

泰国的艾滋病药物倡导经验

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# 生命的权利

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# 出版者简介

第三世界网络(TWN)是一个国际非营利组织联合,国际 秘书处设于 Penang(马来西亚),并在 Goa(印度)、日内瓦(瑞士)和北京有办公室,它积极地参与发展、第三世界和南北事务。 从成立时起,TWN 一直按照它的宗旨,积极地投入和参与不同国际事务的研究、媒体、出版、会议的组织及交流、研讨活动,包括与联合国机构一起,促进发展中国家之间的经验分享。

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Third World Network (TWN) is an independent non-profit international network of organizations and individuals involved in issues relating to development, Third World and North-South affairs. Its international secretariat is based in Penang, Malaysia,has offices in Goa (India) and Geneva (Switzerland) and Beijing (China). Since its formation, TWN has been involved in research, media and publications activities, organized and participated in meetings, workshops and seminars on various international issues, including with UN agency, to facilitate experience sharing between developing countries.

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# 出版者简介

中国全球基金观察项目是一家致力于善治和透明度以及公共政策和法律研究的非营利组织。通过支持艾滋病社区组织的发展,探索民间组织有序的、多元化的发展模式;促进国内国际相关非政府组织、政府机构、学术界和私营部门之间伙伴关系,倡导良好治理和有意义的公众参与,推动各利益相关方的参与和监督机制的建立,以期更有效地解决共同面对的社会问题。

中国全球基金观察的工作领域包括:公共参与、善治和透明度;伙伴关系的建立与非政府组织发展;公共政策法律研究如国际贸易、公共卫生与药物获得,以及探讨和研究中国社会可能面临的一系列由非传统危机引发的不确定性及其应对措施。

China Global Fund Watch Initiative is non-for-profit Organization working on the issue of good governance and transparency, with public policy and legal research. GF WATCH's mission is to promote the development of civil society in China – and hence good governance and public participation – by fostering the development of grassroots HIV/AIDS NGOs and building partnership among NGOs, governments, academics and private sector to address problems of common concern. GF WATCH supports the development of meaningful, pluralistic civil society by encouraging transparency, oversight and participation from all stakeholders, while encouraging their preparedness and response to the numerous societal problems.

GF WATCH's working area include: Public Participation, Good Governance and Transparency; Partnership Building and NGO Development; Public Policy and Legal Research such as International trade, Health and Access to Drugs; Non-traditional security issues that Chinese society faces.

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# 中文版序言

2009 年春夏之交,人类再次面临传染病流行的挑战,突然爆发的甲型 H1N1 流感迅速在全球蔓延。对于象流感这样不断变异的流行病,最有效的控制方法就是及时研制、生产和使用疫苗。但是,在旷日持久的争论之后,一个能有效应对全球性的流感威胁的一揽子预案仍未能实现。拖延了这个关乎全人类健康的重要协定的原因之一,是各国对于研制疫苗所必须的病毒毒株共享和利益分享过程中所涉及的知识产权问题难以达成一致意见。

在这样的时刻,《生命的权利》一书中文版的问世,无疑对于国内公共卫生界、法律政策界和公众读者都具有重要的意义。它在引导我们回顾泰国为保证公共健康利益而运用强制许可的历史的同时,更清晰地提醒我们,正确认识和使用医药知识产权,对于保障人民的生命健康是何等的重要。

在经济全球化迅速发展的今天,公共健康问题也明显呈现出全球化的趋势。传染性疾病的威胁不分国界和种族,但是社会、政治、经济和法律制度的差异却能够使贫穷和富裕人口获得有效治疗和药物的机会呈现巨大的反差。导致这种不平等的根源之一,是知识产权制度全球化过程中,医药专利的盈利性质与维护生命健康作用之间的平衡被打破了。

为了重置平衡,近年来国际社会做出了努力,以艾滋病药物为契机,世贸组织各成员国集体做出了承认国家有通过强制许可和平行进口等制度,来突破药品专利限制,维护人民生命和公共卫生利益的权利的历史性决定。虽然目前中国还没有正式在公共卫生领域运用强制许可制度,但是已经通过法律修改等方式,在持续地为提高药物可及性和公共健康做出努力。

作为一个人口众多的发展中国家,中国面临着更加严峻的各类疾病压力和公共卫生的考验。中国于 2003 年启动了国家艾滋病治疗项目,向患者免费提供部分抗病毒药物。但是由于专利等因素的影响,时至今日,各类有效抗艾滋病病毒药物的持续获得依然是一个悬而未决的问题。除了受到艾滋病、结核等重大传染性疾病的影响之外,中国也是许多非传染性疾病的病患大国,比如癌症、心脑血管疾病、高血压、糖尿病等等。很多这类疾病的有效治疗和预防药物及疫苗,对缺乏或只有很低水平医疗保障的广大民众来说依然是可望而不可及。正在启动的全民医改更显示了如何托善解决药物可及性这一问题的紧迫性。我们应该清醒地认识到,作为医改重要支柱的基本药物目录,决不应该是廉价药物清单,否则医改将难以成功。

在国内热心公益的几位年轻的法律界专业人士努力之下,《生命的权利》得以面世。我相信,面对新发传染病的不断侵袭的人类,在药品专利的商业利益和其维护健康生命的终极属性间是可以达到一种平衡的。泰国已经做出了有益的实践。我坚信,一个

能够发明一国两制化解国家间难题的党和政府,以及能够创造三十年经济发展奇迹的民族,也一定能找到一条既能满足自身药品需求,又能造福发展中国家民众的和谐之路。

邵一鸣 博士

中国疾病预防与控制中心艾滋病首席专家 第十、十一届全国政协委员 2009 年 5 月

### **Preface for Chinese version**

In the spring and summer of 2009, our society faces the challenge of a new epidemic as the A-H1N1 flu rapidly spreads around the world. Pandemic flu is the type of disease that with possibilities of mutating into a new strain, and the most effective way of controlling its spread is to immediately develop, produce and distribute new vaccine. However, after several long debates, a comprehensive global Pandemic Flu Preparedness solution has not yet been agreed upon. One of the key reasons why the negotiators could not agreed upon such a critical protocol related to the fate of public health of the global community is because countries could not get an agreement on intellectual property issues related to the virus strain sharing and benefits sharing that required for vaccine development.

At such a moment, the publication of the Chinese version of "The Right to Life" carries great significance for experts from public health, law and policy fields, as well as the general Chinese public. The book not only reviews the history of Thailand's policy of compulsory licenses to safeguard public health but also clearly reminds us of how important it is to have an appropriate understanding and implementation of medical related intellectual property in order to protect people's life and health.

Today, with the continuing trend of economic globalization, public health issues have become globalized as well. The epidemic threatens people without regard for nationality or race, but the social, political and legal differences, will result a great discrepancy between rich and poor populations in getting access to effective treatment and medicines. One of the root reasons behind such inequality is that the balance between the profitable feature of intellectual property and public health protection was broken during the process of globalizing intellectual property norms.

In order to restore the balance, the international community has made great efforts in recent years, especially with HIV/AIDS medicines., WTO members have made a historical decision in all agreeing that countries have the right to use measures such as compulsory licensing and parallel importation, in order to overpass the patent barriers and to safeguard people's lives and public health interests. Though China has not yet formally used compulsory licensing for public health purposes, it has already taken steps such as amending relevant laws and regulations and increasing access to medicines to protect public health.

As a developing country with a large population, China is facing serious challenges from different diseases and public health issues. In 2003, China launched a national treatment program on HIV/AIDS, providing some antiretroviral drugs (ARVs) to patients for free. However, because of different obstacles, including patent issues, access to all effective ARVs in a sustainable manner is still a pending question for China. Apart from being affected by heavy epidemics such as HIV/AIDS and TB, China also has large number of patients with non-communicable diseases, including cancer, cardiovascular and cerebrovascular diseases, hypertension and diabetes. Many medications and vaccines that effectively treat these diseases are still not available for people who lack or only have limited coverage through medical insurance. The ongoing reform of the national health system in China has highlighted the urgent

and important need to create a practical solution for access to medicines. We should soberly realize that, as an essential pillar of health system reform, the essential medicines list should in no way mean a list of "cheap" medicines; otherwise health system reform will see little success.

With the efforts of a group of Chinese young legal professionals keen on advancing public interests issues, "The Right to Life" is now getting published in Chinese. I believe, as we face continuing attacks from new types of diseases, that human society will finally find a balance between the commercial profitability of medical patents and its ultimate goal of safeguarding human lives. Thailand has seen good results in this regard. I firmly believe, that if a party and government that can invent the "One county two systems" to address the difficulties in international affairs, if a nation that can create the miracle of thirty-years of rapid economic development, that this nation can also find a harmonized solution which can fulfill the need of medicines for its own people and benefits the people of developing countries.

Dr. SHAO Yiming, M.D.

Chief Expert, China National Center of Diseases Prevention and Control Member of the 10<sup>th</sup> and 11<sup>th</sup> National Committee of Chinese People's Political Consultative Conference May, 2009

## 中文版作者前言

2005年初,我应邀去做一个小型的研究项目,该研究涉及关于在8个国家中的专利保护如何导致了必备药物无法获得的问题。这些关于如何促进药物获得的阶段性研究发现,已经在当年晚些时候在一个由泰国民间社会活动人士和学术界举办的关于强行仿制的会议上进行了发布。

从上述这些国家的经验中可以很很明显地看出,他们所面临的"药物短缺"的境遇,很大程度上是因为美国出于巨大的产业利益,正在寻求一种改变当今世界现存的知识产权法律体系的战略。通过这种改变,美国的制药产业在全球范围内试图以尽可能延长其所拥有的专利的保护期,从而尽可能地获取最大化的利润的方式,收紧对其所拥有的技术的垄断。由于发展中国家和全球公共卫生领域已经成功地再次确认公共卫生优先于世界贸易组织关于知识产权问题的规则,美国于是就将它的努力提升到通过双边和区域贸易协定谈判的方式去推动产业界的意图。这样,如果这一努力成功的话,将最终导致TRIPS(与贸易相关的知识产权协定)的根本性改变,而TRIPS协定是知识产权领域最重要的国际标准性文件。进一步而言,美国如果坚持其咄咄逼人的追寻产业利益的政策,并进一步扩张其需求,那么将产生相当负面的后果,而这些后果在很大程度上将落到发展中国家身上。

当我在那次会议上就这些发现做报告的时候,我提出了一个关键性的问题——我们,民间社会的活动家,敢不敢站出来反对甚至挑战美国的这些努力?如果想让这样一场运动获得成功,就需要充满道德勇气的国家领袖们;有着社会责任感和良知的公共和私营部门;强有力的民间社会的参与,包括学者、专家、非政府组织、人民团体和媒体。如果没有类似的社会运动,我们将只有另外一个选择,那就是向美国所推动的专利制度俯首称臣、让这一制度继续剥削穷人并让他们继续的得不到所需的药物。

然而,就在会议结束的时候,当时的卫生部副部长向媒体发出了一个泰国关于强行仿制的态度的申明。他质疑了泰国强仿的能力,因为这只可能将泰国置于受到国际贸易制裁的境地。泰国政客这种短视而狭隘的观点,并没让已经在药物获得领域无畏战斗了二十余年的泰国民间社会消沉下去。有着学识渊博的政策制定者和强有力的泰国民间社会倡导团队,机遇之窗还是被打开了。

今天,我们已经目睹了一些人士是如何在屡战屡败后,依然以坚韧不拔的勇气和毅力去捍卫大众获得药物的权利。在持续的重重压力之下,泰国的活动家们依然推进他们的社会运动,以制定出能够确保泰国人民的公共利益得到保障的公共政策。

强行仿制不会凭空而生,它的产生源自于过去几十年泰国社会中草根组织的努力。并由"移动大山的国际铁三角"所带来。

"移动大山的国际铁三角"不会因为仅仅发了几个强行仿制就洋洋自得。他们现在 正坚定地朝着将获得药物的国家战略转变为可操作的公共政策的方向稳步前进。我在所 参加的不同的国家多次会议中与人分享过泰国的经验,并被告知,类似的社会运动永远 不可能在其环境与泰国不同的国家发生。然而,20年前,泰国人自己也同样认为这一切不可能发生,但这却已经成为现实。

这一史诗般的、矫正商业逐利和人们对于获得药物的需求之间不平衡的战斗,是场依旧在行进中的社会运动。为了补救这种不平衡,需要民间社会和患者群体间共同的努力,以及推动大众对于基础的人权和健康方面的知识的普及和觉醒,还需要有政策制定者们的强有力的政治意愿。只有当这些因素都具备时,我们才能在商业利润和人们获得药物的权利之间达到一种可以接受的平衡。

每个国家都有着类似的为健康权利而斗争的类似境遇,我为能够与中国人民一起分享我们的经验而倍感骄傲。

卡尼卡 (陈妙裳)

2009年5月

### Preface from the Author for Chinese Edition

In early 2005, I was invited to conduct a small research project addressing the problem of lack of access to necessary medicines caused by the patent regime in eight countries. The findings on ways to improve access to medicines were presented at a conference on compulsory licensing held later that year by Thai civil society advocates and academics.

From the experiences of these countries, it is clear that they face a "lack of access to medicines" in large part because the US is pursuing a strategy to change the existing global intellectual property legal regime, primarily because of strong industry interests. Through these changes, the US pharmaceutical industry with global markets is trying to tighten its monopoly on technologies it owns by extending its patents for the longest possible period to allow it to make the highest profits possible. As developing countries and the global public health community succeeded in reaffirming the priority of public health over World Intellectual Property Organization (WTO) rules on intellectual property, the US stepped up its efforts to push industry's agenda through bilateral and regional trade agreement negotiations. If this is successful, it will ultimately lead to fundamental changes in the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), the most important international standard on intellectual property issues. Therefore, if the US persists in aggressively pursuing its industry's interest and it is expected to demand more, there will be negative consequences falling mostly on developing countries.

While presenting my findings at this conference, I posed one crucial question--dare we, civil society activists, stand against and even challenge these efforts by the US? For such a campaign to be successful, it would need: many heads of state with moral courage; public and private sectors with social responsibility and conscience; and strong civil society participation comprised of academics, professionals, non-governmental organizations (NGOs), people's organizations and the media. The alternative to such a campaign would be to simply give in to the US-pushed patent regime and let it continue to deprive the poor and the sick of their needed medicines.

However, as the conference ended, the then deputy health minister issued a statement to the press concerning Thailand's position on compulsory licensing (CL). He questioned Thailand's ability to issue CLs because it would only put Thailand at risk of international trade sanctions. However, such short-sighted and narrow vision by Thai politicians did not demoralize the Thai civil society, who has fought a tireless campaign for access to medicines for over 2 decades. With knowledgeable policymakers and a strong team of Thai civil society advocates, the windows of opportunity then opened.

Today, we have seen how a group of people fighting with determined courage and persistent efforts continue to defend everyone's right to access to medicines despite countless defeats. Amid ongoing pressure, these Thai activists still move forward with their campaigns to create a public policy to ensure that the public interest of Thai people is met.

The CL phenomenon did not materialize out of thin air. Rather, it flourishes because of the grassroots efforts by Thai society over the past few decades. It has been brought by the "Globalized Triangle that Moves the Mountain."

The "Globalized Triangle that Moves the Mountain" will not be happy with just the issuance of CLs on a handful of medicines. Now they are moving forward with single-minded determination to develop national strategies on access to medicines to turn into practicable public policies.

I shared the Thai experience in many conferences in different countries and was told that such campaigns would never happen in countries with different contexts from Thailand. However, 20 years ago, no one in Thailand ever thought this would happen to them but it has.

Our epic battle to correct the imbalance between profit-driven business and people's need to access medicines is an ongoing campaign. To redress this imbalance, there needs to be concerted efforts between the civil society and patients, together with the promotion of public knowledge and awareness of the fundamental human right to health, and strong political will of policymakers. Only when these factors align will an acceptable balance be struck between business and people's right to medicine.

I am proud to share our story with the people of China because similar struggles for the right to health are in every country.

Kannikar Kijtiwatchakul

May, 2009

# 中文版序言

对健康的权利是一项人权,当需要药物治疗危及生命的疾病却不能获取时,则侵害了生命的基本权利。当获得这些救命药物的障碍是一项专利或以其它形式垄断的知识产权保护时,此种情形当然是不可接受的。

对艾滋病感染者和患者来说,已经有许多困难障碍要克服。在泰国,这些有勇气的人们自己组织起来,发出强烈的声音,彼此帮助,成功得到了政府良好的卫生政策支持。然而,由于一些制药公司拥有专利导致的非常高的药价,却阻断了他们获得治疗艾滋病药物的途径。10 多年来,一个由艾滋病感染者和患者、非政府组织、学术界、法律制订者、关注此议题的卫生官员和媒体组成的联盟一起行动,发起了一场令人鼓舞的运动,揭示出那些专利是如何侵犯了生命的权利。泰国卫生部在经过研究和咨询后,决定对一些紧迫需要的艾滋病药物颁发进口和制造的强制许可,这是一个全世界公众健康团体都为之庆贺的胜利。

本书由 Kannikar Kijtiwatchakul 所著,首先以泰文出版,它记录了泰国公民社会运动的发展,及在有关制药公司激烈反对政府行动时,公民社会给予的有力支持。由于本书的社会和教育价值,它也被翻译成了英文。

现在我们也有了这个了不起的故事的中文版。除原著外,我们还增加了泰国卫生部 颁布的白皮书文本,它解释了为尊重泰国人民生命的权利,泰国政府做出这个历史性决定所采用的法理依据和谨慎步骤。

Chee Yoke Ling (徐玉玲)

项目总监 第三世界网络(Third World Network) 2009 年 5 月

### **Preface for Chinese Version**

"The right to health is a human right and when medicines are needed for diseases that can kill, the inability to get those medicines violates the right to life. When the barrier to get access to life-saving medicines is a patent or other form of monopolistic intellectual property protection, such a situation is certainly unacceptable.

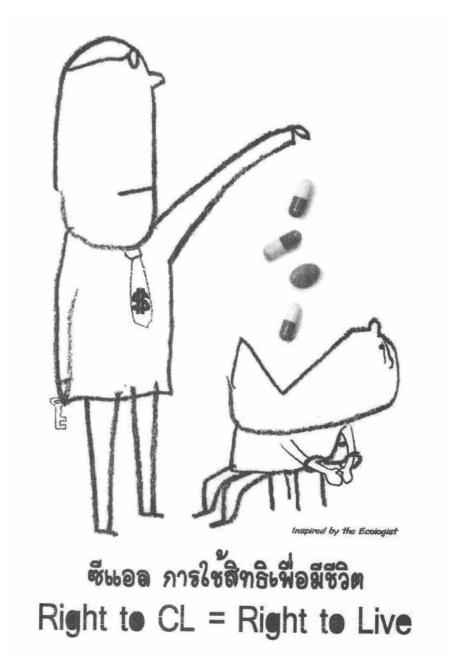
For People Living with HIV/AIDS (PLHA) there are already many difficult obstacles to overcome. In Thailand these courageous people organized themselves to create a strong voice, help each other and succeeded in achieving good government health policies. However, their access to HIV/AIDS medicines was blocked by the very high prices that resulted from patents owned by a few pharmaceutical companies. Over more than 10 years, a coalition of PLHA, NGOs, academics, lawmakers, concerned health officials and the media joined together and created an inspiring movement to expose how patents violate the right to life. When the Ministry of Health, after conducting studies and consultations, decided to issue compulsory licenses to import and manufacture urgently needed ARVs, it was a victory celebrated by public health groups all over the world.

This book by Kannikar Kijtiwatchakul was first published in the Thai language to record the struggle of the Thai civil society movement and its strong support for the government's actions when intense pressure was shown by the pharmaceutical companies concerned. The book was translated to English because of its social and educational value.

We are now very honored to be able to have this remarkable story available in Chinese. In addition to the original book we have added the White paper issued by the Thai Ministry of Public Health that explains the philosophy and careful steps taken by the government in making its historic decision to honor its people's right to life."

Chee Yoke Ling

Director of Programmes Third World Network May, 2009



强行仿制的权利=生命的权利

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