

**Bring the State Back in the Global/Genomic World:
Racial Difference and the Transforming States of Japan, Taiwan and Singapore**

Abstract

Observing the trend that drugs have become more standardized and globalized in the past decade, this paper looks at how East Asia has responded to this change. Considered both as powerful commodities and scientific advancements designed to improve people's health, pharmaceuticals make for a globally interesting narrative subject compared to other products. This also merits an anthropological investigation for the reason that at the interfaces between the West and the East, between the global and the local, between politics and science, we observe issues and disputes that involve how racial difference should be dealt with in an attempt to eliminate unnecessary clinical trials for new drug approvals.

Based on fieldwork surrounding the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), this study is intended as a “deep description” of East Asian states’ response to the attempt to globalize pharmaceuticals and to do this by exploring the intricate process of negotiation, communication and self-government. It will venture beyond a simple explanation of how globalization is sweeping over the non-western region. Japan, Taiwan and Singapore are the subjects of our investigation, and the question at hand is as follows. Through the single example of pharmaceuticals, what are the emerging characteristics of how these three Asian nations are coping with globalization and how does each negotiate the universal standard proposed, while maintaining the overruling legal need to not compromise on health at a national level?

Although “globalization” is the theme of this study, this paper does not wish to bring it to the foreground of our discussion. What we intend to focus on is how “state” and “race”, two classical concepts that constitute a national state, are firstly challenged by global capitalism, and then referenced by the new strategies and visions being developed. Based on the idea that understanding the differences in their respective reactions to change will help our recognition of the nature of states from the global viewpoint, this study would like to call the need of ethnographies for these emerging subjects.

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Racial Difference and the Transforming States of Japan, Taiwan and Singapore

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Introduction

Observing the recent trend of drugs becoming more standardized and globalized over the past decade, this study looks at how Asia has responded to this change. When considering how the global interacts with the local, previous literature has tended to focus on the former, emphasizing the tactics used to impose on individuals and local groups. However, this study will venture beyond a simple explanation of how globalization is sweeping over the non-Western region. Taking into consideration the usual phenomenon of the local's resistance to globalization, it will work at the national level, exploring the intricate processes of negotiation, communication and self-government that occurs when states deal with global capitalism.

The aim of the inquiry at hand is to ask the following. Through the single example of pharmaceuticals, what are the emerging characteristics of three East Asian nations, Japan, Taiwan and Singapore, when coping with globalization and how does each negotiate the requirements for imported drug products, while maintaining the overruling legal need to not compromise health at a national level? Another interesting aspect of this debate is how these nations' different responses involve the ever-present issue of "racial differences." Here, this term does not refer to the typical Caucasian versus non-Caucasian dynamic. Regarded as a "non-tariff barrier" from a narrow-sighted business viewpoint, racial difference becomes a reference surpassing skin color and is imbedded deep in the

cultural and social nuances that separate the three individual nations.

Indeed, it merits an anthropological investigation for the reason that at the interfaces between the West and the non-Western, the global and the local, politics and science, we observe issues and disputes regarding how racial difference should be managed in an attempt to penetrate the state boundary by imposing a universal standard for new drug approvals. It is for this reason that the state is the subject of this study. It is chosen because it is, as Ernest Gellner calls, a political shell in which a culture can be shared and nationalism can be crafted (Gellner 1983). From an interpretive perspective, it is the starting point where we recognize the characteristics of a territory where people work and live from the global viewpoint. Unlike the conventional understanding that the state is either an apparatus simply delivering capitalism to its people without discrepancy or an empty promise after globalization, this study shows its subjectivity as an actor in the global stage. We believe that only by understanding differences in their respective reaction to change will we recognize the post globalization nature of states, their visions of the world and their goals.

The field for this work is conferences surrounding the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH.) For more about this conference, please see its website at www.ich.org. As the first ever attempt to standardize all standards for proprietary drugs, many meetings and symposiums concerning the ICH have been and are held at different levels for different guidelines. They are what I would call lively interfaces where people come, meet, share, update, and refresh themselves, and I have three reasons for choosing them for ethnography. First, the conference is itself a discursive site in which the state presents its current attitudes on certain issues or even brings in new topics. As one would expect

with possible responses and actions, these policies may not yet have been written down or even fully formed. Unlike already established regulations and published papers, these cutting edge ideas are fresh and have the potential to change or to adopt one form from another. As a modern version of the “Universal Exhibition,” conferences visualize and verbalized the desire and will of the state’s actions and thoughts, and thus should be considered a site for interpretative ethnography.

The second reason is related to the conferences’ interactive function. As occasions for discussion or interchanges of opinions, conferences involve two seemingly contradictory functions of comparing different opinions at one hand, and of working together or exchanging views, on the other. It is an arena where both controversies and convention are expected. This is especially true at the ICH and is specifically true for the topic of racial differences. As to the topic itself, the ICH is an attempt to create a universal standard for drugs by neglecting as much as possible bodily differences. However, the issue of ethnicity has resulted in differences among various races. Thus, the conference on this issue presents the best site to see what opinions are expressed and how they tended to merge into one standard. In addition, the contradictory nature of the conference provides the best site where the local acts in the global. Echoing Bruno Latour’s notion about the making of social actions (Latour 1987), my ethnographical investigation explores the idea that the different interests among states have made conferences a complex zone where various people are compelled to trade information and visions.

The third reason I argue for conferences as an ethnographic site can be found in their accumulative and periodical nature. The participants at a conference act upon the information they receive; then their actions will be presented at the next conference along

with others. Additionally, through written and visual technologies, such as proceedings and slides published in papers or posted on websites, the effect of the information is long lasting, spreads and generates new information. It is a living archive. Until a policy can be formed and settled, the information conferences are the only source where these actions can be traced and analyzed. Although it is of no doubt that oral interviews cannot be excluded from our scrutiny, my field experience convinces me that the conferences themselves seem to be more reliable. Already heavily occupied by everyday routine, many experts rely a great deal on this kind of material as a reference for the reconstruction of their memories and these memories represent the nature of the conferences, both fragmental and periodical.

Taking advantages of the rich archive formed by the ICH, this paper's aim is to carry out an interpretative ethnography on the real-time behavior of Asian states regarding globalization. We will see in this paper how "state" and "race", two classical concepts that constitute a national state, were firstly challenged by science and global politics, and then referenced by the new strategies and visions that are being developed.

One attempting to fit all: the uncanny capitalism

In this section I will explore the conventional understanding of pharmaceutical industry, and then provide a new interpretation from the perspective of standardization. There is no doubt that drug development is a long, expensive, high-risk activity. Development times, as given by the PhRMA, have been increasing steadily over the past twenty years to an average of thirteen years (PhRMA 2002). However, there is a need to question what the basis of these numbers is. Let us use the data the PhRMA provides as

an example. It claims that the average cost to bring a new chemical entity (NCE) to the market is in excess of 800 millions US dollars, but in fact development costs of a specific drug is not nearly that much. Much of the cost is spent on NCEs that fail to make the standard during the process of development. The number of these NCEs is astonishing. Only twenty out of five thousand compounds that are screened enter preclinical testing, and only one drug in five that enters clinical trials is approved for use. In other words, most of these costs are spent on the failures and the need to keep an extremely high standard.

Government intervention is crucial in this process, since health is the last thing to be compromised. Nonetheless, this standard is now higher than it was prior to the early 1960s. The amendments of Food and Drug Acts in 1962 required firms to demonstrate the efficacy, as well as the safety of new products, through extensive use of human clinical trials. These more rigorous requirements have lengthened the pre-marketing period for new products. In the mid 1970s, statistics became involved as clinical trials became highly complicated and difficult to manage. Both the regulatory side and industry hired more experts and statisticians for each clinical trial and their efforts made it a highly technical and abstract task to outsiders.

Like other sectors, the pharmaceutical industry has long sought a global market, and the desire has become more intensive in the past twenty years. Although extremely high standards have protected the monopoly by raising the barriers to new market entrants, for those that can afford to pass, there is an urgent need to get back the costs they have paid as soon as possible. The reason is simple, the effective marketing period of approved drugs has shortened and effectively so has the period in which the drug is protected by a patent. Although the regulations set by other governments are not as high as in the United

States, they cannot be simply replaced because of the special requirements and standards used. To a global pharmaceutical company, there appears to be no need to fulfill the increasingly difficult standards one by one. Thus, the standardization of the standards became important. It does not only make it easier to move drugs from one country to another; it creates a larger single market that would reduce costs.

From the perspective of standardization, the ICH presents a unique global project that has never previously existed. Unlike other conferences of this kind that consists of only governments or non-government organizations, the ICH allows industry to work together with the regulators. It knows well that without the industry there would be no initiative to create innovative drugs; however, it is also necessary to have regulators sitting in the conference, since only they can decide whether a product is granted approval. Thus, the ICH had a complicated mission to achieve and it is both commercial and scientific. It is an attempt to “smooth out” these non-tariff barriers and also an attempt in the area of public health to eliminate unnecessary administrative regulations so that the most advanced medicine available can be delivered to the patients in need.

It is important to note its exclusive nature and complicated working process. Unlike other scientific meetings, which are open to all, the ICH carefully selected Europe, United States and Japan, whose pharmaceutical market represents over 85% of the world. The regulators from the three regions and also industry representatives make up the main body of this conference. The International Federation of Pharmaceutical Manufacturing Association, which is an observer, provides the Secretariat and administrative aids needed. In addition, in order to make sure that the guidelines it makes are implemented, the ICH created a complicated working process to achieve consensus. Every proposal for new harmonization has to be initiated by the Steering Committee and discussed in an expert

working group (EWG) assigned to it. Every guideline has to be agreed by all parties before being confirmed and released. Even taking into account these steps, what makes the ICH unique is its final step. A follow-up mechanism is applied to see whether the guidelines are adopted by local regulatory agencies within six months after release. With this lengthy process, a guideline requires at least twelve to eighteen months to be implemented.

Even so, the ICH has achieved much since its foundation in 1990. Up to its sixth conference (ICH6) held in Osaka in November 2003, fifty-four guidelines have been finalized and some others are in the process for harmonization. Industry certainly appreciates. As Stuart R. Walker of CMR international praised, “I believe that the pharmaceutical industry must continue to strongly support the ICH program. As a result of this initiative, the drug regulatory process has become smoother, quicker and less burdensome (IFPMA 2000, p.9). It further attempts to spread the new standard to non-ICH countries. Starting in 1999, the ICH Global Cooperation Group (GCG) was organized and serves as a bridge that reaches out to other countries that are affected by these guidelines. As written, the objective of this group is “to act as a resource for the understanding, and even acceptance, of many of the guidelines” (IFPMA 2000, p.10). Through the standardization of the standards, the ICH continues working to achieve a single global market/health community. For the ICH, one will finally fit all.

One request; three answers: racial difference and the state in the ICH

The East Asian states encountered the ICH in various situations and at different

time points. The request is simple, “to eliminate unnecessary clinical trials”, yet each state responded differently. I will introduce Japan, Taiwan and Singapore, in the order of their appearance, outlining the international situation that they met at the ICH and then their first responses when encountering the question of standardization.

Japan was the first state that interacted with the ICH. Compared to the Europe and United States, where almost all global pharmaceutical industries are located, Japan was involved to the ICH not because of its ability to carry out research and development on pharmaceuticals, but because of its incomparably huge drug market and tough regulation requirements. Before 1986, almost all products that sought a market in Japan had to repeat all the clinical trials required in Japan using Japanese subjects. Even after 1986, when a notification was enacted allowing “in principle” the acceptance of the foreign data, almost no product was granted a waiver. Industry complained that Japan was practicing protectionism with drugs, and it became a target for blame.

It was Japan that brought up the issue of racial difference at the ICH. Doi Osamu, the Japanese representative, thought that it was crucial in judging whether the foreign data was acceptable and the consensus on this topic should be decided at a scientific occasion like the ICH. Upon this insistence, ethnicity was agreed as a topic for discussion. At that time, nobody could image that this later called “E5” issue (the fifth issue to make a guideline under the category of efficacy) became one of the most difficult topics ever in the ICH history. Six years were spent and only a vague guideline was formed. As I will mention later in this section, its vagueness and incompleteness gave Taiwan a chance to speak for itself.

It is not necessary to review in detail the tiresome process of discussion on racial differences at the EWG. To be brief, Europe presumed that individual variation is larger

than interethnic differences and that this supported the idea that further clinical trials should be added only if a real difference among Asians could be proved. On the other hand, assuming the uniqueness and homogeneity of the Japanese race, Japan insisted that no clinical trials should be waived unless the similarity between the Japanese and Caucasians could be proved. Therefore, after an agreement on waivers of PK studies, several proposals were submitted in two divergent directions. While Europe and United States asked for more waivers on Phase II and III studies, Japan, in order to discover possible differences, expected a clinical trial system to have equal contributions of subjects enrolled; that is, Caucasians, Blacks and Asians (i.e., Japanese). None of these proposals pleased all parties, although they were scientists and experts, and deadlock resulted.

An FDA expert's suggestion rescued the dialogue. As a vague concept serving well in both proposals, the idea of "bridging studies" became the key term in making the guideline on racial difference. It was a political compromise. From the Western viewpoint, a bridging study was a test to judge whether the existing data can be extrapolated to the region where the product was seeking to be marketed and was only to be applied when the product was suspected as being racial sensitive. However, in Japan's thought, the bridging study functioned quite differently. Formatted as a full study, but using fewer samples, the bridging study was a local study especially for Japan. It was mandatory unless the applicant could prove similarity of the PK, PD and dose-response curve between Japanese and foreigners. The guideline was finally formed at the ICH4 in 1997 and was implemented in 1998.

Taiwan started noticing the E5 issue at the ICH3 but did not become actively involved until the guideline was implemented. There were two reasons. First, although

hosting 30% of the population of the world, the pharmaceutical market in Asia outside of Japan remained small. Taiwan, like other Asian states, felt highly pressured to bargain for more local trials before granting approvals, not withstanding the regulations on new drug approvals by the global industry. Second and more specifically is Taiwan's political situation. Because of the PRC's illegal interventions under international law, Taiwan has failed to be allowed to join any international organizations for governments, and medical ones are no exception. Although some Taiwanese experts had seen the need to form a network on the regulatory science in Asia, it was hard to realize this without a specific focus.

Agreement on the E5 guideline gave Taiwan a concrete topic to speak out about. Contrasting Japan's ambiguous attitude toward this guideline, the Taiwanese government announced immediately that it would like to be the first non-ICH state in Asia that would adopt this guideline, including the touchiest parts of the E5. The Center for Drug Evaluation (CDE), a FDA like institute, was established in July 1998, offering high quality in-house reviews on new drug applications. It also, in reality, took responsibility for the implementation of the ICH guidelines and handling all international affairs related to regulatory science on drugs.

What made the CDE famous are its evaluations concerning racial differences. On the one hand, it recognized that there were biological differences between Asians and Caucasians; nonetheless it did not insist on racial uniqueness. Based on a genetic survey of Asian populations, the CDE required bridging studies only when the application was considered ethnically sensitive, and all Asian data conducted outside of Taiwan was welcome. Up to 2003, only fifteen out of sixty-two applications were asked to carry out bridging studies, and all of them had convincing reasons for the request. Its

aggressiveness attracted international notice, resulting in it leading a forum working on bridging studies at the APEC, the only international organization where Taiwan is recognized as a state. Starting in 2000, the APEC network provided Taiwan with a way into the ICH. It was invited to present, as the APEC representative, at the satellite meetings of ICH5 and ICH6. It was characterized as an exemplar to show how a non-ICH country deals with the global pharmaceutical industry. Unlike Japan's passive engagement in the process of globalization, Taiwan, which has been long isolated from the world, embraced it as a chance to be heard and made the best use of it.

Among the industrial Asian states, Singapore was relatively behind in following development of the ICH. Although, in 1995, Singapore was proposed as the coordination center for good clinical practice (CCGCP), as an aid to its burgeoning biotechnology, its regulation of drugs was still behind other countries. It did not renew its regulating system until 1998, when a center for drug evaluation was established involving the collaboration of the National Science and Technology Board, the Ministry of Health, and Singapore General Hospital. This developed slowly before being incorporated into the Health Science Authority (HSA), a new institute derived from the existing regulatory section of the Ministry of Health, in 2001. Singapore not only missed the debate over the E5 issue, in which Japan was hugely involved during the early 1990s, it also missed the chance to form a professional and independent institute, like Taiwan did, in the late 1990s.

However, this does not mean that Singapore has no chance to catch up with other Asian states. I have discussed APEC as the gateway for Taiwan to join global village. For Singapore, ASEAN is its platform. The initiative for harmonization of pharmaceuticals in the ASEAN countries is economic. There is a hope to create a single pharmaceutical market through mutual recognition among the different regulatory authorities. A timetable

has been set out, whereby the process would start in 2002 and there would be an implementation of harmonization starting by January 2005.

Even so, Singapore's role in ASEAN is ambiguous. Although ASEAN's goal is clear, what it needs does not well match with Singapore's needs. Singapore is rich and capable enough of enjoying the most advanced chemicals in the world, not just generics of variable quality. On the other hand, Singapore's market is too small to make any claim on the global industry. Like Taiwan, Singapore also needs a regional network that it can rely on. Thus, while it has started being involved in some ASEAN activities, it also keeps showing up at APEC. Even as the global industries set up their Asian subsidiaries in Singapore, it still cannot find its position in the global network.

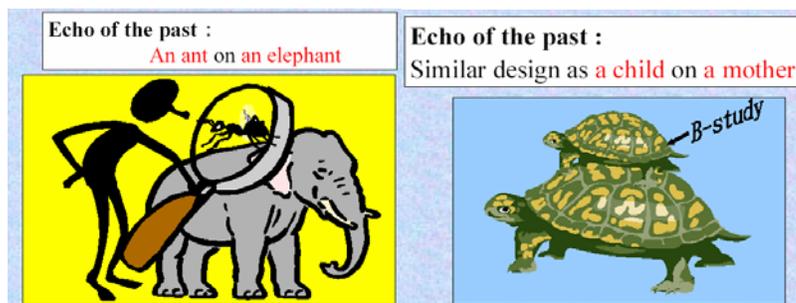
Crafting “genomic” race, saving the state by more bridges, and finding self in global networks: three post-bridging study responses

In this section, I will continue to introduce the strategies Japan, Taiwan and Singapore developed to cope with bridging studies. I will argue that although these responses are related to each other, these responses are distinct. Each state has its own vision and emphasis, which cannot be easily compromised by commercial concerns.

The first state to be discussed is Japan. As described in previous section, bridging studies are not the solution Japan expected. As described by two analogies, the Japanese have been portrayed as either an ant lying on the huge foreign data of an elephant or a baby turtle (bridging data to be born) on the back of its mother (existing foreign data) (Figure 1). Clinical trials in Japan are considered to follow those of foreign countries and the sampling size required is extremely small. For Japan it is regional discrimination; its

thoughts on globalization are that of harmony and Japan's contribution has to be clearly present.

Figure 1 Echo of the past: Japanese impression on bridging study



Source: Mori Kazuhiko's presentation in the APEC 2003 meeting, Taipei, November 17-18, 2003.

Japan's emphasis is clearly to ensure the presence of the Japanese race in clinical trials and the simultaneity of its involvement. It did this by rejecting "retrospective" bridging studies and the approval rate is pretty low at 14% in the total up to October 2003.

Meanwhile, a new discourse called "global drug development" was proposed. It is not a new approach, but in the context of Japan's E5 policy, it must be considered a solution that fulfills two requirements: enough enrollment of Japanese subjects and simultaneous clinical trial design.

For this purpose, two newly developed sciences, the Advanced Life Science Information System (ALIS) and pharmacogenetics, have been introduced to serve this need. The ALIS is a website database on the Japanese genome. It consists of several databanks and is open to the public. Although it is taking an enormous amount of money to achieve this, obviously Japan has its own concerns with this. It seems that Japan want to redefine the Japanese race by this genomic information, as one MHLW official admitted: "from now on the intrinsic factors of racial difference can be replaced by the

genome.”

Yet, this new definition still requires a theoretical tool to make it work in global trials. A statistical method, which can be called “genomic statistics”, was thus created to serve this need. It was promoted by Takeuchi Masahiro and the Kitasato-Harvard symposium was the place to realize his vision. Starting from 2000, this symposium served as an informal channel between the MHLW and the FDA experts on clinical trials. The main idea is as follows. In order to avoid population bias, the genomic information is applied to select the best target groups for clinical trials. Only through this design, can a simultaneous global trial program can be conducted.

According to Takeuchi, it seems that Japan has given up its cultural assumption to embrace the globalization. Indeed, genomics is not a science that belongs to Japan exclusively. However, we should also keep in mind that genomics is an expensive science that not many states can afford. Though not claiming this clearly, Japan is willing to spend as much money as needed to prove their racial uniqueness. What science does not say to us is why Japan is able to lift the bar on cultural protectionism; the reason is because a higher standard of genomics will replace it. Benefiting from its advance science, Japan does not have to worry about competing with other Asian races in the global era. When I reminded Takeuchi that in his explanation of the global clinical trials he always used “Japanese” where he should have used “Asians,” he gave me a charming smile and said: “Well, yes. But do you think it will make any difference if I do?”

Unlike Japan that chose to focus on the concept of the Japanese race, Taiwan tries to confirm the existence of the Taiwanese state. Although the CDE’s strategy to separate race from the state was successful, this advantage is losing as the paradigm was shifting to global drug development. Responding to this, three statistical methods were presented

in the 2003 APEC meeting to “save” bridging studies under this new scheme (CDE 2003).

The first is the group sequential method. It is proposed to facilitate a practical approach that includes of patients from the new region as a part of the recruitment of the whole study for the submission to the original region; that is, the bridging study is considered a sub-study of a “whole” trial. In order to ensure the consistency of the study protocol, special sample sizes and design are required. The second strategy can be called “weighted/discounted” approach. It is derived from the traditional Z-test method, arguing that while conducting the bridging study, the prior information obtained from the study in the original region will hugely affect the partition of sample space in the new study, thus the result obtained requires to be weighted according to the region in which it is conducted. The third strategy can be named “multi-centered/ hierarchical.” Recognizing the fact that Asia-Pacific region is small when bargaining a full clinical trial, this statistical method constructs a hierarchical operational structure that groups the centers recruited in a global clinical trial. In order to have reasonable measures for all regions in which the product would seek to be marketed, this method insists that every region should have a representative center and a “state-national effect” should be attached.

At first glance, these methods are nothing but scientific elaborations. However, like Japan’s proposal in genomics, there are assumptions hiding behind these methods. Using highly abstract statistical methods, these strategies do not only want to prove that bridging studies are still workable, they also try to emphasize the importance of “regional differences”, which do not appear in the E5 guideline, and ask for subjects to be enrolled from every state where the product is to be marketed. Despite the differences in statistical methodologies, the goals are similar. They do not necessarily reflect the trend of the

CDE's policies; instead, they provide visions that Taiwan can follow while the country welcomes globalization.

Compared to Japan and Taiwan, Singapore was far behind at the ICH. Worse, its ethnic diversity is more complicated. It would seem there is no way for Singapore to catch up with other Asian states in the global era. However, Singapore's strategy is to just ignore racial difference so its can "skip" the dispute over bridging studies. It is able to provide the best sites for clinical trials to study Asian people, but does not apply the results to its nationals. Identifying itself as a node in global business, Singapore seems to want to be a global state, a state with no local characteristics. As one Singaporean official claimed at an APEC meeting: "if we are global, there will be no need to bridge."

This strategy can be seen in its new reviewing system, which features two components. The first is the "verification" evaluation, the quickest route applicable to new drugs that have been granted marketing approval by major advanced regulatory agencies. As part of the second-tier drug approval system, Singapore is hoping to accept the results made by these authorities to shorten the time to drug accessibility from the primary reviewers. The aim is clear, since it is hard for Singapore to be a primary reviewer in the world, it hopes to be the first country in East Asia that has access to the latest drugs marketed in the most advanced countries. Secondly, this system requires good connections to countries inside and outside of Asia, and Singapore is qualified. On the one hand, Singapore maintains its former connections. It re-links with these states by mutual recognition and free-trade treaties. On the other hand, it makes connections to states within Asia as well. It does so through regional organizations. While joining the APEC network, Singapore continues participating in the making of ASEAN common technical document (ACTD) with Thailand and Malaysia.

One cannot say that Singapore is the only player to make this global network happen. However, the only thing we can be sure of is that Singapore will definitely benefit from this homogenous market of pharmaceuticals. This is the way Singapore chooses to survive. Unlike Japan's vision of a national state made up of a homogenous Japanese race, or Taiwan's struggle to make itself recognizable as a state, Singapore is seeking itself through global networking. The network exists and therefore the state lives.

Put the State back in the global/genomic world

Using the standardization of the requirements for new pharmaceuticals, this paper examines how East Asian states have coped with the impact of this process. It argues that no state behaves alike in the face of global capitalism; only at the lively interfaces where the state meets the global can we identify their distinct characteristics, which I have named the ethnography of the state. Following Michael Fischer and George Marcus' notion regarding anthropology as cultural critique for the world political economy (Chapter 4), I suggest another direction, where it is necessary to incorporate cultural factors into the traditional interpretation of the modern world and in which the state has been either simply ignored or replaced by transnational terms such as "colonization" or "class."

In the case of pharmaceuticals, this paper would like to portray the state as a regulatory body, an intermediate matrix between the individuals and the global. It completes with others in the world while maintaining its ruling legitimacy in the name of health and thus the state has to create ways to survive, visions to develop, and goals to accomplish, not all of which are mechanical or utilitarian thoughts. At this point, I believe

interpretative ethnography is useful.

For interpreting the state's behavior, this paper brings up the issue of racial difference. As one of the traditional elements that constructed national states and nationalism, race is perhaps the first that has been challenged and buried into the waves of globalization. This is especially true of the nationalisms of the East Asia states, where the "imagined communities" are achieved by many factors other than race (Anderson 1983). Thus, when it was brought up at the ICH, it was already not simply a call back to nationalism. As this paper has tried to show, race has two functions in this story. First, race is itself a topic in a social context, which is fluid and always questionable. Any scientific attempt to clarify it creates more confusion and reveals the cultural and social assumptions behind it. Second, race is a "lens" that gathers the observer's attention. Borrowing Clifford Geertz's analogy of cock fighting (Geertz 1973), race is an issue through which we appreciate the deep play of Asian states in the ICH.

Three transforming views on globalization and the state/race are described. Japan seems to be the only state that holds strongly to the concept of a pure Japanese race. It does not mean that this idea faithfully reflects either the population composition of the Japanese or what Japanese individuals really think of themselves. Instead, it presents a vision of the Japanese state clashing with globalization. According to this vision, the Japanese race and the Japanese state are two sides of the same coin. As we can see from Japan's reaction at the ICH on racial differences, this vision emphasizes the race more on its collectivity than purity. Simultaneously, global drug development nicely realizes its expectation. In order to ensure the niche of Japan, race is the cause for making such a claim, and the state is the subject that insists and benefits from it.

Taiwan has another concern about its race/statehood. Unlike other more "normal"

states, Taiwan is always eager to prove itself a good “citizen” in the global village. This desire drives it to extremes. The greatest and the best are its immediate goals and missions. This does not reflect faithfully the real achievements of Taiwan in the world. It is a vision of the Taiwanese state embracing globalization. As seen in the ICH, although bridging studies presume a worldview of “West-center; East-peripheral”, this is not a problem for Taiwan. Not yet considering whether it should resist or accept, for Taiwan, globalization presumes formal recognition by the world and this should be welcomed. With the same logic, race gives Taiwan a bridge to the world. It always claims that E5 guideline should be considered a “regional” problem rather than one for a single state, and, while Japan started pushing the worldview on global clinical trials by genomics, Taiwan survives bridging studies by making statistical bridges to others. Although these methods are not yet ready for implementation into policies, the vision is to maintain Taiwan’s global visibility and this will keep leading these strategies as long as it can protect its statehood through globalization.

Shining through its biotechnology, Singapore is recognized as a competitive spot in the network of global business. Very few remember the small city-state’s complex racial composition and its government tends not to remind anyone. It is a vision of the Singaporean state than can survive globalization. Unlike Taiwan, which recognized Asian racial differences and took advantage of these through bridging studies, Singapore does not see any benefit because of the complexity of its racial structure and of possible damage to its politics and economy. As a new factor added to global clinical trials, race involves nothing but a chance for contract research organization business. Singapore’s strategy is thus to boost pharmaceutical sector in Asia, and to be its hub.

Although the state is the main concern of this paper, we do not intend to reject other

concerns that link the local to the global within the topic of the body and drugs are major challenges to the state's aim of "protecting its people's health." At this point, this paper has shown that each Asian country has its own concerns, which are not exclusively related to health *per se*. Nonetheless, what entity other than the state can serve as the ultimate guardian when dealing with this global risk? Globalization does not sweep all things away, as many have claimed. Among the genomic/globalized world states, race has gained new life. One must argue that it is too early to declare the funeral of the state and race in the name of "globalization"; the contribution of this paper is that it fundamentally shows how this world is being referenced and changed in terms of state and race.

As an unfinished conclusion, let me cite Gellner's observation on the state in the modern world. Viewing two ethnographic maps before and after the age of nationalism and looking at the ethnographic and political map of the modern world, he observes: "there is little shading; neat flat surfaces are clearly separated from each other, ...we see an overwhelming part of political authority has been concentrated in the hands of one kind of institution, a reasonably large and well-centralized state" (pp.139-140). Upon this notion, this paper further argues that every state deserves ethnography. Gellner is right. In the age of globalization, the state, still, matters.

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