

The learned intermediary doctrine as a special case of exemption from liability

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The US law, along with an independent system of legal regulation of issues of liability for damage caused by defects in goods, works and services, is characterized by a special approach in regulating the issue of liability for the quality of pharmaceutical products. This is due to the nature of this group of goods, as well as the specifics of their delivery to the consumer. Thus, a number of medicinal products are subject to sale only by issuing a “prescription” by a doctor, but there are also medications that are on sale.

For this group of goods in the Anglo-Saxon legal system, the theory of "informed intermediary" was developed.

The relevance of the research topic is determined by the fact that in judicial practice, the number of complaints on inadequate quality of goods and services, which is at odds with the declared properties of the goods, is constantly increasing. This shows that not only the legal awareness of citizens is growing, but the very definition of “lack of goods” does not have all the principles of concreteness. In this regard, one can refer to the experience of other countries, especially those where consumer protection has proven to be effective. These countries include the United States, where not only the culture of consumption is high, but also the legal culture.

The “informed intermediary” doctrine is that the manufacturer of a product or performing work, a service is released from liability if an important condition exists - the presence of a so-called informed intermediary who has an idea of the likely harm from the use of a specific product, work, or service.

The study of judicial practice allows us to conclude that the theory of an informed mediator is not absolutely dominant in court decisions [1]. When considering some disputes, the courts, despite the developed approach, again raised the question of whether the manufacturer is relieved of responsibility for causing harm to the life and health of the consumer of the product on the basis of the theory of an "informed intermediary". Most US lawyers are inclined to believe that a drug manufacturer is not liable only if these drugs can be made available to the consumer only with a doctor’s prescription. Accordingly, the concentration of attention from the manufacturer of the product is transferred to the doctor, namely, to his professional responsibility for assessing the effect of prescribed drugs on the patient’s body. The above requirement for healthcare professionals is enshrined in the 1976 Medicines (Labeling) Regulation, which establishes standards for procedures applying appropriate warning information. At the same time, in the United States in recent decades, requirements for drug labeling have become more and more stringent.

Although case law is widespread in the United States, many courts question the theory under consideration in various cases of harm to patients’ health by medical practices or drugs [2]. For example, a doctor writes a prescription for a drug to a patient. As a result of taking the medication, the patient has side effects. Sometimes these consequences can be very serious, up to the death of the patient. As a result, the patient or his representative applies to court for health compensation. The defendant may be the drug manufacturer. However, the physician who prescribed the medicine acts as a learned intermediary, since his qualifications allow us to

assess all the risks of using a particular drug. Therefore, the victim may file a lawsuit against the doctor.

A number of researchers opposing to the learned intermediary doctrine, emphasize the role of advertising directed to the consumer. It is obvious that advertising can break the relationship between a patient and a doctor. Advertisement often forms a false impression among consumers about the safety of certain drugs. In the United States, the role of insurance companies (payers) in deciding on the appointment of doctors is also great. In addition, consumers have wide access to health information on the Internet. Opponents of the learned mediator doctrine claim that this doctrine is outdated in light of the increasing ability of patients to influence the prescriptive behavior of their physicians. Using these rationales, some US courts have rejected or substantially narrowed the application of the doctrine.

Summing up the above, we can conclude that this theory exempts the drug manufacturer from liability, but at the same time it highlights a special subject of responsibility - a learned intermediary about the possible harmful qualities of goods. This theory is widely used in law of the United States in cases of health compensation caused to a patient by prescription drugs. The learned intermediary doctrine is one of the grounds for exempting the manufactures from liability for harm caused by the defects in goods, work and services. Nature of the learned intermediary rule is determined by the specifics of pharmaceutical industry, as well as medical practice, which necessitate derogation from the conditions of prosecution of prescription-drug manufacturers.

Источники и литература

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