The Current Law on Human Medical Trials in China

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Abstract. Ethical and legal regulations are important factors in regulating human medical trials. Compared with legal regulation ethical regulation is a soft approach, so legal regulation must be involved in human medical trials. In this article we mainly discuss the current definition of law on the aspects of object, means and purposes of the human body medical test. According to the literature and the current status, with strict pragmatic attitude and compensation laws, human medical test will be controlled in the legal range, maximally be eliminated its negative effects and make medical science and technology and the whole life science benefit the mankind.

Introduction

Science in the modern world social consequences inevitably put forward the problem of scientific planning, put forward in such a way—to maximize its beneficial effect, make its may cause the least damage—to control the issue of science.” Through the analysis of the concept of human medical trials and reviews the history of human medical trials we see not hard, the body of medical test has its obvious characteristics of itself. The author from the relationship of human medical testing and medical development, and people come to the conclusion that the relationship between the human body the following characteristics of the medical tests.

The Necessity of Human Medical Trials

Any scientific experiment has its necessity, and the necessity of human medical test has its unique function, it is the necessary link of medical development progress. Review the history of the emergence and development of medical science and technology, if there is no previous brave test, there is no medicine's development and progress, especially the modern western medicine in this aspect is especially obvious. In the development of modern medical science mode, the human body is a indispensable stage, medical test any new drugs (vaccine), a new medical devices and new treatment method after basic theory research, animal test, must pass through human trials to end up in clinical application. The world medical declaration of Helsinki, the ethics of medical research article 4 of the preface part—"medical progress is based on research, to some extent, these studies ultimately depend on the experiments in humans.”

The Human Body, the Purpose of Medical Trials

Each human body medical trial has a specific and clear research purpose, research objects and research methods. Such as HIV/AIDS and atypical pneumonia (SARS) vaccine development work, the researchers will first vaccine does experiment in animal models, such as monkeys, used to detect the virus activity. After a successful animal model test, and then entered the stage of vaccine of human trials, after the success of the human trials, the vaccine will be put into clinical application. So the purpose of the human body medical trials should also need to be specific and clear.
The Number of the Process of Human Medicine

Medical practice, almost all of the human body medical test sample can not only separate individuals, whether drugs (vaccine), clinical trials of medical devices and treatments of human trials, all must have a certain amount of subjects. Otherwise, it is not universal, not the value of promotion. Only ensure the enough quantity of samples of subjects, to ensure the scientific nature and effectiveness of test. This is also the premise condition of such as experimental drug has been applied to clinical. Because of this characteristic, the body determines the medical test subjects is a pretty big group. Once an accident during the experiment, will affect a large number of subjects, so must be taken seriously and protect their rights and interests.

A Party of Voluntary

The first line of the code was solemnly declared, "the voluntary consent is absolutely necessary for human subjects." it's established the basic principle of human body medical trials, the subjects' informed consent. This is the feature of human medical test, the author in the article that the human body and detailed description of the legal nature of some medical test.

The Legal Attribute of Human Medical Trials

Modern human medical test, as a kind of scientific experimental behavior, has its special requirements. The main purpose of the first, the implementation of the human body medical test, not for the treatment of diseases, but in order to define the new drugs, new vaccines, new medical instruments and function and adverse reactions of new medical method, it is national approvals for new drugs and new method and promotion of the premise. Second, the human body medical trials in clinical use have certain risk, the existing medical science does not control all of the results. Scientific experimental or scientific is the logical starting point of the legal nature of human medical trials. Human medical trials is not only a matter of science, because it also involves the rights and obligations of the problem, so it is also a legal issue, has the legal nature, must be included in the law, the specification of the adjustment by law. From the human body medical trials on a person's rights damage analysis, the author divides into the human body medical trials human tort of medical test and human body medical tests of the crime.

Infringement of Human Medical Trials

Under normal circumstances, the medical institutions and patients is formed between the ordinary doctor-patient relationship between rights and obligations. In human medical tests, medical institutions, research institutions and formed between the subjects is a kind of different from ordinary doctor-patient relationship of independent civil legal relationship. Its side body in addition to patients may also be a healthy subjects, the other main body in addition to the general hospital and other medical institutions, research institutions or could have been new drugs (including vaccine), the development of new medical devices agency, test activities of the organizers, the sponsor, etc. If human body medical trials alleged irregularities or illegal, or personal injury event happened despite legal procedure, so the party organization to test the main body for the infringer, namely with the loss of subjects one subject is the victim. In this case, should be in the perspective of law of tort, determine the rights and obligations of both sides, to determine the legal relationship and legal nature.

To be sure, the author here is with the tested party without subjects, because in some cases, for example in the minors or with limited capacity for civil ACTS as the subjects, subjects and subjects are not the same person. Subjects contain and greater than the range of subjects. Say to the subjects' right to know, also have to mention one of the nuremberg trials results the nuremberg code.

In ordinary doctor-patient legal relationship, shall have the right to know their own disease, for patient may take treatment as well as a variety of treatment and harm to their health and disease. In human medical tests, according to the "quality control standard for clinical trials" appendix, the requirements of the relevant test for human medicine should have strict procedures and for the record,
and in these applications should ensure that the participants have full right to know. Test organization party shall ensure that fully informed and fully understand the nature of the test subjects, purpose, test means and methods, may cause harm to health, the impact on the life and the duration and so on. In which the drug clinical trial and the quality control standard for the third chapter "the subjects' rights and interests safeguard" stipulated in article: "in the process of drug clinical trials, the subjects must be given full safeguard the personal rights and interests of, and ensure the scientific nature and reliability of the test. The subjects of rights, safety and health must be higher than for science, and social interests. Ethics committee and informed consent is the main measures to safeguard the rights and interests of the subjects."

Express information, results, and the same important information itself. That on the one hand, the shortage of the in common the doctor-patient relationship has been widely criticized, even now one of the important reasons of doctor-patient conflicts. In the current human medical trials also do not have a mature approach would be generally useful. In general, in order to get the subjects to cooperate, testing organizations to test that the vague, or too simple, or reduce or even avoid the subjects' questions, not to give the participants think time in full, or too professional, ambiguity or the interpretation of the professional knowledge. These conditions will lead to the participants to make incorrect understanding and judgment, resulting in the subjects makes not true meaning expression and choice. In special circumstances, such as the subjects are minors or cognitive ability, ability to identify defective person is how to protect the participants' right to know common thinking worthy of medicine and law. Because the experiment did not fulfill its obligation to inform, causes damage to the subjects party rights cases have occurred.

A Party of Self-determination

First of all, the freedom to choose to attend medical tests or not is to participate in the human body. Force refers to the use of violence or threatened to use violence, forcing others to become subjects. The subjects in the case of no free medical trials were forced to participate in the human body, such a test, no matter what purpose, what form, is against humanity, are extremely evil. Even if it conforms to its own laws, even if it makes a major contribution to medicine, also absolutely cannot be tolerated. Threat refers to if participants agree to participate, not so, test the organizer motioned for the subjects in your health will suffer the loss, economic, or other ways. Human medical test organizers suggested, for example, patients, if not to participate in the test, will not give corresponding treatment. Temptation lure (or improper) refers to the human body organizers took advantage of the resources of medical test improperly intended contrast with guide the participants to make decision. Express or implied if subjects such as organization to attend trials will get bonuses or medical service cost reduction, or patients with economic difficulties and poor economic interests of the participants to offer. The Belmont report in the United States will not lure is defined as "in order to make the other party to comply with the proposed excessive, no guarantee, not appropriate or inappropriate reward or other proposal. In addition, when subjects were particularly vulnerable, generally feasible temptation may become inappropriate temptation.", from the provisions of the civil law, contract law in our country to examine, human body medical test organization cannot have any coercion, fraud, and fishing in the behavior or other improper influence, otherwise, the subjects could according to the relevant laws and regulations, withdraw or change.

Secondly, the consent of the subjects’ ability, its content includes the understanding of relevant information, processing ability, the judgment and choice of ability for their actions. It is specific to the human body in medical experiment, participants can understand test of the whole program, can analyze, evaluate the test, the influence of can expect the consequences of their actions, able to independently to use their own knowledge, rational judgment and decision. The author of the ability is to agree to such according to the provisions of the civil law of civil capacity for civil conduct. But the ability to judge a subjects agreed to standards or basis, the author thinks that, in addition to legal capacity for civil conduct of law, should also be combined with the human body medical trials in this
particular field, should also have its special consideration. Human medical tests, after all, are different from general medical treatment activity, in the process of medical test to the requirements of the consent of the subjects ability to be higher than the requirements of the general medical practice. In general, a normal person, with the theory of civil law on citizen's capacity for civil conduct can determine whether it has the ability to agree.

But in some special cases, such as to do an experiment of new drugs (vaccine), medical equipment or a new treatment is only for young infants and young children, or is in view of the limited capacity of mental patients, the legal representative of these people whether to agree, is still a problem worthy to be discussed. Because the human body medical trials is often associated with the risk of unpredictable, whether legal representatives shall have the right on behalf of the participants agreed to take responsibility for such risk, law is uncertain. Unless the author thinks that, in order to save the people's life, and have exhausted all currently known treatment method, otherwise, the above personnel legal agent can't to agree. In fact, this analysis also is accord with human nature.

Summary

The subjects' right to know and self-determination is essentially a kind of special personality right, the object is not only a health rights and interests, but also a self determine personality interests and human dignity., in turn, from the perspective of human medical test organization, is the important obligation of the organisations to ensure the smooth realization of the subjects right and the right to exercise, require organization must be fully implemented instructions, informed and explanation obligation. On the subjects' right to know and self-determination in the process of tort liability is independent of the test due to the organization staff negligence caused damage to life, health, body right subjects of tort liability, nor even impeccable in the medical behavior resistance was not fully inform the duty tort liability.

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