East Asian Science, Technology and Society: an International Journal (2009) 3:51–72
DOI 10.1007/s12280-008-9066-1

# The Voice on the Bridge: Taiwan's Regulatory Engagement with Global Pharmaceuticals 橋上之聲：全球醫藥法規中的臺灣處遇

**Wen-Hua Kuo**

Received: 16 December 2008 / Accepted: 23 December 2008 / Published online: 17 February 2009


**Abstract** This paper analyzes Taiwan's engagement with the standardization of pharmaceutical clinical trials at the turn of this century. Unlike approaches that treat local encounters with globalization as either reluctant acceptance or lasting resistance, this study calls attention to a complicated process of negotiation, the conceptual gap between the illusion of a unified world and the reality of persistently divided nation-states. To address this gap, an ethnographic investigation is required. Two concepts, "bridging" and "voicing" (fasheng), are introduced in order to capture Taiwan's unstable status, what I term "the voice on the bridge," in this process. Bridging emerged as a technical concept for evaluating pharmaceutical drugs' possible differential ethnic effects. But it also reflects the ambiguous reality of a world in which each state is an islet connected to others by imaginary bridges. Fasheng ("voicing") has to do with Taiwan's long-held desire for world recognition as a state. This paper is an ethnography of globalization and the state that traces how Taiwan created a regulatory resolution through the idea of bridging and how this "voice" was articulated through various social strategies. It explores not only the complexity of interactions in the technical field of regulatory science, but also argues that looking at such entanglements of science and society makes it possible to move beyond simple interpretations of globalization.

An earlier version of this paper was presented in the Annual Meeting of the Society of the Social Study of Science in Vancouver, November 2006. I am grateful for the productive discussions there, which helped me to formulate my arguments for a humanities audience. My thanks also go to Taiwan's Center for Drug Evaluation, especially to its Executive Director Chern Herng-Der, whose generous support in different stages of this work enhances its interpretive power for experts inside of outside of the ICH. Two anonymous readers of *East Asian Science, Technology and Medicine* improved this paper, although I take full reasonability for its views and arguments. This paper is a part of my on-going project on the multi-regional trial policy in East Asia, sponsored by National Yang-Ming University (Aim for the Top University Plan) and by Taiwan's National Science Council (project no: NSC 962412-H010003).

W.-H. Kuo (✉)
Institute of Science, Technology, and Society/Institute of Public Health,
National Yang-Ming University, Taipei, Taiwan
e-mail: whkuo@ym.edu.tw

**Abstract** 本文探討臺灣如何在法規領域中，從臨床試驗標準化趨勢的因應裡開展自己的國家策略。在國際醫療法規協合會（ICH）的全球場域裡，本文透過種族差異要因爭議與「銜接性試驗」（bridging studies）概念的出現與落實，指出「世界大同」理想與各國分立現實之間的落差，與法規作為探討標準化進程例證的可能。另一方面，本文利用「發聲」（voicing）概念，深化過去將科技引進僅為 國家利益服務的看法，嘗試理解非ICH 會員國並且長期孤立的臺灣，如何在提升法規標準時增加自己的國際可見度。本文無意指出在臨床試驗上臺灣是因應全球化的「成功」案例。相反的，當醫藥成為STS 研究的新興課題之際，它提醒傳統人文科學的議題，如國際脈絡下的國家的重要。就此意義而言，在全球法規科學前沿上，在國家定位中躑躅徘徊的臺灣的「橋上之聲」（voice on the bridge），具體呈現全球化下，國家定位、科技政策與身體管制間STS 研究的挑戰與可能性。

**Keywords** Globalization · Pharmaceutical regulation · ICH · Bridging studies · Fasheng

## 1 Introduction

This paper is an ethnographic analysis of Taiwan's engagement with global pharmaceutical regulation and production. In particular, it captures a dynamic moment when the pharmaceutical industry and regulators attempted to establish universal standards for clinical trials for drug approval, and Taiwan suddenly found itself contending with a globalized world at the frontiers of regulatory science.

Despite its interest in the sciences beyond national boundaries,[1] this paper bases its theoretical concerns on the increasingly complicated interactions between world and nation-state in the era of globalization. As sociologist Horng-leun Wang (2000) suggests, in the current era, the nation-state should not be considered merely a self-contained political entity; it defines its existence by various connections and relationships with other states. This paper inquires about the lively dynamics involved in this engagement.

Conventional portrayal of this kind of engagement can be summarized via two different scenarios. One examines the result of Taiwan's acceptance of universal clinical pharmaceutical trial standards and describes it as merely a complimentary chapter in globalization's sweep across the non-Western world. The other assumes Taiwan's lasting resistance to the imposition of global conventions and focuses on the discrepancies between these standards and other Asian states' regulatory

[1] There is a rich literature in science studies concerning the making of science and technology as an international scene that this paper cannot address in depth. Historian of technology Thomas Hughes (1979), for example, portrays Thomas Edison as a "system builder" because of the grand scale of the technology he developed and the resulting social impact. Working from a historical viewpoint, Daniel Greenberg (1999) analyzes how the production mode of large-scale science was developed in an American context. Both illustrate the social and political characteristics of science going big and international. It is also worth mentioning *Big Science* (Galison and Hevly eds. 1992) and *French DNA* (Rabinow 1999). The former is a collection of case studies on this topic from across a wide range of disciplines. The latter is a pioneering work that addresses the problems of big science as its production mode entered into the field of life science.

practices. But unlike these approaches, which portray the encounter of the local arena with globalization as a zero-sum game, this study is an investigation of processes of negotiation and the conceptual gap between the illusion of a unified world and the fact of persistently divided nation-states.

Although the notion of capturing a state in action is tempting, it is by no means an easy task, given the complexity of both the state and the global. In order to focus on the special role that regulatory science plays in these places, some clarifications need to be made on what notions of "the state" and "the global" this paper is referring to. Certainly, bureaucracies and institutions constitute the state as an acting entity. Nonetheless, this paper aims rather to capture how one state behaves from the perspective of a global viewpoint. As Ernest Gellner (1983) reminds us, the state is a political shell within which culture is shared and nationalism is crafted. The aim of the inquiry at hand is thus not to define what the state is or should be; rather, it is to distinguish one "political shell" from others in the face of globalization.[2]

Clarification of the notion of "the global" is also important in this paper. Instead of referring to a convenient yet vague image of the contemporary world as fluid, changeable, and interrelated, this paper addresses one distinctive set of terms by which this complex globalized world renders itself, namely, regulations on pharmaceuticals. To be exact, the paper takes as its object the International Conference for Harmonization (ICH), a series of meetings initiated by the United States (US), the European Union (EU), and Japan that aims to establish uniform standards for proprietary drugs.[3] Notwithstanding its exclusive nature, the ICH exerts considerable global influence; the guidelines it establishes are implemented in all major global pharmaceutical markets, and they aim to rule the rest of the world through commercial means.

This way of looking at the configuration of the world—though both the artificial and the technical—corresponds with Michael Hardt and Antonio Negri's portrayal of globalization (2000). As they argue, "Globalization, like localization, should be understood instead as a *regime* of the production of identity and difference, or really of homogenization and heterogenization" (p.45, original emphasis). This assertion fits well in the discussion of pharmaceutical regulation. Although the guidelines established by the ICH appear powerful, this does not mean that regulatory homogeneity can easily be achieved, even if each state recognizes the importance of regulations and is capable of implementing them. The study by Sheila Jasanoff (2005) of biotechnology policy in the United Kingdom, Germany and the US, for instance, demonstrates how policies can be distinct from one state to another even as they are similarly linked to the latest technologies. On the basis of these discrepancies, Jasanoff argues that while science may be universal, but scientific policies are not. Policies on the life sciences have become a more or less self-conscious project of nation building at a critical juncture in world history.

[2] Further discussion on this viewpoint from a politico-sociological perspective can be found in "Rethinking the Global and the National" by Horng-luen Wang (2000). Wang defines a nation-state as a political and cultural product derived by demarcating a territory within global networks.

[3] The full name is the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. For a concise introduction to the ICH, see Nutley (ed) (2000).

Following Jasanoff's theme, and with specific attention to the tensions between homogenization and heterogenization in the spread of standards, this paper introduces a set of metaphors concerning the world and the states within it, metaphors that center on the image of islets connected by bridges. It argues that the concept of bridging enables us to capture the process of a state's engagement with the world.

As discussed in depth below, "bridging" is a technical concept in regulatory practice that has to do with how to evaluate clinical data from one population and extrapolate it to other populations. That is one of the reasons the term "bridge" appears in this paper's title. Nonetheless, the image of a bridge also captures what might otherwise be elided by the illusion of the world as a homogeneous, unified and transparent whole.

Pharmaceuticals are highly regulated and controlled by the state in the interest of protecting public health. Each state possesses the power to regulate pharmaceutical production and use within its territory, and the international flow of pharmaceuticals is closely monitored and controlled. Following Gellner's description of modern world in which nation-states are its basic unit (1983:139–40),[4] it is easy to see the image of islets connected by bridges, nation-states in the era of globalization. Just as an isolated islet cannot be reached without the labor of building a bridge, globalization, according to this worldview, cannot be achieved in a single step. In the case of pharmaceutical regulation, it requires the formation of regulatory guidelines, the "bridge" that allows pharmaceuticals and the standards regulating them to move between states, and the ICH is the place where these regulations are realized.

Even so, the story of globalization does not end there. In regulatory science, bridges have two functions that make the creation of a "flat" world more complicated. The conventional function of bridges, and the one the pharmaceutical industry favors, is to connect places that are separated. As does the ICH, the industry tends to interpret the concept of bridging as a means to overcome local barriers and to allow products to flow freely across national borders. However, a bridge is also a channel whose traffic can be restricted, and thus the very fact of being connected provides states at each end with a juridical means of control.

Proceeding from the worldview of islets connected by bridges, the rest of this paper elaborates on the dynamics of Taiwan's encounter with the moving frontier of pharmaceutical regulation. The first half describes the problematic of global pharmaceuticals and Taiwan's position within it. It explains how and why a regulatory platform like the ICH was needed as pharmaceuticals began to travel globally. It further discusses East Asia's role in this trend, with specific attention to Taiwan's fraught political relationships with the rest of the world. Only with this context can it be made clear that, beyond public health concerns, the idea of earning Taiwan the global visibility it deserves via "voicing"—in its Taiwanese expression,

[4] Horng-luen Wang (2002) provides a more refined discussion of this political landscape. He urges readers to consider how the state operates when nationalism seems to have paved the way to a post-national/global era. As Wang suggests, "I am not arguing here that nation and nationhood are essential sine qua non in the modern world, nor am I defending state-centered politics in the least. The Leviathan of the modern nation-state … is both gigantic and monstrous. But ignoring it does not mean that it does not exist" (144).

*fasheng* (發聲)—was a crucial goal of the Taiwanese state in its struggles with pharmaceutical regulation.

The second half of this paper is an analysis of Taiwan's exercise of *fasheng* politics over the regulatory bridge made by the ICH. Describing the actions Taiwan took in order to catch up with global trends in clinical trial standards, the paper demonstrates that in fact Taiwan neither passively received these standards nor insisted on alternatives when confronting globalization. Taiwan's various active responses, I argue, constitute a recognizable voice to the world. On the surface, the second half can be read as nothing but a simple story about how Taiwan successfully won the world's attention. But my goal is more than this. Using the metaphor of the islets connected by bridges, this ethnography aims to portray Taiwan's identity as a "voice on the bridge," an unstable position in which the state's situation is constituted through its relation to the world, a relation that keeps changing.

## 2 Global Pharmaceuticals: Standards, Clinical Trials, and the ICH

Over the past two decades, pharmaceuticals and the pharmaceutical industry have become more standardized and globalized, and since the 1990s an increasing number of prescription drugs have been developed and marketed. This trend has made global pharmaceuticals an important and emerging object for research, and in this research trend the standards and regulatory techniques that facilitate the spread of globalization hold special significance. In their introduction to *Global Pharmaceuticals* (Petryna, Lakoff, and Kleinman eds. 2006), Adriana Petryna and Arthur Kleinman argue that standards and regulations are not only used to make pharmaceuticals more scientific and reliable, but also to give pharmaceuticals a cross-cultural and thus unquestionable quality. Pharmaceuticals have become more and more highly regulated since the 1960s. Major pharmaceutical markets have introduced rigorous regulations in response to a series of major drug safety crises.[5] As a result, pharmaceutical regulation has spawned huge, complicated systems. And at this point, marketing concerns began to dominate this initially scientific affair. To obtain a larger and quicker reward in the time before the patents on their products expire, the pharmaceutical industry aggressively pushes markets to accept their products. This reflects Petryna and Kleinman's warning that "As standards travel, their social and economic embeddedness is revealed" (12).

With this perspective in mind, I begin my investigation with the regulatory regime, focusing not on how people may be affected by regulations,[6] but on how the world of pharmaceuticals itself formulates operational standards. The assessment of how knowledge and the state interact and infiltrate each other in a mode of "co-production" by Jasanoff (2004) informs this examination. As mentioned above, the

[5] The thalidomide tragedy was the trigger of these crises. In the late 1950s, Thalidomide was prescribed to pregnant women as an aid to help them sleep. Before it was identified in 1962 as a source of deformities in newborn children of women who took it, approximately 10,000 children in Africa and Europe were born with severe deformities.

[6] A study that does examine the effects of regulation is Joseph Dumit's "Drugs for life" (2002), which argues that people are "destined to become ill" when the criteria for normality change.

main actors at the ICH are the world's major pharmaceutical markets and producers. However, what makes this conference influential is its role in communication between the regulator and the regulated. It includes regulatory agencies—the FDA, Japan's Ministry of Health, Labor, and Welfare (MHLW), and EU regulators—and industry representatives—from the Pharmaceutical Research and Manufacturers of America (PhRMA), the Japan Pharmaceutical Manufacturing Association (JPMA), and the European Federation of Pharmaceutical Industries and Associations (EFPIA). Each party understands that the making of universal standards accelerates global access of the latest cures, and neither side can achieve this access without the other.

The dynamics between industry and regulators, and among different regulatory bodies, can be observed in the ICH's consensus process. The celebrated five-step ICH process that has been drawn up to ensure that each guideline is properly discussed and implemented in all ICH regions has proven to be less a hurdle than a catalyst for the formulation of standards.[7]

This arrangement may strike a chord with readers familiar with Sheila Jasanoff's notion of "republics of science," according to which democracy "is not a singular form of life but a common human urge to self-rule that finds expression in many different institutional and cultural arrangements" (2005:290). Indeed, in acknowledging that science cannot be immune from politics (or as Jasanoff suggests, that scientific cultures are at one and the same time political cultures), the intention of the ICH's diplomatic harmonization procedure is for diverse regulatory practices to be respected in the making of universal standards. From its first meeting, held in 1991, to its sixth (ICH6)[8] in 2003,[9] the ICH has established fifty-four guidelines on drug quality, safety, and efficacy and multi-disciplinary topics.[10] Both industry personnel and regulators appreciate the ICH for its efforts in making the world of pharmaceuticals "flat." Even more important is that through this process, the ICH has made itself a reflection of "the global," an on-going endeavor through which the

[7] This process can be summarized as follows: proposals for new harmonization must be brought to the steering committee to initiate an ICH action. If accepted, a proposal is assigned to an expert working group, which advises on the technical aspects of harmonization topics (Step 1). When a primary guideline is drafted, it must first be distributed to and achieve consensus among all the invited experts (Step 2). When the draft is complete, it is brought back to each region for feedback on related topics (Step 3). Each guideline must be agreed on by all experts and each ICH region before being submitted to the steering committee, where the guideline is confirmed (Step 4). The final step, which makes the ICH unique, is a follow-up mechanism applied to determine whether a guideline is adopted by local regulatory agencies within 6months of its release (Step 5). For an updated and detailed description of the ICH process, see the ICH 2002

[8] In this paper, I refer to ICH conferences using the letters "ICH" with a number denoting chronology. For example, the sixth ICH conference is "ICH6."

[9] ICH7—originally scheduled for 2007—has been cancelled. Even so, the steering committee and expert working group meetings continue to be held in Brussels, Belgium, in May and in Yokohama, Japan, in October.

[10] According to the ICH website (as of November 4, 2008), the number of finalized guidelines has increased to 60. The number of guidelines in the categories of quality, safety, efficacy and multi-disciplinary issues is 24, 12, 19, and 5, respectively.

real world can imagine and transform itself into an ideal one, one in which both public health and commercial needs are met.[11]

Not satisfied with staying within its initial three regions, the ICH has attempted to spread its new standards to the rest of the world by creating more "bridges." Based on a resolution made at ICH4 in 1997, the ICH has begun to expand, seeking to implement as many guidelines as possible in non-ICH regions (ICH 2000). In 1999, the ICH Global Cooperation Group (GCG) was formed to serve as liaison to other countries affected by these guidelines, ensuring that the direction of regulatory flow from the ICH to non-ICH regions was irreversible.[12] Although the markets outside of the ICH regions are too tiny to be incorporated into the original plan, the ICH has decided to extend the margins of its guidelines and incorporate these places.

Thanks to its robust economy and sustaining buying power, East Asia was one of the areas initially influenced by the "bridges" established by the ICH. In fact Japan, the largest national market in the region and the second largest in the world, was the only non-Western member invited to join the ICH. The ICH did make a bridge to Japan, which had long been considered by outsiders to be overly isolated and conservative. For instance, Anthropologist Karl Applbaum (2006) demonstrates the role of the ICH in opening the Japanese market by showing how medical knowledge and capital work together in a top-down, western-initiated approach. The ICH, as mediator, is cast as a mere instrument through which this capitalist wish is fulfilled.[13]

Indeed, in the global distribution of pharmaceuticals, the ICH's power is embedded in its ability to build bridges among regulatory regimes. By standardizing regulations, it continues to work towards the goal of a single global market and health community. For the ICH, the ultimate solution is already here; it is merely a question of when it will be implemented and where this will be done first.

## 3 What is Missing in Between: The Problem of Ethnic Difference and Taiwan's Appearance

The ICH quickly established itself as a unifier of all standards for clinical trials, a move that seemed to make all cultural and social difference disappear into

[11] It should be noted that this superficial harmony cannot easily escape from policy analysts' scrutiny. John Abraham and Tim Reed (2002), for example, criticize some ICH actions as accommodating industry desires to loosen requirements. In a separate paper, Abraham (2002) even casts the ICH as part of a longer trend in the development of pharmaceutical regulations in which the industry plays an aggressive role in making drug approvals easier and faster.

[12] According to *The Value & Benefits of ICH to Industry*, the primary objective of the GCG is "to act as a resource for the understanding, and even acceptance, of many of the guidelines" (Nutley 2000:10). This statement was later modified to: "To promote a mutual understanding of regional harmonisation initiatives in order to facilitate the harmonisation process related to ICH guidelines regionally and globally, and to facilitate the capacity of drug regulatory authorities and industry to utilize them" (ICH 2008). Nevertheless, the hierarchal structure imposing ICH standards on non-ICH regions remains the same.

[13] To make this point, Applbaum cites the ICH's position on the acceptance of foreign clinical data, which I discuss in the next section. Applbaum claims that by facilitating the acceptance of foreign clinical data, the ICH is "most significant for opening the door [of the Japanese market] to global activity in the industry"(91).

unquestionable science. As historian of science Yoichiro Murakami comments (1998:234), when tracing how the concept of security becomes one of the central concerns in modern lives, no "ultimate solution" for all variations and discrepancies is ever free from a particular viewpoint that channels all interests in a certain direction.

If Murakami worries about diminishing cultural variation in the era of globalization, STS scholars are concerned with an emerging division of labor in the production of pharmaceutical knowledge through international-scale human subject experiments.[14] In her paper "Globalizing human subject research", Adriana Petryna (2006) argues that due to pressures to secure large numbers of research subjects in short amounts of time, there is a systematic move of clinical research trials, through contract research organizations, to regions such as Eastern Europe and Latin America where regulatory standards are lower.

I am basically in accord with the above perspectives. However, it is important to be very careful when applying these general notions to the interpretation of the cases at hand. In fact, East Asia is what I would like to call the missing piece in these conceptual images of clinical trials. I say this for two reasons. First, while it does provide test subjects for major drug companies, East Asia is not like underdeveloped states that are populous enough to supply enough subjects yet are too poor to consume the drugs being tested when they finally make it onto the market. East Asia's strong economies are not only capable of hosting high-quality, internationally respectable trials; they also possess buying power for the latest medicines. More importantly, the governments in this region believe that conducting clinical trials can help them to shore up their biopharmaceutical research infrastructures, and they view trials as the best way to catch up with the Western world.[15]

The second and related reason for East Asia's unusual relationship to global clinical trials has to do with attitudes toward ethnic difference. The Western conceptualization of differences among populations, based on a dichotomy between biological concepts and social/cultural concepts of race, offers little insight into understanding how East Asians conceive of themselves. The identity of the Japanese, like that of all other East Asian populations, is related more to an idea of nation, or more specifically of nation-state, that blends ideas of race and ethnicity with the political institutions that manifest them.[16] In contrast to Petryna's image of populations that are guinea pigs for international pharmaceutical companies' clinical trials, China (People's Republic of China, PRC), Japan, Korea (Republic of Korea), and Taiwan typically generate clinical data using their own subjects in order to learn exactly how a drug works on their own people.

[14] For an ethnographic explore of the problems in global clinical trials, see Petryna (2005). For a theoretical exploration of the case of clinical trial in India, see Sunder Rajan (2006) and (2007).

[15] This observation resonates with Steven Epstein's argument on the politics of inclusion in clinical trials in the U.S. (2007). According to Epstein, while minorities were once formally excluded from testing for new therapies, they were later included in clinical trials under an emerging biopolitical paradigm that, through scientific algorithms, confirmed the existing categorization of human races. However, as I argue in a forthcoming paper, on the global level, the problem of ethnicity has different orientations in different settings, including the East Asian case.

[16] This subject requires further research on the origin and development of the idea of "民族" (*minzhu* in Chinese, *minjok* in Korean, and *minzoku* in Japanese) as it traveled, coupled with that of nation-state, throughout East Asian states. For more discussions on how race and ethnicity are considered in the Asian context, see Takezawa (2005).

This very different orientation for how clinical trials are discussed emerged as the ICH enters East Asia. The diminution of cultural varieties that Murakami worries about did not occur. Cultural and public health concerns about Japanese bodies that were raised at the ICH were transformed into technical questions about the applicability of foreign clinical trials when a foreign-tested drug was expected to be used by the Japanese population. The "E5" topic (the fifth topic under the category of efficacy at the ICH) was thus created in order to find a suitable measurement of ethnic difference for these circumstances,[17] and the resulting discussion proved to be one of the toughest in the history of the ICH.[18]

It is not necessary to review exhaustively how differences among populations have been dealt with during the debate at the ICH. From the industry's perspective, the issue was nothing but an "inappropriate non-tariff barrier" in trade negotiations with Japan. However, it is productive to return to Hardt and Negri's perspective and consider the debate at the ICH as a process for creating homogenization and heterogenization. In brief, Western nations stressed the biological unity of humankind and claimed that further clinical trials should be added only if it could be proved that there were real differences unique to Asians. On the other hand, Japan insisted that no trials should be foregone unless the similarity between the Japanese and other ethnic groups, such as Caucasians, could be proved. Neither of these parties found the other's agenda acceptable until the introduction of bridging studies.

Technically, "bridging" means undertaking extra studies to generate the necessary information for the extrapolation of late-phase clinical data to the population of an untested region. In practice, however, it was a compromise that eased tension among ICH members by leaving part of the standardization procedure ambiguous and open. From the industry and some regulatory authorities' viewpoint, bridging studies were a way of testing whether existing data could be extrapolated to a local region where the product was to be marketed, and they were only to be applied if the product was suspected of having ethnically particular effects. From Japan's viewpoint, however, bridging studies were considered the result of bargaining that allowed for additional studies to be designed especially for Japan. Although confusion remained, the E5 guideline on bridging was agreed upon in 1997 and implemented 6 months later.

To continue the bridge metaphor from earlier in this paper, with the E5 guideline, the ICH created an unstable bridge to Asia. The guideline is so arbitrary that each side can have its own interpretation on how traffic over the bridge should be controlled.[19] Even so, it was on this shaky bridge that I heard an opinion on how to cope with ethnic differences in clinical trials—in my terms, a "voice," in this case

[17] The topic's formal title was "Ethnic Factors in the Acceptability of Foreign Clinical Data."

[18] For an in-depth discussion on how the topic of ethnic difference was discussed at the ICH, see Kuo (2008a), in which I argue that the evaluation drugs' ethnic effects is never a problem that can be solved by science alone.

[19] This result echoes Steven Epstein's observation in *Inclusion* about the continuous tension between individual nation-states and the international community over an ultimate definition of ethnicity. Epstein comments on the implementation of the E5 guideline that "at the global level, there is simply no consensus about which ways off chopping up humanity into distinct groups are relevant to the domain of biomedicine, and it is unlikely that an organization such as the ICH could impose such a consensus by fiat" (154).

from Taiwan, another state from the "missing" area in the discussion of global pharmaceuticals. It is an unanticipated voice that deserves serious investigation.

Although Taiwan was influenced both politically and economically by the US under the Cold War order, Taiwan's pharmaceutical sector does not share much in common with Japan's. Taiwan does not have a strong presence in the global pharmaceutical industry, and its market is not large enough to bargain for extra clinical trials for its people. Moreover, the military threat from China inclines Taiwan to lean more toward U.S. positions. As a result, the development of pharmaceutical regulation in Taiwan was not determined solely by the government, but also heavily influenced by PhRMA and the U.S. trade representative.[20]

Complicating the situation further is Taiwan's political status. Considered a "troublemaker" in East Asia by its neighbors, Taiwan is intentionally excluded from almost all governmental gatherings, and hosting its own events is out of the question. A fundamental problem for Taiwan, therefore, is its desire to be seen and heard, and so the Taiwanese notion of *fasheng,* or "voicing," has become an essential component in its strategy for surviving globalization. For Taiwan, globalization is not just about being a part of the wider world; it is also a matter of how to make the country's voice heard through the process of engagement.

The ICH provided such an occasion to address this issue. Cloaked in scientific concepts, the content of the E5 guideline does not addresses any specific state, and the categorization of ethnicity it employs is rough—it makes no differentiation more specific than "Asian." In other words, in creating a bridge to link Japan with the Western world on the basis of ethnic difference, the ICH also created an example that other Asian states in the same situation could follow. In fact, the industry's main concern about the ICH guidelines was always that they would be used as an excuse to request more trials when local authorities updated their regulations. Yet for the guidelines like the E5, the bridge's functionality is also a concern. When it does not work as expected with one state, the ICH, in its role as bridge builder, then wants to see if it will work with others.

Taiwan turned out to be a state that could make the "bridge" of bridging studies work. In 2003, it was reported that local trials were necessary for bridging studies in only 15 out of 62 applications, and there were convincing reasons for each case (Lin et al. 2003). This fact made an impression on the ICH. Elaine Esber, one of the ICH's founders, praised Taiwan for this policy.[21] After listing the industry's complaints about the implementation of the E5 guideline, Esber pointed out that Taiwan's regulatory agency, the Center for Drug Evaluation (醫藥品查驗中心, CDE), had indicated why it was important to strengthen regulatory capability and how much this could increase the acceptance of foreign clinical data under the E5 guideline.

Herng-Der Chern (陳恆德), then the Deputy Director of CDE, explained to me what it was about Taiwan's "good policy" that caught the ICH's attention.[22] In

[20] On the early development of the clinical trial regulations in Taiwan, see Hsiao (1998).

[21] She delivered this message at the meeting of the 2003 Symposium on the APEC Network of Pharmaceutical Regulatory Science, in Taipei, November 17–18, 2003. I return to this meeting later in this paper.

[22] I have done intensive interviews with Herng-Der Chern since we met in 2003, especially during the time we spent at an ICH meeting as Asia-Pacific Economic Corporation representatives. In this paper, I do not specify the occasion of Chern's various remarks unless more background information is necessary.

contrast to Japan's insistence on repeating trials with Japanese subjects in the name of "bridging," Taiwan allowed that while ethnically differential drug effects existed in some cases, nonetheless, these differences could be scientifically evaluated and thereby bridged. This is an intriguing point. The ICH did not destroy Taiwan's regulatory integrity. Between unconditional acceptance and total rejection, Taiwan made the best use of the idea of bridging studies by forming a clear, workable policy.

I could feel Chern's enthusiasm in his comments. But this distinctive approach cannot explain why Taiwan was chosen to appear as a bright spot on the world map of pharmaceutical regulation but other Asian states were not. The following sections of this paper retell Chern's account of Taiwan's engagement with the ICH. This description illustrates that the situation is more complicated than how science on ethnic difference is first ignored, and then later, through proper communication, accepted by the world. Sticking with the metaphor of *fasheng* and emphasizing the technologies that consolidate scientific programs,[23] this recollection analyzes Taiwan as a vivid voice in pharmaceutical standardization by tracing its involvement in the debate over the E5 guideline. As mentioned above, this retelling does not intend to "discover" for readers the story of Taiwan's "success." Instead, it is intended to capture Taiwan's "liminality"[24] and its fleeting moves within globalization.

## 4 Tuning Up, Channeling-in: The Making of the CDE

The story starts with the pre-history of the CDE. It must, because the CDE did not come into being from nowhere, but rather arose from a particular silence. In spite of its *de facto* independence as a state, Taiwan has been cut off from almost all world governmental networks, and the regulation of pharmaceuticals is no exception. Although since 1991, the Federation of Medical Professional Alliance in Taiwan (FMPAT), a group of medical reformists deeply devoted to the international recognition of Taiwan, has organized training courses on the regulation of clinical trials,[25] there existed an information gap. Throughout the early 1990s, the research and development of drugs in Taiwan remained weak, and internationally accepted clinical trials were not a regular practice on the island.[26] Worse yet, Taiwan was vulnerable to harsh threats from PhRMA, whose representatives did not want local trials to slow their sales. In short, despite the millions of people living on the island, Taiwan was stifled in the world of drug regulation.

[23] Some of the technologies shown in this analysis are inspired by the study of Shapin and Shaffer (1986) on the debate between scientist Richard Boyle and politician Thomas Hobbes over the existence of the vacuum.

[24] This term is borrowed from the study of the rites of passage by Victor Turner (1969). According to Turner, liminal entities exist between structures: they are "neither here nor there; they are betwixt and between the positions assigned and arrayed by law, custom, convention, and ceremony" (95).

[25] From 1992 to 1994, the FMPAT held eight trainings. Although these courses were introductions to the regulatory practice of benchmark agencies, they directed local medical professionals' attention to the importance of being able to conduct clinical trials.

[26] The standard practice for importing drugs to Taiwan during this period was to conduct "listing" trials, small-scale studies that fulfilled hospitals' bureaucratic requirements.

The situation began to change after Taiwan's first meaningful contact with the ICH in 1995. It happened when Herng-Der Chern, then a clinical pharmacologist working at National Taiwan University Hospital, attended ICH3 in Yokohama.[27] He was immediately impressed. He realized that Taiwan needed not make regulations of its own (the local regulations first at the US's request and then threatened to abandon); "the task now," he wrote in his personal journal, "is how to follow these (ICH) activities [and guidelines] in a timely fashion."

Chern's ear quickly "tuned in" some topics that intrigued him; chief among these was the E5 debate, which reached its peak at that meeting. Chern quickly absorbed these latest developments in pharmaceutical regulation and was aware of Japan's distinct categorization of ethnic differences. It seemed to Chern that Taiwan might be able to differentiate itself from Japan if it followed the rules set up by the ICH. As a physician, Chern's intuition told him that the differences between populations should not be exaggerated in the way the Japanese were doing. But beyond this, Chern, a member of FMPAT, was keenly aware of the implications for Taiwan's status. Taiwan needed to build an instrument to articulate its voice, and hosting global conferences was a way to sustain such a voice. At the conclusion of the conference he wrote in his journal, "The last day [of the conference] gives me a feeling of attending a historical event and I want to rush back to start a big project or mission, that kind of thing."

Chern began to act as soon as he returned to Taiwan. Taiwan had to "channel" itself to the ICH. Chern wrote a report for the Department of Health (DoH) in which he proposed a 3-year project for FMPAT (1995) that would establish a committee to keep track of ICH actions. A few months later, in the spring of 1996, the ICH in Taiwan committee (hereafter, ICH-Taiwan) was established under the sponsorship of the DoH. Although this task force ran independently without any official relationship with the ICH, Chern's individual seed of thought had found a place to grow.

The main body of ICH-Taiwan was the Steering Committee, under which were three expert working groups (Fig. 1). These groups were not intended to deal with single guidelines; rather, they were oriented toward solving problems that arose during the implementation of ICH guidelines. The most interesting expert working group was the one on foreign relations. This group kept watch on the ICH, hoping to be able to make connections with it and host international regulatory conferences. It even published a bi-annual newsletter, the *ICH in Taiwan Bulletin*, to disseminate current information from the ICH.[28]

Even with all these efforts, Taiwan had to focus and not just passively receive information. The topic of bridging studies appeared as a clear target. This issue came up again at ICH4, in 1997, where Taiwan's first organized delegation, consisting of 36 representatives from the government, academia, industry, and of course FMPAT, was in attendance. In his report on the meeting to ICH-Taiwan (1997), Chern raised

[27] Chern was not the first Taiwanese to attend the ICH. Taiwan had sent representatives there before, one FMPAT staff member to ICH1 and two government officials to ICH2. Even so, their voices were only background noise at the ICH and left almost no trace for Chern to follow.

[28] The official name of this newsletter, in Chinese, is *Guoji Yiyiao Fague XieheHui Taiwan Tuedong Weyuanhui Huixun* [國際醫藥法規協合會台灣推動委員會會訊, Committee for Promoting the ICH in Taiwan Newsletter].

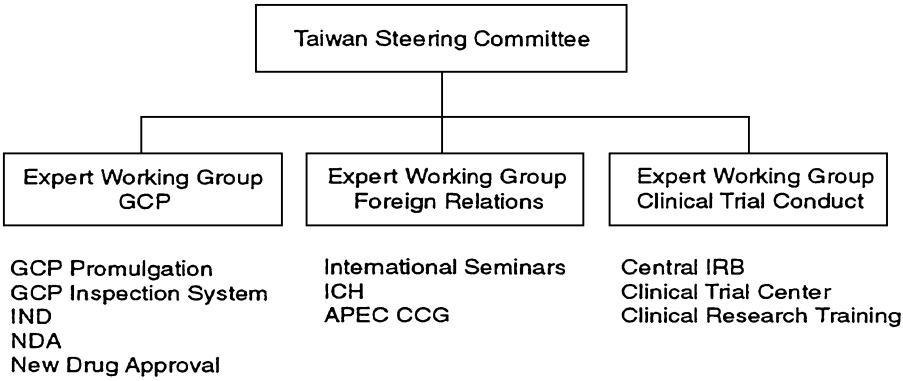


**Fig. 1** Structure of ICH-Taiwan. Source: Chen (1998)

several points, including a clear analysis of Japan's attitude toward ethnic difference. In fact, it was this controversy that allowed Chern to approach ICH members, including Toshiyoshi Tominaga (富永俊義) and Chikayuki Naito (内藤周幸) of the MHW (later renamed MHLW) and Jean-Marc Husson of the EFPIA. All this helped Chern obtain the echoes he wanted. If Taiwan could seize the opportunity to be the first non-ICH state to follow the ICH guideline, Chern suggested, it would constitute a great leap toward the country becoming a center for clinical trials in Asia.

Still, Taiwan needed a stronger signal to prove its visibility. For this, the opportunity to host a Drug Information Association (DIA) meeting was a turning point that came at just the right time. A U.S.-based non-profit organization that enjoys global recognition, the DIA organizes about thirty meetings and workshops every year around the world, including, starting in the 1990s, in East Asia. Through Chern's personal connections Taiwan was able to host one symposium named "Recent Developments in Clinical Trials in the Asian Pacific Region."[29] It gave Taiwan a much-needed opportunity to promote itself—brochures advertising the symposium were distributed at ICH4, along with booklets on Taiwan's regulatory reform.

It was at this point that Chern and his fellow medical advocates started handing their work over the government, which turned ICH-related affairs into an institutional, state-oriented task. The DoH played a role by incorporating the DIA workshop into its on-going biotechnology development policy.[30] Following this policy, the DoH proposed the establishment of a professional organization that would help make Taiwan a center for manufacturing and production. However, this institute, which was to become the CDE, could not know its true mission without

[29] This symposium was arranged through the recommendation of Kiichiro Tsutani, one of Herng-Der Chern's acquaintances from a DIA workshop. I am currently working on a paper with Kiichiro Tsutani and Takatoshi Sato that describes this series of conferences held by the DIA and a more general perspective on regulatory harmonization in East Asia.

[30] In September 1995, the Taiwanese government organized an inter-ministerial committee on the enhancement of the biotechnology industry. A few months later it established a committee on the pharmaceutical industry under the Ministry of Economic Affairs, streamlining the administrative requirements for transfers of technology from one industry to another.

Chern's participation—when it was established, he quit his position at National Taiwan University Hospital in order to join it.

The 1998 DIA symposium acted as a catalyst for all these private and public efforts. Held only a few months after the birth of CDE, it was a festival to celebrate this new entity's bright future. For this groundbreaking event, the most crucial emphasis was on foreign speakers, and the DIA helped to provide FDA officers, including ICH coordinators Roger Williams and Robert Temple, the Director of the Office of Drug Evaluation. More importantly, Taiwan set the focus for the conference: ethnically specific drug effects. It arranged a half-day session on this topic, and Williams, the originator of the concept of bridging studies, shared his experiences on the issue.

Yet the CDE did not stop there. It knew how to promote a conference and how to promote Taiwan. Before the conference, Chern negotiated with the DIA to publish the proceedings as a special issue of the *Drug Information Journal* (vol.32, supplement). Chern selected thirty papers for this publication, half of which were either written by Taiwanese authors or about Taiwan. This was certainly not a direct promotion of Taiwan, but it ensured that information about the symposium and about Taiwan would continue to be disseminated after the event.

It was indeed a nice start. The locally oriented ICH-Taiwan had transformed into the globally connected CDE. As Chern wrote in his comments (1998) after attending the annual meeting of DIA in 1998, "DIA would be a starting point for Taiwan to be the center of clinical trials in Asia. In the 'post-DIA' era, more challenges would come, and we should step forward and welcome them."

## 5 Creating the Stage, Powering the Voice: The Making of the APEC Network

The first task for the CDE in the "post-DIA era" was to form a forum of its own. Knowing that a network can help a single conference's effect last longer, at the end of DIA meeting it had hosted Taiwan proposed the formation of the Asia-Pacific Clinical Research Alliance (APCRA). Chern (unreleased document 1998) carefully explained this network in a memorandum: the APCRA would be an informal network of experts interested in regulatory science and would have no political affiliation. Like the ICH, it would have a steering committee working primarily on bridging studies; it would also deal with the implementation of other guidelines and cooperative initiatives.

The APCRA failed to address this mission, because as an "illegal" resident of the global village, Taiwan was not yet strong enough to initiate and maintain such a network. However, the CDE did not give up. It wisely turned its attention to the existing Asia-Pacific Economic Corporation (APEC), the non-political forum that linked Taiwan to world powers in the Pacific Rim, including its partners Japan and the U.S., and its antagonist, the PRC. A proposal to establish a network on pharmaceutical regulatory science focusing on bridging studies was submitted by Taiwan and discussed at APEC's sixteenth Industrial and Scientific Technology Working Group (ISTWG) meeting in March 1999.[31]

[31] The network is called the Network of Pharmaceutical Regulatory Science-APEC Joint Research Project on Bridging Studies, and its proposal number is 16.B.6.07.

Yet to create a network under APEC's auspices was no less tactical than creating one outside of it. All proposals from Taiwan had to be immune from the PRC's political intervention if they were to be realized. Shortly before the opening of the March 1999 meeting, two groups of Taiwanese delegates were sent to lobby for more support. Some delegates went to Hong Kong, where the ISTWG meeting was being held. The DoH team and FMPAT rushed to Singapore and Malaysia, exhausting all their diplomatic and private connections to earn support.[32]

Taiwan's proposal was initiated smoothly. It garnered sponsorship from Singapore, the Philippines, Mexico, Malaysia, and Australia. However, the attitude of the PRC could not be predicted. The only thing the Taiwanese delegates knew was that the PRC was determined that no proposal from Taiwan be passed. Later it was discovered that the reason behind the PRC's refusal was purely political and had nothing to do with pharmaceuticals.[33] The ISTWG resolved that these projects could be conducted if the conflicts between Taiwan (and its U.S. sponsors) and the PRC could be solved. As with the political clashes since the normalization of U.S.–PRC relations, when the tension between the two countries waned, there was ultimately no reason for the PRC to impede an economic project like the proposed pharmaceutical regulatory network. After waiting for near two years after submission, Taiwan was finally granted a chance to build a stage for global conversation, a series of conference of its own.

The CDE soon prepared the first meeting of the AEPC network (hereafter, the APEC meeting), held in Taipei on May 7 and 8, 2000. Eight countries sent representatives, and various regional directors from leading companies also attended. It was the issue of bridging studies that brought these people here. Taiwan, they felt, occupied a position on the interpretation of ethnic difference that was opposite to Japan's. At the same time, the meeting was an occasion for Taiwan to lead a global conference on its own. It allowed Taiwanese officials to sit with key figures from around the world.

However, the CDE had not provided any scientific basis for its position.[34] It might not be necessary to demonstrate differences between Asians and Caucasians, because those differences are not in dispute. What the CDE sought was a pan-Asian study that would demonstrate how biologically "close" East Asian people were to

[32] K. C. Chen, one of the founders of the FMPAT, recalled in an interview that the visit was a rare success. "Though they are officials, Oliver Hu and Herng-Der Chern are professors and scholars. They helped us to explain the need for harmonization. As for me, I had just been inaugurated as president of the Federation of Asian Pharmaceutical Associations, the biggest organization of this kind in Asia. Thus, it was me who provided the channel needed to reach the top of each country. Fortunately, we obtained all we planned." Interview with K.C. Chen, Taipei, November 6, 2003.

[33] In February 1999, the U.S. Department of Defense issued a report on Security in the Taiwan Strait, mentioning an increasing missile threat by the PRC. In order to achieve effective control, this report recommended the introduction of a Theater Missile Defense (TMD) system that would include Japan, South Korea, and possibly Taiwan (later Taiwan was "formally" excluded by the U.S. but "informally" included by Japan as "peripheral"). This single explosive issue had an immediate impact on U.S. Secretary of State Madeline Albright's visit to the PRC in early March as well as the discussions at the ISTWG meeting during the same period.

[34] Internal documents show that the CDE did not have any idea of the extent to which ethnic difference among Asian races should be taken into account after the 2000 APEC meeting. See, for example, the meeting minutes of the 20th Government-Industry Joint Meeting on Clinical Trials, June 1, 2001.

each other; this would show that bridging studies were necessary and that a single bridging study for all East Asians would be adequate. Such a study appeared when Chern read in a local newspaper about a controversial scientific paper (Lin et al. 2001). This paper addressed the sensitive matter of the ethnic origin of the Minnan (Holonese) and Hakka ethnic groups (both together comprise the so-called "Taiwanese")[35], an issue made even more delicate by Taiwan's political status. This paper came to power the CDE's "voice" and served as the single piece of scientific literature that justified the CDE's policy on ethnic difference.

A briefly review of this paper is in order. Arguing against the assumption that the Taiwanese originated in North China and this belong to the great tradition of Han (華夏*huaxia*) ethnicity, this paper constructed a phylogenetic tree that measured the genetic distances between East Asian races, and the results intrigued readers. The tree shows that Taiwanese people have a close genetic relationship with southern Asian populations, which are said to be the descendants of the Yueh, a southeast coastal indigenous population. On the other hand, the body of this tree loosely encircles populations from the north, including northern Han, Hui, Man, Buriat, Uygur, Kazakhs, Inner Mongolian, Japanese, and Korean.

Despite this paper's claims of scientific objectivity, those familiar with Taiwan's politics can easily detect the study's implications. Taiwan has long been troubled by the question of how to identify itself as an entity separate from the PRC, and this paper seems to provide evidence for that identification. However, in the context of the E5 debate, this paper moved in an opposite direction. Chern pointed out to me on a diagram from Lin's paper (Fig. 2) how close East Asian populations are in comparison to Caucasians and to Blacks.

"Asians should be considered a group", Chern emphasized. "Holonese and Hakka belong to the group of the southern Han. But we should remember that Taiwan also has mainlanders, the northern Han if you like. To put it another way, we have both. If the northern Han are close to the Japanese and Koreans, we can say that Taiwan is perhaps the only state that has both kinds of Asians subjects. That is, we are the best place to conduct clinical trials," Chern asserted.

From a regulatory viewpoint, Chern's interpretation made sense, but it might be a shock to non-scientific readers. While lay audiences saw only the separation between Taiwan and the PRC, Chern saw continuity among all Asian populations, including Han Chinese. This paradox can only be understood if we attend to Taiwan's desire for *fasheng*. Ethnicity was not at stake in Lin's paper—national identity was. Chern's reading revealed a deeply embedded implication in Lin's "racist" discourse that secured the integrity of the Taiwanese state. Lin did not insist on congruence between ethnicity and nation-state as Japanese scientists might do; she just wanted to reject a nationalistic account that could justify the PRC's desire to intervene in Taiwan.

Chern's interpretation, though it may look like a betrayal of Lin, actually complemented her argument. His reading did not reject links to Mainland China, but

[35] This term contrasts Taiwanese with "mainlanders," people who emigrated from the mainland of China as a result of the civil war between the nationalist Kuomintang and the Chinese Communist Party after the end of the Second World War.

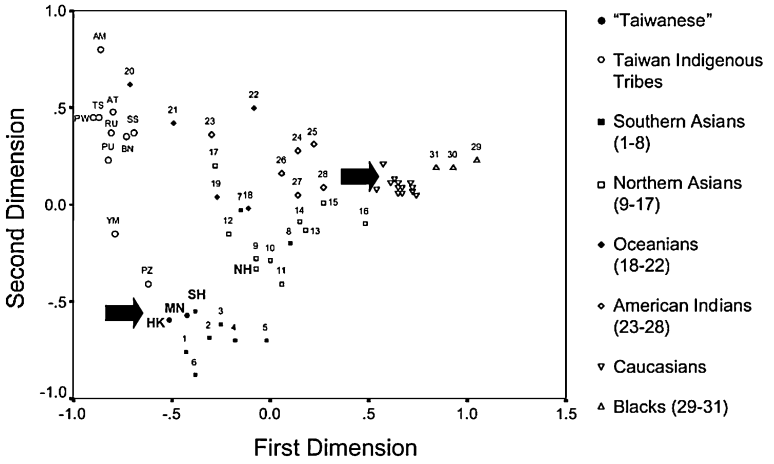


**Fig. 2** Correspondence analysis of "Taiwanese" with other ethnic groups. *Bold arrows* indicate the distance between the Taiwanese (MN and HK) and Caucasians and Blacks. Source: Lin et al. (2001), Fig. 3. *Arrows* are added by the author

it did construct more "bridges" between Taiwan and the world. And it thereby put Taiwan back on the world map as a state and circumvented the PRC in the process. The concept of bridging studies, in this sense, was a political statement: it did not overplay Taiwan's ethnic uniqueness (or the uniqueness of Han Chinese), which would have posed the danger of giving the PRC a reason to "unify" with Taiwan. Instead, it silently replaced the racist assertion that "Chinese are all over the world"—and therefore deserve clinical trials on their own subjects—with the global sentiment, "We are all Asians creating world harmony."

Lin's paper appeared in every subsequent discussion of the E5 guideline. Like a confident child who knew he would get the best possible score on whatever test he was given, the CDE knew that it had located the very piece of data that completed both its strategic discourse on bridging studies and Taiwan's integrity in the transnational network it created.

## 6 Reaching Out to the World, Traveling Around Asia: Sustaining the Voice

Still, Taiwan's voice on bridging studies had not been heard directly at the ICH. Thus, even as it was organizing APEC meetings, the CDE was eager to reach out to the annex of the ICH, the GCG. As mentioned previously, the GCG facilitates the implementation of ICH guidelines. For Taiwan, though, the GCG had strategic significance. Although it lacked the power to bring about any changes in the ICH's operations, it was the only place where the voice of non-ICH countries could be heard. For the ambitious CDE, it was the only available channel by which Taiwan's voice could be heard by the core of the ICH.

Because the GCG only worked with organizations, APEC was Taiwan's ticket on board.[36] It is hard to locate the point at which the CDE initiated its appeal for participation in GCG activities, but some hints of this were apparent at the 2000 APEC meeting, where Bertram A. Spiker, the PhRMA representative of the ICH Steering Meeting and the co-chair of GCG, was invited to make the closing remarks. At this meeting, Spiker was impressed by the CDE's bridging policy, and the effect was swift. Knowing that PhRMA would host a half-day satellite session before ICH5 in San Diego in November 2000, the CDE asked to present its policy on bridging studies there, and PhRMA agreed.

It was a win–win situation. PhRMA had a consistent stance that it did not want any "extra" trials—that is, trials demanded by regions other than those where trials were usually conducted, namely, the U.S. and Europe. Japan's participation at the ICH and the case of the E5 topic had complicated PhRMA's plan to unify all clinical trial standards. Moreover, as the E5 guideline emerged, nobody knew how to implement it or how to prevent requests for additional trials from being made by non-ICH counties. At this point, Taiwan was a good example. On the other hand, Taiwan saw these circumstances as an opportunity. The CDE knew that it was bridging studies that made its presence at the ICH possible. Unlike large developing countries like Russia and India, whose huge markets made them potential invitees to the ICH, Taiwan had to find other ways to catch up with the global.

Taiwan made the best use of its presentation. Herng-Der Chern gave a ten-minute talk as the APEC representative in a panel discussion, and Hong-Jen Chang (張鴻仁), then Deputy Director of Taiwan's DoH, presented Taiwan's efforts to catch up with the ICH on behalf of ICH-Taiwan. Chang became the first high-level government official to make an appearance on such an occasion. This conference enhanced the CDE's connection with the ICH. Important figures from the ICH member entities occupied center stage at the 2001 APEC meeting.[37]

But the CDE did not hold on to this conference, its metaphorical "microphone". APEC decided to move the next meeting, in 2002, to Tokyo and to return to Taipei in 2003. Then it moved to Seoul for the 2004 meeting, returned to Taipei in 2005, went on to Tokyo in 2006, and returned again to Taipei in 2007. When asked about the reasons for this arrangement, Herng-Der Chern, the back-stage force behind the meetings, told me that the CDE could host the meeting as long as it wished, but that Taiwan could not exist without other countries. It had been especially isolated from Asian networks like ASEAN and others in which the PRC dominates. Chern knew that any conference on East Asia without the PRC would fail. "If Taiwan hopes to be

[36] In addition to APEC, the following regional organizations were later invited for ICH6: the Pan American Network on Drug Regulatory Harmonization (PANDRH), the Association of South-East Asia Nations (ASEAN), the Gulf Cooperation Council (GCC), and the Southern African Development Community (SADC).

[37] These ICH-related participants were Elaine Esber, former FDA representative to ICH steering committee and co-chair of GCG; Robert O'Neill, E5 Expert Working Group member; Robert Temple; Bertram Spilker, co-chair of GCG; Yves Juillet, EFPIA's representative to the ICH Steering Committee; Uwoi Tohru (魚井徹), JPMA's representative to ICH Steering Committee; Mori Kazuhiko (森和彦), the MHLW's representative to the ICH Steering committee; and Sato Daisaku (佐藤大作), MHLW's ICH coordinator.

a real leader of the Asia-Pacific region," he reminded me, "it has to give this meeting some freedom to travel around. We will be much rewarded when it returns."

Chern was right. The theme of the 2003 APEC meeting shifted from the narrow subject of bridging studies to the broader issue of "Regulatory Communication," and the speakers were even more enticing than in 2001. In addition to those present at the 2001 meeting, two key persons, Murry M. Lumpkin, Principle Associate Commissioner of the FDA, and Thomas Lonngren, Executive Director of the European Agency for the Evaluation of Medicinal Products, joined the proceedings. Of course, they would not fly halfway around the world just for this conference, but since ICH6 was held in Osaka that year, the APEC meeting was intentionally arranged to directly follow it. Taiwan was still not a magnet for world's big names, but with APEC, it got close.

At the meeting, I spoke with Elaine Esber, an ICH founder who had been familiar with the CDE since its inception and had openly praised its E5 policy. She told me that it was her idea to have the APEC meeting back-to-back meeting with ICH6. I told her I appreciated her suggestion. Apparently, Chern and Esber had become friends. I commented to her about Chern's enthusiasm and aggressiveness in promoting Taiwan, and she smiled. "Yet he is always polite, isn't he?" she said.

## 7 Globalization, State and *Fasheng*: Challenges and Possibilities for STS

Let me review the points this paper has made. I began with a reflection on globalization. The ICH, at first glance, presents a conventional understanding of globalization as paving the way for the flow of commodities by diminishing the boundaries between states. However, the E5 issue complicates this worldview. The state, I claim, has its own regulatory rationality, and these priorities influence its response to globalization. These circumstances produce what I have described as a pharmaceutical world made up of islets connected by regulatory bridges.

In order to capture the dynamics of the process of the state regulatory engagement with globalization, this paper carefully analyzes the interaction in a step-by-step fashion, giving particular attention to the politics of *fasheng* and the ways that the state renders a voice for itself through the process of globalization. Taiwan's engagement with the ICH is a salient example of these issues. Taiwan is neither just another market for the pharmaceutical industry nor a place that passively accepts universal standards. As a state that has been officially ignored, Taiwan is always seeking opportunities to bring itself back to the global. The result, as we have seen in this paper, is the complicated interaction between Taiwan and the world surrounding the concept of bridging.

Taiwan's actions—in my terms, the "voice on the bridge"—require a new frame for evaluation. Departing from a "silent" mode in which its modest market and ambiguous political status did not allow it a say in the world of drug regulation, Taiwan bred its voice through the E5 controversy. But this perspective presents only one aspect of this voice. We see other aspects in the establishment of the CDE, the instrument for voicing; in Taiwan's effort to host a DIA workshop, a meaningful global forum for discussion; in the attempt to organize and sustain the APEC meetings, an international platform for drug regulation; and in seeking the "scientific

evidence" that validated bridging studies. All this created for Taiwan a voice that complemented its relationship with globalization. To reiterate: globalization is not a "to be or not to be" question for Taiwan; instead, the crucial issue is making and maintaining its voice to the world, its own expression or *fasheng*.

Although it is not the main goal of this paper, some updates should be made here for those who are curious about the consequences of Taiwan's engagement with the ICH. In a recent paper on the evolution of bridging studies in East Asia (Kuo 2008b), I argue that the year 2003 was a turning point at which the ICH, the representation of the "global," began losing its drive to lead regulatory harmonization. Japan and Taiwan, coincidentally, consolidated their own transnational visions of clinical trial regulations. They are "voices" in cooperation and competition. However, it is important to keep in mind that the promise of improving the regulatory environment does not equal progress in domestic industry and public health. Taiwan's recent pharmaceutical development, for instance, is stagnating from the lack of a comprehensive frame for directing the state's infrastructure and mission beyond its borders. Even so, I would not simply call this a "failure." Like all other states encountering globalization, Taiwan is refashioning itself through this process.

Finally, I would like to emphasize the significance of my exploration of this voice for readers of this journal. First, the process of Taiwan's *fasheng*, according to STS literature, resembles a "trial of strength" process as described by Bruno Latour in his study on Pasteur (1993). Indeed, on the surface both share some strategies and tactics in common; but the story of Taiwan's engagement with globalization is not a parodic version of a twentieth-century "Taiwanization of the world" in which Chern and later the CDE manipulate and scientifically justify the policy of bridging. And as such, this story is not just an STS case as such.

This paper also does not intend to suggest that the scientific justification of bridging has secured real statehood for Taiwan, although an incipient statehood sometimes seems visible on the horizon. Only a handful of international organizations, governmental or nongovernmental, include the Republic of China—Taiwan's official name—on their rosters. Even when Taiwan is allowed to join, its membership is limited and distorted, as if to say, "This is not a state." Such is the case with the ICH. Even though Taiwan was invited to the GCG, this was strictly on the behalf of APEC and under the unexceptionable name "Chinese Taipei." I have argued elsewhere that the building of Taiwan's practical statehood is not a planned project but rather the result of a historical contingency concerning the prospect of the country's population growth (Kuo 2002). The case of bridging study policy confirms Taiwan as what political scientists refer to as an "oddity" in a global world.

The STS essence of this story, I argue, lays at the interesting intersection of postcolonial technoscience and global politics, an emerging field that, as Warwick Anderson suggests (2002), science studies and cultural studies both fail to address. The respective situations of Taiwan and Taiwanese science in the world should be considered together, which poses certain questions: if science is not just a socially constructed fact or just in the service of some scientists' interest, what is its meaning to the world? If the state is not merely a faithful mediator between individuals and the global, how might the state behave differently given its historical roots, current predicament, and future visions? Although this paper cannot answer all of these questions, it reveals the necessity for new methodologies and problematics.

Let me conclude with the notion of the people's voice by Ranajit Guha (1988). According to Guha, this voice should be considered an *autonomous* domain. The exploration of this voice neither accuses any historiography of lacking such a voice nor argues for an ontological entity that makes such a voice. This paper treats Taiwan's "voice on the bridge" in the same manner. I would like to call it a "countermelody" that, along with existing scenarios of rejection or acceptance, composes a fugato called "globalization." Through this paper, Taiwan's voice on the bridge is restored.

I do not want to argue that a fugato sounds better than monophonic piece. Instead, I will share the portrait of culture by way of conclusion by Michael Fischer (2003).

> Culture is not a variable; culture is relational, it is elsewhere, it is in passage, it is where meaning is woven and renewed, often through gaps and silences, and forces beyond the conscious control of individuals, and yet the space where individual and institutional social responsibility and ethical struggle take place. (p.7)

I wonder whether this portrait applies to states at the global level if we swap the words "state" for "individual" and "globalization" for "culture." Globalization does not sweep all things away; in global pharmaceuticals, the state and regulatory science take on new lives. These "emergent forms of life", as Fischer would call them, pose challenges and possibilities for STS researchers.

## References


Abraham, J. (2002). The pharmaceutical industry as political player. *Lancet*, *360*, 1498–1502 (November).

Abraham, J., & Reed, T. (2002). Progress, innovation and regulatory science in drug development: the politics of international standard-setting. *Social Studies of Science*, *32*(2), 337–369.

Anderson, W. (2002). Introduction: postcolonial technoscience. *Social Studies of Science*, *32*(5–6), 643–658.

Applbaum, K. (2006). Educating for global mental health: American pharmaceutical companies and the adoption of SSRIs in Japan. In A. Petryna, A. Lakoff, & A. Kleinman (Eds.), *Global pharmaceuticals: ethics, markets, practices* (pp. 85–110). Durham, NC: Duke University Press.

Chen, K. C. (1998). ICH in Taiwan. *Drug Information Journal*, *32*(S), 1301–1307S.

Chern, H.-D. (1997). Canjia ICH4 ganxian yu jianyi: efficacy zu [參加 ICH4 感想與建議: Efficacy 組, Report on the participation of ICH4: the efficacy group]. TCOG News, no. 27. Retrieved at http://www.nhri.org.tw/nhri_org/ca/news/art27.htm#p2704, on August 11, 2003.

Chern, H.-D. (1998). 1998 DIA Taipei International Meeting," *ICH in Taiwan Bulletin* 4. Website version at http://www.cde.org.tw/03center/write/book04/DIA%201998%20Taipei%20International%20Conference.pdf. Retrieved on March 20, 2008.

Dumit, J. (2002). Drugs for life. *Molecular Interventions*, *2*, 124–127.

Epstein, S. (2007). *Inclusion: the politics of difference in medical research*. Chicago: University of Chicago Press.

Fischer, M. M. J. (2003). *Emergent forms of life and the anthropological voice*. Durham, NC: Duke University Press.

Galison, P., & Hevly B. (Eds). (1992). *Big science: the growth of large-scale research*. Stanford: Stanford University Press.

Gellner, E. (1983). *Nations and nationalism*. Oxford: Blackwell.

Greenberg, D. (1999). *The politics of pure science*. Chicago: Chicago University Press.

Guha, R. (1988). On some aspects of the historiography of colonial India. In R. Guha, & G. C. Spivak (Eds.), *Selected subaltern studies* (pp. 37–44). Oxford: Oxford University Press.

Hardt, M., & Negri, A. (2000). *Empire*. Cambridge, MA: Harvard University Press.

Hsiao, M.-L. (1998). Current status of clinical trials and GCP in Taiwan. *Drug Information Journal*, *32* (supplement), 1203S–1208S.

Hughes, T. (1979). The electrification of America: the system-builder. *Technology and Culture*, *20*(1), 125–161.
ICH, the. (2000). The Future of the ICH: Conference Statement by the ICH Steering Committee on the Occasion of the Fourth International Conference on Harmonisation. Website version available at http://www.ich.org/cache/compo/276-254-1.html. Retrieved on October 6, 2008.
ICH, the. (2002). The ICH Process for Harmonisation of Guidelines. Website version at http://www.ich.org/cache/compo/276-254-1.html. Retrieved on October 7, 2008.
ICH, the. (2008). Mission Statement of the ICH GCG. Website version available at http://www.ich.org/cache/compo/276-254-1.html. Retrieved on October 6, 2008.
Jasanoff, S. (2004). The idiom of co-production. In S. Jasanoff (Ed.), *States of knowledge: the co-production of science and the social order* (pp. 6–12). London and New York: Routledge.
Jasanoff, S. (2005). *Designs on nature: science and democracy in Europe and the United States*. Princeton, NJ: Princeton University Press.
Kuo, W.-H. (2002). When state and policies reproduce each other: making Taiwan a population control policy; making a population control policy for Taiwan. In A. K. L. Chan, G. K. Clancy, & J.-C. Loy (Eds.), *Historical perspectives on East Asian science, technology and medicine* (pp. 121–138). Singapore: Singapore University Press.
Kuo, W.-H. (2008a). Understanding race at the frontier of pharmaceutical regulation: an analysis of the racial difference debate at the ICH. *Journal of Law, Medicine, and Ethics*, *36*(3), 498–505.
Kuo, W.-H. (2008b). Acting with global science: pharmaceutical regulation as transnational vision and strategy. Paper presented in 4S annual conference, Rotterdam, 8.21–23, 2008.
Latour, B. (1993). *The pasteurization of France*, translated by Catherine Porter. Cambridge, MA: Harvard University Press.
Lin, M., Chu, C. C., Chang, S. L., Lee, H. L., Loo, J.-H., Akaza, T., et al. (2001). The origin of Minnan and Hakka, the so-called 'Taiwanese', inferred by HLA study. *Tissue Antigen*, *57*, 192–199 (March).
Lin, Y.-L., Chern, H.-D. & Chu, M.-L. (2003). Taiwan's experience with the assessment of the acceptability of the extrapolation of foreign clinical data for registration purposes. *Drug Information Journal*, *37*, 143–145. (November).
Murakami, Y. (村上陽一郎). (1998). *Anzengaku* [安全学, on security]. Tokyo: Seidosha.
Nutley, C. (Ed). (2000). The value & benefits of ICH to industry. Website version available at http://www.ich.org/MediaServer.jser?@_ID=458&@_MODE=GLB. Retrieved on October 6, 2008.
Petryna, A. (2005). Ethical variability: drug development and globalizing clinical trials. *American Ethnologist*, *32*(2), 183–197.
Petryna, A. (2006). Globalizing human subject research. In A. Petryna, A. Lakoff, & A. Kleinman (Eds.), *Global pharmaceuticals: ethics, markets, practices* (pp. 33–60). Durham, NC: Duke University Press.
Petryna, A., & Kleinman, A. (2006). The pharmaceutical nexus. In A. Petryna, A. Lakoff, & A. Kleinman (Eds.), *Global pharmaceuticals: ethics, markets, practices* (pp. 1–32). Durham, NC: Duke University Press.
Rabinow, P. (1999). *French DNA: trouble in purgatory*. Chicago: University of Chicago Press.
Shapin, S., & Schaffer, S. (1986). *Leviathan and the air-pump: Hobbes, Boyle, and the experimental life*. Princeton, NJ: Princeton University Press.
Sunder Rajan, K. (2006). *Biocapital: the constitution of postgenomic life*. Durham, NC: Duke University Press.
Sunder Rajan, K. (2007). Biocapital: Indian clinical trials and surplus health. *New Left Review* (August 2007). Website version at http://www.forliberation.org/site/archive/issue0807/article020807.htm. Retrieved on October 7, 2008.
Takezawa, Y. (竹澤泰子) (Ed.) (2005). *Jinshugainen no fuhensei wo tou: seiyoteki paradaimu wo koete* [人種概念の普遍性を問う： 西洋的パラダイムを越えて, is race a universal idea? transcending the Western paradigm]. Kyoto: Jimbunshoin.
Turner, V. (1969). *The ritual process: structure and anti-structure*. Chicago: Aldine.
Wang, H.-l. (2000). Rethinking the global and the National: reflections on National imaginations in Taiwan. *Theory, Culture and Society*, *17*(4), 93–117.
Wang, H.-l. (2002). Mind the gap: on post-national idea(l)s and the nationalist reality. *Social Analysis*, *46* (2), 139–147.