"Good" Manufacturing by Whose Standards? Remaking Concepts of Quality, Safety, and Value in the Production of Tibetan Medicines

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Abstract

This essay analyzes the impacts of global and national pharmaceutical governance on the production of traditional medicines—specifically the making and marketing of Tibetan medicines in contemporary China. Based on research conducted in Tibetan medical factories and with practitioners, producers, and consumers of Tibetan medicines in the Tibet Autonomous Region (TAR) and Qinghai Province between 2002–2010, this article presents ethnographic evidence for the ways Tibetan knowledge systems and the value of medicines themselves are being transformed through interlinked engagements with science, technology, and the market. I focus on the implementation of Good Manufacturing Practices (GMP) and related regulations: state-mandated standards that govern the conditions under which raw materials are evaluated, medicines are made, and finished products are sold. This article responds to calls for an anthropology of pharmaceutical practice in the context of social transformation. I propose that ethnography of Tibetan pharmaceutical production provides an apt illustration of global governance in action because it shows how shifts in med-

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ical production practices are tied to much larger processes of political and economic change within China and beyond. Further, my examination of points of incommensurability and ambivalence with respect to GMP regulations contributes to an anthropological analysis of the constitutive role cultural politics plays in the construction of value and meaning with respect to traditional medicine. [Keywords: China, Tibet, traditional medicine, Good Manufacturing Practices, governance, commoditization, cultural identity]

> *"It is not a problem to make money. The problem is how we make the medicines now, what the ingredients are like, how they are collected. Before, we prepared medicines by first harvesting the ingredients well—taking care with the time we collect, the tastes of the medicines, how much we take when, the nature of our minds when we collected. Then we mixed the ingredients together and ground them by hand. If you read the texts, there are even different descriptions of how your body should feel—where you should be in pain—after making medicines. But now, from Beijing and other parts in China and the world that buy our medicine, they tell us that each ingredient has to be clean, and that you should mix the medicines in big machines. But what do they mean by 'clean'? It is different than how we have been taught to make medicines. Now they even make new kind of* rilbu [Tibetan for 'pill']*, that aren't really* rilbu. *They call these medicines 'capsule.' They are strange, but people say they're cleaner. They look like western medicine. We make a lot of them."*
>
> — A Tibetan doctor in Lhasa, speaking to the author in the Tibet Autonomous Region, China (October 2002)

> *"Good Manufacturing Practice (GMP) is like the Cultural Revolution. But it is worse, because it is not just in China. It is across the whole world."*
>
> — A Tibetan doctor and monk, speaking to the author in Washington, DC (November 2003)

Introduction

This essay analyzes the impacts of global and national pharmaceutical governance on the production of Asian medicines—specifically the making and marketing of Tibetan medicines in contemporary China. Based on research conducted in Tibetan medical factories and with practitioners,

producers, and consumers of Tibetan medicines in the Tibet Autonomous Region (TAR) and Qinghai Province between 2002-2010, this article presents ethnographic evidence for the ways Tibetan knowledge systems and the values of medicines themselves are being transformed through engagements with science, technology, and markets. I focus on the implementation of Good Manufacturing Practices (GMP) and related regulations: standards that govern the conditions under which raw materials are evaluated, medicines are made, and finished products are sold. Specifically, GMP regulations delineate how medications and medical devices are produced; they include quality control regimes and product testing.

This article responds to calls for an anthropology of pharmaceutical practice in the context of social transformation (Nichter and Vuckovick 1994; Whyte, van der Geest, and Hardon 2002; van der Geest 2006). My exploration of Tibetan medicine production is theoretically productive for anthropology in that it analyzes the ways global governance regimes shape local social practices (Collier and Ong 2005). I propose that ethnography of Tibetan pharmaceutical production can advance our understanding of how global governance operates: what it produces on the ground in a place like Tibet, and how it helps to articulate relationships between so-called "traditional medicine" and biomedicine.[1] Ethnography of GMP implementation reveals how shifts in medical production practices are tied to much larger processes of political and socioeconomic change within China and beyond. Further, my examination of points of incommensurability (Kuhn 1962) and ambivalence with respect to GMP regulations contributes to anthropological analyses of the constitutive roles cultural politics play in the construction of value and meaning with respect to traditional medicine (Scheid 2007, Pordié 2008, Langford 2002).

I use the emergence of GMP certification for Tibetan medicines produced within a minority region of China to argue three main points. *First*, Chinese state implementation of GMP for the commercial production of Tibetan medicines must be understood within the context of global pharmaceutical governance of traditional medicine as a whole, and within expanding international markets for "complimentary and alternative" (CAM) therapies. Normative biomedical and techno-scientific assumptions set forth by bodies such as the World Health Organization (WHO) and the United States Food and Drug Administration (US FDA) about heavily value- and culture-laden terms such as "quality," "safety," and "efficacy" undergird the creation and implementation of GMP in China. These same

assumptions often guide patterns of consumption among non-local consumers who expect standardized markers of safety and quality, even as they are attracted to aesthetic markers of "the traditional" employed in the marketing of such products. *Second*, national iterations of global governance regimes have specific cultural and political effects when connected to a minority nationality (Ch. *minzu*) such as Tibetans in China. Not only are the parameters by which the quality, safety, and efficacy of Tibetan medicines are determined at stake; so, too, is the future of Tibetan medical science and related issues of cultural identity and environmental stewardship, given the technical expertise and natural resources upon which Tibetan medicine depends. *Third*, Tibetans involved in the industry are *themselves* divided about the impacts and meanings of regulations such as GMP, and the larger process of commoditizing and standardizing Tibetan formulas in which such regulations are enmeshed. Regimes of global governance are enacted in specific ways in the Chinese national context, and ultimately have particular effects on the subjectivities of Tibetan practitioners and producers. A contested ethical terrain emerges through compliance with global and national governance, wherein "ethics" become a set of constraints, motivations, or possibilities for creative action in relation to medicine.

Until quite recently, Tibetan medicines were primarily made and circulated within local and regional spheres. Notions of medical quality, safety, and efficacy were determined and regulated, in great part, by expert practitioners who made them, in consultation and interaction with the patients to whom they were prescribed. A medicine's quality was often directly tied to the spiritual accomplishment of the practitioner-producer and to medico-religious precepts adhered to during the production process (Pordié 2003). As articulated in key texts, as well as through oral transmission of medical knowledge, Tibetan medical theory provided a basis for standards by which *materia medica* should be harvested and prepared (Dawa 2002, Dorje 1995, Men-tsee-khang 2001, Kletter and Kreichbaum 2001). Likewise, extensive pharmacological literature detailed specific named recipes that were produced throughout culturally Tibetan communities in which iterations of this medical system have been practiced for centuries (Tsenam 1995, Meyer 1995, Tsarong 1986, Glover forthcoming). A medicine's value was determined not only within a particular cultural context, but also within the constraints of local and regional economies—particularly with respect to the availability of plant, mineral, and animal

products on which Tibetan pharmacy is based (Cardi 2005)—and an ethics of medical practice that in many ways actively discouraged commoditization (Blaikie 2009, Millard 2002). This is not to say that historically everyone who desired Tibetan medicines could access them. Hierarchies of medicinal value do and have existed in Tibetan areas (Beckwith 1978). Theoretical "best practices" of medical production have often been adapted to local conditions and systems of substitution (*tshabs*) are widely acknowledged (Aschoff and Gerl 2005).[2] Nor is it to say that these more localized modes of production have completely vanished; they still exist throughout the greater Tibetan Plateau and Himalaya, including rural, culturally Tibetan areas of China (C.f. Schrempf 2010). However, today, many Tibetan medicines produced in China are fancily packaged, highly marketed, state certified commodities that are prohibitively expensive for most Tibetans to purchase and that aspire to global circulation (Janes 2002, Pordié 2008, Hoter 2009). This transformation has been as profound as it has been rapid: most of the changes described herein have occurred within the last decade.

In the most politically benign sense, GMP regulations were first created to protect consumers of biomedicine from experiencing adverse effects and to enable medical practitioners to prescribe with confidence. However, this rationale has emerged from specific cultural systems and epistemologies, which, in turn, reinforce particular scientific and medical models. A certain type of relationship between patients, health care providers, and makers of pharmaceuticals is presumed—one that is defined by the disaggregation of those who produce medicines from those who prescribe medicines and manage illness. We might take this distinction for granted within conventional biomedicine, at least as it has been practiced in the wake of Upton Sinclair's *The Jungle* and the Safe Food and Drug Act in 1906, as well as the monopolization of American medicine by conventional biomedicine at the expense of other medical traditions such as homeopathy (Starr 1982, Coulter 1999). We might even view this separation between medicine production and medical prescription as a cornerstone of bioethics (Fox and Swazy 2008). In sum, GMP regulations can be traced to social, political, and scientific agendas that emerged at the turn of the 20th century, of which the creation of the US FDA is emblematic (Immel 2000).

When viewed through the lens of contemporary Tibetan medicine, such historically contingent and culturally inflected yet normative policies can be productively engaged. Good Manufacturing Practices and related regu-

lations are quite recent exports to China, particularly as they are applied to the production of non-biomedical formulas. In China, GMP implementation has required that Tibetan medical enterprises adopt methods of production that are *doubly derivative*. By this phrase, I mean these regulations were first created for the manufacture of biochemical pharmaceuticals, as outlined in Chinese-language protocols adopted from the US FDA and the WHO, and then further derived from regulations developed for the production of Traditional Chinese Medicine (TCM). By virtue of the theoretical flexibility yet practical strictures of GMP, power relations within and between nations are revealed and hierarchies of scientific knowledge are reinforced through their implementation.

Tibetan medicine in China is well supported by the state, albeit intertwined with Tibet's troubled political history (Janes 1995, 1999; Adams 2001, 2002a). Many Tibetan medical institutions' primary mandate, at least on paper, is to provide health care to Tibetans. Yet as my ethnography shows, Tibetan medical institutions are directly affected by the push toward privatization, capital accumulation, and even market-based approaches to health care that have taken hold in China at an ever-increasing pace since its entrance into the World Trade Organization (WTO) in 2001. In the WTO, we have an institution of global governance *par excellence*. Even more germane, however, to the production of Tibetan formulas—their discursive, regulatory, and aesthetic transformations from local medicines to "national heritage" drugs in some cases and to "nutritional supplements" in others[3]—is the role of the WHO, the US FDA, and China's State Food and Drug Administration (SFDA). As the epigraphs of this article make clear, these changing forms of production reflect shifts in value systems and embodied practices.

Yet GMP implementation for Tibetan formulas is not only linked to questions about commoditization and engagement with new markets at a time of rapid economic change across China. The enactment of GMP regulations on Tibetan terrain is also located within national and transnational political contexts in which being associated with Tibet carries distinct liabilities and possibilities. This is particularly true in the wake of civil unrest and state repression that swept across many corners of the Tibetan Plateau since late winter 2008, of which the March 14, 2008 riots in Lhasa were emblematic. Today, many Tibetan areas of China are still mired in de facto martial law. In these places, the Tibetan pharmaceutical industry provides a powerful social space in which Tibetans rival Chinese in terms

of the cultural and economic capital at their disposal—even as this "growth industry" depends on limited (and often wild-crafted) natural resources from one of Earth's most extreme environments.

In what follows, I present three ethnographic vignettes that illustrate and expand upon the three main points I've made above. Although points of overlap exist in each story, this ethnography moves synchronically and diachronically: the first episode is from 2002, the second is from 2004, and the third is from 2010. The first section focuses on interactions between institutions of Tibetan medicine and the specters of global governance, as well as potential global markets for Tibetan medicinal products. The second section focuses on ethnography from the factory floor, so to speak, and particular points of dissonance and incommensurability that have surfaced through GMP implementation. The third section explores creative, if still constrained, solutions to these problems of incommensurability, as well as questions about ethics and value that have surfaced through the "scaling up" of the Tibetan medical industry.

(Ad)venture Capital

Steam wafts from the cup of jasmine tea around which my friend Pema[4] wraps his hands, on this cool autumn morning in Lhasa, circa 2002. Beyond the tin and concrete tea house in which we sit, morning commuters scuttle along Jiang Su Liu, a main corridor in Lhasa city center, on which the Inpatient Division of the Mentsikhang (*sman rtsis khang*) is located. Founded in 1916 at the behest of the 13th Dalai Lama, the Mentsikhang, literally the "house of medicine and astrology," is the Tibet Autonomous Region's (TAR) premier state institution of Tibetan medicine. Pema and I are waiting for a potential foreign investor in Mentsikhang.

A few weeks ago, a middle-aged Irishman—strapping, strawberry blonde, and somewhat brazen—appeared on the expatriate scene in Lhasa. He said he was looking for industries in which to invest and that Tibetan medicine was a possible avenue for the venture capital at his disposal. When the Irishman picked up on Pema's casual English fluency and learned that his wife was a doctor at Mentsikhang, he approached Pema and asks him to arrange a meeting with Dr. Dorje, the aging, soft-spoken director of this institution. Pema agreed, but in turn asked me to come with him. "I don't trust this guy," Pema had said. "But if he is interested in Mentsikhang, it is my duty to help."

This morning, a taxi pulls up beside the teahouse, just outside the Mentsikhang gates. The Irishman steps out. "Hello," he says, tipping his baseball cap with bravado. "Shall we get started?" Pema and I lead the Irishman toward Dr. Dorje's office. The Mentsikhang director is a stately man, hair slicked back to reveal a caramel complexion marked by few lines. His eyes are small and narrowly set. As he shakes my hand, I imagine what his grip would feel like as he takes a pulse: light, smooth, subtle. Although Dr. Dorje has spent the past decade as an administrator, he has been a practitioner of Tibetan medicine since his teens.

Dr. Dorje has been briefed about the Irishman's interests and intentions, and begins the meeting as follows: "In the history of Tibetan medicine, there was never really a need to *sell* our medicine. There was especially no idea about selling medicine to foreign places (*phyi rgyal*). These days, there is this need. We have to open up. There is a big opportunity for the world to benefit [from Tibetan medicine]. Before, nobody knew about our medicine. Now it is gaining a reputation in China and throughout the world."

The Irishman answers, "I'm sure you're right about the market potential for your medicines," he says. "But what about export regulations, clinical testing, things like that? In Mongolia and Russia it is easier to export herbal products than from China. I imagine it would be difficult for Tibetan medicine to keep up with manufacturing and regulatory standards of TCM."

Pema translates and Dr. Dorje nods in agreement. "Yes, difficulties. But Tibetan medicine is being developed," Dr. Dorje replies. "You will see when you visit our factory. Soon, Tibetan medicine will be famous in the world."

"I want to help preserve Tibetan culture," the Irishman responds. "Investing in Tibetan medicine might be a good way to do this. But you'll need to improve production methods and do more marketing if Tibetan medicine is going to keep up with TCM and other complementary and alternative medicines—you know, aromatherapy, acupuncture, things the New Agers go for. As standards improve, then we can start addressing regulatory issues for export to other Asian markets, the US and Europe, even other underdeveloped countries, like parts of Africa, where Chinese medicine is already popular. My associates and I could help add value to your products and increase the quality of the medicines produced in your factory. Of course, you would need to follow strict regulatory protocol—Good Manufacturing Practices, GMP, all of that."

Pema looks aghast as he tries to translate this flood of jargon, but Dr. Dorje interjects. A flash of recognition passes across the old doctor's face.

"*GMP*," he nods. "*Yes, very important,*" Dr. Dorje says in halting English. Pema whispers to me. "How do you say '*quality outputs*' in Tibetan? What is '*added value*'?"

The Irishman goes on to say that Mentsikhang would need to improve their record keeping, fiscal planning, and marketing capacity if he and his associates were to invest in the factory. Of course, he has yet to see any financial records for the institution, let alone the factory to which he is now laying a certain entrepreneurial claim. Pema squirms and translates selectively. I find the exchange both shocking and fascinating—in part because the language of venture capital is different than the vocabulary that defines development discourse, with which I am more familiar. Yet both involve assumptions about "underdevelopment" and a sense that Tibet is in need of "saving"[5] as well as an interest in profiting from Tibetan resources, both cultural and natural.

Dr. Dorje arranges for a driver to take us to the factory. We are shuttled into a black Land Rover and head north toward the Tibetan Traditional Pharmaceutical Factory of the TAR. From my place in the back seat, I glimpse the golden roofs of Sera Monastery rising above edge of Lhasa's urban sprawl. The architecture in this part of the city reflects an informal economy aesthetic. Rows of concrete buildings with low ceilings—in which one can buy anything from shellacked pressboard desks to pirated Mariah Carey CDs or a freshly slaughtered pig—are nestled up against bicycle repair shops, kiosks selling bananas and Asian pears imported from Sichuan Province, and gatherings of off-duty rickshaw drivers, smoking or sleeping in their cabs. The occasional government office building interrupts this low-lying tableau with official verticality: three or four floors of steel, tile, and Mylar-covered windows, identified in bilingual block letter signage. Poplar and cottonwood saplings line the road. The trees, like the Chinese migrants who make their living under their dappled shade, have been transplanted here but have begun to put down roots in this place.[6]

"We've arrived," says the driver as he veers across the boulevard's double yellow lines to park, facing oncoming traffic.

"How long has the factory been in this location?" I ask.

"About seven years," the driver replies. "But many of the buildings are new. Some are still under construction. You'll see, once you go inside."

Pema, the Irishman, and I walk into the factory complex. Lhakpa, a senior-level manager, meets us at the entrance to the new GMP-certified building. The imposing three-story structure is canary yellow and

bedecked with banners: Tibetan and Chinese characters painted in crisp white tempera across what can only be described as communist red cotton fabric. The banners announce the recent ground-breaking ceremony for a sales and marketing complex that is being erected beside the still virginal, if mammoth, GMP-compliant structure.

"Welcome to our factory," Lhakpa, extends his hand in greeting toward the Irishman.

"Impressive," says the Irishman, speaking to nobody in particular.

"Since Mentsikhang was founded up to the present, we have been working continuously to produce the best medicines," Lhakpa begins. I note the collapse of history here, the ways he washes over Tibet's troubled past, creating a narrative of continuity where there has been much change and conflict in the field of Tibetan medicine and beyond. "Now we are combining modern technology and scientific methods with traditional practices. We have many important drug registration numbers,[7] including the one for the famous Tibetan long life pill.[8] The nectar (*bdud rtsi*) of Traditional Tibetan Medicine is becoming a national heritage trademark in China. Today, the factory is worth more than 150 million Remenbi (US $18.7 million). We employ more than 200 people," Lhakpa speaks as if reading from the factory brochure as he ushers us inside. I make a note of this concept of trademarked ethnic heritage.

As we pass through heavy glass doors into the factory foyer, the Irishman leans in toward me, "This is prime real estate. I'd guess they had to use this land as collateral to secure bank loans for construction. I'm skeptical they could be selling enough medicine to afford this expansion. Either that, or they must have some pretty big investors already." Although I did not know this at the time, I soon learn that TAR and Chinese central governments have indeed made provisions for low interest loans and other state subsidies to help spur on this industry. By 2008, the Chinese government had invested heavily in this process of bringing Tibetan medicine to market—200 million Yuan ($27 million) by some estimates.[9] This support included government loans and subsidies, incentive and training programs, and other forms of support for Tibetan medical factories, particularly those that are partially or fully state-owned.

"We must now dress in the special clothes," directs Lhakpa. I pass through a set of metal doors. A Tibetan woman instructs me to sit down on a low steel bench that divides the room in two.

"Put these slippers over your shoes," the woman explains. I slip the flimsy green plastic sheaths over my soles.

"Gown, hat, face mask," the woman continues. She hands me a paper surgical gown and a hairnet. "For keeping the factory clean," the worker explains. "Otherwise the medicines won't be good." The worker wears the same plastic booties, head covering, and mask that I now sport. She is dressed in a baggy beige uniform that lends her an androgynous inmate look. I tuck my hair into the plastic cap and position a surgical mask across my nose and mouth. The young worker leads me down a long corridor, where the rest of the group is waiting.

The Irishman turns to me and confides, "I don't know what you were expecting, but I was picturing huts and people squatting in the dirt."

"Really?" I stammer. My mind races and I feel oddly defensive, even as the scale of this enterprise makes me dizzy. Ethnocentrism comes in all shapes and sizes, and imperialist assumptions can seem deeply doubly imbedded here. The Mentsikhang factory is one of the leading players in what has become a multi-million dollar industry that harnesses both government and private capital and that spans five Chinese provinces (TAR, Qinghai, Sichuan, Gansu, and Yunnan). At this time in 2002, the Mentsikhang Factory was one of approximately 20 enterprises in the TAR en route to GMP-compliance, and one of more than 50 such enterprises within China.[10]

We pass a set of double pane windows that do not open but that look out over the factory's courtyard. Lhakpa explains that the building was designed in Lhasa, but that final approval for the plan was only granted after consultation with Beijing experts. In one room, half a dozen workers operate an elaborate machine that counts, sorts, and weighs pills. In the next room, factory workers use another machine to shrink wrap groups of three pills in red and gold foil packets. We are not allowed to see the actual sites of medical production—the areas where raw materials are sorted, ground, and mixed.

"We produce about 40 medicines according to GMP standards. But we plan to make more than 50 GMP medicines by 2004. Right now, the other 200 medicines are just for use at Mentsikhang hospitals and clinics. These medicines are made in the old building, out behind this one. But in the next few years we will replace that building and make all medicines according to GMP. *Export quality,*" he says in English.

"Good," says the Irishman. "This is encouraging."

Lhakpa tells us they have plans for a separate wing devoted to producing *rinchen rilbu,* the "precious pills" which are some of the hottest commodities and, pharmacologically, the most complex formulas in the Tibetan medical repertoire (Aschoff and Tashigang 2001). Lhakpa explains that in the GMP setting these pills will be made according to modified recipes that do not use alchemically transformed heavy metals. "Within our medical system we have methods to remove poisons. But it is difficult to convince people who do not know our medicine that ingredients like mercury are safe, so we are making some medicines differently now."

"Have there been any tests to see if these changes affect the quality (*pu tse*) or potency (*nus pa*)[11] of the medicines?" I ask Lhakpa.

"We consult with many traditional doctors," he answers obliquely. "The medicines are now very clean. It is difficult to know about changes in potency without many expensive studies. For now, we are investing in new facilities to get GMP certification, because, without this, we cannot sell." I am struck by the distinction here between a medicine being "clean" (*tsang ma*) in a materialist sense and potent or powerful according to Tibetan pharmacological theory.

"Some people I've spoken with say the benefits (*phan thogs*) and potency of rinchen rilbu and other Tibetan medicines are decreasing," I comment.[12] "Lhakpa, do you think this is true?"

"People who say this do not know the meaning of *scientific method*," he answers, his tone sharp and polished, the last words spoken in English. "We have to follow the path of modernization. We must use the traditional wisdom combined with modern technologies and knowledge. This is the way forward." My questions of altered potency and changed capacities for efficacy are left unanswered.

Caught in the middle of this translation, Pema interjects, only in English, directing his comments to the Irishman. "Common Tibetan people may not know western science, but this *is* what they say. They say the new medicines look fancy but they are not as powerful as the medicines made in the old days." I am struck both by Pema's thinly veiled political commentary and by the neat dichotomy Lhakpa draws between wisdom and knowledge—specifically the sense that the former can be enfolded within the latter. Why is it that *wisdom* must be located in experiences that are perceived of as non-Cartesian, un-scientific, or even (heaven forbid) religious, while *knowledge* is a catch-all for what is ascertainable to a modern, capable of digesting wisdom, processing the past? As Bruno Latour (1993)

has taught us, this "great divide" is a social project emerging out of the specifics of Enlightenment thinking and the crafting of modernity as social fact. But I wonder how Lhakpa actually envisions this integration between traditional wisdom and scientific knowledge. Is it enough that modified recipes produced under highly altered circumstances bear traces of a Tibetan (and Buddhist) *aesthetic* of healing? That they come in packages stamped with images of Himalayan peaks and the Potala Palace?

These questions about pharmacological methods do not faze the Irishman. Nor does he seem particularly concerned about issues of sustainable sourcing when I bring up this topic. Lhakpa quickly addresses this issue by saying, "We are thinking about the future, but our Tibet is big. There is a lot of land. We can still get what we need." Over the coming years I will encounter this opinion many times: a sense that the vastness of the Tibetan Plateau will somehow "naturally" counterbalance the problem of resource depletion. And yet I also continue to hear about the rising costs of raw materials and the difficulty in finding adequate quantities of some of the most rare yet pharmacologically important ingredients.

"I recognize the huge global potential for Tibetan medicines," the Irishman says, addressing Lhakpa. "Building the Tibetan medicine industry is an important way to help Tibet. But the most important thing for us, if we were to invest, is that your factory meet GMP certification, that the raw materials also pass regulatory standards, and that we can compete in the marketplace. If this means changing some of the recipes or the ways some medicines are made, that is your business—as long as the products pass quality controls. The rest of it—ancient healing treatments for modern problems—people eat that up." Again, Pema struggles to translate, selectively.

Lhakpa nods, "We will meet GMP certification by the deadline in 2004—maybe even ahead of schedule." The factory administrator leads us down a flight of stairs, back toward the dressing rooms where we began our tour. After shedding our plastic booties and other sterile paraphernalia, Pema, the Irishman, and I bid farewell to Lhakpa, who turns toward the Irishman. "Come back another day and I will show you the sales building," he promises. "We can talk more about markets." The Irishman nods and pumps Lhakpa's hand.

I sense that, despite his enthusiastic displays, the Irishman will not be back. Later that day, Pema confides that he has the same feeling. Although my friend kept cool during the tour, he allows himself agitation

now. "He has a lot of pride," Pema says, "I want to tell Dr. Dorje not to bother with him, but I cannot do that. Mentsikhang needs sponsors. Chinese, European, whatever. But people like Lhakpa—it is like he is not really caring for Tibetan medicine. I think about people like this and the duty of being a doctor, like my wife. There is no comparison. This is not medicine. It is business."

Pema's assessment is fitting. By the summer of 2004, when all commercial factories had to be GMP compliant or risk state-enforced closure, the Tibetan medicine industry was well established. Estimates of the production value from this industry vary and press reports may be unreliable, but Chinese sources put these figures at approximately $32.5 million in 2004, $53 million in 2005, and $75-78 million in 2006.[13] Then, as now, the commercial sale of Tibetan medicines has been touted as an "economic cure" for the TAR's perceived "backwards" economy—which remains heavily dependent on central government subsidies—and as an "economic backbone" in the development of an historically marginalized and politically contested region (Dickie 2004).[14]

As the Irishman's crass yet apt market sensibilities reveal, the implementation of GMP regulations for the production of Tibetan formulas in China has occurred within the context of increasing attention being paid to traditional medicines worldwide, and, as such, increasing global governance of this sector. Consider the following: The global market for herbal medicines is more than $60 billion (WHO 2005). It is estimated that between 80-90 percent of Germans have used an herbal or traditional therapy at least once; in China, the sale of TCM amounted to $9.8 billion in 2007 (WHO 2005, Baoyan et al. 2005). This increasing patient use of "integrative" and Complementary and Alternative Medicine (CAM) has become the object of much scholarly discussion and clinical debate (Baer 2004; IOM 2005; Kaptchuk and Eisenberg 2001a, 2001b). This must also be squared against the oft-cited WHO statistic that 60-80 percent of the global South relies primarily or exclusively on traditional medicines to meet their primary health care needs. Of course, the key question remains: what constitutes "traditional medicine" in these diverse contexts?

By virtue of its structure, its mandate, and its relative power, the WHO epitomizes global governance. Over the past decade, WHO has invested significant energy and resources toward the development of policies on Traditional Medicine (TM) and CAM, as have national institutes of health in the US, the UK, and the European Union (Sweeney 2009). The WHO's

Traditional Medicine Strategy (2002-2005) included as part of its mandate the requirement that Member States develop domestic legislation and regulatory models for the production and quality assurance of traditional formulas. This Strategy outlines a variety of challenges to developing international standards for the production and evaluation of such therapies. Chief among these are: 1) issues of *policy*, including the integration of TM/CAM into national health care systems; 2) issues of *safety*, *efficacy*, and *quality*, including the need for evaluation, guidance and support for regulations; 3) issues of *access*, particularly ensuring the availability and affordability of TM/CAM; and 4) *rational use*, which means the promotion of therapeutically sound use of TM/CAM by providers and consumers (Zhang 2005, emphasis in the original). The WHO Strategy recognizes the correlation between the safety, efficacy, and quality of herbal medicines and source materials. Yet they also note this is notoriously difficult to discern—particularly in compounded formulas as opposed to single botanical remedies. In sum, the WHO Strategy document states that the quality of source materials is determined by what it calls "intrinsic" factors, which are essentially defined in terms of genetics, and "extrinsic" factors including environmental conditions, cultivation and harvesting, field collection and post-harvest transport, and storage (WHO 2005). Significantly, such "extrinsic" factors do not include a socio-cultural component or a way of acknowledging different scientific epistemologies about what makes a source material "safe" or of high "quality." This point illustrates the "forms of compression and representation of actions" (Lampland and Star 2009:4) that occur through the process of devising standards. This is a process in which arbitrary boundaries are drawn around particular ways of knowing that, in turn, validate some knowledge and render other knowledge invisible—and, in a techno-scientific sense, unknowable or even dangerous.

Building on the WHO TM Strategy, the Beijing Declaration, adopted by the WHO Congress on Traditional Medicine in China's capital on November 8, 2008, explicitly connects the as-yet unmet goals (articulated at Alma Ata in 1978) of providing global primary health care, and the aim of meeting Millennium Development Goals by 2015, to the use of Traditional Medicine. Citing the 2003 World Health Assembly (WHA) resolution regarding TM, the document advocated that such medicines should be "respected, preserved, and promoted," even as it recognized that the term "traditional medicine" itself was broad and variable. Despite, or perhaps because of, this variability, the declaration further articulated that while Member States may have

different legislation, regulatory responsibilities, and delivery models for traditional medicines, the development of such policies, standards, and regulations were crucial to ensure the "appropriate, safe, and effective use of Traditional Medicine" worldwide (WHO 2008). The declaration posited that the standards by which TM should be measured emerge from biomedical "best practices." A speech given at the Beijing Congress by Dr. Margaret Chan, Director-General of the WHO, illustrates this point:

> Some systems of traditional medicine have histories dating back thousands of years. Over a comparatively short period of time, modern medicine has developed powerful methodologies for proving the efficacy, ensuring quality, standardizing good manufacturing practices, testing for safety, and conducting post-marketing surveillance for adverse effects. Many, but not all, traditional medicines have an inadequate evidence base when measured through these standards.

One is left wondering which medical systems or practices are presumed to have adequate evidence bases, how this is determined, and if it is not simply a rehashing of another set of dichotomies between "big" and "little" or "scholarly" and "folk" traditions (Bates 1995).

Chan acknowledges the ways that "modern medicine" presumes a global relevance by virtue of practices and processes she takes to be biological and scientific universals; according to these standards, traditional medicine just doesn't measure up. But the sense of inevitability and even benevolence in her speech reveals the ways that TM should behave in relation to contemporary techno-science and related standards. As the WHO Traditional Medicine Strategy makes clear, it is assumed that safety, efficacy, and quality standards for TMs should be driven by conventional biomedical standards. There is an implicit assumption in such policies that traditional medicine will become more scientific, and therefore more effective (and, I would add, more marketable) in the process. However, "quality" and "safety" are context-dependent; they emerge from the admission of particular types of evidence, whether generated in the laboratory or in the clinic.

These WHO positions illustrate a classic double standard in which traditional medicines must adhere to accepted norms that biomedical therapies, techniques, and practices do not always meet themselves (Waldram 2000). Furthermore, while the underlying social and economic costs of

complying with WHO directives and related, state-mandated changes to TM production is only briefly mentioned in Dr. Chan's speech, the working assumption remains that standardizing traditional medicines is not only the "good" thing to do in a bioethical sense, but that it will also, somehow, help to address health inequality. I argue this is an untested, even paradoxical, proposition. Consider the assumptions of people like the Irishman. At the risk of sounding too plainly Marxist, I argue that GMP implementation reflects larger problems of scientizing and commodifying heterodox healing systems and therapies, on the one hand, and the alienation of labor and fragmentation of production in (late) capitalist societies, on the other. These paradoxes are borne out by the WHO sensibility that traditional medicines should at once be "respected and preserved" and also "promoted." In these and other forums, issues of culture and power, with specific reference to how regimes of global governance impact much more local cultural forms are rarely addressed (Adams 2002b, Pordié 2005, Lock 1990).

Holy Water and Polluting Flowers

Although my watch reads 8:30 a.m., the cool light of dawn has just begun to overtake Lhasa's clear night sky. Thousands of miles from Beijing, we are still on Beijing time. My friend Minduk arrives, out of breath, cheeks apple red. Her hands are tucked into a puffy synthetic jacket. Her face, rimmed in the fake fur lining of her hood, registers a look of concern. "Why are you not wearing a hat?" she scolds gently, by way of saying good morning. It is late March 2004, but that still counts as winter in Tibet. The driver we've hired for the day leans back against his aging jeep, blowing on his hands. We hop into the car and head out of town toward the Shiong Ba Lha Chu Tibetan Medicine Factory. This institution is located not far from Lhasa, in Dulung County. Shiong Ba Lha Chu is named for a sacred spring that flows near the cliffs above the factory. This factory rests beside the birthplace of Yuthog Yonten Gonpo the Elder, the mytho-historical figure often described as the "father" of Tibetan medicine and the progenitor of the *Four Tantras* (*rgyud bzhi*), core texts in the Tibetan medical cannon.

"These days it is difficult to find medicine that is really good quality, made by people of ability (*yon btan*), with the proper blessings and the right way to prepare ingredients," says Minduk as we chat on the way to the factory. Although Minduk is a skilled Tibetan doctor, she lives an

urban life and rarely makes her own medicines. She buys medicines from Shiong Ba Lha Chu and a few other factories or directs her patients to fill her prescriptions with their products, whenever possible. "Nowadays there is a *lama* from eastern Tibet who lives in the small temple just up there," she points. "Near to the spring. He is very accomplished. It brings good benefit to the factory." I am struck by the idea, so commonsensical to Minduk, that the specificities of place and the power of a resident master could actually, could *directly*, affect the quality of medicines produced here. Although the landscape surrounding Shiong Ba Lha Chu is rapidly becoming an extension of greater Lhasa—complete with cement and chemical factories and rows of Chinese-run industrial greenhouses—a sense of sacred geography and medical lineage remains central to how many, including Minduk, imagine Shiong Ba Lha Chu. This vision also finds its way into the factory's marketing strategies: in English and Chinese, the place is called "Holy Water Tibetan Medicine Factory."

The factory sits on a small plain at the foot of a tawny mountain ridge. It retains some architectural coherence with the agricultural village located just outside its gates, and with the signature pagoda-style entrances that mark many official spaces in China. As we approach the factory, I note the ripening barley fields and whitewashed adobe homes, the dirt road mottled by wind and rain. Shiong Ba Lha Chu is half privately owned by a rehabilitated remnant of Lhasa's pre-1959 landed nobility (*sku drag*), and half owned by a prefectural-level state-supported Tibetan medical hospital. Shiong Ba Lha Chu neither boasts the multi-million dollar returns of the Chinese-owned Cheezheng Group with headquarters in Gansu Province, nor the Arura Group in Qinghai. Nor does it benefit from the large state contracts and official designation of the Mentsikhang factory. However, it had a good reputation. One of the factory's directors is renowned for his knowledge of Tibetan medical pharmacology.

Although it is not yet 10 a.m. when we arrive at the factory, several boom boxes are already blasting Chinese and Tibetan pop tunes. Budweiser cans have been stacked in a pyramid beside the showroom. Unsure of the cause for celebration, I wonder if I have forgotten a Tibetan holiday, until I asked the first factory worker I met what is going on.

"We're having a GMP party!" she says. Apparently, the factory directors have just received word that they passed all GMP inspections. They will be issued their compliance certificate before the June deadline. In celebration, the directors have decided to throw a bash for their employees. After

months of halted production and nervous energy, they can now begin producing medicines in the new GMP-standard building.

I last visited Shiong Ba Lha Chu about four months earlier. This morning I am astounded at the rate and scale of change. A three-story stucco structure with Tibetan-style awnings has replaced the older, smaller buildings devoted to drying and cleaning materials. The garden and herb cultivation plots that used to be at the center of the compound now sit on adjacent land, outside the factory compound's high walls. Palsang, the production manager, tours us around the outside of the new production facilities. He tells us we cannot enter the GMP building because "there are not the right people on duty who can give us the right clothes to put on." I recall the plastic getup at the Mentsikhang factory. The manager traces his fingers across an architectural plan of the new GMP factory—a map of the manufactured terrain in which a new kind of medical and social efficacy is being constructed. The sales department is not yet finished, but looms large.

As Minduk and I chat with Palsang, we learn that Shiong Ba Lha Chu currently employs about 50 people, and their operation includes departments for raw materials, facility operations and personnel management, standardization, and quality control. I ask what the quality control department does. "Those people are experts," he answers. "They check using the laboratory for dirt, molds, and other impurities. This work is more connected to Good Supply Practice (GSP) than GMP, but they are related. Other people who know Tibetan medicine are still testing the medicine ingredients' taste and smell—all the traditional ways of knowing if something has good potency and quality."

"What happens if there is a disagreement about the quality of a raw material or a medicine?" I ask.

"We are a small factory so people can still talk to each other and come to agreement. But now that we have GMP, we have to listen to what the quality experts say." I am reminded of the ways a particular techno-politics linked to modernity emerges through the jurisdictions around which "expertise" is created (Mitchell 2002).

One part of the main production building had been fitted with a greenhouse-style roof. "What is that?" I ask.

"A special room we built for drying some ingredients," Palsang answers. "That way, we can still have sunlight, like the old ways of drying medicines, but none of the dirt from the medicines being outside." This strikes me as innovative—an example of how working within the strictures of GMP,

using them creatively, is possible. Tibetan medical theory advises that medicinal ingredients should be dried under varying climatic conditions (shade, direct sun, etc.) depending on their nature (*ngo bo*). In most GMP-certified factories I have observed, large indoor dryers were the norm. This factory's innovation with respect to the creation of special rooms that meet GMP climate control requirements *and* comply with Tibetan medical theory is notable, and relatively rare.[15] As the tour continues, I learn that Shiong Ba Lha Chu uses large mortar and pestles fashioned into mechanized grinders, so that ingredients are crushed and ground with stone instead of metal, for the latter is said to alter *nus pa*, potency.

"We also have a special filter for our water," says Palsang. "Now we don't have to boil water before we use it to clean the ingredients. The water tastes different, but we can keep using the water from the holy spring. The filter machine cost 100,000 Remenbi [approximately $12,500 at that time], but we all thought it was worth the expense, since this factory is known for its pure, medicinal water."

Palsang leads us into another building, toward a shrine room. The walls are lined with images of the Medicine Buddha and a coterie of wrathful protector deities. "Shiong Ba Lha Chu also does *sman grub,*" Minduk says as we stand by the altar. She is referring to the medicine consecration ceremonies that have historically been part of the medicine production process. These ceremonies were not conducted during the strictest years of social control amidst the Cultural Revolution, but they were revitalized since the early 1980s and are now allowed, even at state institutions like the Mentsikhang factory. To Minduk, a devout Buddhist practitioner as well as a doctor, these ceremonies are a crucial component of what makes a medicine efficacious and of quality. The fact of such blessing is also something that can be marketed to different audiences, and can lend medicines another layer of value (Craig and Adams 2009).

This morning spent at Shiong Ba Lha Chu helps me to articulate two main areas of incommensurability that were consistently raised during my interactions with factory workers and Tibetan medical practitioners. These points emerge as Tibetan medical producers are compelled to adopt new practices of garnering techno-scientific "evidence" about "good" production—practices that are accountable to national and international governance regimes as well as the market.[16] These two main areas of incommensurability are: 1) factory design, construction, and labor needs; and 2) ingredient sourcing, drying, and compounding meth-

ods. Here, I note pragmatic challenges and ethical concerns that illustrate a politics of culture (being Tibetan in China today) as much as they are about making "good" medicine, in local, national, and global terms.

The quest for GMP certification has precipitated the construction of new factories or extensive retrofitting of existing factories. These GMP facilities are much more expensive to build, maintain, and operate than non-GMP production sites. They also consume more energy and rely on high-tech equipment that requires additional expertise to maintain and repair. In the years leading up to 2004, I observed that Tibetan medicine companies were engaged in a type of competition with each other to see who could build the biggest, most expensive facilities. Some factories were availed of government loans for this purpose. In many cases, this has led to significant factory debt.[17] The new drug manufacturing regulations did not, in themselves, force the closure of non-GMP factories, so long as medicines produced at such sites were only destined for use in Tibetan medicine hospitals and clinics. Nor did they directly mandate price increases for medicines. But these have been two powerful effects of GMP implementation.[18] In many cases, investments in technology and infrastructure have been extreme. In addition, personnel must be of a different sort than those who used to staff non-GMP factories; even low-level factory workers are required to complete GMP trainings and certification courses. Salaries are often higher, even though most employees' overall knowledge of Tibetan medical theory, history, or clinical practice is decreasing.

As we stand outside Shiong Ba Lha Chu's GMP-certified factory, which cost US $1.3 million to build, Palsang explains, "With GMP many things have become more expensive: electricity, labor, things like that. This changes what we have to charge for medicines. Using our old system, we could pay someone 500 Remenbi a month [$60 at the time] and that was considered a decent wage for a medicine-making assistant. Now, the training required for GMP means we are hiring people who need to be paid at least three times that, sometimes more. Still, it is difficult for us to find good people to work for us. We want to hire from Tibetan medical colleges—either here in Lhasa or other places. We don't want to just hire people trained in business, because they won't know *our* business. People didn't have to know GMP before. Now they do. Getting this experience takes away from their studies of Tibetan medicine. So the overall quality of people studying Tibetan medicine is in decline (*nyams*). It is hard to find 50 percent of students who can explain the basics of Tibetan medicine well."

This production manager goes on, "In the West, maybe people think new technology actually makes things cheaper and more efficient. But here, this is not the case. When we made medicines in the older way, we didn't have to worry about buying fancy machines to clean the air and water. We could also pay local villagers without much education to work with us, grinding and sifting medicines, helping to make pills. It was good for them and good for us. Now, GMP tells us we need experts to make sure all medicines are standard and that they have high quality. This costs more. We need to bring in people from the outside."

While this financial analysis does not surprise me, I make a note of the ways meeting the demands of new pharmaceutical governance regimes is impacting the value, meaning, and structure not only of Tibetan medicine production, but also of Tibetan medical education and local relations of production. The next generations of graduates from Tibetan medical colleges in China are being "tracked" in new ways. While some will still go on to serve Tibetan patients in rural and urban facilities, many become quality assurance officers, marketers, clinical researchers, and pharmacists. GMP compliance has also come to signify changed labor relations within sites of medical production, and between these enterprises and the places in which they are located. Not long ago, a worker's sensory relationship with the plants, minerals, and animal products that comprise Tibetan formulas was a dominant feature of medical production; it required physical strength and drew on local labor pools. In all of the new GMP-certified factories, employees are physically separated from materia medica through ritualized acts of donning disposable scrubs, masks, and plastic gloves. While this keeps things "clean" it also changes the embodied nature of producing Tibetan medicine. People now work in increasingly mechanized environments. Socializing is discouraged. This is not to say that factories are "unfriendly" places, but rather that spaces and times for social interaction have become distinct from those devoted to labor.

Compliance with GMP regulations has also had a profound effect on how space is conceived and what constitutes a "good" environment for making medicines. On this visit to Shiong Ba La Chu, I recall the feel of the factory courtyard before GMP certification. During previous visits to the factory, there were stands of cosmos everywhere. Several plots of cultivated medicinal plants poked up from behind the buildings. I note the new landscaping: clinical, closely shorn sod. "What happened to the flower garden?" I ask the manager.

"Now we can't accept flowers in the factory area. According to GMP, flowers cause pollution."

The comment stops me short because it so perfectly illustrates the semantic, epistemological, and material shifts occurring within Tibetan medicine production. The GMP regulations inspire a fetishization of cleanliness in the sense of hygiene and refashions what is conceived of as a potential contaminant, with respect to raw materials sourcing and preparation. Though GMP regulations do not directly address sourcing issues, the fact of GMP compliance, in combination with Chinese Drug Administration laws and Good Supply Practices (GSP), has raised concerns over where and under what circumstances raw materials are procured and how they are deemed to be of quality.

A pharmacist in his fifties who worked at the Mentsikhang Factory, in the section of the enterprise that, in 2003, was not GMP compliant and, at that time, was slated for closure, once explained this dynamic as we talked near a sheltered slab of concrete where a host of raw materials were being dried in indirect sun.

"The Seven Limb Procedure (*yan lag bdun*) in the *Four Tantras* tells us that we should use herbs that are harvested by people with good hearts (*sems bzang*)," he said. He went on to stress the importance of *not* using materials that were polluted (*grib*), meaning defiled in a spiritual sense, and that were also clean (*tsang ma*) in a material sense.

"According to GMP, we could collect plants even from a place that is at war, like Iraq or Afghanistan, and use these ingredients in medicines, so long as the bags of ingredients were not mixed with grass or stones or dirt," this pharmacist continued. "But to us, this would be very bad, if the people collecting were also engaged in killing and fighting. This would have a karmic effect on the quality and benefits of the medicines. But GMP [regulations] does not think of such things. GMP is about making sure everything is clean according to outside ideas."

Clearly, there is an ethical tenor to these debates over "good" practices—a sensibility that addresses the moral epistemology, tied to Buddhism, which underlies Tibetan medical theory (Samuel 1999, Pordié 2003). Becoming GMP-certified has corresponded to an increasing concern with avoiding material contamination and promoting new sensibilities with regard to "clean" and "dirty" production environments. Many people involved in contemporary Tibetan medical production equate sterile factories with a higher order of cleanliness that stems from a modern,

techno-scientific aesthetic. In some cases, this trumps more "cultural" concerns regarding the loss of medical efficacy linked to poor ethical conduct of those harvesting raw materials or producing medicines. This concern with cleanliness in a GMP sense can also override an examination of ingredients according to methods for discerning quality based on Tibetan principles, namely through examination of an ingredient's tastes (*ro*), potencies (*nus pa*), and post digestive tastes (*zhu rjes*). Ingredients used in GMP-certified factories must pass state inspections that not only screen for dirt and molds—a use of technology most of my interlocutors felt was useful—but also for consistency of species, even though standardizing Tibetan materia medica in Linnean terms remains a very tricky issue (Boesi 2006). Furthermore, such consistency of species does not necessarily reveal anything about a specimen's potency and efficacy. These factors can vary significantly depending on the soil and climatic conditions in which a species was grown and harvested.

This theme of cleanliness and contamination points toward pharmacological conflict as well as cultural incommensurability. While Tibetan medical texts distinguish not only how, but also *when* and *for how long* animal, vegetal, and mineral ingredients should be used to ensure maximum potency, many of these directives contradict GMP strictures about "shelf life" and expiration dates. Most of the time, GMP compliance renders materials unusable well before a physician-pharmacist, or even a factory pharmacist, may deem them to have lost their potency. To some people I interviewed, this was a benefit of GMP: it would help ensure that Tibetan medicines were made with materia medica that had not been sitting on a dusty shelf for years. To others, this was further illustration of fundamental conflicts between GMP regulations and Tibetan medical knowledge. Either way, this has created specific problems for some ingredients which are supposed to be aged for a certain amount of time and/or kept under certain conditions to reach maximum potency—time frames that can render these ingredients unusable within the framework of new drug administration regulations.

Sourcing issues also reflect the paradoxes of an industry that depends, in part, on raw materials that hail from high altitude environments. This issue predates the GMP, but is exacerbated by it, particularly since these and related Good Agricultural Practices (GAP) regulations speak only obliquely to environmental impact with respect to what is considered "good" sourcing. Instead, emphasis has been placed on adhering to new legislation that

requires all materia medica enter China through an authorized port by an authorized importer, which requires an expensive license; ingredients are then tested in an official drug testing office, also an expensive process (Saxer 2010, forthcoming). In such milieu, there is no distinction made between the importing of *a ru* (*Chebulic myrobalan*), one of Tibetan pharmacology's key species, and antibiotics (Saxer 2010). This has changed the social and economic landscape of cross-border trade in medicinals between Nepal, India, and China—thereby compromising a major source of income for many people and, in some instances, inciting smuggling. These changes have also resulted in a higher value being placed on "audit culture" (Strathern 2000) than on the maintenance of reliable and renewable sourcing relationships with individuals and communities. What constitutes "good"-ness—in the form of quality, safety, or value—depends on the parameters put in place to measure them.

But this also begs the question: Were Tibetan materia medica being collected and harvested, bought and sold, only in places undefiled and by people of pure intention *before* the GMP? The answer is clearly no. Nor has GMP stopped traders throughout the Himalaya from overharvesting plants with high market value, trafficking in endangered species, or even using highly prized saffron (*ka che gur gum*) from embattled Kashmir, Afghanistan, or Darjeeling. Yet this does not mean that the pharmacist quoted above was insincere. Rather, these concerns point to competing epistemological frames and ethical registers for the standards by which "good" practice should be evaluated.

For many people with whom I spoke, the term "GMP" came to stand for much more than the construction of new factories and the adoption of novel drying and processing techniques for materia medica. One elderly and extremely well-respected Tibetan pharmacologist at the Tibetan Medical College in Lhasa put it this way,

> GMP [implementation] is a very new situation for an old system of knowledge. Sometimes we are afraid that by making Tibetan medicine to GMP standards it is like making clothes that look good on the outside, but that do not fit, or that are the wrong color. It is hard to compare old knowledge of Tibetan medicine with these new rules. We have a long history and have used our medicines for thousands of years, but we need to find a way to translate this to the outside.

And, given the moral responsibility—akin to the Hippocratic Oath but more Buddhist in orientation—that Tibetan medical practitioners must do no harm and benefit their patients, this idea of medicine that looks good but lacks Tibetan medical validation of its quality, safety, and efficacy is an ethical issue.

My interlocutors have referred to this dynamic in terms of the rights (*thob dbang*), power (*tshad dbang*), and authority (*dbang cha*) to make medicines in ways that ensure quality on their terms. Many producers spoke directly, in vernacular, to what we might call the biopolitics of global pharmaceutical governance. They resented that Tibetan medicine was being made to follow "the laws of your country" (*kye rang gyi lung ba'i khrims*) [meaning the USA] or "western science" (*nub phyogs gyi tshan rig*). When discussing GMP, interviewees would often refer to the terms WHO or FDA in English or Tibetan (*'dzam gling 'phrod bsten rtsa 'dzugs* and *a me ri kha sman rdzas dang zas rigs do dam cu,* respectively), as the source of irrelevant and even harmful strictures being placed on the production of formulas whose safety, quality, and efficacy should be determined by other means. This, even though they understood that GMP implementation in China was the purview of the *Chinese* SFDA and related bureaus.

In China, GMP and associated standards are crafted and enforced by the SFDA; yet they draw on US FDA as well as WHO guidelines. Chinese GMP regulations were first promulgated for biomedical pharmaceuticals in 1998, and have gone through several revisions in the last decade (Xie 2007). The regulation of traditional and herbal formulations in the PRC began in earnest with the 2001 Drug Administration Law of China.[19] These regulations emerge from a long history of collaboration and contestation between various forms of indigenous and biomedical practices in China. Official doctrine on traditional medicine has shifted several times since the collapse of the Chinese Imperial order in 1911 and the creation of the People's Republic in 1949 (Scheid 2002, Farquhar 1995, Taylor 2004). Since 1958, China has experienced the interpenetration of biomedicine and traditional medicines, from mainstream *zhongyi,* associated with the Han ethnic majority, to "minority nationality medicines," including Tibetan medicine. However, in practice the Three Roads (Ch. *san daolu*) policy—wherein biomedicine and traditional medicine were used concurrently and integration was encouraged—has often reinforced the dominance of both modern biomedicine as it is practiced in urban China and Han majority culture (Fan and Holliday 2006; White 2001; Janes 1999, 2001). Indeed, a strong

ideological commitment to science in the People's Republic of China has also fueled a state health care system that, while often lauded for its "integrative" ethos, is still one in which biomedicine remains hegemonic, and in which even mainstream TCM occupies tenuous and shifting positions (Farquhar 1992, Scheid 2002, Zhan 2009). Non-biomedical epistemology and practice is often marginalized even within institutions that are nominally devoted to traditional medicine (Fan and Holliday 2007, Adams and Li 2008). In an article that includes case studies of Tibetan, Uighur, and Mongolian medicines in China, Fan and Holliday (2007) argue that an "ideology of science" which assumes that all traditional forms of medicine should be produced, evaluated, and reformed according to biomedical standards, rests on unstable empirical ground. Yet the ideology of science—particularly in the context of Chinese socialism—remains strong (Chen 2005, Crozier 1968, Anagnost 1997, Ong 1997).

There is another layer to all of this. As noted in the introduction, Chinese GMP regulations for Tibetan medicine are *doubly derivative*. They are based, first, on conventional methods for producing and regulating biomedical pharmaceuticals across the globe; and, second, on GMP regulations first crafted for the production of biomedicines and standardized TCM formulas in China. This is true despite significant differences in materia medica, pharmacology, and medical theory between Chinese and Tibetan medicine. The SFDA's decision to model Tibetan regulations on those for TCM could be viewed as a logical extension. I argue, however, that this Beijing-level policy decision is also tied to a political project in which Tibetanness *must* fit within an overarching model of Chineseness. The assumption that Tibetan medicine should follow the path carved out by TCM also speaks to the political transformations that Chinese medicine, in all its plurality, has undergone since the late 19th and early 20th century (Scheid 2002, 2007; Hsu 1999; Taylor 2004). Institutional TCM and a Chinese embrace of biomedicine hold powerful sway in shaping today's "minority nationality medicine" policies. In this sense, Tibetan ambivalence about GMP regulations extends outward from the realm of biomedicine and techno-science to illustrate larger concerns about the place of Tibet and Tibetans in the context of contemporary China, and state regulation of minority nationality (minzu) subjectivities generally (Harrell 2001, Davis 2005, Litzinger 1998, Hillman 2003, Makley 2007). Yet this alone does not make GMP implementation a biopolitical process. Rather, the ambivalence with which Tibetans involved in the industry *experience*

these transformations and *respond* to them reveal the ways that regimes of governance regulate populations through the application and impact of political power. This political power is exercised in direct and oblique ways, filtering through diverse strands of human activity, including making medicines.

Translation, Trust, and Tradition Transformed

On an early morning in July 2010, I make my way toward the Qinghai Province Tibetan Medical Hospital in the city of Xining. I arrive filled with the sights, sounds, and smells of this growing metropolis of more than two million people on China's western frontier, in a region Tibetans call Amdo.[20] The hospital sits off one of Xining's thoroughfares in a bustling, Muslim-dominated corner of this provincial capital. Bakers knead and fold dough into leavened disks; butchers arrange slabs of pork and yak meat beside whirring fans. As I walk through the entrance to the hospital I pass patients and their families—Tibetans, Uighers from Xinjiang province, local Hui and Salar Muslims, and Han. Some linger on the lawn. Others walk slowly, arm in arm, toward the inpatient ward. Unlike other Chinese hospitals, or even the Mentsikhang in Lhasa, the main buildings of this hospital bear a distinctly Tibetan aesthetic. The architecture is reminiscent of a fortress (*rdzong*), such as those that once marked sites of Tibetan imperial power. Although this hospital receives state support, it is owned and operated by the Arura Group, China's largest Tibetan medical enterprise. Aside from the hospital, the Arura Group includes a Research Unit, a for-profit GMP-certified pharmaceutical company, a Tibetan medical college, and an impressive cultural museum.[21] Although Arura does not market its medicines internationally at present, they hope to expand to new non-Chinese markets in the coming years.

My research assistant, Dolkar, a master's degree student at the Tibetan Medical College, meets me in the courtyard. "Demo," she calls, in typical Amdo greeting. "*Dr. Kunga is expecting now we will arrive*," she continues, in confident if imperfect English. I follow Dolkar into a building beside the outpatient unit and into the office of the medical production facility director. Dolkar and Dr. Kunga greet each other warmly, with a sense of respect, even though age and title renders Dolkar much the junior in this interaction. Dr. Kunga has a warm smile and looks to be in his early forties. He

wears a crisp white lab coat embossed with the Arura insignia. The director pours us small paper cups of steaming water.

Over the years, my research has led me, logically, to Arura. Unlike other sites of Tibetan medical practice and production with which I've interacted, Arura has *consciously chosen* to distinguish between the business of producing GMP-certified Tibetan formulas for high-end consumer markets and that of producing Tibetan medicines for the express purpose of treating the people of Qinghai—primarily, but not exclusively, Amdo Tibetans. This agenda has evolved over the past 15 years, and reflects the vision of Arura's chief executive, a biomedically-trained Tibetan social entrepreneur who has sought to promote high quality Tibetan medical care, support aspects of Tibetan science and culture, and yet do so in a way that has garnered intense interest and market-based respect from members of China's governmental and private-sector elite.

There have been points of compromise in the building of this institution, but also much foresight. For example, since GMP became standard practice in 2004, several institutions including the Mentsikhang in Lhasa have begun lobbying to *recreate* non-GMP facilities to produce medicines specifically for clinical use, in part because GMP-certified drugs are more expensive to produce.[22] However, to my knowledge, the Arura Group is the only Tibetan medical institution that produces for the commercial market *and* for local patients that, during the height of the GMP craze, did not turn all of its attention toward the primacy of GMP compliance. Like Shiong Ba La Chu, Arura has fashioned their GMP-certified factory in pioneering ways. For example, in addition to meeting state requirements for commercial manufacture, they still perform the demanding alchemical process of detoxifying heavy metals and gems for use in their formulas. They have even created special rooms in which precious ingredients are dried by moonlight, as instructed in traditional medical texts. Medicine empowerment ceremonies are performed at both factories. Workers are encouraged to recite prayers (*mantra*) as they work. Most significantly, with respect to the ways local practice meets global and national governance regimes, Arura's executives have thought proactively about the extent to which, and the domains in which, they need GMP compliance.

Dolkar and I settle in to leather recliners, beside a small room brimming with medical texts and herbal samples. All Tibetan medicines being prescribed at this hospital are made in this building—more than 260 different formulas. This internal production unit is also a site of research

and experimentation. Dr. Kunga explains that he and others are working on some new variations on old recipes, and new forms of medicine and other health products created explicitly for local clinical use. Displayed on Dr. Kunga's desk are an array of new products under development in this non-GMP facility: a Tibetan herbal toothpaste and mouth spray, a medicated bandage for joint problems, and a type of medicinal wine reputed to be good for strengthening bones.

"This recipe," Dr. Kunga explains, gesturing toward the medicinal wine, "comes from an old master doctor in Xunhua"—a region east of Xining. The medicated bandage and the mouth spray are his own inventions, based on preparations he learned under the tutelage of a lama and doctor with whom he studied during his vacations from medical school. Here, a sensibility that values oral practice, lineage-based knowledge, and pharmacological variation comes to rest *within* a factory context in which scaling up and standardizing production—even if for local clinical use—also remains the goal. What have been points of angst and incommensurability in other factories seem to be reconciled here in compelling, if still somewhat paradoxical, ways.

"We want to make Tibetan medicines easier to use, and to improve the public health and hygiene of the people," Dr. Kunga says. "The toothpaste has been especially difficult, but we hope it will be successful. It is challenging to find the perfect combination of modern forms for medicines with traditional principles and old recipes." I think back to the Mentsikhang factory and the way Lhakpa espoused abstract ideas about "traditional wisdom" and "scientific knowledge." Here, in this simple tube of prototype toothpaste, is a concrete example of such efforts.[23]

"We try to just use one modern material," Kunga continues, fingering the medicated bandage. "With this one, we use a modern method to make the bandage stick to the body. It is less messy than the traditional ways [of making herbal poultices] and very convenient. You keep these patches on for 24-48 hours on the affected area—the knee, for example. We also give the patient herbal medicines to eat." The consumers of these medicines are almost exclusively those seeking treatment at this hospital or their family members. It is technically illegal to sell these formulas commercially, and the state set price for non-commercial formulas at a maximum rate of five percent every five years. The fact that medicines produced here are *not* GMP certified helps to *encourage* patients to seek care from a Tibetan physician instead of just purchasing medicines over the count-

er. "We want to make the best relationship with doctor and patient," the director goes on. "Here, we are different than the GMP factory. Here, we don't study *MBA*. We just want to do good for our patients."

True, I think. And yet it is precisely the for-profit entrepreneurial spirit and market-driven success through the GMP-certified phamaceutical factory that allows this branch of Arura to focus on clinical care and practical innovation. Across town, at Arura's commercial factory, novel forms of old recipes and even several new therapies are being made—but under different production regimes, and for retail prices as much as ten times more expensive than medicines sold through the hospital's pharmacy.[24] The glitzy showroom at the GMP facility is filled with backlit mahogany-stained shelves on which sit Tibetan treatments for menopause and precious pills marketed for their capacity to improve immune system function, face creams that contained traces of key Tibetan herbs, and bottles of *ophiocordyceps sinensis*[25] that cost nearly $1,000 for several ounces. In a very direct way, the profits generated from Arura's high-end Tibetan pharma—traded in retail outlets across cosmopolitan China by Han salespeople dressed up in ethnic Tibetan garb—are funneled back into this production unit and the hospital itself, which provides quality health care at affordable prices to local people.[26] Before coming to Qinghai, I had my doubts about this marriage of altruistic ideals and market-based practices. Yet the more time I spend at Arura, the more intrigued I have become with the ways this institution navigates the murky waters between governance, profit, and benefit—indeed charts its own course. Their path involves the defense and transformation of "tradition" at multiple levels: in how medicines are produced at both production facilities; in the strategic accumulation and deployment of "connections" and social capital (Ch. *guanxi*) with respect to observing regulations and marketing products; and in the deliberate division of labor between the two production facilities. In some senses, Arura is attempting to give all the players in the regulation, production, and consumption of Tibetan medicines what they want.

Knowing that Arura has explicitly decoupled commercial, GMP-certified production from the hospital pharmacy, I want to learn more about what distinguishes the two sites. I ask Dr. Kunga about sourcing. I am particularly interested in this issue because I have already learned that Arura has one central sourcing unit, from which raw materials are then sent either to the GMP factory or to this hospital production unit.

"Most hot, lowland ingredients from places outside China—Nepal, India. They come in through middlemen, and sometimes through connections we have with other factories. We like to send people from Arura to markets so we can pick the best ourselves. But this is not always possible or efficient. There is a lot of variation in quality of each plant. Plants, seeds and roots should be harvested at different seasons, depending on the nature of the plant. We cannot always tell when something was harvested, so we need to check before we buy very carefully. For the benefit of the patients, we want to find the best quality."

"What about herbal medicines, minerals, or animal products that come from high altitude areas, from Tibet?" I ask.

"For this we have relationships with the people who work here, since they are from all over Qinghai, and sometimes other Tibetan places in China. When they go home every year, they make relations with local people to collect ingredients that grow there, and that we know to have good potency. Our doctors explain what to collect and also give training to these people in how to harvest. For example, if you use the flower in medicine, you don't pick the entire plant including the roots," Dr. Kunga explains.

"Before we started doing this training, people did not know. Sometimes they would pick the whole plant even when this was not necessary. This is still a problem sometimes, but it has improved," the director continues. I note that, at a most basic level, Arura's mandate for producing quality medicines begins with a set of *social* relationships and a sense of place, even though these ingredients are used to produce medicines for *both* a commercial market and to meet local health care needs. Dr. Kunga goes on to say that factory employees are required to do this work without any direct financial incentives or gain; this raw material sourcing is part of their basic job responsibilities. However, I still wonder how "quality" is determined when it comes time to produce medicines themselves? Who makes these decisions?

Dr. Kunga answers, "We work differently than other factories—at least from what I know. We have 80 people working in our quality department. In this place, we use machines to test for dirt and mold, but first we use traditional methods based on taste, smell, and so on. This is most important."

"Three times a year someone from the government does special testing," Dr. Kunga continues. "Mostly the government unit determines whether or not the ingredient is the correct species and also if it has other things mixed in with it. This is investigated according to medicine production laws. We do

not have control over this. But we make decisions about potency and taste. The main difference between here and our GMP factory is not about sourcing, but about standards of hygienic conditions for the place where medicines are made, and then marketing and packaging. We are only GPP—Good Pharmacy Practice. This is enough for us here." I acknowledge the ways regimes of pharmaceutical governance creates hierarchies of knowledge and practice, with GMP embodying the pinnacle of "scientific production" in that it functions as the gateway to commercial sale.

When it comes to sourcing, then, Arura has not escaped issues of incommensurability. "Traditional" standards of potency and quality are still bound to practices of matching diverse Tibetan plant names with their western botanical equivalents, according to Chinese-language compendiums issued by the central government and used by provincial-level drug administration bureaus. Furthermore, Arura relies on middlemen to source significant quantities of ingredients that derive from South Asia. In the enactment of these border regimes, quality testing must be performed at ports of entry into China in a domain that is dominated by techno-scientific laboratory testing rather than Tibetan medical expertise (Saxer forthcoming). However, at least for ingredients sourced from within China, materia medica used at the commercial facility and the hospital production unit is still screened by a cadre of senior doctors. A first order of "quality testing" remains oriented around Tibetan medical theory. State-sanctioned or not, these patterns of determining the quality of raw materials *does* influence production in the GMP factory because the sources are one and the same.

As we talk, I note differences in how Dr. Kunga speaks about these issues of GMP regulations now, in Qinghai in 2010, as compared with similar conversations had with other producers—particularly during the years when GMP compliance was first being mandated by the Chinese state, and in the more politically restrictive TAR. In that milieu, a sense of strife pervaded those conversations. Many people thought the way forward was to create a Tibetan language GMP. For, GMP regulations to which Tibetan medical production must adhere are not only doubly derivative in terms of their epistemological assumptions; they are also written in Mandarin.[27] Tibetan factories are inspected primarily by Chinese specialists who know little to nothing about Tibetan medicine and who rarely speak or read Tibetan. As such, a gap in communication exists between those who are charged with writing regulations and inspecting factories

and those whose primary task it is to produce Tibetan formulas. Much is lost in the translation.

One factory executive with whom I spoke in Lhasa in 2003 put it this way: "GMP regulations are not easy to understand in Tibetan. They are written in Chinese, with a more modern way of thinking. But without being an expert Tibetan doctor, it is difficult to know how to make GMP better for Tibetan medicine, more true to Tibetan knowledge." In the years since 2004, Tibetan translations of GMP regulations have been produced with some success (Tso forthcoming, Phuntsok 2004). However, this process has required the creation of Tibetan neologisms that can confuse fundamental issues. Consider the challenges of precisely translating concepts like "particle contaminant ratios" into Tibetan and "post-digestive tastes" into Chinese. These "translation issues" are also proxies for deeper and more complicated conflicts and ambivalence with respect to the regulation of Tibetan ways of knowing by biomedical and Chinese arbiters. Another doctor in Lhasa said, in 2002, "A Tibetan GMP would ensure that our standards are met—that we work according to our ideas of 'warming' and 'cooling' ingredients, for example. But doing this will be very difficult because it would mean GMP experts would have to trust us. They would have to believe our ways of knowing what makes good quality medicine. And this is difficult because of language and culture."

To some Tibetan pharma producers I interviewed, though, GMP compliance filled them with hope. As Lhakpa, the factory executive from my visit to the Lhasa Mentsikhang in 2002, had put it, "GMP is the key to the door of the outside world." From this perspective, GMP regulations often became symbols of larger processes that would allow Tibetan medicine and the benefits (*phan thogs*) it promises humanity to go global, all the while creating new economic opportunities for Tibetans in China. A gregarious young Tibetan woman, a GMP specialist at the Mentsikhang factory, put it this way, "The people of the old society (*phyi tshogs rnying ba*) and today's situation (*dings sang gyi gnas tshul*) are not the same. Now we must follow GMP, and there are some problems…Before, there was a lot of cultural knowledge (*rig nas*), but not so much experience with economic forces when considering medicine—what makes it high quality, how to sell it. Today the main concern is the economy, not only with healing." Of course, many people I interviewed disagreed with this perspective; but it was honest, in its own right. In contrast, some people doubted the quality of medicines being produced in what has clearly become a money-making venture because they viewed

it as a departure from the ethical purpose of producing Tibetan medicines *at all*. Others derided their fellow countrymen for doubting the quality and efficacy of "modern" Tibetan medicine, as epitomized by GMP, and chastised those who would value "superstitious" and "backwards" production practices of the "old society"—itself a reference to Tibet prior to its "liberation" in the 1950s—over those promulgated by GMP.

Some producers feel the need to embrace an ideology of science and aspire to global recognition for Tibetan medicine through the taming of tradition by way of standardization and compliance with pharmaceutical governance. Other producers carving out discursive and physical spaces in which GMP ceases to be relevant, is directly challenged, or is selectively ignored. These realities return us to the idea that regimes of global governance can manifest in diverse, contested ways in particular localities (Collier and Ong 2005). For example, some pragmatists within the industry have told me that it is often easier to falsify their Standard Operating Procedure (SOP) registers than it is to deal directly with the issues of incommensurability that arise while implementing GMP regulations at their factories. Compared with such acts of resistance, Arura's agenda seems sophisticated, novel, and ethical. They are mapping out new realms of possibility for creative action that are at once attentive to markets and compliant with governance regimes but also driven by an ethics of care and a spirit of medical and social practice that emerges from Tibetan sensibilities. This institution seems to have found a middle way that neither requires total conformity nor direct conflict with global and national governance. Indeed, it seems that Arura has in some instances even turned areas of incommensurability into strengths, creating spaces in which ideologies and practices of Tibetan and biomedical science need not compete, but can complement each other.

Nearly all of my interlocutors, across both time and space, have noted that GMP implementation was a challenge Tibetans had to face. They implicitly understood that Tibetan medical factories must make commercial products whose safety and efficacy can be validated in understandable and acceptable terms within the context of contemporary China, as well as by global regulatory agencies and non-Tibetan consumers. Yet we have seen most explicitly with Arura, this does not necessarily require a total rejection of "traditional" forms of practice. However, in order to envision contemporary methods of Tibetan medical production that comply with global and national governance but that allow for measurements of quality and safety determined, at least partially, according to Tibetan medical

theory and practice, there needs to be a pressing incentive to do so. Such a transition demands the power, confidence, and authority to innovate. Many Tibetans invested in the industry struggle through these changes and wrestle with the ambivalent ethics of practice engendered by them.

Of course, the elephant in the room is environmental depletion of the rare and endangered ingredients that are wild-crafted from high altitude environs and that, in many ways, make Tibetan medicine uniquely *Tibetan*. During our conversation, Dr. Kunga mentions several such ingredients whose prices have more than trebbled since 2006 and that are becoming increasingly difficult to find in quantities that meet clinical and commercial production demands. As a senior administrative officer at one factory said as we were talking, frankly, about the political ecology of medicinal plant use and the future of Tibetan medicine, "We don't think of the environment. We are not like small countries like Bhutan. In China—also in America—we just use things up. After we use them up, we worry about what to do." Here, the lack of explicit environmental regulations on sourcing for GMP or non-GMP sites of production, and related questions about what makes for "good" manufacturing, perpetuate and deepen ethical dilemmas associated with the scaling up of this traditional medicine industry. We might even say that it is an *absence* of coherent regimes of governance at this level that frames the moral impasse.

Conclusion

In this article, I have argued that GMP and related regulations are shifting the episteme under which Tibetan medicines are made.[28] GMP regulations clearly emerge from both national and global governing bodies as well as ideologies of science and modernity that take root within a minority region of China in specific forms, and that come to live within the subjectivity of individuals, and within institutions they create, in particular ways. The enactment of GMP compliance requires the adherence to new hierarchies of knowledge, which, in turn, create new possibilities for action and new practical and ethical dilemmas. Here, we might note an interaction between two Foucaultian concepts: governmentality and technologies of the self. The former connotes the art and techniques of government that at once encompass the institutions and organizational practices through which citizen-subjects are governed; the latter focuses on the forms of knowledge and strategies that "permit individuals to effect

by their own means or with the help of others a certain number of operations on their own bodies and souls, thoughts, conduct, and way of being" (Foucault 1988:18). As we have seen, the terrain of Tibetan medical production is ethically charged, inflected with a difficult cultural politics, and constrained by techno-scientific convention.

Those changes in Tibetan medical production are occurring within the context of a global pharmaceuticals industry expanding its resources and its reach (Petryna, Lakoff, and Kleinman 2006); global health agendas in which traditional medicines are considered integral to meeting health care needs, but are also subject to policies that aim to evaluate their safety, quality, and efficacy according to biomedical parameters (Langwick 2008, Shea 2006); and an international milieu in which the "gold standard" of randomized controlled trials (RCTs) has come to dominate what is known about therapies of all sorts (Kaptchuk 2001). Furthermore, these processes are tied to increasingly privatized, market-based medicine in China and beyond, (Rylco-Bauer and Farmer 2002; Bloom and Xingyuan 1999; Carrin, Ron, and Hui et al. 1999), to new models of medical pluralism that include desires to consume and profit from the "traditional" (Harrington 2008, Zhan 2009, Cant and Sharma 1999, Banerjee 2009, Bode 2008), and to the parameters within which clinical "evidence" and "good" scientific practice are constructed and deployed (Quah 2003, Harding 2006, Latour 1999). Finally, these processes are implicated in issues of biodiversity conservation and ethnobotanical knowledge, with specific reference to Himalayan and Tibetan materia medica (Thomas, Karki, and Gurung et al. 2005).

In sum, the transformation of Tibetan medicines from locally and regionally produced substances tied to specific patterns of production and regimes of value into widely circulating commodities beholden to national and global pharmaceutical governance is a compelling and fraught process.[29] The issues lie not in the need to monitor medicine production or adhere to safety and quality guidelines. Nor are biomedicine, techno-science, or global governance, *sui generis,* problematic. The work of science studies and medical anthropology makes clear that these are dynamic praxes in which people invest, and which people shape, for particular historical, political, economic, and ethical reasons. Rather, the problem with regimes of global governance such as GMP rests in *assumptions* about what "safety" and "quality" mean, and who gets to define them. As recent scholarship makes clear (Franklin and Roberts 2006, Anagnost 2006) the social construction of concepts such as "quality" is a fruitful site for ethnographic analysis because it

cut to the core of positivist suppositions about what constitutes evidence of "good" practice. Additional dilemmas surface as we watch processes of drug safety and quality assurance cascade into issues of medicine access and affordability on the one hand, and the depletion of natural resources upon which this "traditional" medicine depends, on the other.

ENDNOTES

[1]I use scare quotes for "traditional medicine" in its first use to point out the ways this phrase operates at different registers: as a normative discursive category used by different types of people, including many of my interlocutors, to describe healing practices that are viewed as distinct from biomedicine and that are often compared or at times conflated with "complementary" and "alternative" medicines; as a modern product, socially constituted within particular national(istic) frameworks; as a category created by institutions of global governance such as the WHO for a range of highly variable therapies, practices, and knowledge systems that are demarcated in opposition to ideas of "conventional" medicine or "biomedicine" at the level of policy.

[2]Similar dynamics have been noted with regard to *gso ba rig pa* in Mongolia (see Sabernig 2002). Sabernig (2002) also describes substitution practices in Amdo (northeastern Tibet). Today, the process of substitution is articulated at different registers. At times it is discussed as an imperative in a post CITES context, in which regional enforcement of global conservation governance impacts Tibetan pharmacology. In other moments, the need for substitutes articulates to economic and ecological limitations or scarcities. Finally, substitution can emerge from a moral/religious mandate related to Tibetan Buddhist ideals about not harming or killing sentient beings.

[3]While "official" export of Tibetan medicines to countries outside of China is still a relatively recent phenomenon (China Tibet Information Center 2007c), Tibetan pharmaceutical products produced by GMP-certified factories in China have been available for purchase over the internet for several years; they have also begun circulating regionally and globally through the tourism industries in Tibetan areas of China. In the United States, such products are marketed as "nutritional supplements" (see Adams 2002b, Prost 2008:99).

[4]All Tibetan names in this article are pseudonyms.

[5]See Adams (2005) for a discussion of this idea of "saving" Tibet.

[6]Fischer (2005) provides detailed qualitative and quantitative data on the rates and types of Chinese migration into Tibetan areas, as well as a useful analysis of the nature of the Chinese state's place in facilitating this migration.

[7]Drug registration numbers are akin to patents, but not identical. Three phases of clinical testing (chemical toxicology, animal testing, and testing on humans in a clinical trial) are required to procure a drug registration number. Processes differ slightly for medicinal compounds that are viewed as "old"—e.g., that are referenced in Tibetan medical texts—as opposed to "new" formulas that are the work of contemporary Tibetan physician-pharmacists. Until 2004, some Tibetan formulas that had drug registration numbers were not being produced according to GMP standards; however, since June 2004, all registered drugs must now be produced in GMP-certified facilities; non-compliance would result in

the factory losing its drug registration number for that particular compound. Drug registration numbers are proprietary; they also contribute to the rising costs of Tibetan pharmaceuticals.

[8]Tibetan medicine, like its Chinese counterpart, includes a variety of formulas and medico-religious practices geared toward extending life and increasing vitality. See Gerke (2008) and Samuel (forthcoming) for an anthropological discussion of long life rituals and medico-religious practices.

[9]This figure was reported through AsiaInfo Services (2008).

[10]The China Tibet Information Center (2006) reported there were 19 GMP certified factories in Tibet. However, this raises questions about what qualifies as a Tibetan medical factory. Some Chinese pharmaceutical companies produce several drugs that they label "Tibetan," while there are also several small-to-medium sized Tibetan enterprises that produce some Tibetan formulas, as well as incense. My research did not focus on such enterprises, but they do figure into how such statistics are generated by Chinese media, including the China Tibet Information Center.

[11]The term "potency" (*nus pa*) points to the action that a substance may originate by means of its features and qualities. In Tibetan medicine this expression designates both particular qualities of medicinal substances, which constitute their therapeutic properties (the eight nus pa), and their therapeutic effect (Boesi 2006:2).

[12]As Aschoff and Tashigang (2001:45-46) write: "It seems consensus among Tibetan physicians from different regions in Tibet, from the Himalayas and Northern India, that over the past decades the potency of jewel pills has declined. Whereas in the past patients responded well to doses as low as one jewel pill per week, the same effect today may require as many as one pill per day. Among the factors blamed for reduction [in] the pill's power is today's poisoning of the environment with chemicals, radiation and fertilizers, while there may also be a lessening in the mental and concentrational powers of the Tibetan master physicians manufacturing these pills."

[13]Factories have been known to under-report their revenue for tax reasons. Statistics vary widely and it is never clear how they are calculated. The figures presented here are cited in Chinese media sources (Xinhua 2004, *China Daily* 2004), and from the China Tibet Information Center reports (2006, 2007a, 2007b).

[14]Fisher (2005) provides an excellent summary of the relationship between ethnicity, economic policy, and social exclusion in Tibetan areas of China. An important strategy for the regional government and business is foreign direct investment (FDI). Total FDI in 2000 was $160 million in the TAR involving investment into 125 enterprises, loans to seven projects, and financial support of 49 programs. Main investor countries were the United States, Japan, Germany, Hong Kong, Malaysia, Nepal, and Macao. Of these, the first four have sustainability indexes and active SRI groups. Furthermore, in recent years, small Tibet-focused social capital organizations have appeared in these same countries. While interest in FDI—both giving and receiving it—has increased in recent years, and measures have been taken to raise communication, accessibility is still limited. Opportunities for Himalayan businesses to meet potential business partners and investors, dialogue and analysis to plan business strategies, and motivation for cross-cultural business, scientific, and environmental understanding are all limited. Accessed from http://www.arunamgyal.com/5W/Industry/people.htm May 21, 2005.

[15]By 2007, when I conducted follow-up interviews with several key interlocutors in the TAR, industrial sized microwave ovens were considered state-of-the-art in drying technology. In practice, however, they were rarely being used because of producers' wariness about the effects of radiation on the nature and potency of materia medica.

[16]This dynamic is compellingly illustrated for conventional pharmaceuticals through Petryna's (2009) work on the global clinical trials industry.

[17]In an interview with the vice director of Mentsikhang factory (August 29, 2007), he said that funds for GMP compliance were garnered through the Bank of China and that the interest rate was paid for a period of time by the "concerned with poor people department" (*min zong wei*) and the "Training for needy people department" (*nong mu ting*). The cost of building the new Mentsikhang factory was RMB 40 million ($5 million US at the time). An interview with a senior administrator at the Tibetan Medical College factory, also a state-run institution, in contrast, said their factory retrofitting cost RMB 1.3 million ($162,500). This difference also reflects the range of size and scale within this industry.

[18]The issue of changes in the prices of Tibetan medicines, and the GMP's relationship to this, is worthy of consideration in its own right. It is explored in Hofer (2009) from another perspective, and mentioned in China Tibet Information Center (2006). Many of the people I interviewed indicated that GMP implementation had contributed directly to increasing costs of commercially available medicines. There is internal contradiction and dissent, however, in the data on this point. Health Bureau and Tibet Drug Administration regulations officially "fix" prices for Tibetan medicines, a practice that is also connected to the state health insurance regulations. Some people have indicated that this network of regulations about production and distribution was creating more difficulties for state-owned factories to turn a profit (Martin Saxer, personal communication, January 2009). Interviews with representatives of private companies and public-private partnerships indicated the reverse.

[19]There is now an updated 2007 version of this law (see http://eng.sfda.gov.cn/cmsweb/webportal/W45649037/A48335975.html?searchword=(pharmacopoeia).

[20]Amdo (*A mdo*) is one of three main divisions of what scholars have alternately dubbed "historical" or "ethnographic" Tibet. The other divisions are Kham (*khams*) and U-Tsang (*u btsang*). Amdo corresponds to parts of Qinghai and Gansu provinces; Kham includes regions of Qinghai, Sichuan, and Yunnan provinces as well as the Tibet Autonomous Region; U-Tsang, also called Central Tibet, is entirely encompassed by the Tibet Autonomous Region, and actually includes further internal divisions, including Ngari (*ngas ri*) in the far west.

[21]For more on Arura's organizational structure and ethos, see Adams, Dhondup, and Le (2010) and Saxer (2010).

[22]I credit Martin Saxer (personal communication, September 2009) for this information about the Lhasa Mentsikhang Factory.

[23]This issue of translation of science across cultural divides with respect to Tibetan medicine and clinical research in China is described in more detail in Adams and Li (2008); Adams, Miller, Craig, et al. (2005); Adams, Dhondup, and Le (2010); and Craig (2010).

[24]I have yet to do a thorough economic analysis of the price differentials between the GMP-certified factory and the hospital production unit, but as an example the very popular precious pill Ratna Sampel sells for Y. 12 per unit at the hospital pharmacy while a box of four such pills retailed at Y. 320 at the GMP-certified showroom.

[25]Known in Tibetan as "summer grass, winter insect" (*dbyar rtswa dgun 'bu*), this hybrid caterpillar moth-fungus is highly valued within China and beyond. It can cost as much as US $40,000 per kilogram, and is collected and sold throughout Qinghai. For more information on the socioeconomics of *cordyceps* in Tibetan areas of China, see www.danielwinkler.com.

[26]Other profits are being used to digitally catalog, reprint, and make available to new generations of Tibetan doctors hundreds of extant Tibetan medical texts, to publish a Tibetan

language scholarly journal about Tibetan medicine, and to conduct a variety of clinical research projects on Tibetan medicines.

[27]The 2001 China Drug Administration law was translated to Tibetan (see-http://eng.sfda.gov.cn/cmsweb/webportal/W43879541/A59542656.html?searchword=%28Tibetan%29). There have been attempts to translate GMP regulations into Tibetan (see Tso forthcoming and Phuntsok 2004).

[28]Foucault (1980:197) defines *episteme* as "The strategic apparatus which permits of separating out from among all the statements which are possible those that will be acceptable within, I won't say a scientific theory, but a field of scientificity, and which it is possible to say are true or false. The episteme is the 'apparatus' which makes possible the separation, not of the true from the false, but of what may from what may not be characterized as scientific."

[29]Interestingly, traditional medicines are becoming standardized and commodified just as aspects of biomedical practice—from pharmaceutical production and clinical research to therapeutic practices—are being indigenized (Etkin, Ross, and Muazzamu 1990; Miles 1998; Castegrade 2005; Selby 2005; van der Geest and Whyte 1989).

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