expert opinions generally have a considerable positive impact. As shown above, expert opinions will affect the decision on liability, and after the determination of liability, they will also be used as important evidence to assess the scope of causation and fault that needs to be taken into

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account in determining the amount of compensation. The degree to which the obligation to inform and the suitability of the product for older persons are lacking are likely to reduce the amount of compensation under product liability law. In terms of compensation determination, this also indicates that a breach of the duty to inform or a product design that fails to meet the special needs of older persons is considered a serious breach of duty. The court will impose a negative evaluation and thus increase the compensation amount accordingly, demonstrating the high requirements for the duty of care of manufacturers and medical staff.

Table 6. Results of multiple linear regression

Variable	Coefficient (β)	Standard Error (SE)	t-value	p-value	VIF
Constant	8.812	0.631	13.96	0.000***	—
Product Geriatric Adaptability (Adap)	-0.678	0.185	-3.66	0.000***	1.20
Product Defect Type (Def)	-0.352	0.169	-2.08	0.039*	1.24
Product Registration Status (Reg)	-0.571	0.177	-3.23	0.001**	1.17
Duty of Disclosure Cognitive Adaptation (Inf)	-0.721	0.189	-3.81	0.000***	1.23
Geriatric Medication Compliance (Med)	-0.485	0.180	-2.69	0.008**	1.15
Patient Age Subdivision (Age)	0.515	0.173	2.98	0.003**	1.22
Patient Fault Type (Fault)	-0.539	0.183	-2.94	0.004**	1.14
Whether Judicial Appraisal Conducted (Jud)	0.283	0.176	1.61	0.109	1.11
Appraisal Opinion Tendency (Exp)	0.808	0.191	4.23	0.000***	1.27
Severity of Damage Consequences (Sev)	0.932	0.192	4.85	0.000***	1.33
Regional Economic Level (Econ)	0.100	0.163	0.61	0.542	1.09
Court Level (Level)	0.075	0.170	0.44	0.660	1.08
R^2	0.731	—	—	—	—
Adjusted R^2	0.695	—	—	—	—
F-statistic	19.02	—	—	0.000***	—

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.1$.

4. Judicial Approaches to Product Liability Disputes Involving Medical Products for the Elderly

An empirical analysis of 237 judicial documents reveals that judicial rulings on product liability disputes involving medical products for the elderly have shown a tendency to emphasize the unique characteristics of the elderly population, rely on expert opinions, and focus on ensuring a proper alignment between liability and damages. However, issues remain, including vague criteria for determining specific factors, a lack of specialization in judicial appraisals, and inconsistent standards for determining compensation. Therefore, this study combines

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empirical findings with regulatory requirements to propose recommendations for judicial application in the following three areas.

4.1. Strengthen the statutory weight given to factors specific to the elderly in the determination of liability

Empirical studies have shown that, as core factors in measuring the protection of the special rights and interests of older adults, product suitability for older adults and the conformity of the duty to inform with the cognitive capacity of older adults are statistically significant in determining liability and the amount of compensation. Therefore, it can be seen that judicial practice has spontaneously formed a tiered system for dealing with cases of harm caused by medical products to older adults. However, due to the lack of specific regulatory provisions, such provisions have been ad hoc and inconsistent. This is most clearly shown by the relatively high rate of successful claims in cases where these factors have not been taken into account; thus, it can be seen that the courts are generally willing to adjust the existing general standards for product liability and the duty to inform through factual presumptions. To unify judicial standards and systematically implement the principle of preferential protection for elderly consumers - a particularly vulnerable group - it is necessary to promote factors specific to older persons from being discretionary grounds for consideration to becoming mandatory conditions in law in the following three areas[18].

First, set the requirements for product suitability for older persons as an independent judicial review standard for determining defects. In line with the spirit of the "Regulations on the Supervision and Administration of Medical Devices", which promote the optimised design of products and risk disclosure suitable for older people, specific review criteria should be established in judicial practice. The main idea of this way is that a product has a design or warning defect if it fails to take into account the physiological characteristics of older adults in its design or if the warning instructions are not suitable for older adults' cognitive abilities. If the products found after the review fail to meet reasonable suitability standards, then the rule of reversal of the burden of proof may be applied. The defect would be deemed to have existed, and the manufacturer or seller would bear the burden of proof that they had fulfilled their obligation of reasonable suitability for older people. Thus, it can be hoped that there will be fewer cases of under-protection in court due to the general nature of the standards for product defects.

Second, cognitive adaptation should be designated as the actual measure for satisfying the duty to inform. In the past, the implementation of the duty to inform focused on formal compliance; however, given that older patients may have cognitive impairment, it is now necessary to go beyond formal notification and ensure that they have truly understood. The duty of disclosure for medical institutions and staff should require them to provide explanations in a way that elderly patients can understand well, such as using local dialects, simple language, or adding supplementary diagrams and models, so that the patients are aware of and comprehend the main risks, expected effectiveness, and other options of medical products. To achieve the above norm, the medical institution may be obliged to retain the record of the disclosure process and obtain written consent from the patient and their family or conduct simultaneous audio and video recording. Based on empirical data, cases with a discrepancy in the understanding of the duty to inform have reached a compensation approval rate of as high as 86.1 per cent, providing strong support for the necessity of imposing a strict standard. A legal presumption can be established: if a medical institution fails to prove that the disclosure has reached a level of cognitive alignment, it shall be directly considered to have failed in its duty to inform and explain as provided for in Article 1219 of the Civil Code.

Thirdly, fairly differentiate between the causes that can be attributed to the elderly patient themselves and the scope of product liability, and apply the rule of contributory negligence

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cautiously. Regression analysis shows that the patient's fault is indeed a basis for reducing liability; however, in cases involving the elderly, its application should be restricted. The first is to differentiate strictly between "attributable subjective fault" and "non-attributable physiological limitations"; omissions in medical history due to age-related memory decline, or improper use of products stemming from mobility problems or poor eyesight—all behaviours arising from the physiological changes of aging—should not be deemed to constitute legal fault and thus should be used to reduce the tortfeasor's liability. Only in cases where the patient intentionally conceals the serious information or refuses to comply with necessary treatment without a justifiable reason - that is to say, in behaviour with subjective culpability - will the rule of contributory negligence in Article 1173 of the Civil Code be applied. The goal is to prevent the physiological weaknesses of older people from being falsely identified as legal faults and thus ensure the fairness and humanity of the system of tort liability[19].

4.2. Regulations on the Assessment and Admissibility of Specialized Appraisals for the Elderly in Judicial Expertise

Firstly, specific assessments relating to the elderly should be made a mandatory component of judicial expert appraisal commissions. When commissioning an expert assessment, the court should, in accordance with the requirement in the 'Provisions of the Supreme People's Court on Several Issues Concerning Evidence in Civil Proceedings' that the subject matter of the assessment must be relevant to the facts to be proven, explicitly instruct the assessment body in the terms of reference to conduct a specific assessment and provide an explanation regarding: the suitability of the product's design for the physiological functions of the elderly; whether the manner and content of risk disclosure are consistent with the cognitive characteristics of the elderly; and the degree of causality between the elderly patient's pre-existing underlying conditions and the harm caused by the product in question. For implantable medical devices, an assessment must be made as to whether the complexity of the operating procedures exceeds the practical capabilities and comprehension of the average elderly patient. For pharmaceuticals, it must be examined whether the package leaflet clearly sets out dosage adjustment schemes for elderly patients with reduced liver and kidney function. This measure aims to prevent, at source, expert assessment activities from being confined to general standards for product defects, whilst neglecting safety considerations specific to the elderly user group.

Secondly, it is necessary to clarify that forensic assessment activities should cite professional standards from the field of geriatrics as their core basis. To ensure the scientific rigour and relevance of assessment criteria, assessment bodies should be required, when judging key issues such as the compliance of medication for the elderly and the suitability of products for this demographic, to no longer rely solely on medical standards applicable to the general adult population, but must instead incorporate and apply authoritative literature specific to geriatrics. For instance, when assessing the compliance of medication use, one must take into account the physiological decline in liver and kidney function commonly observed in the elderly to determine whether the actual dosage exceeds the safety threshold for that age group, rather than simply drawing conclusions by comparing it to standard adult dosages. This will effectively enhance the professional credibility and applicability of expert opinions in cases involving the elderly[20].

Thirdly, the duty of judges to conduct a substantive review of expert opinions must be strengthened, with a particular focus on whether geriatric factors have been adequately considered. In response to the judicial discrepancies revealed in practice, which stem from expert reports failing to adequately consider geriatric factors, judges must conduct a rigorous judicial review of such reports before accepting them. The core of this review should be to examine whether the reports address the following key questions: Has the expert report

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analysed the compatibility between the product's characteristics and the physiological and psychological functions of the elderly? Has it employed scientific methods to reasonably distinguish between the product defect itself and the elderly patient's own medical condition in terms of their respective causal contributions to the resulting harm? Where expert opinions fail to adequately address the above points, the court should, on its own initiative, order the expert body to provide supplementary explanations or written responses to queries. Where necessary, the court may, upon application by a party or on its own initiative, call upon an expert witness specialising in geriatrics to appear in court to cross-examine and debate the scientific rigour and comprehensiveness of the expert opinion. This will break the path dependence of blindly accepting specialised evidence and ensure that the expert opinion ultimately relied upon as the basis for the judgment stands up to scrutiny both in legal and geriatric medical terms[21].

4.3. Quantitative Standards for Unifying Compensation Discretion and Mechanisms for Balancing Interests

Based on the empirical data, the standard deviation of the logarithm of compensation amounts is as high as 1.563; therefore, there are significant arbitrariness and uncertainty in the exercise of discretion over compensation for harm caused by medical products to older adults in current cases. To correct for the above deficiencies and address the particular circumstances of harm to older adults more accurately, an improved quantitative system of discretion can be built based on the two basic principles of baseline standards and specific deviations.

First, a general model for calculating personal injury compensation that takes into account the specific features of older adults should be built. Although the 'Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Personal Injury Compensation Cases' is used as a reference, all the calculation parameters need to be adjusted for an aging population. When calculating medical expenses, costs for rehabilitation care and functional assistive devices for older adults need to be added separately. When determining the length of disability benefits, take into account other factors, such as the average life expectancy of older people in the area, and be mindful of giving the right to life a full lifespan; otherwise, a mechanical extension of the statutory maximum period should not be applied to elderly victims, especially those aged 80 and over. When determining the amount of compensation for mental harm suffered by older people, one should consider their age and other reasons for declining mental health, and the level of compensation should be adjusted accordingly.

Second, while honouring the substantive rights of older victims to the extent possible, a reasonable financial burden on the responsible party must also be borne to maintain the long-term balance of interests. According to the data above, although there has been a rise in death compensation for residents, countermeasures need to be taken against adverse effects, such as using defensive medicine by medical institutions and a reduced incentive for producers to provide aged-care services. Among the powers given in law, the first is to ensure that older individuals filing a lawsuit are not disadvantaged financially and can obtain full indemnity for direct and necessary losses, such as medical and rehabilitation expenses. If the manufacturer of the product can demonstrate that it has met a reasonable duty of adaptation and gone beyond general standards in areas such as product design and warning labels specifically tailored for older people, the court should be permitted to take this into account in determining the final compensation ratio, even if there are minor defects in the product. The above will motivate and guide the judicial branch of the industry to pay more attention to and make more investments in the silver economy, thereby achieving a harmonious coexistence of protection for older people and the promotion of industrial development [22].

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5. Conclusion

Based on an empirical analysis of 237 judicial rulings on medical product liability cases involving older adults, this study found that the courts have spontaneously begun to consider the special physiological and cognitive characteristics of elderly patients, make extensive use of expert opinions in fact-finding and determining liability, and seek a proportionate link between liability and compensation. However, serious deficiencies still exist, such as unclear standards for evaluating the age-friendly adaptability of products and cognitive-friendly disclosure, a lack of geriatric-specific specialization in judicial appraisals, and inconsistent standards in the discretionary determination of compensation amounts. Accordingly, this paper puts forward a three-dimensional judicial application system: First, to promote the specific consideration of elderly-related factors—such as product geriatric adaptability and the cognitive suitability of the duty to inform—we propose establishing such factors as statutory conditions for determining defects and assigning liability, while cautiously applying the rule of contributory negligence to differentiate between attributable subjective fault and non-attributable physiological limitations arising from ageing; Second, we suggest introducing mandatory geriatric assessments in judicial expert commissions, requiring appraisal bodies to apply geriatric medical standards rather than general adult benchmarks, and strengthening the substantive review power of judges over expert opinions to ensure that elderly-specific factors are fully considered; Third, a particular system for quantitative compensation discretion is to be constructed that comprehensively accounts for the special damages suffered by elderly victims, including rehabilitation and nursing costs, as well as psychological trauma, and appropriately balances this against the financial burden on the liable party to avoid defensive medical practices or an industrial reluctance to serve the elderly market. This study has thus provided theoretical support and empirical references for judicial practice, promoting the all-round protection of the rights and interests of elderly consumers and promoting the development of a healthy, elder-friendly medical product industry in accordance with the provisions of the Civil Code.

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