Open Acces
Scientific Reports

Open Access Scientific Reports

Research Article Open Acces

Introduction

I am personally very interested in the interfaces between clinical research, the ethics of clinical research, and China since I have just completed a long career doing clinical research with new drugs, overseeing clinical research as Director of an academic (the Johns Hopkins University School of Medicine) Division of Clinical Pharmacology, regulating clinical research and the ethics of human experimentation as chair of an Institutional Review Board (IRB), and teaching about clinical research as a physician-scientist at a research oriented medical school and as a founder and teacher in the rst Ph.D. degree granting program in clinical investigation in the United States, namely the Johns Hopkins Graduate Training Program in Clinical Investigation (GTPCI) [1]. In addition, for over 40 years I have been a faculty member of a medical school committed to helping my medical school become a global institution with a mission to help educate the future leaders of medicine (both in the United States and internationally) by creating relationships between our faculty and the faculty of various foreign institutions.

It was then somewhat surprising for me to realize that the juxtapositions of clinical research in the U.S. and China have only rarely been written about. is may be because clinical research has predominantly been developed as a result of drug development and, prior to the 20th century, there was very little formal and serious drug development (clinical research) anywhere in the world. is, in turn, may well have been because so few drugs then were both e ective and acceptably safe. In fact, Oliver Wendell Holmes, Senior (1809-1894), a physician (and father of the American Associate Supreme Court Justice Oliver Wendell Holmes, Junior), toward the end of the 19th century is said to have declared, "If all the drugs were thrown into the ocean, it would be all the worse for the shes and all the better for mankind" [2]. I believe that this was true at that time in both the United States and China and in the rest of the world as well.

Clinical research (and drug development) has grown in the last hundred years primarily in the United States and Europe. Clinical research has still not "gained traction" and prospered in China. In fact

iTel: 1(410)337-9541; Fax: 1(410)337-9541; E-mail: plietman@jhmi.edu

Received October 24, 2012; Published October 30, 2012

Citation: Lietman PS (2012) Clinical Research, Ethics of Clinical Research in China. 1:456. doi:

while the Western countries are already new, What keeps China back. It's a natural question." He goes on to say "What keeps China back is that she has no science. e e ect of this fact is not only plain in the material side, but also in the spiritual side, of the present condition of Chinese life. China produced her philosophy at the same time with, or a little before, the height of Athenian culture. Why did she not produce science at the same time with, or even before, the beginning of modern Europe? is paper is an attempt to answer this question in terms of China." herself Professor Fung ends the introduction to his paper by stating "At the end of this paper I shall venture the conclusion that China has no science, because according to her own standard of value she does need any."

In the sixth and nal section of his paper Professor Fung nishes by saying "In one word China has no science, because of all philosophies the Chinese is the most human and the most practical. While the philosophers of the West are proud of their clear thinking and scienti c knowledge, the Chinese philosopher would say with Marcus Aurelius ' anks, too, that in spite of my ardour for philosophy I did not fall into the hands of a professor, or sit poring over essays or syllogism or become engrossed in scienti c speculations. Nothing is more disheartening than the weary

t42236(t)-4183n e,16(cusT5)s8(o)b1uf58cgy"---

was used as the excipient to dissolve the sulfa drug. Ethylene glycol wa terribly toxic and over 100 persons (mostly children) died. is act then required proof of safety before release of the drug onto the market. It was and is clear that the public needs to be protected from drugs or that are unacceptably toxic. But what is unacceptable toxicity? It is a truism that all drugs (and probably all herbal medicines as well) are toxic in some dose to some people. e identi cation of an adverse event and the proof of its severity and causal relationship with a drug can be very complicated and di cult. is has been seen over and over again in the US with drugs that either cause severe toxicities only very rarely (such as chloramphenicol) or drugs that cause toxicity that is disproportionate to their bene t. Perhaps another unusually good example is the toxicity caused by herbal medicines containing aristolochic acids from Aristolochia or other plant species [10].

Yet another disaster, this time in Europe, took place between 1957 and 1961 when thalidomide was widely sold and widely used as a mild sedative [5]. In 1961 an unusual type of birth defect (called phocomelia) was clearly shown to caused by the intake of thalidomide during the rst trimester of pregnancy and thalidomide was removed from the market in the U.S. and Europe in 1961.

In what might be seen as an over-reaction to this last disaster, another revision was made in the Federal Food, Drug, and Cosmetics Act in 1962 [5]. is added several new regulations onto the act that extended the drug regulatory power of the FDA. is Harris Kefauver or Drug E cacy Amendment added the following to the Federal Food, Drug, and Cosmetics Act. Now, for the rst time, it was required that a drug be proven to be e ective for some symptom e e drug berCrug8

development is where the interface between clinical research and ethics and both China and the U.S. is best appreciated.

Excellent clinical research is pivotal for both drug and herbal medicine development. No amount of preclinical or basic research (chemistry, biology, biochemistry, molecular biology, genetics, genomics, proteomics, cell biology, basic pharmacology, physiology, animal model study, or animal toxicology) can ever su ce for approval for clinical sales or use without the ultimate demonstration of e ectiveness (and acceptable safety) in humans. is is the pivotal nature of clinical research.