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"There is No Regulation, Actually":

The Private Market for Anti-TB Drugs in India

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Introduction: "74%"

Ten years ago, Paul Farmer called tuberculosis the "forgotten plague" (Farmer 2000: 185). While millions of people were dying every year of TB, the disease had become invisible for people living in rich countries. TB used to be at the forefront of public interest when it was rampant in the richer industrialized countries. But thanks to better nutrition, healthier living conditions, and more effective drugs, TB "ceased to bother the wealthy" (2000: 185). Against this forgetfulness, Farmer urged anthropologists to listen to the voices of the poor and to record their stories of deprivation and discrimination. But he also said that ethnography was insufficient to grapple with the problem. A comprehensive perspective on tuberculosis "must link ethnography to political economy and ask how large-scale social forces become manifest in the morbidity of unequally positioned individuals in increasingly interconnected populations" (2000: 197). Ethnographers could touch on "structural violence," but were unable to fully analyze it with their own methods.

Since the WHO declaration of TB as a global emergency in 1993, the fight against tuberculosis has received far more attention than previously, and even pessimists would now find it difficult to call TB a "neglected" disease. Several global initiatives have emerged to bring effective anti-TB drugs to even the world's poorest regions. For example, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) has distributed US$19.3 billion to 572 programs in 144 countries (Global Fund 2010) since its

foundation in 2002. The WHO's push to spread directly observed treatment, short-course (DOTS) across all countries through their national TB control programs was also of great importance. DOTS aims to detect all TB cases through sputum microscopy and to enroll all patients into a treatment regime lasting six to eight months. DOTS has had many successes, and the global number of cases per capita has been falling by about 1% per year since 2004. However, the total number of cases is still growing due to overall population growth (WHO 2009: 1).

More awareness of the limits of this approach has led to the expansion of DOTS from 2005. The "Stop TB Strategy" (WHO 2010) contains six components: 1) expand and enhance DOTS; 2) focus on the poorest people, on HIV-co-morbidity, and on multi-drug resistant TB (MDR-TB); 3) strengthen primary health care; 4) engage all care providers; 5) empower people with TB; 6) promote research into new diagnostics, drugs, and vaccines. The strategy to "engage all care providers" entails plans to involve an array of voluntary, corporate, and private providers and to extend collaborations in "Public-Private Mixes (PPM)" (WHO 2009: 34).

In this paper, we explore how public-private collaborations can be successful in India. PPMs are an important part of the Stop TB campaign globally, but they are especially vital in India. One reason for this is the sheer number of TB patients. India has more people suffering from TB than any other country. Among 9.27 million cases of TB worldwide in 2007, 2 million lived in India (WHO 2009: 1). Another reason is the

number of patients being treated in the private sector, and the lack of quality care they receive. The WHO highlights that ensuring rational use of drugs *outside* the government-sponsored program is a particular concern in India. Previous research in India has demonstrated poor compliance with NTP/WHO treatment regimens among private doctors, with mistakes in both dosage of drugs and duration of treatment, as well as inflated costs for medicines (Arora et al. 2003; Uplekar & Shepard 1991; Singla et al. 1998; Prasad et al. 2002). In light of these findings, the WHO started a closer collaboration with the Indian Medical Association (IMA) to get a better grip on the situation (WHO 2009: 109). WHO claims that DOTS is provided by 100% facilities under the Indian Ministry of Health since 2006, up from only 30% in 2000 (WHO 2009: 109). It also claims that PPMs are spreading rapidly, with nearly 21,000 Indian private practitioners now being involved in PPMs (WHO 2009: 111). Yet these figures tell nothing about what percentage of cases is actually treated within DOTS or DOTS-allied PPMs. And they tell nothing about the scale of the problem: if there are *eight million* private prescribers in India (WHO 2010b: 47), how can even a decent few of them be included?

Why private prescribers are such a headache for DOTS also emerges from research commissioned by the Global TB Alliance on how anti-TB medicines are distributed worldwide. The Alliance's mission is to speed up the development of faster-acting drugs against TB. Launched in 2000, the TB Alliance is itself a public-private

collaboration between academics, donor organizations, and corporations. Among its corporate stakeholders are, for example, Eli Lilly, Novartis India, and Lupin. In contrast to WHO research, the TB Alliance also draws on data from corporate sources, above all from IMS Health Inc., a world-leading market research firm. For India, these data show the magnitude of private sector treatments of TB (TB Alliance 2007: 8). Drugs procured through public tender for government-sponsored facilities make up only 12% of the entire Indian anti-TB market. A larger share of drugs supplied to DOTS centers comes from the Global Drug Facility (GDF), which was launched by the Stop TB Partnership in 2001. India is the world's number one destination for both GDF-supplied drugs and for GDF grant support (TB Alliance 2007: 4). Yet GDF drugs only constitute another 14% of the Indian anti-TB market. The remaining 74%, the lion share of the market, is entirely private and, therefore, entirely outside of DOTS. In light of these market data, the claim that DOTS covers "100%" of India's needs for treatment rings hollow.

The unusual position of India in the global anti-TB drugs market becomes clearer in a cross-country comparison (TB Alliance 2007: 8). India not only consumes more TB drugs in the public sector than any other country (US$25 million in 2006), it also consumes more drugs in the private sector than any other country (nearly US$70 million in 2006). According to the TB Alliance, there is no private market for first-line TB drugs in China, and high-income countries such as the US, UK, France, and Japan, have no market for private TB treatments at all.

The language of public-private mixes suggests that the Indian Ministry of Health, with the support of the WHO, vertically controls TB treatments through the Revised National TB Control Programme (RNTCP). A number of recent studies suggest that Indian PPMs are successful at including private practitioners (e.g., Kelkar-Khambete et al. 2008). Official statements on PPMs never openly state that their ultimate aim is to gain control over private prescriptions, but in our interviews, this is how WHO-allied people routinely described them. For example, one of WHO's Delhi-based medical officers for TB told us in an interview in 2007 that Indian patients needed more protection from the private sector's "therapeutic anarchy," and that most private treatments were irrational and not compliant with WHO regulations. An officer for the German Leprosy and TB Relief Association (GLRA), which promotes DOTS referrals among West Bengal's rural GPs, pharmacists, and unlicensed "quacks," said that PPMs aimed at gradually fuming out treatments by private practitioners: "Only if we involve them, we can make them zero." But faced with a 74% market share of drugs prescribed outside of DOTS, the balance of power seems heavily skewed against public sector control. PPMs in India are less about a strong vertical program generously inviting outside participants than a desperate effort to get a grip on a sprawling private market.

Farmer's call for more ethnographies of TB has certainly not been in vain, and many excellent studies have been written on how patients experience TB and how they navigate different paths to health. Such ethnographies can convey both immensely

detailed insights into people's everyday deprivation and also point to wider structural problems. For example, Veena Das and Ranendra K. Das's (2007) longitudinal study of health-seeking experiences in a Delhi slum shows that it is not always patients who fail DOTS, but also that DOTS can fail patients by "consistent institutional neglect and incoherence" (2007: 85). For Nepal, Harper (2005) has shown how the very categories designed *for* entry into the public program can be used to *deny* entry for those who do not fit the criteria.

To date, however, anthropologists have hardly looked beyond TB *patients*. Farmer's idea of linking ethnography to political economy suggests an essential difference between what can be studied through local ethnography and what can only be studied through political economy. This chapter -- an ethnography of marketing practices by a private pharmaceutical corporation -- offers a different yet complementary perspective. We look at pharmaceutical production, distribution, and retailing and present a snapshot of the upstream forces behind anti-TB drug prescriptions. Here we focus on sales representatives for Lupin Ltd., India's leading producer of anti-TB drugs. To our knowledge, no similar research has yet been published in relation to TB control. Farmer is right to say that ethnography alone cannot provide the full "structural" picture, but ethnography can explore the point of view of the people whose daily work is to actually build the political economy behind drug prescriptions.

The data presented in the following are drawn from "Tracing Pharmaceuticals," a collaborative project on the production, distribution, regulation, and prescription of pharmaceuticals in India and Nepal. We took biomedicine's "magic bullet" paradigm of drug effects and turned it from its head to its feet: we selected molecules and followed them around wherever they went. To start with treatments instead of symptoms is, to some extent, an inversion of Kleinman's (1980: 104-118) classic formulation of explanatory models. Implicit in the idea of explanatory models is that they are ordered in a clear temporal sequence: first, people perceive illness symptoms; then they tried to make sense of the symptoms; then they seek medical help; then a doctor gives a diagnosis; based on that diagnosis, then treatment is prescribed. This order is so commonsensical that it appears counterintuitive to question it. Yet conceptual work done in the history of medicine and in science and technology studies opened up other possibilities. For example, Ian Hacking's (1995) "looping effects" demonstrated that medical classifications interact with what they are classifying, and that it is often impossible to say what came first: the patients of the disease, or the classification of the disease? Bruno Latour (1987, 1993, 2005) showed how relations between humans and nonhuman things can be traced. Taking these ideas and pushing them further, it became clear that it was possible to take a particular drug as a point of departure and to ask Kleinman's questions in reverse: what are the available drugs for treatment? How does the presence of drugs influence the perceived causes of illness? How does the

availability of drugs transform perceptions of illness? (Ecks 2008).

The three drugs that we selected in the collaborative project were rifampicin, oxytocin (Syntocinon), and fluoxetine (Prozac). Rifampicin was chosen from among the anti-TB drugs because it is an essential component of every short course regimen. Rifampicin is the only first-line drug that combines early bactericidal activity, sterilizing effects, and the ability to prevent resistance. Indeed, the very rationale for the introduction of DOTS was the protection of rifampicin. In the course of our research, we identified the leading brands of rifampicin in India and Nepal, traced them through various distribution channels, and explored the pathways by which they reach patients. Lupin Ltd. is the focus of this paper because of its dominant position both in the Indian private market, as well as in the Indian and global anti-TB drugs procurement process.

"Champions of the Chest": The Rise of Lupin Ltd.

Lupin is one of India's largest pharmaceutical companies. Founded in 1968 with an initial capital of only Indian Rs. 5,000 (ca. US$700 at late 1960s exchange rates), it has been one of India's top firms since the 1990s. Calling itself "Champions of the Chest," the corporation is especially well-known for its production of anti-tuberculosis medicines. For the anti-TB drugs rifampicin, ethambutol, isoniazid, and pyrazinamide,

Lupin has gained a globally dominant market share. Lupin established itself in the anti-TB product segment when it started manufacturing ethambutol in bulk in 1981. Two of Lupin's bestselling brands, R-cinex and AKT, are tuberculostatic remedies (Lupin 2009: 28). R-cinex is the brand name of a range of fixed-dose combinations (FDCs) of rifampicin, isoniazid, ethambutol, and pyrazinamide. AKT is a brand of "kits" that bundle single tablets of these four molecules in different combinations and dosages, for example, AKT-4 contains separate tablets of rifampicin 450mg, isoniazid 300mg, ethambutol 800mg and pyrazinamide 1500mg. Altogether, Lupin produces 40 different antitubercular products, making it, in the words of one of its marketing directors, a "one-stop shop" for TB treatments. A recent addition to its product range is Ributin (rifabutin 150mg), which is marketed as an HIV-tuberculostatic. Lupin has market dominance not only in formulations, but also in active pharmaceutical ingredients (APIs): for rifampicin and ethambutol, Lupin is the world's leading bulk manufacturer (Chaudhuri 2005: 51). Its API fermentation plant at Tarapur (Maharashtra), which was established in 1992, is the world's largest plant for the production of rifampicin and one of only three global plants approved by the US FDA. Lupin is also one of the six global companies prequalified as a supplier for the Global Drug Facility, which distributes the company's products to 50 different national tuberculosis control programs worldwide. Since the Indian TB program is the world's number one recipient of GDF supplies (TB Alliance 2007 intro p.4), a good share of Lupin drugs stays in the country itself.

Aside from anti-TB drugs, Lupin is trying to diversify its portfolio and produces a range of other remedies. Lupin has also become a world-leading bulk producer of cephalosporins, a class of antibiotics, and it is focusing on cardiovascular, diabetic, asthma and non-steroidal anti-inflammatory drugs. Lupin is one of the Indian pharmaceutical firms that managed to go global. For example, in 2007-08, Lupin was the third fastest-growing company in the US prescription market. It acquired majority stakes of companies based in G8 countries, such as Germany's Hormosan and Japan's Kyowa.

Lupin's strong presence in the anti-TB drugs market, both in India and globally, went through several phases (Chaganti 2007). In the 1970s, Indian doctors treated TB with para-aminosalycilic acid (PAS), isoniazid, and thiacetazone. At that time, the Indian anti-TB market was held by Pfizer India and Biological E. Limited, then a medium-sized Indian company. But in the late 1970s, ethambutol, pyrazinamide, and rifampicin came to the market. Internationally, rifampicin came to replace the injectable streptomycin, and ethambutol replaced PAS (Ryan 1992). Pfizer India and Biological E. had not anticipated such quick shifts in treatment regimes, and within a few years they lost their foothold in the anti-TB market. By the 1990s, the Indian market for the older generation of drugs had shrunk to 3%. During the same period, Lupin "began flexing its muscles in the late seventies and was actively looking for opportunities to satiate its ravenous appetite for rapid growth" (Chaganti 2007: 56). When Lupin introduced

rifampicin, ethambutol, and pyrazinamide in 1981, it was only ranked at No. 62 in India. By 1988, it had captured nearly 30% of the anti-tubercular market share and had risen to No. 12 in India. By 1992, Lupin's share had risen to 50% and by 2006, Lupin was ranked 9th in India overall with 2.3% of the market share for pharmaceutical sales in India, and had 45.6% of the Indian anti-TB market by sales. Lupin's annual report 2008-2009 stated that it had become India's fifth largest pharmaceutical company.

Combined data from three drug databases (CIMS, IDR and MedCLIK) indicate that there are at least 52 Indian manufacturers of anti-TB drugs. From among the 36 companies listed in CIMS, 34 firms combine rifampicin and isoniazid; 12 combine it with isoniazid and ethambutol; 19 combine it with isoniazid and pyrazinamide; and 19 combine all four drugs (CIMS 2007). Despite this proliferation of brands, it is likely that lesser companies are gradually pushed out of the segment by the now-established leaders. For example, while the overall market for anti-tuberculars shrunk by 5.9% in 2009, Lupin's share grew by 5.6% (Lupin 2009: 30). Bengal Chemicals, a government enterprise based in Kolkata, used to be one of the state's main suppliers of non-combined rifampicin, ethambutol, and pyrazinamide, but in an interview with us, the General Manager of Marketing explained that these are going to be abandoned because of a shrinking market. In Nepal, Lupin's increasing dominance of the market has resulted in local companies no longer being able to compete. Lupin's market share for rifampicin, ethambutol, isoniazid and pyrazinamide is so solid that it does not need to

fight off serious competitors anymore. Instead, the company's challenge is to diversify its product range to shake off an overreliance on anti-TB drugs. If the TB Alliance actually succeeded in introducing faster-acting drugs in the next few years, Lupin's current market dominance would be up for grabs.

"The Most Vital Role": MRs' views of the anti-TB drug market

One of the main research methods in "Tracing Pharmaceuticals" was to conduct semistructured interviews with people on all levels of the pharmaceutical business and in the regulatory and scientific bodies around it. We carried out a total of 475 interviews, most of them in Delhi, Kolkata, and Kathmandu, as well as in several smaller towns of Nepal and Northern India (Jeffery 2009). Among these were 42 interviews with medical representatives (MRs), 30 of which were set in India and 12 in Nepal. This chapter highlights findings from interviews with eight MRs of Lupin Ltd. conducted in Delhi, Kolkata, Bijnor (Uttar Pradesh), and Kathmandu. Six of our interviewees were low-level reps in charge of visiting private practitioners; one of them was an area manager; one a regional manager supervising several employees. Our questions ranged from the MRs' daily work experience to their views on the private anti-TB market. Depending on the respondent, the interview language was either

English, Bengali, Hindi, or Nepali. All the interviews were recorded and transcribed into English.

In our interviews, all the MRs said they were proud that Lupin was the leading company in the field, and one with an excellent reputation for quality. What distinguished Lupin from its competitors was that its drugs were readily available all over India, making it possible for patients to travel across regions while still being able to buy their prescribed doses from any shop. The quality of Lupin drugs was so high, they suggested, because the company produced its own active pharmaceutical ingredients: "No other company can provide that quality to the patients, only Lupin can do that, because almost all the companies are purchasing the raw materials from Lupin only." Their production plants were run with internationally established quality standards: "It is certified by WHO, it is approved by USFDA, there are various certificates, it's really good." The MRs felt that Lupin's commanding market presence was well deserved. It was a "good company" with a great sense of social responsibility. One MR pointed out that Lupin did not enter the anti-TB market during the 1980s for profit reasons, but out of a feeling of social commitment to the people of India. During this time, he said, multinational companies were withdrawing from the Indian market and were not meeting the Indian people's demand for these drugs, and this was when Lupin stepped in to help. Another MR said that after having worked in Lupin's anti-TB segment for several years, he felt more "like a social worker" than like a regular sales

representative, and that his aspiration to fight tuberculosis transcended his day-to-day job. The MRs found that Lupin was also a good company in relation to its own workforce. While the job of a medical sales representative was tough and driven by tight sales targets, at least Lupin had a "humane culture compared to other companies." Even the MRs who were active in the trade union for medical reps, the Federation of Medical Representatives Association of India (FMRAI), said that Lupin compared favorably to the work practices found in other companies. (In turn, this sense of working for the market leader gives Lupin reps a reputation for arrogance among MRs working for other firms. This was especially evident in Nepal.)

Lupin's marketing sales force for anti-TB drugs is organized in the same way as other such divisions. There are area managers who monitor a group of medical representatives who go out and meet prescribers. Above the area managers, regional managers supervise larger geographic areas. For example, a regional manager for West Bengal and Sikkim looks after four area managers and 19 medical reps. Overall supervision of all areas in India is under the product management team (PMT) at the Mumbai head office. The PMT develops overall strategies and tailors them to different regions: "Gross strategy has been formed at our headquarters where the product management team is there, the marketing team is there. They are seeing the total market scenario and the growth pattern and the prescription habits of the doctors and after observing everything, they are making the gross strategy. And then, according to the

region, the strategy is formulated for West Bengal, Orissa and all. It has been formulated according to the regions. The gross strategy is the same, a small plus-minus will be there."

Lupin MRs get regular updates on the company's overall performance. The MRs we interviewed portrayed the company similar to what its annual report says: that Lupin is the world's leading manufacturer of rifampicin and ethambutol; that the anti-TB segment shows a "degrowth" and that the product range needed to be further diversified: "TB segment is de-growing, that's why Lupin has ventured into vascular segment, now shortly we are going into gyne [gynecology] segment, into cardiac segment, and diabetic segment." Lupin's recent introduction of Ributin (rifabutin), which had been approved by the US FDA as early as 1992, is seen as an exceptional event in an otherwise stagnant market. Speaking about rifampicin, which was first developed in the late 1950s by Sensi and colleagues (who named it after the 1955 heist movie *Rififi*): "The brand, as you know, is archaic." It seems that the Mumbai PMT team constantly changes the marketing guidelines not least because it needs to counter a sense of tedium with such a stagnant set of drugs among its sales force.

Since all the existing remedies against TB have been used for decades, and since no newer drugs have yet been developed, Lupin's dominant position in the market is based on producing high-quality drugs at the largest possible scale, in a wide variety of doses and in a variety of combinations. In a market where all companies, even the

largest, do not compete by holding exclusive product patents but by quality, scale, dosage, and combinations, marketing muscle greatly matters. In a market crowded by off-patent products that are all looking "similar" (see Hayden 2007), the lines between what counts as a "brand" and what counts as a "generic" are drawn in peculiar ways. In India, a "brand" is a recognized generic product from a "good" company. In turn, a "generic" drug is seen as a dubious product from a small or untrustworthy company. This is why Lupin's MRs speak condescendingly of "generics" as the product of other companies. Even more than with other medicines, anti-TB drugs had to be of the highest possible quality, and to accept anything less imperiled not only the patient, but the population at large through multidrug-resistant strains: "Tuberculosis is such a dangerous disease and bioavailability of each drug is very important. But it is important to have the quality for drugs. If there is a slight difference in the quality, then MDR-TB is spreading." For the Lupin MRs, the biggest problem in their day-to-day business was the circulation of "generics." They perceived the proliferation of companies and products as so strong that even Lupin was forced to frequently introduce "me-too" combinations. About a new fixed-dose combination brought out by Macleods, a rival company, an MR at Lupin said that the company quickly introduced its own me-too version: "Lupin has introduced, it's not like only Macleods is having … *Question: They copy you, you copy them?* Specifically, I would say. In this market, if we have to survive, we have to fight." The lines between their own products and those of the competitors

were so blurry that it was difficult to distinguish between what is a "generic" and what is an "unethical" or counterfeit drug: "These generics drugs, this is the number one problem ... Generics coming, plus unethical drugs also coming ... it's a problem for patients, problem for medical representatives, problem for all the people." The MRs grumbled that the Indian government risked rising rates of MDR-TB by licensing companies that clearly had lower quality standards than Lupin.

Lupin MRs are proud of knowing their customers better than their competitors. When asked what skills are needed in their line of work, they said that "identifying the customer" is first, and "giving him what he wants" is second. This meant giving private physicians the products they desired. It also meant giving services and gifts that convinced them to write Lupin products. MRs also have to liaise with retailers and distributors to ensure that Lupin products are widely available for sale: "In marketing, what is important is, first, we need to identify our customer, who is our customer, that's number one. And number two is, we need to give the customer our services. Like, we need to promote our brand continuously, we need to request for prescription, and we need to request the customer for our brand ... Plus ensuring availability. Our brand should be available everywhere."

Despite Lupin's dominant market share, even small fluctuations in demand had to be monitored carefully. Even a one percent drop in prescriptions were seen as a "big amount" that needed a quick response. The MRs relied on different sources to gauge

market movements. First, Lupin's own sales data were fed back to the marketing team daily. Second, the MRs were daily briefed on data provided by the commercial research organization ORG-INS, which conducts sales audits with retailers and distributors on the market shares of different companies and products. Third, the MRs also monitored the career of their products by keeping in touch with prescribers, retailers, and distributors. Through this mix of data sources, MRs were able to know precisely how many times individual doctors prescribed their brands and how other companies were doing by comparison. Since there were different data sources, any mismatch could be picked up and be further investigated. In other words, there is no hiding from an alert sales force: "ORG is giving some different data, that doctors are very fond of fixed-dose combination rather than kit, and I am getting the data that they are more fond of kit, then there is a mismatch. Then you have to intervene more in the market and we have to go more to the chemists and survey more doctors as to what goes wrong." Another MR described how he talks to retailers to know how much a doctor writes: "Normally, at a chemist near him, I go there and try to analyze -- *bhai, kitna likh rahe hain?* [brother, how much is being written?]. The retailers usually give this information without further ado. The MRs also ask from which distributor or wholesaler the retailers receive their products, and can easily double-check if they got the true picture: "So what I will do, I will nab those two distributors, see the records, if that chemist is telling the truth or not."

While the briefing of MRs is a "downward" feed of information top-down through the hierarchy, there is also an "upward" feed back from the field force to the area managers, regional managers, and ultimately the Mumbai PMT. The MRs did not see themselves as passive recipients of centralized information and sales targets, but as the best all-round source of information. A Kolkata-based regional manager proudly said this:

> "Because [the MRs] keep better information on how is the market, how is the market reacting, how the patients are reacting, and how the prescription habits of the doctors are different. Suppose [the MR] meets two hundred doctors in a month. We have 19 representatives, so 19 times 200 doctors there are in total every month. So all these experiences first come to the area managers, then area managers again finalize on the important experiences that he will share with the regional manager, like me. Out of that, I will share with my sales manager and that will go to the GM [general manager] of the PMT department."

One MR summed up this position by saying that "medical representatives play the most vital role in the market," because they knew more about tuberculosis and its treatments than anyone else.

"Husbands and wives": MRs' perceptions of private prescribers

Participant observation in India and Nepal revealed that MRs were frequently treated as a nuisance by doctors. The MRs often had to wait in a long queue and were given only one or two minutes to rush through their sales presentation and to leave a few product samples. In our interviews, the MRs aired their frustration with being held in low esteem, not only by doctors, but also by society at large. It was a "mental blockage in society" that MRs were seen on par with door-to-door salesmen. In truth, they were on par with doctors. Indeed, in some respects, they were better than doctors: "You are going to a person who is really more educated than you ... his mental or IQ level is more, compared to me, and I'm standing in front of him ... so I should be able to have a *better* way of talking, a *better* knowledge."

Lupin MRs highlighted that they knew as much about the correct prescription regimes as about profits and markets. Being an MR meant more than mere selling: it was "concept selling." To convince the doctors to prescribe their drugs, they first had to be fully confident of what they were telling them: "Confidence is very necessary because, if confidence is not there, there won't be any confidence in the product." All the MRs said that this level of confidence was much easier to gain with a market leader than with a lesser company: "Doctors trust whatever Lupin speaks in TB. It is told to us that 'You are the leaders, whatever you speak, doctors understand that. So be positive

and whatever you speak, it should be correct.'" For representing Lupin, one had to know everything about the right treatments, because "we are playing with the lives of people and doctor is trusting on us." Tremendous trust in Lupin echoed in our interviews with doctors. When asked about what drugs they used, they frequently referred directly to Lupin's brands, such as "AKT," instead of the generic molecules.

The MRs said that they visited the widest possible array of doctors, both by specialty and by level of expertise: "*Every* doctor is treating TB. If he gets a single patient also in one year, he is treating them ... Every doctor *has* to treat TB because the patient, who is scared of getting treatment, will obviously die."

Specialist pulmonologists received most attention from Lupin's sales force because they wrote up to four times more prescriptions than other types of doctors. After chest physicians came general practitioners, thereafter other specialists such as pediatricians, orthopedic surgeons, or gynecologists. Specialists other than the pulmonologists had to be visited because tuberculosis does not exclusively affect the lungs, but can also affect the bones, the guts, or the eyes.

Different specializations made for different kinds of relations. The Lupin MRs whom we interviewed all felt that the doctors who had the most expertise also valued their input most: "They want to know of the latest developments and they are more interested because it's their subject." The knowledgeable doctors fully appreciated that they could learn much from the MRs: "They realize the importance of medical reps,

because medical reps give them the information."

Surprisingly, the specialist doctors were most eager for the MRs' input because they liked to *deviate* from treatment guidelines. They always experimented with their own regimes and preferred "individual choices" over an automatic implementation of WHO guidelines. Similarly, the fixed-dose combinations that had been brought to the market by Lupin and other companies were useful suggestions rather than a law that had to be followed always: "Few like to give fixed doses and then some other doctors like to administer individual drugs. So it entirely depends on their preference." One of the doctors' motivations for prescribing tailor-made doses, as opposed to fixed-dose combinations, was that toxic side effects could be better controlled: "Anywhere in India, leading chest specialists normally prefer individual therapy ... maybe the patient is hepatotoxic to rifampicin ... or maybe this drug is resistant and not giving him the proper results." Top prescribers used individualized regimes to minimize drug interactions and to maximize bioavailability: "Rifampicin: empty stomach. After breakfast: take ethambutol. And then after 15 minutes, take pyrazinamide. Like that." Side effects of anti-TB drugs were inescapable and ranged from an alarming red discoloration of the patient's urine to irreversible liver damage. Getting the dosages right depended on a host of factors, for example, the patient's body weight and possible prior exposure to anti-TB drugs. Indeed, as we learned from interviews with chest physicians, one of the key complaints against DOTS was that it did not allow for

enough dosage flexibility.

One MR even said that "there is no regulation, actually" for the range of doses and combinations in use. Adjusting treatment to the individual patient had a lot of ins and outs: "Suppose my weight is 40 kilograms today ... I am prescribed as per my body weight. But after two months, after treatment, my body weight gets increased to 50 kilograms. So my doses will be increased." Pharmaceutical companies marketed an assortment of doses and combinations to allow private practitioners to fine-tune their treatment in any way they preferred: "Because of this, there are different varieties, different combinations available in the market." That individual drugs were more expensive than fixed-dose combinations was an added boon to the physicians, because more expensive regimes means more rewards from the pharmaceutical industry.

While top doctors were receptive to Lupin's recommendations, general practitioners were less so, because they were busy with so many other diseases and did not pay as much attention to what the MRs were telling them. The lack of interest shown by private doctors troubled the MRs, since the MRs could save them from malpractice: "We are the only source for private practitioners. Even to the government doctors, because the government is not also providing day-to-day updates ... only pharmaceutical companies today, they are providing continuous medical education." The lower one got down the hierarchy of specialization, doctors decided less by quality than by affordability: "Price is a major factor in rural villages, and in areas where people

are not that much capable to purchase ... Low-end doctors, there price matters." Lupin's prices are mostly pitched in the middle of the market: several companies have more expensive brands, but there are also many companies offering cheaper fare than Lupin.

Since the MRs always had to "know their customer," they also visit prescribers at the lowest end: quacks without any medical qualification. The so-called rural medical practitioners (RMPs) are, in many areas of India, the only people to give medical care to the local population, even if they have no license to do so: "Basically they are quacks. So that is very dangerous." The MRs agreed that the RMPs' treatment of TB was appallingly bad. Although they did not know much about TB, RMPs treated it in their own way, for example, they began treatment and stopped after only one month. RMPs also put price far over quality, because their patients could not afford long-term treatments with quality brands. To convince RMPs to write Lupin products, the MRs had to resort to direct bribery: "For those kinds of doctors, you need money. Because in India, everybody is *paisa* [money]." In any case, RMPs could not choose quality "because they don't understand the quality."

According to the MRs, however, one should not blame the RMPs alone for the messy situation. First, everyone prescribing anti-TB drugs could get it wrong: "Even big, big doctors also make mistakes. Don't believe that only RMPs are committing mistakes." Second, the basic infrastructure was not in place: "The last 37 years we [Lupin MRs] are telling, we are shouting. But tuberculosis, instead of finishing, it is flourishing. So there

must be some basic problem at the root." The Indian government failed to provide basic care to all its citizens, and failed to train health personnel. For the Lupin MRs, they had to pick up the pieces and inform providers of rational drug uses where the government had left a void: "Because there is no other machinery to teach them, now pharmaceutical companies have started also village level CMEs [continuing medical education]." That the easy availability of anti-TB drugs in the private market could be part of the problem, rather than part of the solution, was not mentioned by the MRs.

The many nuances in dosages and combinations required top doctors to act as opinion leaders. For Lupin's overall marketing strategy, the leading physicians had to be spokespeople for the company. If marketing succeeded in getting one opinion leader to write a Lupin prescription, this resulted in 100 prescriptions by other doctors down the line: "One prescription gives 100 prescriptions ... because if they are writing it, that means 'Oh yes, this doctor is writing,' that means, 'OK, this brand is good, this company is good.'"

The MRs had a precise calculation for how much it cost to visit a doctor. Considering all expenses for salaries, training, transportation, gifts and samples handed out, each visit to an individual doctor cost between Rs. 250 (US$5.50) and Rs. 400 (US$8.50). Given that an MR will only get a few minutes' face time with a doctor, or sometimes none at all, each visit was an investment that needed to bring revenues: "Why should I invest my money? I'm not a fool."

Such investments were not paid by Lupin alone. Two MRs active in the trade union said that newly recruited reps have to give up half their salaries to doctors and retailers to achieve their sales targets. Even area managers sometimes had to give black money to meet targets. This was a particular bone of contention with the Nepali MRs, who were singled out for blame by the country's Department of Drug Administration (DDA) for unethical marketing practices in 2007.

Despite such questionable exchanges, the MRs said that they had "good relations" with doctors, especially if they worked with them for longer. One MR even described the relation as one between "husband" and "wife," with the MR as husband and the doctor as wife: the "wife" gives faithful service, and the "husband" gives gifts to express his gratitude: "My wife is daily making food for me and she is doing everything for me ... so it's my duty to provide her love, maybe a sari, beautiful sari on her birthday, maybe on our anniversary." Like with a married couple, the obligation to care for each other did not cease instantly when one side failed to live up to expectations. Hence even underperforming doctors continued to receive gifts from the MRs: "Commercially that doctor is not valuable, [but] ... because of our relationship, we cannot leave that doctor." Nevertheless, the MRs still got most joy from getting the business: "I'm working hard and I get to see my brands' prescription written on a paper, on a prescription pad, and a patient is going to a chemist, and I'm standing there, it gives me real pleasure."

"Different Target Customers": MRs' views on DOTS

In the anti-TB segment, where all the available drugs have been around for decades, companies compete on quality, availability, price, and perks for prescribers. What keeps the anti-TB market moving are not new molecules, but new combinations and new dosages. In this way, treatment regimes recommended by the World Health Organization can give companies a welcome opportunity to reposition themselves in the private market. Lupin's own products were always following WHO guidelines, which favor fixed-dose combinations to minimize the risk of monotherapy and the effects of a patients' noncompliance (WHO; 1998; 2002;). AKT and R-cinex, Lupin's two leading anti-TB brands, were formulated in response to WHO recommendations for a 4-dose FDC (see WHO 2002): "WHO said, to increase the compliance, you should come up with fixed-dose combinations. So now companies have started manufacturing, and it is getting very very popular among doctors." Not least the company's global reach made it a necessity for Lupin to focus on products endorsed by WHO and the Global Drug Facility (GDF): "Internationally, you cannot market other than this." The MRs underlined that the real challenge for marketing lay in exploiting differences without violating WHO guidelines. Lupin offered the same products in both private markets

and public tenders, but the promotional pitch had to be adjusted according to audience: "There is no separate strategy here. The company purely decides ... how a product has to be promoted in front of a particular doctor, what kind of input to be given and what kinds of gifts are to be presented." The way that Lupin spins global regulatory guidelines to differentiate its products toward customers in local markets is a typical trait of "near-liberalism" (Ecks 2010).

While WHO guidelines directly informed Lupin's promotional strategies, DOTS (Directly Observed Therapy Short Course) was seen as a world of its own. An MR described patients' use of DOTS as follows: "You have a box mentioned in your name. You go there, you take one strip, eat that, put that empty strip there, go back. Next day, one day gap. Then once again." The Lupin MRs said that they promoted "market drugs" to private prescribers, and such market drugs were different from the drugs given in DOTS centers. The MRs had no contact with DOTS because the drugs used there are supplied through a tendering process. It was not necessary to visit DOTS center staff because they were in no position to select Lupin over other companies: "We have different target customers." There were contacts with doctors in government hospitals, because they could recommend patients to buy Lupin products from private shops instead of going to the DOTS -- and because these also usually have their own private chambers where they could prescribe in their own fashion.

What interested the MRs most about DOTS was if the program decreased private

sales. The MRs we interviewed were in two minds about this. Some said that Lupin's anti-TB drugs were on a downward trend because of the expansion of DOTS. Others said that there was no change to sales, because the total number of TB patients was rising and DOTS could not absorb them: "[DOTS] has not affected our strategies because we are working on one trend and they on another. The number of patients is growing very fast. That is the basic reason why there is no effect on the strategies of either." The Nepali MRs felt that the sales were stagnant because the relatively greater success of the Nepal DOTS program eliminated Lupin's gains in overall market share.

The MRs neither saw DOTS as the best answer to TB, nor as deserving everyone's support. Anyone who could afford private treatment should chose it instead, because it was more effective and more convenient. DOTS was for "poor people" only. In its current form, DOTS was a near-complete failure: "If there are 100 DOTS program centers, only few, hardly five centers are functioning properly." The entire "system" around it was faltering. First, the government did not do enough to advertize DOTS, so even the people who needed it most did not know about it: "The patient is very much uneducated and unaware also. Whether you give medicines free of cost or if you charge, they don't understand." Second, in their opinion, staffs in DOTS centers were not sincere enough in carrying out their duties to the patient. For example, if patients did not come into the clinic in time, it was the duty of DOTS staff to visit them at home: "Sometimes patients are not getting full course of medicines, right? If I am working in a

DOTS center, then my job is to go to the patients' home and administer the medicine right in front of my eyes." Moreover, DOTS' target-driven audit culture made center staff manipulate the records of attendance and cure rates. Third, DOTS relied too much on sputum tests. Yet there are many types of TB that could not be diagnosed accurately through sputum only, for example, bone TB or abdominal TB. The emphasis on those forms of TB that could be found through sputum tests created major blind spots: "DOTS therapy is ... a partial therapy."

While DOTS was, for the MRs, a *near*-complete failure in the first-line treatment of TB, it was a *complete* failure in its approach to multi-drug resistant TB (MDR-TB). This form of TB is caused by bacterial strains that do not respond to two or more of the first-line drugs including rifampicin and isoniazid. MDR-TB is usually the result of a patient not taking the full course of medicines, or doctors prescribing the wrong kinds of medicines. At the time of our interviews (2006-2008), the extension of DOTS to include MDR-TB in an approach called DOTS-Plus had only just begun.

For the MRs, MDR-TB was the Achilles' heel of DOTS. First, MRs compared the success rates of DOTS unfavorably to private treatments. In their own off-the-cuff estimates, private sector treatments achieved much higher success rates than DOTS. That meant, to them, that the blame for rising numbers of MDR-TB patients fell on DOTS. Second, DOTS was neither equipped to diagnose MDR-TB patients properly, nor to administer the right medicines. Even an MDR-TB patient who presented herself to a

DOTS center could never receive appropriate treatment. While the RNTCP was aware of this critique, both the accreditation of laboratories to diagnose MDR-TB as well as the roll-out of DOTS-Plus had been too slow.

DOTS was too inflexible to allow for treatment decisions that took into account the individual patient's needs. Such was its inflexibility that even those therapeutic choices that were entirely within the boundaries of international evidence-based best practice were disallowed. DOTS made it nearly impossible for patients to work in other areas or go traveling: "You cannot get DOTS treatment other than your center. Suppose I am going for a marriage in some other city, I will not get the medicine [there] and you are not giving medicine for those periods to carry on with me."

Furthermore, the Indian DOTS program -- as opposed to the programs introduced in several other countries, including Nepal -- had opted for "intermittent" instead of daily doses. "Intermittent" means that patients only have to come to the DOTS center every three days to receive their medicine, instead of a daily visit. This has obvious advantages, for example, that patients save time and money spent on traveling.

In India, intermittent therapy was chosen because it was cheaper: fewer patients' visits to DOTS centers meant fewer hours of staff time are needed. The downside of intermittent therapy was that it is much harder for patients to remember which days of the week they had to visit the DOTS center. Even worse, to miss a day's dose in the intermittent regime effectively meant missing three days' doses. Therefore it was

obvious to the MRs that the daily therapy, as preferred by private practitioners, had a higher success rate than intermittent therapy. In any case, it was too much part of people's habits to take pills at the same time, every day: "It is the psychology of the patient, especially in India, to take the medicine daily ... But if you tell them that you will have to take this medicine intermittently ... they may not follow that, because that is not tuned in their mind."

Finally, DOTS was too obsessed with collecting statistical data as that private practitioners had any incentive to be bound to it: "Many doctors are not ready to become DOTS in-charge, because of so much administrative work which they have to do, so many records they have to maintain. So, because of that, they are reluctant." (Our interviews with doctors also made this abundantly clear.) All this meant, for the MRs, that private practitioners had no incentive whatsoever to support DOTS in public-private mixes.

Conclusions

In global health policy, tuberculosis is not a "forgotten plague" (Farmer 2000) anymore. Nor is TB a forgotten subject in medical anthropology anymore. But more ethnographic engagement with perspectives beyond the patients is needed. Specifically, while work

has been done on the private sector, this has tended to focus on private doctors, with little attention given to other players. This chapter highlighted the sheer magnitude of the private drug market in India and tried to capture ethnographically the perspective of one of its key actors: the medical representatives for Lupin Ltd., one of the world's leading producers of anti-TB drugs.

The Revised National TB Control Programme (RNTCP) and the World Health Organization's move to involve the private sector in India has, so far, focused on propagating public-private mixes to private prescribers. The problem that they face is one of sheer scale: how can eight million private prescribers be convinced to support DOTS? The main point of contact here, to date, has been the Indian Medical Association. Involving the IMA is a sensible tactic, but it is likely to have only limited success. The IMA has practically no influence over individual doctors' therapeutic choices. And as long as private doctors depend on both the fees paid by patients and on kickbacks from pharmaceutical corporations, they have little financial incentive to collaborate with the DOTS campaign. Moreover, we have learned from the Lupin MRs (as well as from interviews with doctors) that the opinion-leading chest physicians prefer their own tailor-made treatments over those used in DOTS. Hence the doctors that would be most immediately in contact with the IMA are also the doctors who are least likely to believe in DOTS. That this is the case became evident on many levels. For example, among all the four DOTS awareness seminars for various groups of

prescribers that we saw in West Bengal, it was only at the IMA-sponsored event that the audience of doctors loudly challenged the presenters and generally disagreed with what they had to say about the benefits of DOTS. In contrast, audiences of municipal health workers or rural medical practitioners all listened carefully and never openly questioned that the government-sponsored DOTS program should be the standard treatment.

Our ethnographic findings indicate that WHO treatment guidelines have been spreading among private practitioners in India, but not because of any educational efforts or because of PPMs. Instead, private doctors prescribing habits have come closer to DOTS because of the rise of WHO-endorsed kits and fixed-dose combinations in the private market. The rise of kits and FDCs in the market is corroborated by sales figures, such as Lupin stating that R-cinex and AKT are their bestselling drugs (Lupin 2009: 28). One crucial insight from the Lupin MR interviews is that WHO recommendations are becoming more common among doctors because of the availability and active promotion of these products, rather than any awareness-raising campaign by public health bodies. During an interview with a WHO TB officer in Delhi, we showed him a list of 52 Indian companies that produce rifampicin either alone or in fixed-dose combinations. While he knew all the big brands, he was surprised by the huge range of companies and products, and said that this peculiar market needed to be better understood.

It is our contention that the Indian market for anti-TB drugs presents a unique opportunity for the WHO and other international organizations to extend public-private collaborations. Despite an apparent "therapeutic anarchy," there are only a handful of producers who both have a major share in the private market and in the procurement of drugs for DOTS. Leading corporations, above all Lupin, might be convinced that supporting DOTS would not decrease their overall product sales, but simply shift demand from the private to the public sphere. It could even be argued that such a shift toward the public domain would strengthen Lupin's competitive position, because the share of smaller companies would be further reduced. At the moment, however, Indian companies make more profits from promoting drugs to private practitioners than from supplying DOTS centers. If this balance of profits could be tilted in favor of the public market, companies such as Lupin would have a real incentive in promoting DOTS over private treatments.

Another potential inducement for companies to support DOTS lies in rights of access to *future* drugs. Just as Pfizer and Biological E. Ltd. lost their market shares when a new generation of anti-TB drugs came to the market, so are companies like Lupin threatened by more effective drugs. Once new drugs should actually be available, Lupin either gets access to them or loses this market. Hence it makes perfect sense for Lupin to be one of the corporate stakeholders in the TB Alliance. From a public health point of view, it would be worth thinking about making access to future drugs

dependent on providing active support for DOTS in the present.

Listening to the medical representatives provided several ideas about how corporate headquarters might be able to build support for DOTS into their day-to-day work. Lupin MRs are proud of how much they know about WHO-endorsed treatments, and they crave more recognition from doctors. If the RNTCP and the WHO could tap into their desire for higher status, they would come more on its side. That some of the MRs described themselves as "social workers" and as fighting against TB beyond narrow profit calculations opens a door to a closer contact between them and the public health field. The village-level awareness events that the MRs are already organizing could be better aligned with RNTCP/WHO campaigns. Also, if it is true that MRs have to give up parts of their own salaries to achieve their sales targets, would it not be possible that Global Fund resources be allocated to MRs who actively promote DOTS? Moreover, it could be discussed with Lupin's product management team in Mumbai if persuading doctors to refer patients to DOTS centers could not be built into the incentives of their sales force. At the same time, RNTCP and WHO must deal with the fact that MRs hold very negative views of DOTS, and that they need a lot of convincing that DOTS is not the all-out failure that they see in it. This would also require RNTCP and WHO to re-examine the choice of the intermittent regimen and to allow greater flexibility in the direct observation regimes of patients.

As one of the Lupin MRs said, he takes great pride in seeing patients demand his

company's brands at the local medicine shop. If the incentives for MRs could be transformed so that they are taking as much pride from seeing patients going to DOTS centers, then the strategy of involving the private sector through PPMs would have a much greater chance of success.

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