A Costly Illusion?:

An Empirical Study of Taiwan's Use of Isolation to Control Tuberculosis Transmission and its Implications for Public Health Law and Policymaking

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I. Introduction

Despite decades of effort, tuberculosis ("TB") remains a global health concern. Although many prosperous countries have experienced a significant reduction of this so-called "white plague" during the 20th century, TB has reemerged with the HIV/AIDS pandemic. In 2009, an estimated 1.7 million people died—about 45,000 deaths a day—from TB.

When TB reemerged, it reemerged resistant to two of the most effective first-line drugs.³ This form of TB is known as the multidrugresistant tuberculosis ("MDR-TB"). Its growth highlights the complexity of eliminating TB because it demonstrates that the TB treatment used for more than half-a-century may not be effective for patients who have the MDR-TB. These MDR-TB cases are particularly problematic because they have higher mortality rates and lower cure rates than drug-susceptible TB,⁴ and pose a higher transmission risk to the public.⁵

¹ The HIV/AIDS pandemic has been a global public health issue since the first cases of acquired immunodeficiency syndrome ("AIDS") were reported in 1981. It is estimated that sixty-five million infections and twenty-five million deaths have occurred since then. See Dep't. of Health and Hum. Services, Ctrs. for Disease Control and Prevention, The Global HIV/AIDS Pandemic, 2006, 55 MORBIDITY AND MORTALITY WKLY REP. 841, 841 (Aug. 11, 2006), available http://www.cdc.gov/mmwr/PDF/wk/mm5531.pdf. The number of people living with HIV worldwide reached an estimated 33.4 million in 2008 and continues to grow. See JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, AIDS DECEMBER UPDATE 2009 7 (2009),http://data.unaids.org/pub/Report/2009/JC1700 Epi Update 2009 en.pdf.

² WORLD HEALTH ORG, GLOBAL TUBERCULOSIS CONTROL: WHO REPORT 2010 7 (2010), *available at* http://whqlibdoc.who.int/publications/2010/9789241564069_eng.pdf.

³ Multidrug-resistant TB ("MDR TB") is a form of TB that is resistant to both isoniazid and rifampin. These two drugs are considered first-line drugs and are used to treat all persons with TB. Treatment of MDR-TB relies on second-line drugs (amikacin, kanamycin, or capreomycin), which have more side effects, are more expensive and less effective than first-line drugs, and require longer treatment regimens. See Philip LoBue et al., Dep't. of Health and Hum. Services Ctrs. for Disease Control and Prevention, Plan to Combat Extensively Drug-Resistant Tuberculosis: Recommendations of the Federal Tuberculosis Task Force, 58 (RR-3) Morbidity and Mortality Weekly Report 1, 2 (2009), available at http://www.cdc.gov/mmwr/pdf/rr/rr5803.pdf.

⁴ See id.

⁵ For example, in 2007 a U.S. MDR-TB patient allegedly disregarded health department advice to postpone his travel plans and flew to Italy from Atlanta. This case raised the question of an individual's ethical duty to avoid infecting others as well as the justifiability of the state to limit individual liberty in the era of MDR-TB See John Schwartz, Tangle of Conflicting Accounts in TB Patient's Odyssey, N.Y. TIMES, June 2, 2007, at A1; see also Julie L. Gerberding, Recent Case of Extensively Drug Resistant TB: CDC's Public Health Response, CDC CONGRESSIONAL TESTIMONY, June 6, 2007, http://www.cdc.gov/washington/testimony/2007/t20070606.htm (last visited Mar. 10,

The reasons for increasing cases of TB and the emergence of MDR-TB are multifaceted. Human immunodeficiency virus ("HIV") infection, the collapse of a TB control system, the rising number of immigrants, and patients having socioeconomic or medical problems all contributed to the difficulties in eliminating the disease. In addition, public-health policymakers and physicians emphasize the fact that many patients fail to take their pills, resulting in treatment failure and relapse. As a result, several international jurisdictions have had to consider ways in which to control the spread of TB.

Since the 1990s, these international jurisdictions have turned to detention as a TB control strategy. Much research has been done on the management of patients that do not comply with their TB treatment regimen. In response to the lack of compliance, the directly observed treatment ("DOT") program was created. The DOT program involves a public health agent physically observing the patients taking their medication. In order to implement the program, the patients need to be under closer observation. Consequently, detention was thought to be a

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 $^{^6}$ Inst. of Med., Ending Neglect: The Elimination of Tuberculosis in the United States 27 (2000).

⁷ See id.

⁸ See Dep't. of Health and Hum. Services Ctrs. for Disease Control and Prevention, A Strategic Plan for the Elimination of Tuberculosis in the United States, 38 (S-3) MORBIDITY AND MORTALITY WKLY REP. 1 (Apr. 21,1989), http://www.cdc.gov/mmwr/preview/mmwrhtml/00001375.htm [hereinafter A Strategic Plan for the Elimination of Tuberculosis in the United States] (reporting that almost 12 percent of patients are not known to be currently receiving therapy, and more than 17 percent of tuberculosis patients do not take their medication continuously).

⁹ See William J. Burman et al., Short-term Incarceration for the Management of Noncompliance with Tuberculosis Treatment, 112 CHEST 57 (1997); Linda Singleton et al., Long-term Hospitalization for Tuberculosis Control, 278 JAMA 838 (1997); Tom Oscherwitz et al., Detention of Persistently Nonadherent Patients With Tuberculosis, 278 JAMA 843 (1997); M. Rose Gasner et al., The Use of Legal Action in New York City to Ensure Treatment of Tuberculosis, 340(5) NEW ENG. J. MED. 359 (1999); D. Weiler-Ravell et al., Compulsory Detention of Recalcitrant Tuberculosis Patients in the Context of a New Tuberculosis Control Programme in Israel, 118 Pub. Health 323 (2004).

¹⁰ See Burman et al., supra note 9, at 57; Singleton et al., supra note 9, at 838; Oscherwitz et al., supra note 9, at 843; Gasner et al., supra note 9, at 359; D. Weiler-Ravell et al., supra note 9, at 323.

¹¹ See Burman et al., supra note 9, at 57; Singleton et al., supra note 9, at 838; Oscherwitz et al., supra note 9, at 843; Gasner et al., supra note 9, at 359; D. Weiler-Ravell et al., supra note 9, at 323.

¹² See Michael D. Isemanet et al., Directly Observed Treatment of Tuberculosis—We Can't Afford Not to Try It, 328 NEW ENG. J. MED. 576, 576 (1993).

good public health intervention to prevent transmission and ensure patient compliance with the treatment regimen. ¹³

When it comes to extensively drug-resistant TB ("XDR-TB") patients, the ethical and legal issues regarding the legitimacy of detaining noninfectious, non-compliant patients are amplified and become more complicated. To prevent transmission of XDR-TB during the initial stage of treatment, patients may need to be isolated. They may require extensive isolation even when adhering to their treatment, because a prolonged treatment regimen is inevitable. Even worse, the appearance of XDR-TB may bring us back to the beginning of TB control. In the late nineteenth and early twentieth centuries there was no effective treatment and patients were simply segregated from the public, sometimes indefinitely. Infortunately, this type of treatment has already occurred in Taiwan.

The World Health Organization ("WHO") responded to the alarming emergence of XDR-TB cases by recognizing the possibility of restricting individual liberty in the interest of safeguarding the public. However, it has also acknowledged the importance of setting limitations on governmental detention power. As a result, in January 2007, the WHO issued cautionary guidelines about the use of detention. It asserted that restrictions are justifiable if the five criteria defined in the Siracusa Principles adopted by the U.N. Economic and Social Council are met, 19

¹³ See Burman et al., supra note 9, at 57; Singleton et al., supra note 9, at 838; Oscherwitz et al., supra note 9, at 843; Gasner et al., supra note 9, at 359; D. Weiler-Ravell et al., supra note 9, at 323.

¹⁴ See LoBue et al., supra note 3, at 5-6.

¹⁵ See id. at 6.

 $^{^{16}}$ See Richard J. Coker, From Chaos to Coercion: Detention and the Control of Tuberculosis 147 (2000).

¹⁷ Cai Wenji & Wang Changmin (蔡文居、王昶閔), Chaoji Kangyaoxing Jiehe Nan Wuxianqi Geli (A Man with XDR-TB Isolated Indefinitely) [超級抗藥性結核男無限期隔離], ZIYOU SHIBAO (自由時報) [LIBERTY TIMES], June 3, 2009, at A9.

¹⁸ See WHO Guidance on Human Rights and Involuntary Detention for XDR-TB Control, WORLD HEALTH ORG., Jan. 24, 2007, http://www.who.int/tb/features_archive/involuntary_treatment/en/ (last visited Apr. 30, 2013).

¹⁹ *Id.* The five principles are:

^[1.] The restriction is provided for and carried out in accordance with the law; [2.] The restriction is in the interest of a legitimate objective of general interest; [3.] The restriction is strictly necessary in a democratic society to achieve the objective; [4.] There are no less intrusive and restrictive means available to reach the same objective; [5.] The restriction is based on scientific evidence and not drafted or imposed arbitrarily i.e. in an unreasonable or otherwise discriminatory manner.

and if restrictions are of a limited duration and are subject to review and appeal.²⁰

Prior to the issuance of the WHO's guidelines, the shocking severe acute respiratory syndrome ("SARS") epidemic in 2003 and a desire to keep pace with the WHO's global plan to stop TB launched in 2006 triggered the revival of Taiwan's TB control efforts. The Department of Health ("DOH") of Taiwan's Center for Disease Control ("CDC") launched a Ten-Year Mobilization Plan aimed at halving TB incidence from 66.7 per 100,000 persons to 34 per 100,000 persons by 2015. The plan adopted multiple control methods, including the WHO's Directly Observed Treatment Short Course ("DOTS") strategy for all patients with positive TB test results. In addition, the plan adopted a *compulsory* isolation program authorized by the 1999 Communicable Disease Control Act ("Act"). The health authorities' willingness to exercise the legal power of isolation on TB patients represents a departure from previous voluntary control strategies.

Although containing the spread of TB is a legitimate public health concern, the history of detention warns that no matter how well-intentioned, restrictive power has the potential to be abused. After the first year of the Ten-Year Mobilization Plan, CDC data indicated that 1312

²⁰ See id. In 1985, the Siracusa Principles were developed in a non-binding document adopted by the U.N. Economic and Social Council in response to the practice of detaining indefinitely large numbers of dessenters in the name of national security or emergency during the political unrest in certain countries during the 1970's and 1980s. See United Nations Economic and Social Council U.N. Sub-Commission on Prevention of Discrimination and Protection of Minorities, The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights, U.N. Doc. E/CN.4/1985/4, Annex (1985), available at http://www.unhcr.org/refworld/docid/4672bc122.html (last visited Apr. 30, 2013).

²¹ This statement is based on the author's observations.

²² Xingzhenguan Weishengshu (行政院衛生署) [DEPARTMENT OF HEALTH, EXECUTIVE YUAN], JIEHEBING SHINIANJIANBAN QUANMIN DONGYUAN JIHUA (結核病十年減半全民動員計畫) [MOBILIZATION PLAN TO HALVE TUBERCULOSIS INCIDENCE IN TEN YEARS] 7, 11 (2006) available at http://www.cdc.gov.tw/downloadfile.aspx?fid=3E051FC98B0F8696 (last visited Apr. 30, 2013) [hereinafter MOBILIZATION PLAN TO HALVE TUBERCULOSIS INCIDENCE IN TEN YEARS].

²³ See id. The Directly Observed Treatment Short Course ("DOTS") strategy may be traced back to the WHO's TB program launched in 1994. The WHO recommended that countries with a TB problem provide standardized short-course chemotherapy, i.e. six months or eight months regimen to all sputum smear positive patients. See World Health Organization, WHO Tuberculosis Programme: Framework for Effective Tuberculosis Control 11(1994) (WHO/TB/94.179), available at, http://whqlibdoc.who.int/hq/1994/WHO_TB_94.179.pdf.

 $^{^{24}}$ See Mobilization Plan to Halve Tuberculosis Incidence in Ten Years, supra note 22, at 29-30.

people (out of 15,378 newly registered cases or 8.53 percent) were subjected to mandatory isolation in 2006.²⁵ This number is extremely high considering that only 139 people out of 8000 patients (1.73 percent) were detained for treatment over a two-year period when New York City reached its peak of TB cases in the 1990s.²⁶ It suggests the possibility of an overuse or abuse of public health power, and as a result, attention must be paid to the legitimacy of compulsory interventions.

To justify the adoption of compulsory interventions, scrutiny of its use is indispensable. This article asks whether Taiwan's use of isolation for TB patients is justifiable, and whether isolation was warranted to control TB. The author designed an empirical study to specify how Taiwan's stated isolation scheme was implemented during its first three years, from the beginning 2006 to the end of 2008. The author conducted qualitative semi-structured interviews with twenty-nine Taiwanese health care workers and officials involved in the implementation of the regulatory scheme. This article then provides an analysis of the results of this study to determine whether isolation was warranted as a strategy to control TB. This analysis can inform future public health policymaking.²⁷

²⁵ See Zizhurenzhu Jiehedouzhi (自助人助 結核都治) [Help Yourself and Others Will Help You, Tuberculosis Can Be Cured with DOTS], WEISHENGSHU JIBING GUANZHIJU (衛生署疾病管制局) [CENTERS FOR DISEASE CONTROL, DEPARTMENT OF HEALTH],

http://www.cdc.gov.tw/professional/info.aspx?treeid=BEAC9C103DF952C4&nowtreeid=8485C76642109C5B&tid=FE76FA7E96B4A5F8 (last visited Mar. 3, 2010).

²⁶ See Gasner, et al., supra note 9, at 362.

²⁷ To better orient the reader, an explantion of terminology needs to be provided. Although "isolation" and "quarantine" are often used interchangeably, there are distinctions between them. See LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW, POWER, DUTY, RESTRAINT 209-10 (1st ed. 2000) [hereinafter GOSTIN 1st ed.]. "Isolation" is defined as "the separation, for the period of communicability, of known infected persons in such places and under such conditions as to prevent or limit the transmission of the infectious agent" because modern science can usually identify whether a person actually has an infectious condition through testing or physical examination. See id. However, English-language literature commonly uses the term "detention" in discussing personal restrictions on TB patients. See Barron H. Lerner, Catching Patients: Tuberculosis and Detention in the 1990s, 115(1) CHEST 236 (1999). Also, New York City's TB regulation uses the term "detention" to refer to the physical confinement of patients with active TB against their will in a hospital or other treatment facility. See NEW YORK CITY, N.Y., HEALTH CODE, § 11.47 (1993). Detention orders may be issued to patients who are infectious or noninfectious. See NEW YORK CITY, N.Y., HEALTH CODE, § 11.47(d)(4)&(5)(1993).

In this article, the term "detention" is used instead of "isolation" when quoting bibliographic sources to avoid confusion. However, several terms are used interchangeably. "Isolation care," "mandatory isolation care," "compulsory hospitalization," and "compulsory hospitalization isolation care" in the Communicable Disease Control Act ("Act") and regulations promulgated by the Department of Health ("DOH") and Center for Disease Control ("CDC") are used synonymously. For clarity, this article uses the term "isolation" to denote the legal power of health authorities to

This article proceeds in three parts. Part II lays out the background information regarding the biological and epidemiological aspects of TB. It also provides an overview of the use of detention power to control TB worldwide, as well as Taiwanese TB isolation regulatory scheme. This includes the two channels through which the isolation process can be initiated, the procedural requirements, and the reimbursement system. Part III describes the study's methodology, and presents the results from interviews with local health officials, physicians, nurses, and TB case managers. In addition, this section discusses the ramifications for the actual practice of isolation in view of Lawrence Gostin's five-point evaluation framework for public health regulations. Part IV concludes by elaborating on the implications of the empirical study for the design of a legitimate TB isolation program.

II. TUBERCULOSIS AND CONTROL STRATEGIES

Restricting personal liberty to contain infectious disease is not new to human history, but the rise of drug-resistant TB reinforces the tension between public health and individual liberty. Several countries have adopted detention as a part of their TB programs in order to prevent the development of drug-resistant forms of TB despite concerns of legal and ethical issues in this strategy. To demonstrate how coercive public health measures were used along with the changes in the epidemiology of TB and the development of drug treatment, section A and B will provide a brief overview of TB from a biological and epidemiological perspective and how the disease may be treated. Section C describes the legal basis for the use of isolation in Taiwan.

A. What is Tuberculosis and How It is Spread

Historically, TB referred to as consumption in Europe and the United States, was believed to be a disease acquired due to environmental conditions and hereditary predisposition.²⁹ However, Robert Koch's 1882

demand that individuals with a communicable disease stay in a designated facility to receive treatment. However, when reporting interview results, the term "compulsory hospitalization" is occasionally used.

 $^{^{28}\,\}text{Lawrence}$ Gostin, Public Health Law, Power, Duty, Restraint 53-70 (2nd ed. 2008) [hereinafter Gostin 2d ed.]

²⁹See BARRON H. LERNER, CONTAGION AND CONFINEMENT: CONTROLLING TUBERCULOSIS ALONG THE SKID ROAD 1-2 (1998); Henry I. Bowditch, *Consumption in America*, in FROM CONSUMPTION TO TUBERCULOSIS: A DOCUMENTARY HISTORY 57, 63-68 (Barbara G. Rosenkrantz ed., 1994); Barbara Gutmann Rosenkrantz, *Introductory Essay: Dubos and Tuberculosis, Master Teachers, in* THE WHITE PLAGUE: TUBERCULOSIS, MAN AND SOCIETY xiii, xxii (Rene Dubos & Jean Dubos, 1952, *reprinted* 1996). The disease was named tuberculosis because the TB bacteria enters the lungs and remains inactive in the air sacs after the TB bacteria enters the lungs, where it is enclosed in hard grey capsules, called tubercles. Bowditch, *supra*, at 58.

discovery of the bacterium that causes TB led to a fundamental change in the understanding of this disease.³⁰ TB is now known to be an airborne infectious disease spread from person to person, usually through coughing, sneezing, speaking, or singing.³¹ The bacterium that causes TB, *Mycobacterium tuberculosis* (*M. tuberculosis*) or *tubercle bacilli*, may infect almost any part of the body, such as the brain, kidneys, or spine.³² TB most commonly attacks the lungs when bacteria enter the airways of a non-infected person.³³ Extra-pulmonary TB is more common in immune-suppressed persons and in young children.³⁴

In most cases, patients infected with TB do not have noticeable symptoms nor are they contagious to others.³⁵ The body's immune system can usually suppress the invasion of the bacteria, but a small number of *tubercle bacilli* may still survive.³⁶ At this point, the disease enters an inactive stage called latent tuberculosis ("LTBI").³⁷ People with LTBI show a positive reaction to a tuberculin skin test.³⁸ They cannot eliminate the TB bacteria without proper antibiotics.³⁹ Although the bacteria remain dormant for a variable length of time, maybe for life, infected people still remain at risk of developing the disease at any time, especially if their immune system weakens.⁴⁰ If the bacteria overcome immune system defenses, they may begin to multiply, resulting in the progression from a TB infection to a TB disease.⁴¹ This typically occurs when a person's

³⁰ See LERNER, supra note 29, at 16-17.

 $^{^{31}}$ U.S. CTRS. FOR DISEASE CONTROL AND PREVENTION, CORE CURRICULUM ON TUBERCULOSIS 6 (4th ed. 2000) [hereafter CORE CURRICULUM].

³² *Id.* at 7.

 $^{^{33}}$ See A Strategic Plan for the Elimination of Tuberculosis in the United States, supra note 8.

³⁴ CORE CURRICULUM, *supra* note 31, at 8.

³⁵ *Id.* at 5.

³⁶ *Id.* at 7.

³⁷ *Id.* at 7.

³⁸ *Id.* at 25. The Mantoux tuberculin skin test ("TST") is the standard method of determining whether a person is infected with *Mycobacterium tuberculosis*. The TST is performed by injecting 0.1 milliliter of tuberculin purified protein derivative into the inner surface of the forearm. Between fourty-eight and seventy-two hours after administration, health care providers must measure the area of induration around the site of injection and decide if the patient is classified as positive. *Id.* at 29-31.

³⁹ *Id.* at 55-57.

⁴⁰ *Id.* at 7.

⁴¹ *Id.* at 7. In the United States, approximately five percent of individuals that have been infected with *Mycobacterium tuberculosis* will develop TB disease in the first year or two after infection if not treated, and another five percent will develop the disease later in life. Individuals with competent immune function have approximately a ten

immunity is reduced, such as by HIV infection, advancing age, or diabetes. 42 However, the bacteria can also become active in individuals who are not immune-compromised. 43

The risk of transmitting TB depends on several factors, including how advanced the disease is, the duration of exposure, and the ventilation in the patient's quarters. 44 These bacteria can survive in the air for several hours, depending on the environment. 45 Although TB can be spread to others without intimate or even physical contact, it is not as contagious as many airborne viral infections, such as measles and chicken pox. 46 Prolonged, frequent, or intense contact with a person with infectious TB is usually required for the disease to spread to an uninfected individual. As a result, close contacts, such as family members, roommates, friends and coworkers are all at a very high risk of becoming infected.⁴⁷ In contrast, a single or a casual contact with an infectious person in a public place (such as subways, airplanes, or movie theaters) is not likely to transmit TB.⁴⁸ The degree to which a patient is infectious diminishes rapidly once effective treatment is initiated.⁴⁹ Within a couple of weeks of starting medication, the patients often become noninfectious. Therefore, adequate treatment and adherence to the prescribed regimen are often emphasized in preventing transmission.⁵⁰

percent lifetime risk of developing active tuberculosis after a variable period of dormancy if not treated with preventive anti-tuberculosis drug therapy. *See id.*

⁴² *Id.* at 8.

⁴³ *Id*.

⁴⁴ *Id.* at 6.

⁴⁵ *Id*.

 $^{^{46}}$ See Office of Tech. Assessment, United States Congress, The Continuing Challenge of Tuberculosis 28 (1993) [hereinafter The Continuing Challenge of Tuberculosis].

⁴⁷ See CORE CURRICULUM, supra note 31, at 6.

⁴⁸ See The Continuing Challenge of Tuberculosis, supra note 46, at 28.

⁴⁹ See CORE CURRICULUM, supra note 31, at 6.

⁵⁰ See id. at 6. Generally, most studies agree that two weeks of treatment may render a patient noninfectious. See Ian A. Campbell & Oumou Bah-Sow, Pulmonary Tuberculosis: Diagnosis and Treatment, 332 BRIT. MED. J. 1194, 1197 (2006). However, some have cautioned that the claim that patients are no longer infectious after two weeks may be misleading. See Kevin Schwartzman & Dick Menzies, Tuberculosis: 11. Nosocomial Disease, 161 (10) CAN. MED. ASS'N J. 1271, 1274 (1999) (that patients who are initially smear positive may remain contagious as long as their cultures are positive even though they may be smear-negative after treatment).

B. Strategies to Treat Tuberculosis

Although TB can now be cured with antibiotics, for a long time its "treatment" focused on building resistance in a patient's body. In Europe and the United States, private sanatoria were established in remote areas to provide fresh air, bed rest, nutritional support, and gradual exercise, which were believed to help regain health.⁵¹ Dr. Edward Livingston Trudeau, diagnosed with consumption, pioneered the establishment of sanatoria to treat TB in the United States after his own consumption had benefited from fresh air in the Adirondack Mountains.⁵² After he opened his Cottage Sanitarium at Saranac Lake in 1885, similar institutions were established across the United States.⁵³ Because these facilities were usually located in the mountains, they segregated ill individuals from the community for years and helped protect the general public from infection.⁵⁴

The introduction of these sanatoria was followed by the introduction of curative antibiotics for TB in the late 1940s, which brought great hope for eliminating the disease. ⁵⁵ Although the availability of effective drugs allowed TB treatment to occur on an outpatient basis, it also led to a need to monitor patient compliance with the treatment. ⁵⁶ Currently, TB that is not resistant to drugs can be treated with a six-to-nine month course of "first-line drugs," including isoniazid and rifampin, which cures over ninety-five percent of patients. ⁵⁷ MDR-TB, which is resistant to isoniazid and rifampin, can be treated by so-called "second-line drugs" through a strictly supervised eighteen-to-twenty-four month regimen. ⁵⁸ However, these drugs are far more expensive, more harmful,

⁵¹ The concept that tuberculosis patients could be cured by rest in fresh air dates back to 1854, when a Germen physician, Hermann Brehmer, established an institution for treating tuberculosis patients in the mountains of Silesia. His work gave impetus to the sanatorium movement all over Europe and inspired Dr. Edward Livingston Trudeau, to open a similar institution for tuberculosis patients in the United States. *See* RENEE DUBOS & JEAN DUBOS, THE WHITE PLAGUE: TUBERCULOSIS, MAN AND SOCIETY 175-80 (1952, *reprinted* in 1996); *see also Medical News*, 2(2869) BRIT. MED. J. 947(1915).

⁵² Medical News, supra 51, at 947.

⁵³ See id.; see also Barry R. Bloom & Christopher J.L. Murray, *Tuberculosis:* Commentary On a Reemergent Killer, 257(5073) SCIENCE 1055, 1099 (1992).

⁵⁴ See LERNER, supra note 29, at 25.

⁵⁵ See LERNER, supra note 29, at 57-59.

 $^{^{56}}$ See Georgina D. Feldberg, Disease and Class: Tuberculosis and the Shaping of Modern North American Society 205-06 (1995).

⁵⁷ See Julie L. Gerberding, Recent Case of Extensively Drug Resistant TB: CDC's Public Health Response, CDC CONGRESSIONAL TESTIMONY, Jun. 6, 2007, http://www.cdc.gov/washington/testimony/2007/t20070606.htm (last visited May 8, 2010).

⁵⁸ See id.

and less effective, making patient adherence to treatment challenging.⁵⁹ Patients with MDR-TB have higher mortality rates and lower cure rates than those with drug-susceptible TB. ⁶⁰ Most TB patients can be successfully treated by regularly taking medication, but thoracic surgery may be necessary to treat drug-resistant strains of TB. ⁶¹ XDR-TB is a subset of MDR-TB caused by strains of bacteria that are resistant to the most effective first-line and second-line drugs. ⁶² Reported mortality rates among persons with XDR-TB are extremely high, ⁶³ especially in immune-compromised persons. ⁶⁴ With limited drugs available to treat drug-resistant forms of TB, the worst case scenario may lead us back to the 19th century when TB was untreatable and patients were kept separate from others until they died.

C. Taiwan's Tuberculosis Isolation Program

While the WHO warned of TB's resurgence in 1993, Taiwan was marching toward a stable decrease in mortality rates, and TB had not been a top ten cause of death for years. ⁶⁵ Although TB control programs

⁵⁹ See Michael D. Iseman, *Treatment of Multidrug-Resistant Tuberculosis*, 329 NEW ENG. J. MED. 784 (1993). MDR-TB has an eighty-three-fold greater risk (11.6 percent vs. 0.15 percent) of treatment failure, and a twofold (eleven percent versus five percent) greater risk of relapse. *See id*.

⁶⁰ But the mortality rate and cure rate of MDR-TB are improving. In a 1993 study of MDR-TB patients treated from 1973 to 1983, the overall cure rate was only fifty-six percent, and the overall mortality rate was thirty-seven percent in spite of intensive hospital-based chemotherapy. *See* Marian Goble et al., *Treatment of 171 Patients with Pulmonary Tuberculosis Resistant to Isoniazid and Rifampin*, 328 NEW ENG. J. MED. 527 (1993). But in a 2005 study, long-term success rates at the same institution were seventy-five percent and death rates were twelve percent. *See* Edward D. Chan et al., *Treatment and Outcome Analysis of 205 Patients with Multidrug-resistant Tuberculosis*, 169 AM. J. OF RESPIR. CRIT. CARE MED., 1103 (2004). The improvements were associated with surgical resection and fluoroquinolone therapy. *See id*.

⁶¹ See Jose G. Somocurcio1 et al., Surgical Therapy for Patients with Drug-Resistant Tuberculosis: Report of 121 Cases Receiving Community-Based Treatment in Lima, Peru, 62(5) THORAX 416 (2007).

⁶² See LoBue et al., supra note 3, at 3. XDR-TB is defined as TB that is resistant to isoniazid and rifampin, and in addition is resistant to any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin). See U.S. Centers for Disease Control and Prevention, Notice to Readers: Revised Definition of Extensively Drug-Resistant Tuberculosis, 55(43) MMWR 1176 (2006), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5543a4.htm.

⁶³ See Edward D. Chan et al., Treatment Outcomes in Extensively Resistant Tuberculosis, 359 New Eng. J. Med. 657 (2008).

⁶⁴ LoBue et al., *supra* note 3, at 4.

⁶⁵ See Xingzhengyuan Weishengshu Jibing Guanzhiju (行政院衛生署疾病管制局) [Centers for Disease Control, Department of Health, Executive Yuan], Minguo Jiushinian Jiehebing Fangzhi Nianbao (民國九十年結核病防治年報) [TUBERCULOSIS

established since the 1950s continued, decreasing government and public attention no longer made the disease a public health priority. However, the SARS epidemic and the increasing international efforts to combat TB not only revived the Taiwanese government's ambition to eliminate the burden of TB, but also spurred a revision of the Act and formalization of the regulations. Eventually, the regulatory scheme for isolation was translated into practice and at the same time a reimbursement system was established by the CDC. Examination of the formation of Taiwan's TB isolation program requires an understanding of the epidemiology of TB in Taiwan as well as how the legal and health care system guided activation of efforts to fight the disease.

1. Epidemiological Background of Tuberculosis

In the last few decades, Taiwan has made substantial progress in reducing the burden of TB. TB mortality rates dropped drastically from 294.44 per 100,000 persons in 1947 to 2.8 per 100,000 persons in 2010.⁶⁹ This achievement has been construed as evidence of the specialized TB control system's success at detecting and educating patients as well as improving access to treatment. After World War II, a bureaucratic infrastructure was developed with aid from the United Nations International Children's Emergency Fund, the WHO, the Sino-American Joint Commission on Rural Reconstruction, and the Council on U.S. Aid, to implement TB control policies.⁷⁰ These policies included the Bacille

CONTROL ANNUAL REPORT 2001] 15 (2001) [hereinafter TUBERCULOSIS CONTROL ANNUAL REPORT 2001], available at http://www.cdc.gov.tw/professional/info.aspx?treeid=56CA56252A0FA705&nowtreeid=32B13BB28F1CDA3F&tid=8902B3AE3C8AFC90.

⁶⁶ See Suo, Ren (索任), Taiwan Fanglao Gongzuo Huigu (台灣防療工作回顧) [Review of Taiwan's Tuberculosis Control Work], 13(3) GANRAN KONGZHI ZAZHI (感染控制雜誌) [INFECTION CONTROL J.] 173, 176 (2003).

⁶⁷ See Suo, Ren (索任), Taiwan Fanglao Gongzuo de Jinxi (台灣防療工作的今昔) [Past and Present of Taiwan's Tuberculosis Control Work], 24(3) YIQING BAODAO (疫情報導) [TAIWAN EPIDEMIOLOGY BULLETIN] 169, 176 (2008); CTRS. FOR DISEASE CONTROL, DEP'T. OF HEALTH, EXEC. YUAN, CDC ANNUAL REPORT 2005,8 (2005) [hereinafter CDC Annual Report 2005]; CTR. FOR DISEASE CONTROL, DEP'T. OF HEALTH, EXEC. YUAN, CDC ANNUAL REPORT 2006 4, 96 (2006).

⁶⁸ See infra Parts II.C.2, II.C.3.

⁶⁹ See Tuberculosis Control Annual Report 2001, supra note 65, at 15; Ctrs. for Disease Control, Dep't. of Health, R.O.C (Taiwan), Taiwan Tuberculosis Control Report 2011 20 (2011), available at http://www.cdc.gov.tw/uploads/files/201206/ccfec372-80f3-4256-9c3a-077fb8ccfa08.pdf.

⁷⁰ See Zhang Shuqing (張淑卿), Fanglao Tixi Yu Jiankong JiShu: Taiwan Jiehebing Shi Yanjiu 1945-1970s (防療體系與監控技術: 台灣結核病史研究(1945-1970s)) [Tuberculosis Control System and Surveillance Techniques: The History of Tuberculosis in Taiwan from 1945 to 1970s] 127-35 (2004) (unpublished Ph.D.

Calmette-Guérin ("BCG") vaccination, X-ray and sputum screening, and free medication programs.⁷¹ Patients with serious conditions or in need of surgeries might be admitted to TB control centers for hospitalization.⁷² By 1985, TB was no longer among the top ten causes of death in Taiwan.⁷³ Consequently, the publicly-funded TB control system waned and was gradually replaced by a medical system under the National Health Insurance program ("NHI"), launched in 1995.⁷⁴

Despite great achievements in reducing death rates from TB, the incidence rates remains relatively high. In 2008, Taiwan's TB incidence rate was sixty-two per 100,000 people, while the U.S. rate was 4.8 per 100,000 people and Japan's was twenty-two per 100,000 people. The Moreover, drug resistant forms of TB have become a new public health problem. Since MDR-TB was added to the CDC's surveillance system in October of 2007, there are more than 150 new cases registered each year.

dissertation, Tsing-Hua University).

⁷¹ *Id.* at 140-41.

⁷² See Taiwansheng Fanglaoju (台灣省防癆局) [Taiwan Provincial Tuberculosis Bureau], TAIWANSHENG DE FANGLAO GONGZUO (台灣省的防癆工作) [TUBERCULOSIS CONTROL IN TAIWAN PROVINCE] 49 (1977).

 $^{^{73}}$ See Tuberculosis Control Annual Report 2001, supra note 65, at 42.

⁷⁴ See infra Part II.C.2.

⁷⁵ See Ctrs. for Disease Control, Dep't of Health, R.O.C. (Taiwan), **TUBERCULOSIS** REPORT 2012 3 (2012),available http://www.cdc.gov.tw/uploads/files/201303/9ea28ba2-69c7-4f27-af3b-55be5ec7e35c.pdf (last visited Apr. 25, 2012); United States of America Tuberculosis Profile, World **HEALTH** ORG., available https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/ EXT/TBCountryProfile&ISO2=us&outtype=pdf (last visited Mar. 29, 2013); Japan World **Tuberculosis** Profile, **HEALTH** ORG., available at https://extranet.who.int/sree/Reports?op=Replet&name=/WHO HQ Reports/G2/PRO D/EXT/TBCountryProfile&ISO2=jp&outtype=pdf (last visited Mar. 29, 2013).

⁷⁶CTRS. FOR DISEASE CONTROL, DEP'T OF HEALTH, R. O. C. (TAIWAN), STATISTICS OF COMMUNICABLE DISEASES AND SURVEILLANCE REPORT, REPUBLIC OF CHINA 2008 VIII, available 5 (2009),http://www.cdc.gov.tw/uploads/files/201210/8bb92a35-39e7-4bbd-954a-6fbf303edb98.pdf; CTRS. FOR DISEASE CONTROL, DEP'T. OF HEALTH, R. O. C. (TAIWAN), STATISTICS OF COMMUNICABLE DISEASES AND SURVEILLANCE REPORT, REPUBLIC OF 2009 5 **CHINA** (2010),available http://www.cdc.gov.tw/uploads/files/201210/7cfe515c-b506-44cd-b05f-b106-44cd-b05-46cd-b05-42416942bbed8.pdf; CTRS. FOR DISEASE CONTROL, DEP'T OF HEALTH, R. O. C. (TAIWAN), STATISTICS OF COMMUNICABLE DISEASES AND SURVEILLANCE REPORT, REPUBLIC OF 2010 5 (2011),available http://www.cdc.gov.tw/uploads/files/201210/291a1d4a-e194-462d-b08d-66ba17329d46.pdf.

In keeping with the desire to strengthen connections with the WHO's global anti-TB efforts, the Taiwanese government launched a Ten-Year Mobilization Plan, aimed at halving incidence rates from 66.7 per 100,000 people to 34 per 100,000 people by 2015. The DOTS program, recommended by the WHO as an international standard to control TB, was adopted in efforts to provide supervised treatment from government agents. Moreover, the government demonstrated its willingness to use a more coercive form of measure in the plan: to provide infectious TB patients with "mandatory isolation care," a public health intervention authorized under Article 44 of the Act. The adoption of isolation as a strategy shows not only the government's ambition but also a different public health approach to tackle TB control.

2. The Regulatory Framework for Tuberculosis Isolation

The Act and related regulations allows treating physicians to nominate patients for isolation and public health officials the ability to isolate patients if necessary. Under Article 44 of the Act, competent authorities (i.e., the DOH, the municipality and county governments) may isolate TB patients in designated hospitals if necessary. Patients subject to isolation orders must be treated at designated hospitals, which are reimbursed from the government's budget based on payment standards set by the NHI. To guide the implementation of the isolation measure, the DOH promulgated the Procedure of Operation for Isolation Care and Reassessment of Patients with Notifiable Communicable Diseases ("the

 $^{^{77}\,}See$ Mobilization Plan to Halve Tuberculosis Incidence in Ten Years, supra note 22, at 7, 11.

⁷⁸ See id. at 23.

⁷⁹ See id. at 29-30.

⁸⁰ Xingzhengyuan Weishengshu Jibing Guanzhiju (行政院衛生署疾病管制局) [Ctrs. for Disease Control, Dep't. of Health, Exec. Yuan], JIEHEBING FANGZHI GONGZUO SHOUCE (結核病防治工作手冊) [TUBERCULOSIS CONTROL MANUAL] 166-67 (1st ed. 2002) [hereafter TUBERCULOSIS CONTROL MANUAL 2002].

⁸¹ Xingzhengyuan Weishengshu Jibing Guanzhiju (行政院衛生署疾病管制局) [Ctrs. for Disease Control, Dep't. of Health, Exec. Yuan], JIEHEBING FANGZHI GONGZUO SHOUCE (結核病防治工作手冊) [TUBERCULOSIS CONTROL MANUAL], 176 (2nd ed. 2009) [hereafter TUBERCULOSIS CONTROL MANUAL 2009].

^{**}Singzhengyuan Weishengshu Jibing Guanzhiju (行政院衛生署疾病管制局) [Ctrs. for Disease Control, Dep't. of Health, Exec. Yuan], Wei Shu Jiguan Jian Zi Di 0930021540 Hao (衛署疾管監字第 0930021540 號) [Notice No.0930021540], Dec. 21, 2004 [hereinafter Ctrs. for Disease Control, Notice No. 0930021540, Dec. 21, 2004]; Xingzhenguan Weishengshu (行政院衛生署) [Dep't. of Health, Admin. Yuan], Shu Shou Ji Zi Di 960000722 Hao (署授疾字第 0960000722 號) [Notice No. 0960000722], Sept. 6, 2007 [hereinafter Dep't of Health, Notice No. 0960000722. Sept. 6, 2007].

Procedure") and related DOH forms.⁸³ The Procedure allows the isolation process to be initiated by sending a referral to nominate patients for isolation under either of two scenarios. First, treating physicians may send a referral bearing the seal of the hospital to local health administrations if, in their opinion, a patient needs isolation.⁸⁴ Second, workers at township health centers may fill out a referral to their local health administration requesting an isolation order if they come across patients who are not compliant with treatment.⁸⁵ If local authorities approve the referral, Article 44, paragraph 2 requires an isolation notice to the patient, requesting patient submission to a designated treatment institution (Figure 1).⁸⁶ As of 2008, 136 hospitals equipped with qualified isolation facilities were designated by the DOH as institutions responsible for providing inpatient care for patients with communicable diseases.⁸⁷

⁸³ These documents were previously adopted in a manual published by the CDC for public health workers. *See* TUBERCULOSIS CONTROL MANUAL 2002, *supra* note 80, at 195-97.

⁸⁴ *Id.* at 166.

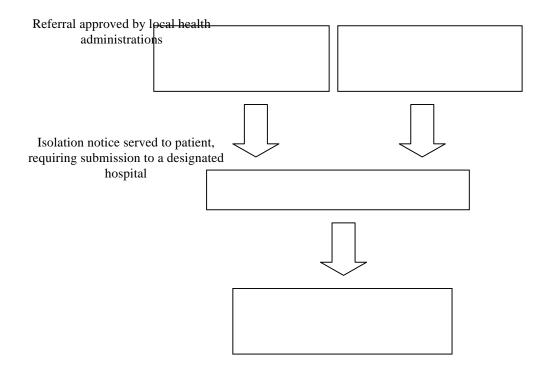
⁸⁵ *Id.* at 167.

⁸⁶ Article 44, paragraph 2 of the Act states "[a]n isolation care notice must be delivered to the patient or the family, and a copy to the isolation care institution, within the next three days of mandatory isolation care or transfer." Xingzhenguan Weishengshu (行政院衛生署) [Dep't. of Health, Admin. Yuan], Weisheng Fagui Ziliao Jiansuo Xitong (衛生法規資料檢索系統) [Health Regulations Inquiry System], http://dohlaw.doh.gov.tw/Chi/Default.asp (last visited May 20, 2012).

⁸⁷ Xingzhenguan Weishengshu (行政院衛生署) [Dep't. of Health, Admin. Yuan], Shu Shou Ji Zi Di 0970000435 Hao (署授疾字第 0970000435 號) [Notice No.0970000435], Aug. 8, 2008. The Department of Health's power to designate hospitals is currently authorized under Article 14, paragraph 4 of the Act. See id.

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Figure 1: Two Scenarios for Referrals to Request Isolation Orders⁸⁸



At the launch of the isolation program, on March 1, 2006, the CDC sent local health administrations an official document requiring them to enforce isolation of sputum smear-positive patients⁸⁹ who were homeless and living in congregate facilities, or uncooperative.⁹⁰ The CDC also issued guiding principles defining discharge requirements and specifying conditions under which patients with sputum smear-positive test results

⁸⁸ The author created this table.

⁸⁹ A sputum smear test is a microbiologic examination to detect acid-fast bacilli ("AFB") in stained smears. The result may provide the first bacteriologic clue of TB. It is a quick and easy procedure, but only it only identifies the likeliness of TB. To confirm a TB diagnosis requires culturing *Mycobacterium tuberculosis* organisms in a specimen taken from the patient. *See* CORE CURRICULUM, *supra* note 31, at 42-44.

⁹⁰ See Xingzhenguan Weishengshu Jibing Guanzhiju (行政院衛生署疾病管制局) [Ctrs. for Disease Control, Dep't. of Health, Exec. Yuan], Wei Shu Jiguan He Zi Di 0950006402 Hao (衛署疾管核字第 0950003403 號) [Notice No.0950003403], Mar. 1, 2006 ("To eliminate the source of infection in communities, and to achieve the goal of halving the tuberculosis rate in ten years, those who are confirmed TB cases with sputum homeless, residents of congregated facilities [such as nursing homes or psychiatric hospitals], or uncooperative cases should be given preference—shall be forcibly sent to 'Designated Hospitals for Infectious Disease Isolation Care' for isolation. They cannot be discharged until two weeks after the hospitalization or until they have sputum smearnegative test results.").

could be exempted from mandatory isolation. 91 According to the Principles for Tuberculosis Compulsory Hospitalization Isolation Care, and Conditions of Exemption from Compulsory Hospitalization Isolation Care (collectively, "the Guidelines"), patients with sputum smear-positive test results who have been subjected to mandatory isolation should not be discharged unless: (1) patients have taken standard anti-TB medication for two weeks, (2) there have been three sequential sputum smear-negative test results, and (3) clinical conditions have improved. 92 Homeless patients or "uncooperative cases" should not be discharged until completing their treatment. ⁹³ Moreover, patients with sputum smear-positive test results can be exempted from mandatory isolation if: (1) their treatment can be monitored by public health nurses, (2) they started taking standard anti-TB medication and the DOTS program has been offered and accepted, (3) there are no children under 4 or immune-suppressed persons living in the same household, (4) there will not be any new contacts who may contract TB in the patients' households, and (5) patients agree not to go out other than for medical-related matters and to wear masks. 94 The Guidelines reveal that infectious patients should be principally considered as candidates for isolation unless they meet exceptional conditions. Patients who are homeless or deemed uncooperative may be subject to a longer period of isolation. 95 As to the expenses of isolation, the DOH is responsible for paying the cost to the designated institutions under the requirement of the Act.⁹⁶

3. The Reimbursement Scheme

Although the Act requires the DOH to cover the cost of treating patients subject to isolation orders, it was not until 2006 that the CDC provided a budget to fund the reimbursement system. ⁹⁷ To save the NHI

⁹¹ Xingzhenguan Weishengshu Jibing Guanzhiju (行政院衛生署疾病管制局) [Ctrs. for Disease Control, Dep't. of Health, Exec. Yuan], Wei Shu Jiguan He Zi Di 0950006402 Hao (衛署疾管核字第 0950006402 號) [Notice No.0950006402], Apr. 18, 2006 [hereinafter Ctrs. for Disease Control, Notice No. 0950006402, Apr. 18, 2006] (copy on file with author).

⁹² *Id*.

⁹³ *Id*.

⁹⁴ *Id*.

⁹⁵ *Id*.

 $^{^{96}}$ Ctrs. for Disease Control, Notice No. 0930021540, Dec. 21, 2004, supra note 82.

⁹⁷ See MOBILIZATION PLAN TO HALVE TUBERCULOSIS INCIDENCE IN TEN YEARS, supra note 22, at 22-23; See Jiehebing Yiliao Feiyong Zhunian Naru Gongwu Yusuan, Baozhang Binghuan Jiuyi Quanyi, bing Tisheng Fangyi Xiaoneng (結核病醫療費用逐年納入公務預算,保障病患就醫權益,並提升防疫效能) [TB Medical Expenses Covered by Government Budget Gradually, to Protect the Interests of Patients for

from bankruptcy, the government adopted the Multiple Micro-Adjustment Plan in 2005. This plan allowed the costs of preventive care, treatment for patients with reportable communicable diseases, and subsidies to teaching hospitals—all previously covered by the NHI program—to be paid out of the public budget rather than from the NHI pool. Since 2006, CDC's budget has covered expenditures for TB isolation cases, but reimbursement is processed by the Bureau of National Health Insurance ("BNHI"), the single-payer insurer of NHI, which may periodically bill the CDC for repayment.

CDC reimbursements may have some financial advantages for the hospitals when compared to reimbursements from the NHI's pool. To control costs, the NHI has been using a global budget scheme under which medical services are reimbursed through the fee-for-service model within the limit of the global budget determined by the BNHI. ¹⁰¹ Due to the fact that reimbursements are constrained by the cap (i.e. the total NHI healthcare expenditure in a given year), reimbursements are based on floating point-values multiplied by the price set by the BNHI, and the point-value is negatively associated with the total service volume. ¹⁰² As a result, if the nationwide service volume increases, the point-value goes down. Since this system was applied to hospital services in 2002, the point-value has always been less than a dollar per point. ¹⁰³ However, CDC reimbursements guaranteed full payment of covered services related to TB isolation cases. ¹⁰⁴ For example, one isolation bed may receive 1786 points

Medical Treatment, and Improve Disease Prevention Performance], WEISHENGSHU JIBING GUANZHIJU (衛生署疾病管制局) [CTRS. FOR DISEASE CONTROL, DEP'T. OF HEALTH],

http://www.cdc.gov.tw/info.aspx?treeid=45da8e73a81d495d&nowtreeid=1bd193ed6dabae6&tid=EB43B32232C61A85 (last visited May 5, 2013).

⁹⁸ Xingzhengyuan (行政院) [Executive Yuan], Jianbao Gaige Duoyuan Weidiao Fangan Xinwengao (健保改革多元微調方案新聞稿 [News Release for Multiple Micro-Adjustment Plan for National Health Insurance Reform], Waijiaobu (外交部) [Ministry of Foreign Affairs, Republic of China (Taiwan) (Feb. 18, 2005), http://internationalnewsstation.tw/lp.asp?CtNode=4619&CtUnit=318&BaseDSD=23&m p=1 (last visited Mar. 4, 2013).

⁹⁹ *Id*.

¹⁰⁰ WEISHENGSHU JIBING GUANZHIJU (衛生署疾病管制局) [CTRS. FOR DISEASE CONTROL, DEP'T. OF HEALTH], JIEHEBING GONGWUYUSUAN ZHIFU YILIAO FEIYONG ZUOYE SHOUCE (結核病公務預算支付醫療費用作業手冊) [OPERATIONAL MANUAL FOR TUBERCULOSIS BUDGET FOR MEDICAL PAYMENT] 8-9 (2007).

¹⁰¹ See Shou-Hsia Cheng et al., Hospital Response to a Global Budget Program Under Universal Health Insurance in Taiwan, 92(2) HEALTH POL'Y 158, 158-59 (2009).

¹⁰² *Id.* at 159.

¹⁰³ See id.

¹⁰⁴ Ctrs. for Disease Control, Notice No. 0930021540, Dec. 21, 2004, *supra* note

per day for reimbursement according to the BNHI's payment standard. Hospitals could receive 100 percent of the 1786 points per day if qualified for CDC reimbursement. Under the global budget scheme, however, the point-value for inpatient services of hospitals was on average 0.8886 in 2006. Hospitals could be reimbursed for only 1587 point per day (88.86 percent of 1786). Claims for services related to isolation are reimbursed at 100 percent of the payment standard set by the BNHI from the CDC's budget rather than floating point-values under the NHI's global budget scheme. ¹⁰⁵ In addition, even if hospitals increased the volume of CDC-covered services, this growth of expenses would not have a negative impact on the point-value of other services covered by the global budget scheme. ¹⁰⁶

This reimbursement system moved the TB patient isolation policy from proposal to action. However, evaluating the cost-effectiveness of isolating TB patients nor assessing the burdens on patients was performed. The extent to which the isolation measure actually benefited affected individuals and public health may only be examined by unveiling the particulars of the actual exercise of the regulatory power.

III. IMPLEMENTATION OF TAIWAN'S TUBERCULOSIS REGULATION

History warns that no matter how well-intentioned, the power of detention has the potential to be abused, and socially marginalized people may be inequitably subject to this coercive power. To justify the use of detention, scrutiny of its actual use is indispensable. ¹⁰⁷ This part will present results from interviews in an effort to articulate the actual

^{82;} Dep't of Health, Notice No. 0960000722. Sept. 6, 2007, supra note 82.

¹⁰⁵ Ctrs. for Disease Control, Notice No. 0930021540, Dec. 21, 2004, *supra* note 82; Dep't of Health, Notice No. 0960000722. Sept. 6, 2007, *supra* note 82.

¹⁰⁶ Ctrs. for Disease Control, Notice No. 0930021540, Dec. 21, 2004, supra note 82; Dep't of Health, Notice No. 0960000722. Sept. 6, 2007, supra note 82. Under the NHI's global budget scheme, if the nationwide service volume increases, the point-value goes down. To prevent financial loss, hospitals need to keep a balance between the service volume and reasonable point-value. As a result, hospitals would have strong incentive to "police" inappropriate practices taken by others, which is a significant advantage of the global budget scheme in reducing expenses. Conversely, hospitals would not pay as much attention as to the volume of services reimbursed by the CDC's budget. Quanmin Jiankang Baoxian Yiliao Feiyong Xieding Weiyuanhui (全民健康保險 醫療費用協定委員會) [Nat'l Health Insurance Medical Expenditure Negotiation Comm.], QUANMIN JIANKANG BAOXIAN YILIAO FEIYONG ZONG-E ZHIFU ZHIDU WENDAJI (全民健康保險醫療費用總額支付制度問答輯) [Q & A FOR THE NATIONAL HEALTH INSURANCE GLOBAL BUDGET PAYTMENT SYSTEM] 7, 17-18, available at http://www.nhi.gov.tw/Resource/webdata/Attach 13636 2 8.2%EF%BC%9A%E7%B8 %BD%E9%A1%8DQA%E6%89%8B%E5%86%8A%E7%AC%AC%E5%85%AD%E7 %89%88%E5%90%AB94%E5%B9%B4.pdf (last visited May 20, 2013).

¹⁰⁷ See LERNER, supra note 29, at 170.

application of the regulatory scheme. Then this part will elaborate on and analyze the legal implications of the practice.

A. Study Methodology:

After receiving approval from the Human Subjects Division of the University of Washington, the author conducted a series of semi-structured interviews with two groups of informants between March and July 2009: (1) officials from local health administrations who were charged with implementing the isolation regulation, and (2) health care workers at designated hospitals, including physicians, nurses, and TB case managers. The author designed the study to investigate how the TB isolation regulations have been applied.

The author recruited officials with the assistance of reference letters and referrals by a DOH official to seven local health administrations in counties/cities with the top ten highest number of newly registered TB cases in 2006. The author faxed the reference letter, in addition to a supplementary letter explaining the purpose of the research and showing sample interview questions, to the director or deputy director's offices. The author then arranged interviews with officers who agreed to be interviewed. The author used referrals to recruit additional interviewees. Mayoral offices in three county/city governments gave the referrals and helped identify officials responsible for TB control in local health administrations.

A total of eleven interviews were conducted with fifteen officials from ten local health administrations (referred to as county/city A to J) that accounted for 62.03 percent (9540 out of 15,378) of all newly registered cases in Taiwan in 2006. The process for approving a referral involved obtaining signatures from the official who first reviewed the referral, the head of the local disease control division, and the director or deputy of the local health administration. This group of interviewees included those officials. Among them, eight were responsible officials, four were heads of the disease control division of their local health administration, one was a deputy director, and two were directors of local health administrations.

The second group contained health care workers at designated hospitals, including physicians, nurses, and TB case managers. Interviews with physicians helped the author understand their decision-making process for sending referrals. These nurses and TB case managers were likely to have the most direct contact with TB patients subject to isolation. Head nurses at the isolation wards manage all patients admitted into the

 $^{^{108}}$ According to the author, rresponsible officials are called "chengbanren" (承 辦人) in Chinese. They are the first-line officials dealing with TB-related administrative affairs. These officials are the first officials to review isolation referrals sent by physicians or township public health workers.

ward; TB case managers are the contact people in the hospitals for TB-related matters. The BNHI requires hospitals reporting over 100 TB cases per year to have TB case managers. Usually, the TB case managers are senior nurses who receive additional training and education about TB control. They track patient visits, educate patients on health matters, update patient information in the central database, and coordinate patient management with public health nurses and local health officials. ¹⁰⁹ Essentially, TB case managers are responsible for all TB-related matters in the hospitals.

To recruit this group, the author asked local health officials if they could refer particular health care workers at designated hospitals. When officials agreed, the officials called the potential interviewees to determine if they were willing to be interviewed. Then the author faxed a letter or sent an e-mail explaining the purpose of this research and providing sample interview questions. A total of eleven interviews were conducted with fourteen health care workers from eight designated hospitals. The interviewees consisted of six chest and infectious control physicians, two head nurses of the isolation wards of more than fifty beds, and six TB case managers. Of the eight designated hospitals visited, two were private and six were public hospitals. The hospitals were located in eight counties/cities.

These twenty-two interviews were all conducted in person. Most (seventeen out of twenty-two) were done on a one-on-one basis; the rest were conducted with two or three interviewees at once due to the limited time available. Interviews lasted one hour on average. Prior to the interview, informants were given an informed consent form, explaining the purpose of the interview and stating that their conversation would be kept confidential, and their remarks anonymous. They are referred to by code instead of their names. Interviewees were then asked to respond to a series of questions, included, infra, in Appendix A. Although the author prepared a list of interview questions to ensure all areas of interest were covered, she judged the flow of the conversation and did not necessarily ask all the questions. The author followed up on responses when interviewees revealed some new information or interesting perspectives. To ensure that these interviewees felt comfortable enough to talk candidly, no interviews were recorded. However, the author did take notes during the interviews. The results may not necessarily be generalizable to other local health administrations and hospitals, because these interviewees

¹⁰⁹ See Cheng-Yi Lee et al., Application of Pay for Performance in Tuberculosis Care—The Taiwan Experience, 28(19) TAIWAN EPIDEMIOLOGY BULLETIN 286, 294 (2012). TB patients remaining in treatment for an adequate period of time is critical for disease control. But patients may need to be reminded of medical appointments referring them to specialists and social services. TB case managers working in hospitals are specialized full-time professionals dedicated to TB patients. They work closely with public health nurses and officials to ensure patients adhere to their treatment. See id.

were purposely selected. There is no guarantee that this purposive sample was an accurate representation of the whole public health and medical care communities, but data gathered from these interviewees is instrumental in understanding underlying issues of the actual practice.

B. Interview Results

The isolation processes may be initiated by treating physicians as well as public health workers. Practices in these two cases will be presented respectively. In each case, the number of notices, the grounds for sending referrals, how referrals were reviewed, the procedure for notice issuance, and the discharge decision-making process will be reported respectively to provide insights into the actual practice of the regulatory scheme. Thoughts and opinions by officials regarding the isolation regulations will also be described to reflect the appropriateness of the regulatory design.

1. Process Prompted by Treating Physicians

Number of Notices

Except for the reported 1312 patients subjected to isolation care orders in 2006, no figures regarding the number of isolation notices issued have been published since the law came into effect in 1999. To know how frequently isolation measures were used, local health officials were asked about the number of notices issued. A few interviewees provided the number by looking it up on their computers. But more commonly, they needed to find old files and count the copies of notices. In some cases, the files were either stored in warehouses or could not be tracked down. This made it difficult to compile complete data. Based on the available data provided by interviewees from 2006 to 2008, on average over ninety-five percent of isolation processes were prompted by treating physicians' referrals (96.89 percent, 2006; 97.16 percent, 2007; 93.32 percent, 2008). The percent of isolation processes were prompted by treating physicians' referrals (96.89 percent, 2006; 97.16 percent, 2007; 93.32 percent, 2008).

Grounds for Physician Referrals

110 In the updated Tuberculosis Control Manual of 2009, local health administrations are required to report isolated cases to the CDC monthly. If this requirement is enforced, the CDC should have complete statistics regarding isolation cases for tuberculosis patients after 2009. TUBERCULOSIS CONTROL MANUAL 2009, *supra* note 81, at 202.

¹¹¹ Interview with O5, Health Official, in TAIWAN (Mar. 18, 2009); Interview with O7, Health Official, in TAIWAN (Mar. 19, 2009); Interview with O8, Health Official, in TAIWAN (Mar. 19, 2009); Interview with O9, Health Official, in TAIWAN (Mar. 27, 2009); Interview with O6, Health Official, in TAIWAN (Apr. 1, 2009); Interview with O1, Health Official, in TAIWAN supra note 111; Interview with O10, Health Official, in TAIWAN (June 3, 2009); Interview with O13, Health Official, in TAIWAN (June 9, 2009); Interview with O12, Health Official, in TAIWAN, (May 13, 2009); Interview with O15, Health Official, in TAIWAN (June 29, 2009).

To understand physician basis for sending referrals, local health officials were asked about the referral content. Most officials (six out of nine) mentioned the sputum smear-positive test result and some description of the patient's clinical condition. 112 Other answers included chest X-ray results and comments about patient noncompliance with treatment. In spite of these general answers, seven interviewee comments suggested that physician decisions to send referrals might have been motivated by the financial incentive provided by the government's reimbursement policy. 114 For example, during one interview with an official that had over twenty years experience in TB control, she brought out a stack of files and put them on the desk. Then, she suddenly raised her voice and said, "[y]ou said you want to know why physicians send these referrals? Then, you do not need to ask physicians. It is the hospital administrative managers' idea to send these referrals." 115 She angrily explained that "since the cost of isolation was paid by the CDC instead of being covered by the Global Budget scheme of the National Health Insurance program, treating physician referrals were 'as numerous as snowflakes.,,,116

Six other respondent answers to the question about the conditions under which treating physicians would send referrals indicated a correlation between physician decisions to send referrals and reimbursement from the government. Respondent O1 replied that the

¹¹² Interview with O5, *supra* note 111; Interview with O7, *supra* note 111; Interview with O9, *supra* note 111; Interview with O2, Health Official, in TAIWAN (Apr. 14, 2009); Interview with O3, Health Official, in TAIWAN (Apr. 14, 2009); Interview with O1, *supra* note 111; Interview with O10, *supra* note 111; Interview with O13, *supra* note 111.

¹¹³ Interview with O3, *supra* note 112; Interview with O7, *supra* note 111; Interview with O13, *supra* note 111.

Interview with O9, *supra* note 111; Interview with O1, *supra* note 111; Interview with O10, *supra* note 111; Interview with O15 *supra* note 111; Interview with O12, *supra* note 111; Interview with O2 *supra* note 112; Interview with O6, *supra* note 111.

¹¹⁵ Interview with O9, supra note 111. In Taiwan, physicians working in hospitals are considered to be hospital employees, rather than independent contractors. See Lu Juifen (盧瑞芬) & Hsieh Cheeruey (謝啟瑞), Taiwan Yiyuan Chanye de Shichang Jiegou Yu Fazhan Cushi Fenxi (台灣醫院產業的市場結構與發展趨勢分析)[An Analysis of the Market Structure and Development of Taiwan's Hospital Industry], 30(1) JINGJI LUNWEN CONGKAN (經濟論文叢刊) [TAIWAN ECON. R.] 107, 108 (2003.) This may be the reason why the interviewee mentioned that hospital administrative managers were the decision-makers since they were in charge of billing the insurer.

¹¹⁶ Interview with O9, *supra* note 111.

Interview with O6, *supra* note 111; Interview with O2, *supra* note 112; Interview with O1, *supra* note 111; Interview with O10, *supra* note 111; Interview with O15, *supra* note 111; Interview with O12, *supra* note 111.

physician would generally send a referral if "the physician and the patient had reached a consensus on admission; sending the referral is for payment purposes." Because the reimbursement for isolation comes from the CDC's budget rather than the BNHI, claims for isolation care would not be reviewed and/or denied. Hospitals liked the 100 percent reimbursement from tax money for isolation since they had to find a way to use their idle isolation rooms anyway. But "not every hospital sent referrals, even though they had negative-pressure facilities for the isolation of infected patients. Some physicians were worried about the risk of cluster infections in hospitals." One respondent, in answering the question "on what grounds did physicians send referrals?," gave a detailed account of the isolation policy. He stated that

[a]fter SARS, we think we need to preserve the resource and capacity of disease control and focus on TB and AIDS during peace time. We are concerned that these two diseases may converge in the near future; therefore, we encourage utilization of negative-pressure isolation rooms, so we reimburse the isolation care from the public budget to encourage physicians to use isolation measures. The physicians are the most difficult to manage, so we need to put an incentive on the table. Physicians are looking for financial benefits that comply with the state's public health policy as well. If the criteria are met, patients may be admitted into the isolation room . . . The isolation policy might not be perfect, but the government is learning by doing. 123

On the other hand, the physicians interviewed had diverse answers concerning how they decided whether or not to send a referral. Two physicians revealed that they had never filled out a referral. ¹²⁴ Respondent

¹¹⁸ Interview with O1, *supra* note 111.

¹¹⁹ Interview with O10, *supra* note 111; Interview with O15, *supra* note 111; Interview with O12, *supra* note 111.

¹²⁰ Interview with O10, *supra* note 111; Interview with O15, *supra* note 111; Interview with O12, *supra* note 111.

¹²¹ In order to prevent transmission of TB in hospitals, patients known to have or suspected of having TB should be placed in an isolation room. Well equipped isolation rooms have negative pressure relative to other parts of the facility. Air flows from the corridors into the isolation room. *See* CORE CURRICULUM, *supra* note 31, at 90.

¹²² Interview with O6, *supra* note 111.

¹²³ Interview with O2. *supra* note 112.

¹²⁴ Interview with P3, Physician, in TAIWAN (May 19, 2009); Interview with P4, Physician, in TAIWAN (May 19, 2009).

P3, an infectious disease specialist, explained that usually he would be called for medical counsel when a hospitalized patient was suspected of having TB. Whether to send a referral was the attending physician's call, not his. He also revealed that medical centers usually do not like to admit TB patients due to concerns about cluster infections and high demand for beds for acute patients. The other physician who reported that he never sent a referral gave a detailed explanation for his reluctance to do so. He first expressed his doubt on the adequacy of the isolation policy by criticizing that targeting sputum smear-positive patients for isolation is meaningless because these patients usually have been infectious for quite a long time before being diagnosed with TB. Those who are at high risk of being infected, such as family members in the same household, might have already been infected.

Under these circumstances, isolating patients in a hospital for weeks upon diagnosing until their smear test turns negative is unlikely to prevent the spread of infection. In his opinion, admitting TB patients for isolation makes no difference; it is much more important to ask patients to start taking medication immediately because once they start treatment, the infectiousness can be reduced dramatically. For most outpatients, he usually would not suggest hospitalization. He further explained that some patients might be sent to the emergency room and diagnosed with TB. Normally, under this condition, these patients usually have other more severe medical conditions and often are too sick for outpatient care. In these cases, he had never seen any patients who refused to be admitted to the isolation ward, and that is why there is no need to send a referral for isolation. 131

Four other physicians explained how they decided whether to send a referral. Respondent P2 said that the use of referrals was extremely discretionary. "It depends on a physician's conscience and moral standards because the laws are vague, and the purpose of isolation is unclear." Respondent P1 said he prefers to isolate uncooperative patients, such as patients who do not acknowledge their TB disease, patients who would lose contact after discharge, and those whose infectiousness was unlikely

¹²⁵ Interview with P3, *supra* note 124.

¹²⁶ Interview with P4, *supra* note 124.

¹²⁷ *Id*.

¹²⁸ *Id*.

¹²⁹ *Id*.

¹³⁰ *Id*.

¹³¹ *Id*.

¹³² Interview with P2, Physician, in TAIWAN (Apr. 22, 2009).

to be reduced in two weeks.¹³³ He also revealed that he knew that some hospitals took advantage of the payment system in order to shift the cost, but the CDC had recently declared that CDC officials would pay close attention to these cases.¹³⁴

Respondent P6 commented on the use of referrals after asking about the motivation behind this research. After the author stated the purpose of this study, respondent P6 asked, "[w]hat motivated you to do this research?" The author responded that the isolation program was the first time that the government decided to pursue TB patients for isolation, and the CDC's news release stated that there were 1312 patients subject to mandatory isolation care in 2006 according to the CDC news. She told respondent P6 that this had piqued the author's curiosity about how the program worked. Respondent P6 then told the author with an outspoken tone that

a large portion of the 1312 patients did not meet the criteria for isolation To my knowledge, most of the isolation cases were due to consideration of receiving full reimbursement from the CDC because under the NHI's global budget scheme, the payment is less than a dollar per point. 137

He explained that the CDC intended to prevent the spread of infection after diagnosis for two weeks. To do so, it needed to use the payment system to support its isolation policy. In his opinion,

[t]he isolation policy is an issue of resource distribution and allocation. During the first few years of the isolation program, physicians would send a referral as long as the patient needed to be hospitalized or agreed to be hospitalized. In order not to get themselves into trouble, physicians would only send a referral when the patient was in fact willing to be hospitalized. But the isolation policy might have an adverse effect because patients stayed home in the past [and] caused an infection of their family members; now patients are admitted to the hospital and may transmit the disease to the people in the hospital. ¹³⁸

¹³³ Interview with P1, Physician, in TAIWAN (Apr. 22, 2009).

¹³⁴ LA

¹³⁵ Interview with P6, Physician, in TAIWAN (Jul. 13, 2009).

¹³⁶ Zizhurenzhu Jiehedouzhi (自助人助 結核都治) [Help Yourself and Others Will Help You, Tuberculosis Can Be Cured with DOTS], supra note 25.

¹³⁷ Interview with P6, *supra* note 135.

¹³⁸ *Id*.

Interestingly enough, when the physicians were answering the questions regarding factors considered when sending a referral, one physician revealed that she had sent two referrals at the request of the responsible official. On one occasion, the patient was a parolee with no money, housing or medication. The responsible official called and asked if she could send a referral and admit the patient. With the intention to help, she agreed. On another occasion, a patient was sent to the hospital by the responsible official with assistance from the police. The physician also agreed to send a referral at the request of the responsible official. Besides these experiences, she stated that she had heard peers talking about sending referrals and how it could augment the hospital's revenue. ¹³⁹

Three TB case managers and one nurse interviewed also provided their observation on how physicians decide when to send referrals. Respondent M3 said, "I know that hospitals X and Y used to send a referral as long as a patient came. Here, we follow the reimbursement rules."¹⁴⁰ One nurse said that "our physicians do not like to send referrals but I do know that some people used [referrals] a lot. Most of our isolated patients were sent by responsible public health nurses." ¹⁴¹ She further explained that isolation demands patient cooperation; if patients do not want to be admitted, they will be let go. 142 Respondent M1 said, "I don't know why other people sent a lot of referrals; our physicians are very careful about using [referrals]; isolation represents public power, after all."143 However, one TB case manager revealed that physicians in her hospital had never sent a referral to local health administrations. This is due to the fact that "at the very beginning of the isolation program, the chief of the chest department of the hospital had made it clear that if patients need to be admitted, persuasion is enough; it is not necessary to use compulsory measures." However, she knew some hospitals used referrals for reasons of reimbursement because "under the constraints of the global budget, the reimbursement is less than a dollar per point; but if you meet the criteria of isolation, you get full reimbursement." ¹⁴⁵ These respondent observation strongly suggested that the use of physician referrals might be related to the reimbursement system.

¹³⁹ Interview with P5, Physician, in TAIWAN (June 18, 2009).

 $^{^{140}}$ Interview with M3, Case Manager, in TAIWAN (June 19, 2009). The respondent specifically mentioned the names of two private hospitals nearby. *Id.* To preserve anonymity, the author used X and Y instead of the names of the hospitals.

¹⁴¹ Interview with N1, Nurse, in TAIWAN (May 23, 2009).

¹⁴² *Id*.

¹⁴³ Interview with M1, Case Manager, in TAIWAN (June 10, 2009).

¹⁴⁴ Interview with M6, Case Manager, in TAIWAN (June 29, 2009).

¹⁴⁵ *Id*.

How Were Physician Referrals Reviewed?

Under Article 44, patients with notifiable communicable diseases may be isolated in designated hospitals if necessary. According to the Procedure, local health administrations have to review physician referrals and decide whether to approve them. In doing so, the CDC's Guidelines require officials to take several factors into account when they make decisions regarding isolation. These include whether or not the patient's treatment can be supervised either by public health nurses or the DOTS program, and whether further infection of close contacts can be prevented by taking infection control measures.

When local health officials were asked how they reviewed physician referrals and what factors they would consider in making decisions, four replied that they respect and trust physician opinions. 150 Respondent O6 said that "in principle, we approved all the referrals." ¹⁵¹ Four other respondents, in replying to this question, mentioned the criterion of test results. 152 For example, respondent O1 said that when they are reviewing referrals, the responsible official would first look at medical test results to see whether there was a sputum smear-positive test result. He explained that the responsible official and the hospital would communicate via phone and reach a consensus before the hospital sent the referral "[o]therwise, our relationship with hospitals would be jeopardized."¹⁵³ In his opinion, "the reviewing process is more like a route to help hospitals complete the administrative requirements." 154 Respondent O9 answered the question in a straight-forward manner by stating, "[t]o be honest, I would not dare to refuse them. As long as the referral indicated that the patient had had a sputum smear-positive test result, I would approve it."155

Nine officials were asked whether they had ever refused to approve physician referrals, and only two replied that they had done so on a couple

¹⁴⁶ TUBERCULOSIS CONTROL MANUAL 2009, *supra* note 81, at 176-77.

¹⁴⁷ TUBERCULOSIS CONTROL MANUAL 2009, *supra* note 81, at 178-79.

 $^{^{148}}$ Ctrs. for Disease Control, Notice No. 0950006402, Apr. 18, 2006, supra note 91.

¹⁴⁹ *Id*.

¹⁵⁰ Interview with O3, *supra* note 112; Interview with O7, *supra* note 111; Interview with O10 *supra* note 111; Interview with O15, *supra* note 111.

¹⁵¹ Interview with O6, *supra* note 111.

¹⁵² Interview with O1, *supra* note 111; Interview with O9, *supra* note 111; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111.

¹⁵³ Interview with O1, *supra* note 111.

 $^{^{154}}$ Id

¹⁵⁵ Interview with O7, *supra* note 111.

of occasions. 156 Respondent O12 recalled that he had refused to approve one or two referrals sent by physicians. He emphasized that he would not blindly approve these referrals, therefore, he would call the hospital to find out the degree to which the patient had been uncooperative with treatment. 157 If the patient had been admitted and did not show any sign of non-compliance, he would tell the hospital staff that the referral would not be approved. 158 Respondent O9 revealed that she had refused to approve on very limited occasions because there were not sputum smear-positive test results recorded in the referral. She complained that when she called the hospitals to inform them that she intended to disapprove their referrals, she would have to argue with physicians. She specifically recalled that on one occasion, the treating physician argued that although the patient's test result was negative, there is a possibility that he might have a positive test result next time. Despite this obvious contradiction with the regulatory requirement, she did not directly refuse to approve, but simply asked the hospital to provide the supplementary documents or the follow-up test results later. 159 The reviewing process reported by local health officials shows that the officials were likely to treat physician referrals deferentially, without following the Guidelines.

Procedure for Notice Issuance

The Act and the Procedure require that upon approving a referral, "local health authorities shall fill out the Notice for Isolation Care and send the original copy to the patients or their family through confidential mail and another copy to the isolation care institution." ¹⁶⁰ If patients refuse to comply with isolation orders, the manual states that local health authorities may impose a fine and/or seek assistance from the police. ¹⁶¹

¹⁵⁶ Interview with O9, *supra* note 111; Interview with O12, *supra* note 111.

¹⁵⁷ Interview with O12, *supra* note 111.

¹⁵⁸ *Id*.

¹⁵⁹ Interview with O9, *supra* note 111. Respondent O8 indicated that the requirement of sputum smear-positive results in deciding isolation orders is intended to change physician practice in diagnosing tuberculosis. Physicians in Taiwan used to depend on X-rays for tuberculosis diagnosis, which are less reliable than sputum smear test results and inconsistent with the WHO's guidelines. The CDC, therefore, makes sputum smear test results a criterion for isolation and reimbursement with the expectation of changing the standard of diagnosis for tuberculosis. Interview with O8, *supra* note 111. Interview results show that most isolation cases were supported by the sputum smear test results, with very rare exceptions. Interview with O5, *supra* note 111; Interview with O7, *supra* note 111; Interview with O9, *supra* note 111; Interview with O10, *supra* note 111; Interview with O10, *supra* note 111; Interview with O13, *supra* note 111.

¹⁶⁰ TUBERCULOSIS CONTROL MANUAL 2009, *supra* note 81, at 179.

¹⁶¹ TUBERCULOSIS CONTROL MANUAL 2009, *supra* note 81, at 181.

However, interviews revealed that the regulatory notification procedure was seldom followed.

Four officials indicated their practices when referring a patient. First, hospitals faxed referrals to the local health administration offices. Upon approval, notices were faxed to hospitals. Patients were then asked to sign the notice by TB case managers or nurses. After doing so, notices were faxed to the responsible official. Two officials revealed that hospitals would fax both the referral and the notice with the patient's signature that proves the receipt of the notice to the local health administration office. The faxed notice would be faxed back to the hospital after approval. Nonetheless, one of the officials said they "hardly ever follow the procedural requirement of sending the order through confidential mail to the patient."

Two other counties/cities simplified the procedure for reasons of convenience. Respondent O5 revealed that the referral was not used in her county/city; they only used the notice. She explained that in the beginning of the isolation program, once patients were admitted for isolation, public health nurses would go to the hospital to ask the patient to sign the notice. But "this paperwork was too exhausting." Therefore, they asked the hospital to fax the notice with the patient's signature to the responsible official. After approval, the notice would be faxed back to the hospital. In contrast, respondent O15 reported that the notice form was not used in her county/city. She explained that upon receiving physician referrals, officials would sign for approval, and that "notifying the patient was dealt with by the hospital."

Health care workers interviewed described a similar practice. TB case managers or nurses at the isolation ward would usually be required to obtain the patient's signature, although they generally disliked doing so. For example, one nurse complained that "if physicians would like to isolate their patients, they should go talk to their patients and explain the rules to them." She said that most patients would just sign the notice without asking questions. But if patients asked what the notice was for, then she would tell them, "[p]lease help me with the form and sign it, so

¹⁶² Interview with O1, *supra* note 111; Interview with O6, *supra* note 111; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111.

 $^{^{163}}$ Interview with O9, supra note 111; Interview with O11, Health Official, in TAIWAN (June 3, 2009).

¹⁶⁴ Interview with O11, *supra* note 163.

¹⁶⁵ Interview with O5, *supra* note 111.

¹⁶⁶ *Id*.

¹⁶⁷ Interview with O15, *supra* note 111.

¹⁶⁸ Interview with N1, *supra* note 141.

that you can get free hospitalization and meals."¹⁶⁹ This was the most useful tactic in obtaining patient signatures. ¹⁷⁰ Interview results show that TB isolation referrals and notices were not used consistently in local health administrations. Additionally, the legal procedural requirements were not fully followed.

Grounds for Discharge

The CDC's guiding principles require the evaluation of three conditions before discharging patients that have sputum smear-positive tests and are subject to isolation orders.¹⁷¹ First, the patients have taken standard anti-TB medication for two weeks; second, there have been three sequential sputum smear-negative test results; and, third, their clinical conditions have shown improvement. 172 However, when local health officials were asked how patients subject to isolation orders could be released, their answers revealed that discharge is at the sole discretion of the treating physician. ¹⁷³ In most cases, if the patient had one sputum smear-negative test result, the treating physician would approve discharge. ¹⁷⁴ On some occasions, patients would ask to leave the hospital before their sputum smear tests turned negative, and physicians would agree to discharge them if they had already taken the medication on a regular basis for fourteen days. Moreover, some patients were released because of diagnosis changes or death. ¹⁷⁵ Upon discharge, patients would be asked to sign the Notice on the Removal of Mandatory or Isolation Care of Patients of Notifiable Communicable Diseases, which would then be faxed to the local health administration. ¹⁷⁶ The actual practice revealed

¹⁶⁹ *Id*.

¹⁷⁰ *Id*.

 $^{^{171}}$ Ctrs. for Disease Control, Notice No. 0950006402, Apr. 18, 2006, supra note 91.

¹⁷² *Id*

¹⁷³ Interview with O7, *supra* note 111; Interview with O1, *supra* note 111; Interview with O5, *supra* note 111; Interview with O6, *supra* note 111; Interview with O9, *supra* note 111; Interview with O11, *supra* note 163; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111.

¹⁷⁴ Interview with O1, *supra* note 111; Interview with O6, *supra* note 111; Interview with O11, *supra* note 163; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111.

¹⁷⁵ Interview with O1, *supra* note 111; Interview with O13, *supra* note 111; Interview with M1, *supra* note 143. Interviewee O13 was proud to tell the author that there had been no patients subject to isolation orders because of a changing diagnosis. Interview with O13, *supra* note 111.

¹⁷⁶ Interview with O1, *supra* note 111; Interview with O5, *supra* note 111; Interview with O6, *supra* note 111; Interview with O9, *supra* note 111; Interview with O11, *supra* note 163; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111; Interview with O15, *supra* note 111.

in these interviews suggested that discharge decisions were discretional and did not necessarily comply with the criteria laid out in the Guidelines.

2. Process Prompted by Public Health Workers

The TB isolation regulatory system allows both physicians and local public health workers to initiate the isolation procedure. Compared to the number of isolations orders initiated by treating physicians and hospitals, few cases were instigated by public health workers. These cases present another scenario under which the isolation power is exercised and provide insight into public health worker attitudes toward the use of isolation as well as problems they faced while doing their jobs.

Number of Notices

As noted earlier, because there is no official data available regarding the number of orders issued, interviewees were asked if they could provide the author with the numbers of notices for isolating TB patients and notices prompted by treating physician referrals. They were also asked whether notices had been issued in the absence of a physician's referral. Three respondents stated that notices issued that are not based on physician referrals are called notices from Ju Duan (局端, the administration).¹⁷⁷ They revealed that these notices were not necessarily initiated by referrals sent by the chief of the township health center; notices might also be issued in the absence of any referral. ¹⁷⁸ On the other hand, three respondents reported that notices would always be issued based on a referral, either by physicians or by the chief of the township health center. 179 A similar result is shown when two respondents reported that all notices issued were based on physician referrals. ¹⁸⁰ On average, approximately 4 percent of isolation processes were initiated by public health workers (3.11 percent, 2006; 2.84 percent, 2007; 6.68 percent, 2008).181

¹⁷⁷ Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O15, *supra* note 111.

¹⁷⁸ Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O15, *supra* note 111.

¹⁷⁹ Interview with O1, *supra* note 111; Interview with O11, *supra* note 163; Interview with O13, *supra* note 111.

¹⁸⁰ Interview with O7, *supra* note 111; Interview with O4, Health Official, in TAIWAN (Apr. 14, 2009).

¹⁸¹ Interview with O5, *supra* note 111; Interview with O7, *supra* note 111; Interview with O8, *supra* note 111; Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O10, *supra* note 111; Interview with O10, *supra* note 111; Interview with O13, *supra* note 111; Interview with O15, *supra* note 111.

Grounds for Imposing Isolation

When isolation processes were initiated by public health workers, the notices were based on different grounds. Nine officials from nine out of ten local health administrations called these patients "non-compliant" or "uncooperative." Respondents described several behaviors they deemed to be uncooperative. Among the most frequently mentioned was "not obedient in taking their medications." Patients with the following behaviors might also be deemed non-compliant or uncooperative: patients who had positive smear or culture results but no reported treatment record, who were not willing to receive treatment, who were not compliant with scheduled revisits to their treating physicians, who were reluctant to join the DOTS program, who were difficult to locate for responsible public health nurses or DOTS care workers, or who had a history of leaving hospitals prior to discharge. Respondents also referred to these patients as "difficult cases," or "real compulsory cases," or patients who "had difficulties or were in need of real compulsory [measures]." 187

In explaining how they tackled the patient compliance problem, several officials mentioned a common tactic of increasing the frequency of home visits. First, responsible public health nurses would visit patients to persuade them to go see a doctor, to take medication as prescribed, or to join the DOTS program. If not successful in securing the patient's cooperation, the physician or chief of the township health center would visit the patient. If the patient remained uncooperative, county/city health officials would pay the patient another visit. If necessary, CDC officials at local branches would also visit the patient. During home visits, public health workers would try to persuade patients with threats of punishments,

¹⁸² Interview with O5, *supra* note 111; Interview with O1, *supra* note 111; Interview with O6, *supra* note 111; Interview with O8, *supra* note 111; Interview with O9, *supra* note 111; Interview with O10, *supra* note 111; Interview with O10, *supra* note 111; Interview with O13, *supra* note 111.

¹⁸³ Interview with O8, *supra* note 111; Interview with O6, *supra* note 111; Interview with O10, *supra* note 111; Interview with O13, *supra* note 111.

¹⁸⁴ Interview with O5, *supra* note 111; Interview with O1, *supra* note 111; Interview with O6, *supra* note 111; Interview with O8, *supra* note 111; Interview with O9, *supra* note 111; Interview with O10, *supra* note 111; Interview with O13, *supra* note 111; Interview with O15, *supra* note 111.

¹⁸⁵ Interview with O5, *supra* note 111; Interview with O6, *supra* note 111.

¹⁸⁶ Interview with O15, *supra* note 111.

¹⁸⁷ Interview with O9, *supra* note 111.

¹⁸⁸ Interview with O5, *supra* note 111; Interview with O1, *supra* note 111; Interview with O6, *supra* note 111; Interview with O13, *supra* note 111. Respondent O13 revealed that the home-visits tactic was also used to persuade patients to join the DOTS program. Interview with O13, *supra* note 111.

such as fines or isolation, from time to time. ¹⁸⁹ One official revealed that some public health nurses who had connections with local policemen would ask them to help. ¹⁹⁰ Patients were usually afraid of the policemen, so the presence of policemen made public health workers more authoritative, and this was helpful in earning patients cooperation. ¹⁹¹ Some patients would agree to cooperate with officials by seeing a doctor and taking medication, because they could not stand the home visits anymore. ¹⁹² But for others, they might remain uncooperative. In these cases, two officials reported that they would send the patient an official governmental document requesting that they revisit the doctors and to comply with the treatment regimen or they would risk being fined. ¹⁹³ Respondent O10 observed that sending a warning document to them usually worked, especially for the elderly or economically disadvantaged patients because they might be worried about being fined by the administration. ¹⁹⁴

Although fines were often threatened, which is allowed under Article 69 of the Act, ¹⁹⁵ officials were in fact reluctant to pursue a fine-based compliance strategy. ¹⁹⁶ These patients were usually impoverished and not in a position to pay the fine. ¹⁹⁷ Only two out of eight respondents reported that they had actually imposed fines on uncooperative patients, despite their reluctance to do so. ¹⁹⁸ Based on his unpleasant experience,

¹⁸⁹ Interview with O5, *supra* note 111; Interview with O1, *supra* note 111; Interview with O6, *supra* note 111; Interview with O13, *supra* note 111.

¹⁹⁰ Interview with O13, *supra* note 111.

¹⁹¹ *Id*.

¹⁹² *Id*.

¹⁹³ Interview with O5, *supra* note 111; Interview with O10 *supra* note 111.

¹⁹⁴ Interview with O10 *supra* note 111.

¹⁹⁵ TUBERCULOSIS CONTROL MANUAL 2009, *supra* note 81, at 181.

¹⁹⁶ Interview with O5, *supra* note 111; Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O1, *supra* note 111; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111; Interview with O15, *supra* note 111.

¹⁹⁷ Interview with O5, *supra* note 111; Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O1, *supra* note 111; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111; Interview with O15, *supra* note 111.

¹⁹⁸ Interview with O12, *supra* note 111; Interview with O15, *supra* note 111. Interestingly, when these two respondents were asked about the situations, they reported that although they were hesitant to fine these patients, they were forced to do so since these patients had caught the CDC's attention and became "indices." They had no choice but to impose a fine. Interview with O12, *supra* note 111; Interview with O15, *supra* note 111.

one official gave a detailed explanation of his unwillingness to actually impose a fine. He reported that despite the CDC instructions for health administrations to impose fines on uncooperative patients, he thought that imposing a fine would cause a lose-lose situation. He concluded that "these patients could not possibly afford to pay the fine. If they do not pay the fine, the official would have to send the case to administrative enforcement agencies for collection [and] the administrative enforcement process would definitely anger the patient and make the patient refuse to cooperate even more firmly." In addition, as respondent O6 commented, "[f]rom the public health perspective, the most important thing is to resolve the problem."

As for the use of isolation, five officials asserted that they preferred to keep trying persuasion and to visit the patient without any further action. ²⁰¹ Two officials stated that mandatory isolation measures would be pursued if patients were deemed uncooperative and all persuasion, threats, or warning letters tactics had failed. 202 The unwillingness of officials to impose mandatory isolation against uncooperative patients is due to their concerns about possible future legal disputes that may jeopardize the relationship with patients. 203 For example, one official said, "I don't want to use the mandatory isolation measure. I have many other matters that need to be dealt with; if I issue the order, it would be endless. You could not possibly endure arguing with or having a quarrel with the patient." On the other hand, two other officials were concerned that isolation would ruin the cooperative relationship with patients during the months-long treatment. They noted that if patients are angry at public health workers, it would be difficult to locate patients for the follow up visits, and to ask them to behave compliantly or cooperatively. 205

Other than previously mentioned concerns, one official questioned the necessity of isolation due to the public health risks posed by these patients.²⁰⁶ In his opinion, "for many," the risks may not be enough to confine them, particularly when they were elderly people whose activity

¹⁹⁹ Interview with O12, *supra* note 111.

²⁰⁰ Interview with O6, *supra* note 111.

²⁰¹ Interview with O5, *supra* note 111; Interview with O1, *supra* note 111; Interview with O12, *supra* note 111; Interview with O10, *supra* note 111; Interview with O15, *supra* note 111.

²⁰² Interview with O13, *supra* note 111; Interview with O6, *supra* note 111.

 $^{^{203}}$ Interview with O12, *supra* note 111; Interview with O10, *supra* note 111; Interview with O15, *supra* note 111.

²⁰⁴ Interview with O10, *supra* note 111.

²⁰⁵ Interview with O12, *supra* note 111; Interview with O15, *supra* note 111.

²⁰⁶ Interview with O7, *supra* note 111.

areas were limited.²⁰⁷ In contrast, respondent O9 believed that patient non-compliance or uncooperativeness must be related to a "social factor."²⁰⁸ Trying to resolve patient difficulties is preferable to compulsory measures to enhance a patient's willingness to take his or her medication properly.²⁰⁹

Reluctance by officials to impose isolation prompted the question: Which patients were actually isolated? Informants who have experience with initiating or approving the isolation process revealed a tacit definition of non-compliance or uncooperativeness. They disclosed that these socalled "uncooperative cases" were sent for isolation in order to take advantage of the free treatment provided by the isolation program.²¹⁰ Respondent O9 disclosed that she had initiated the isolation process herself several times because she had no choice. She revealed that those patients were not actually uncooperative; they did not purposely refuse treatment, their uncooperative behaviors were due to "complicated problems."211 Most of them are socially marginalized people who lack family support, are homeless, unemployed, or suffer from mental illness or alcohol abuse. 212 For example, she told a story about a jobless patient who was a domestic violence offender and had been prohibited from contacting his family. The patient later could not be relocated for follow up after being reported by a hospital. At last, the workers at the township health center found the patient living in an abandoned building. After persuasion and negotiation, "the patient agreed to submit himself to a designated hospital for mandatory isolation" so that "he could have a shelter and stop suffering from starving."²¹³ She further elaborated that in her two decades of experience with TB patients, costs and fees are the first things that patients are concerned with when they are faced with the decision to receive treatment or take medication. These indigent patients did not really refuse treatment, but were just too poor to go to the clinics because they could not even afford even the *guahaofei* (挂号费, check-in fee).²¹⁴ The check-in fee is usually 100 NT dollars (approximately 3 USD) in most clinics and 200 NT dollars (approximately 6 USD) for hospital outpatient service, and these fees are not covered by the NHI.²¹⁵ Sometimes, these

²⁰⁷ *Id*.

²⁰⁸ Interview with O9, *supra* note 111.

 $^{^{209}}$ Id.

²¹⁰ Interview with O12, *supra* note 111; Interview with O9, *supra* note 111.

²¹¹ Interview with O9, *supra* note 111.

²¹² *Id*.

 $^{^{213}}$ *Id*.

²¹⁴ *Id*.

²¹⁵ *Id*.

patients did not even have NHI cards. She stated that she "ha[d] little choice but issue notices to resolve their economic difficulties. If they are deemed uncooperative cases and admitted under an isolation order, they do not need to pay a single dime."²¹⁶

Two other comments by officials also revealed the financial factor in labeling a patient as uncooperative. One official stated that in his opinion, TB patients do not need to be isolated for care, except for those who are not obedient in taking their medication. However, if patients had economic difficulties, the official would approve orders even though these patients did not actually refuse to cooperate.²¹⁷ He thought that what he did was helpful for these patients. ²¹⁸ The other official expressed similar considerations. He insisted that isolation notices should be issued only when patients had been uncooperative. That is why he refused to approve physician referrals blindly. Meanwhile, he admitted that he would take the economic status of patients into consideration when initiating the isolation process.²¹⁹ If the patient could not afford related fees for treatment, he would speak with the treating physician and then issue an order to the patient. ²²⁰ For example, he once initiated an isolation process against a patient who had just been released from prison. The parolee had no money, housing, or medication. In order to keep the patient under supervision while he was still infectious as well as to provide him a place to stay, he initiated the isolation process in order to keep the patient in a designated hospital's isolation room for a month.²²¹

Other than economic difficulties, the same official recognized that patients with alcohol abuse problems are the most difficult cases. He said that these patients could only be persuaded to take medication when they were awake, but "once they are on the drink, they do not know anything." Therefore, admitting patients with alcohol abuse problems limits their access to alcohol, and allows hospital workers to monitor their medication compliance. ²²³

Two TB case managers shared their experience in taking care of "uncooperative" patients. Their answers echoed those of the other respondents that officials used isolation as a method to resolve practical problems in some cases. Respondent M6 observed that among these so-

 $^{^{216}}$ Id.

²¹⁷ Interview with O8, *supra* note 111.

²¹⁸ *Id*.

²¹⁹ Interview with O12, *supra* note 111.

²²⁰ Id.

²²¹ *Id*.

²²² *Id*.

²²³ Id.

called "uncooperative cases" sent to isolation, the majority are either homeless or from a low-income family. They were issued isolation orders so that they could take advantage of the free treatment. 224 Respondent M1 indicated that patients who were sent to the designated hospital as "uncooperative cases" were mostly suffering from poverty. 225 "We knew in our minds that these patients were unable-to-be-cooperative," she said. 226 She explained that if patients were deemed uncooperative cases, the CDC would cover all the costs for treatment, for the use of the negative-pressure isolation room, and meal fees. Moreover, they could decide to stay even if their test results became negative. 227 "For some patients, they had nothing," but during the isolation period, they were provided with food and a place to stay. ²²⁸ She told me that once there was an indigenous patient sent to the hospital for isolation because of an "unable-to-be-cooperative" condition. The family had nothing; the baby did not even have a diaper to wear. One parent was issued the notice, but the whole family ended up staying in the isolation room for weeks.²²⁹

Procedure for Notice Issuance

As to "uncooperative" patients, the admission procedure described by respondents revealed that patients were usually persuaded with gentle warnings or threatened with threats to call the police, and escorted by public health nurses to the designated hospitals. Only in very few cases were patients sent to designated hospitals with police assistance. After admission, any referral signed by the chief of the township health center would be faxed to the local health administration for approval. The notice would then be either faxed or mailed to the hospital and served to patient by nurses or TB case managers. Uniquely, respondent O5 said she asked hospitals to fax the notice with the patient's signature to the local health administration, and after approval the notice would be faxed back to

²²⁴ Interview with M6, *supra* note 144.

²²⁵ Interview with M1, *supra* note 141.

²²⁶ *Id*.

²²⁷ Id.

²²⁸ Id.

²²⁹ Id.

²³⁰ Interview with O5, *supra* note 111; Interview with O1, *supra* note 111; Interview with O9, *supra* note 111; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111.

²³¹ Interview with O5, *supra* note 111; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111.

²³² Interview with O1, *supra* note 111; Interview with O9, *supra* note 111; Interview with O13, *supra* note 111.

the hospital.²³³ On the other hand, respondent O12 had asked physicians to send referrals for approval, and notices were then issued to patients.²³⁴ Respondent O15 said that her office had issued only a total of three notices in the absence of physician referrals.²³⁵ In all three cases, patients were sent for isolation by the CDC; issuance of the notices was made at CDC request.²³⁶

When police assistance was needed to enforce isolation the responsible official would contact the local policemen, and they would be assigned to locate and bring in the patient to the responsible public health nurse. After admission, the notice would be faxed or mailed to the hospital, and nurses or TB case managers were asked to get the patient's signature. The notice would then be faxed back to the official's office.²³⁷

Health care workers interviewed shared similar comments about the practice. Most "uncooperative" patients were escorted by public health nurses to designated hospitals for isolation and were likely to receive isolation notices after admission. However, they expressed concerns about a patient's right to know of the isolation process. One nurse mentioned that

[e]very time public health nurses send patients in for isolation, our nurses are asked to explain what isolation means to patients. The notice only shows the governing law without explaining the contents of the law and the following rules that patients should obey. As a result, many patients are not aware of that their rights have been restricted. Patients would angrily argue with us and ask for discharge. Sometimes, I have to ask patients to write down the rules that they should follow. ²⁴⁰

²³³ Interview with O5, *supra* note 111.

²³⁴ Interview with O12, *supra* note 111.

²³⁵ Interview with O15, supra note 111.

²³⁶ *Id*.

²³⁷ Interview with O13, *supra* note 111. Among all counties interviewed, respondent O13's county had the highest percentage of isolation cases initiated by public health workers among ten counties/cities covered in this study. In 2008, thirteen out of the eighteen notices issued in the county/municipal were initiated by public health workers; three out of those thirteen notices were enforced with assistance from the police.

 $^{^{238}}$ Interview with N1, *supra* note 141; Interview with N2, Nurse, in TAIWAN (Jul. 13, 2009).

²³⁹ Interview with N1, *supra* note 141; Interview with N2, *supra* note 238.

²⁴⁰ Interview with N1, *supra* note 141.

Nurse N2 expressed similar complaints by saying that "to say it in a bad way, some patients were deceived into coming for admission."²⁴¹ She revealed that while patients were mostly persuaded by public health workers before going to the hospital for isolation without any physical enforcement by the police, some patients had complained that they did not know they were being admitted under isolation orders and that this prohibited them from leaving at will.²⁴² Often public health workers tended to use vague words—"if the patients know about the situation, then, they would not have come to the hospital."²⁴³ In her opinion, "there should be someone from the local health administration who is responsible for informing patients that they are being admitted under mandatory isolation orders, similar to the informed consent processes."²⁴⁴ Otherwise, "patients do not know under what conditions they can be discharged which may result with an argument."245 Respondent P6 conveyed the same concerns regarding the procedure for notice issuance by saying that "many public health workers deceive patients in order to take them in; they didn't tell patients that they could not leave For them, once they send patients in, the burden from their responsibility is dramatically reduced."²⁴⁶

Grounds for Discharge

For "uncooperative" patients, the CDC requires completion of treatment before the discharge.²⁴⁷ However, interview results suggested that even though this discharge standard was recognized by a majority of, or five out of seven, officials, in practice only a few so-called uncooperative patients actually stayed in the hospital until the completion of treatment.²⁴⁸ For example, one official revealed that of thirteen isolation cases based on referrals sent by the chief of township health centers in 2008, only one was discharged after completion of treatment.²⁴⁹

Officials explained that the failure to retain "uncooperative" patients was mainly due to practical difficulties in managing different

²⁴³ Id.

²⁴¹ Interview with N2, *supra* note 238.

²⁴² *Id*.

²⁴⁴ Id.

²⁴⁵ *Id*.

²⁴⁶ Interview with P6, *supra* note 135.

²⁴⁷ Ctrs. for Disease Control, Notice No. 0950006402, Apr. 18, 2006, *supra* note 91.

²⁴⁸ Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O1, *supra* note 111; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111.

²⁴⁹ Interview with O13, *supra* note 111.

patient's different problems and characteristics. ²⁵⁰ TB case managers would complain to officials about how patient behaviors lead to management problems. ²⁵¹ For example, patients would leave the isolation ward at will, go out to drink, lock themselves inside their rooms, or sexually harass the nurses in the isolation ward. Under these circumstances, if a patient's sputum smear turned negative and he or she has shown some cooperation, such as taking medication as prescribed, the physician and the official would agree to discharge them and rescind the order. ²⁵² As one TB case manager put it: "We hope that patients who cause disturbances do not stay."

Respondent O9 also revealed the difficulties in ensuring treatment to completion. She reported that usually, if the patient had been compliant during isolation and had a regular place to live, the order could be rescinded. But for patients who are homeless, who have financial difficulties or who are hard to locate due to the lack of a fixed residence, she would negotiate and make a deal with them.²⁵⁴ Although patients promised to stay until completion of treatment, quite often they would leave the hospital before their discharge. "They simply go in and out of the hospital. But based on my experience, once they can't survive on their own, they will show up in front of us again," she said.²⁵⁵ Moreover, in some cases if the patient is too aggressive in asking for discharge, such as causing damage to the hospital's facilities, the hospital would just let the patient go.²⁵⁶

Interviews with health care workers echoed the officials' descriptions about discharge decisions for "uncooperative" cases, which were likely to be made on a case-by-case basis and depended exclusively on physician discretion. Two physicians, both of whom worked at public hospitals, indicated that patient willingness to stay was an important factor in physician practice. For example, when the author asked under what conditions "uncooperative" patients could be discharged, respondent P2 frankly said that "[i]t depends on my discretion." She mentioned that if the sputum smear test result turned negative, if the patient is willing to join

²⁵⁰ Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O13, *supra* note 111.

^{251 1.1}

²⁵² Interview with O6, *supra* note 111; Interview with O13, *supra* note 111.

²⁵³ Interview with M5, Case Manager, in TAIWAN (June 22, 2009).

²⁵⁴ Interview with O9, *supra* note 111.

²⁵⁵ *Id*.

 $^{^{256}}$ Id

²⁵⁷ Interview with P2, *supra* note 132; Interview with P6, *supra* note 135.

²⁵⁸ Interview with P2, *supra* note 132.

DOTS, and if family support is available for the patient, then she would discharge the patient. However, if the patient insisted on leaving, she told the author that "I do not like to force my patients. If you force them to stay, the relationship would be ruined, thus they will not listen to your advice They just won't die and won't get well."²⁵⁹ The other physician, in reporting how to make discharge decisions, expressed that "we can only decide whether the patient is infectious or not. We do not know whether the patient's promise is trustworthy or not. We can't tell whether the patient can comply with the treatment or whether the local health administration can handle it."²⁶⁰ Therefore, "it really depends on whether the patient wanted to stay or not."²⁶¹

In addition, one nurse working at the isolation wards revealed a number of management problems in discharging patients. She stated that "generally if [a] patient's sputum smear results turn negative, after that, [he or she] can go home, usually in a month. Those who are homeless need to stay until completion of treatment, usually at least 180 days." But not everyone would comply with this requirement. For some patients, the isolation rooms have everything they need, such as air-conditioning, cable TV, personal bathrooms, and food. But some people still cannot stand the isolation. They may continuously ask to be discharged. She further expressed that "usually if the weather is cold, they [will] stay because being outside [is not] better than being here." However, "for those who . . . ever r[a]n away from the hospital and got caught, we would impose access control in order to force them to stay until completion of treatment." ²⁶⁶

Local Health Official Views on Using Isolation

The isolation regulatory scheme drew both praise and criticism from officials when they were asked their opinions about the isolation program. Three officials expressed admiration for the physician role in initiating the isolation process. They commented that the system was good because hospitals would be willing to admit infectious TB patients, which would help to eliminate spread of the infection in the community. ²⁶⁷ As

²⁵⁹ *Id*.

²⁶⁰ Interview with P6, *supra* note 135.

²⁶¹ Id

²⁶² Interview with N1, *supra* note 141.

²⁶³ *Id*.

 $^{^{264}}$ *Id*.

²⁶⁵ *Id*.

²⁶⁶ *Id*.

²⁶⁷ Interview with O6, *supra* note 111; Interview with O10, *supra* note 111;

respondent O6 stated that "[w]e think it is good; it is easier for us to manage." ²⁶⁸

However, four officials criticized the way in which referrals were used. One respondent said,

[i]n the past, the procedure of imposing compulsory hospitalization measures was very strict You had to first give the patients an official governmental document to warn them and then you could consider whether to impose compulsory hospitalization measures. After 2006, the use of compulsory hospitalization measures became abusive . . . The CDC was giving out money to the medical care system If this is the way CDC preferred, we would have to play with it. 269

Another official stated that hospitals used the referral system incorrectly. As long as a patient had a sputum smear-positive test result, hospitals sent a referral in order to apply for reimbursement. Local health administrations did not care much about these cases since it was the central government's money. Two other respondents questioned the adequacy of granting physicians the ability to instigate the isolation process. Respondent O7 said, "[t]he procedure is odd" and questioned why physicians should be granted the power to submit referrals for approval. Respondent O8 doubted the legitimacy of granting physicians the authority because only those who cannot adhere to the treatment regimen need to be hospitalized for monitoring. Respondent O8 stated that "[w]hether to isolate a TB patient should belong to the decision of the public health case manager, and not doctors."

As to isolation pursued by public health workers, some interviewees provided their thoughts and concerns. Respondent O7 said that public health workers "are more suitable to do the work of visiting, persuading and convincing the patient; locking a person up is a serious thing . . . We, who are responsible for enforcing it, need a better mechanism." This official continued that "CDC asked us [the officials] to forcibly put the patient into isolation as long as the patient is a confirmed TB case and not cooperative with treatment, but being

Interview with O15, supra note 111.

²⁶⁸ Interview with O6, *supra* note 111.

²⁶⁹ Interview with O9, *supra* note 111.

²⁷⁰ Interview with O12, *supra* note 111.

²⁷¹ Interview with O7. *supra* note 111.

²⁷² Interview with O8, *supra* note 111.

²⁷³ Interview with O7, *supra* note 111.

uncooperative is hard to define. We local officials think something is missing here."274 In his opinion, if the isolation could be decided by an impartial third party and enforced by the police, there will be fewer issues. He stated that "[i]t is just odd to ask a public health nurse to detain patients." 275 Respondent O10 echoed the concerns appropriateness of the local officials' role in making and enforcing isolation measures, their ability to comply with all procedural requirements, and possible legal disputes with patients. She reported that in order not to give patients any excuses not to comply, local officials have to follow all procedural requirements when imposing an isolation measure.²⁷⁶ She further elaborated that she did not have legal counsel to ask for an opinion although there was a legal affairs office in the local health administration. "The staff of that office are very busy because they have to take care of all divisions of administration," she said. 277 Other than procedural concerns, respondent O9 was critical of mandatory measures as being possibly effective and quick, but too arbitrary. ²⁷⁸ She expressed that "[c]ompulsory hospitalization is a violation of human rights; [and] is the worst measure."279 "The CDC asked the public to accept patients with TB, but ironically, its policy reflects the opposite," she said. 280 The plural view by officials on the isolation regulatory scheme reflects on substantial and procedural elements of the power to isolate, including the roles of physicians and local health officials in the isolation process as well as the legitimacy of exercising the isolation power against non-compliant patients.

C. Discussion of Results

The actual use of isolation on TB patients described *infra* raises legal and ethical issues. Due to the physicians also being key players in the regulatory scheme in terms of their relationship with patients and the government, this section will first examine and elaborate on the implications of the treating physicians' practice initiating the isolation process. This section will also assess the extent to which public health worker practices in using isolation measures to control TB were warranted.

²⁷⁴ *Id*.

²⁷⁵ *Id*.

²⁷⁶ Interview with O10, *supra* note 111.

²⁷⁷ Id.

²⁷⁸ Interview with O9, *supra* note 111.

²⁷⁹ *Id*.

²⁸⁰ Id.

1. Physician Practices in Initiating Isolation

Granting physicians the ability to initiate the process of isolation for TB patients, while well-intended, has a tendency to be misused. Research on physician practice in Ireland in initiating detention powers has shown that physicians used the threat of detention as a strategy to obtain TB patient compliance. A majority of responding physicians indicated that they had threatened the patient with seeking formal detention to achieve the patient "consent" for hospital admission, and this strategy was deemed successful in achieving compliance in most cases. However, this approach may expose physicians to liability for false imprisonment because the validity of a patient's consent to admission may be in doubt.

In Taiwan, interview results tell a different story. Under its isolation regulatory scheme, treating physicians can send a referral to local health administrations to propose an isolation order. This regulatory design relies on the rationale that physicians have the knowledge and ability to determine whether the patient has active and infectious TB. As one physician mentioned, physicians are able to diagnose whether the patient is infectious, they are not in the position to judge whether the patient is reliable and will comply with the treatment regimen.²⁸⁴ It seems that the purpose of physician referrals is to work as a reminder or warning of the risk the patient poses to public health and prompt local health authorities to evaluate the necessity of imposing isolation. ²⁸⁵ For example, physicians may find that their patients are not adhering to their treatment regimen or failing to take infection control measures. If the local health administration decides to impose isolation, a notice would be issued to the patient requiring submission to isolation. However, interview data suggests that the referrals are probably not being used as intended. While physician referrals indicated evidence of patient infectiousness, physician decisions to send referrals might not be based solely on their judgment of the risk the patient posed. Rather, they were likely to be used as a means for receiving reimbursement from the CDC. ²⁸⁶ Although physicians do

²⁸¹ See S.T. Duffy, The Power of Detention in the Management of Non-compliance with Tuberculosis Treatment: A Survey of Irish practitioners and Analysis of Potential Legal Liability, 123 (1) PUBLIC HEALTH 81, 81-85 (2009).

²⁸² *Id.* at 84.

²⁸³ *Id*.

²⁸⁴ Interview with P6, *supra* note 135.

²⁸⁵ TUBERCULOSIS CONTROL MANUAL 2002, *supra* note 80, at 166.

²⁸⁶ Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O2, *supra* note 112; Interview with O1, *supra* note 111; Interview with O10, *supra* note 111; Interview with O12, *supra* note 111.

not directly benefit from the CDC's reimbursements, their employers—the hospitals—do. ²⁸⁷

The customary practice by physicians of sending referrals has several implications. From the patient perspective, if physicians advised inpatient care for patients in order to qualify for the guaranteed 100 percent reimbursement rather than out of the belief that they needed to be admitted, physicians probably failed to act in the best interest of their patients. This could potentially constitute a breach of fiduciary duty to their patients. 288 Within the patient-physician relationship, physicians, as fiduciaries, are obligated to protect the interests of, and do what is best for, patients who seek their assistance.²⁸⁹ In cases of TB treatment, physicians interviewed generally agree that the standard of care in clinical settings is to prescribe appropriate medications and send patients home.²⁹⁰ Reasons included: (1) the infectiousness of TB patients can be greatly reduced once they start to take their medications;²⁹¹ (2) if the patient wears a face mask or stays separated from others, the risk of transmission can be minimized;²⁹² and (3) inpatient care for infectious TB patients increases the risk of hospital-acquired infection for health care workers and other patients. 293

If patients should have been treated as outpatients but were instead advised by physicians to be admitted to hospitals in order to receive reimbursement for the benefit of a hospital's revenue, physicians failed to give medical advice based on the profession's standard of care and the patient's best interests. On the other hand, if physicians thought that their patients needed to be admitted, due to concerns about medication side-effects or preexisting conditions, but the referrals were filled out as routine paperwork for the purpose of receiving full reimbursement from the government, physicians would likely have not disclosed their attempts to patients.²⁹⁴ Patients are likely not fully aware of the meaning of signing the notice. In these circumstances, physicians may have also breached

²⁸⁷ Interview with O9, *supra* note 111. In O9's opinion, using physician referrals for reimbursement purposes was likely required by hospital managers since it might be financially beneficial to hospitals' revenue. *Id.*

 $^{^{288}}$ Barry R. Furrow et al., Health Law: Cases, Materials and Problems 268 (6th ed. 2008).

²⁸⁹ Id. at 199-200.

²⁹⁰ Interview with P4, *supra* note 124; Interview with P5, *supra* note 139 (June 18, 2009); Interview with P6, *supra* note 135.

²⁹¹ Interview with P4, *supra* note 124.

²⁹² Interview with P5, *supra* note 139.

²⁹³ Interview with P4. *supra* note 124.

 $^{^{294}}$ This is a summary of the information that the author learned while doing the interviews.

their fiduciary duty to patients through concealment of important information regarding their patients' interests.

From the third-party payer's point of view, physicians sending referrals to local health administrations out of a desire to be qualified for the guaranteed reimbursement may be committing civil and criminal fraud against the state. Interview data suggests that physician referrals might nominate patients who had already consented to be admitted, rendering isolation orders unnecessary. Physicians and hospitals may have billed the government with the knowledge that their claims were not qualified for reimbursements.²⁹⁵ Despite the procedural hurdles of proving the elements of fraud, physicians should be wary of this practice. If proven, it may warrant their criminal prosecution.

2. Local Health Official Practices in Reviewing Physician Referrals

To evaluate whether a public health regulation that intrudes upon individual rights is acceptable, Professor Gostin, a well-known public health law expert and professor from the Center for Law & the Public's Health at Johns Hopkins and Georgetown Universities, proposes a five-criteria framework: significant risk, effectiveness, reasonable cost, the least restrictive alternative, and fairness (Table 1). ²⁹⁶ These criteria represent important elements of a justifiable public health intervention measure. To systematically evaluate and analyze the problems in the use of isolation in Taiwan, the following discussion will be structured around these criteria.

Table 1. Gostin's Framework for Evaluating Public Health Regulation

- 1. Is the risk significant?
- 2. Is the regulation effective?
- 3. Is the regulation cost-effective?
- 4. Is the regulation the least restrictive alternative?
- 5. Is the regulation fair?

When applying the above-mentioned five elements in analyzing the use of isolation by physician referral, local health official practice of approving physician referrals produces doubt about the justification of isolation. First of all, despite the evidence of possible infectiousness, (e.g., a positive sputum smear test result) patients subject to isolation orders did not necessarily pose significant risks to others. If patients could take proper infection control measures, separate themselves from others, and take medication as prescribed, they pose limited risks to public health.²⁹⁷

²⁹⁵ Interview with P6, *supra* note 135.

²⁹⁶ GOSTIN 2nd ed., *supra* note 28, at 53-70.

²⁹⁷ TUBERCULOSIS CONTROL MANUAL 2002, *supra* note 80, at 165.

However, officials seemed to treat physician referrals deferentially and issued orders without actually identifying the risks that warrant intervention. They thus failed to exercise their legal power to the full extent to which they were allowed under article 44 of the Act.

Second, with some exceptions, patients were generally isolated until their sputum smear result turned negative. As a result, the isolation measure was presumed to be effective at preventing transmission. This may be the case, but isolation measures entail costs, including those to the government, to individuals affected, and in opportunities to intervene with a different method. The government needs to justify the use of isolation by demonstrating the effectiveness of reducing the risk at a reasonable cost relative to benefits. The expenditure of isolation was probably excessive because less-costly measures, such as wearing masks and staying home from work or school, might also be effective in preventing transmission. Moreover, the tax money spent on isolating patients seems to be unnecessary. As noted earlier, referrals and notices were treated as routine in order to meet the document criteria for reimbursement from the CDC. Patients nominated by physicians for isolation might have consented to being admitted, rendering isolation orders needless. In these cases, since patients were willing to be admitted, there was no necessity to issue notices and force patients into isolation. Therefore, the costs of treating these patients should have been borne by the NHI rather than by tax money from the CDC.

Other than the possible waste of public money, Taiwanese society also lost the opportunity to address a more significant factor contributing to the risk of transmission. As one physician emphasized in the interview, patients with active TB in Taiwan were infectious long before they were diagnosed and prescribed the anti-TB drugs. ²⁹⁸ An epidemiological research study based on national data found that patients in Taiwan with active TB remained untreated for fifty-three days on average. ²⁹⁹

²⁹⁸ Interview with P4. *supra* note 124.

Ziliao Jinxing Renkou Jichu de Fenxi (台灣結核病診斷與治療延遲的流行病學研究: 以健保申報資料進行人口基礎的分析) [Epidemiological Study of Diagnostic and Treatment Delay Among Tuberculosis Patients in Taiwan: a Population-Based Study using National Health Insurance Claims Data], 20 (2007) (unpublished graduate thesis, Graduate Institute of Public Health, National Cheng Kung University) (on file with the author). The research for this thesis is based on patient data from 2005 from the National TB Notification Registry and National Health Insurance program's claims data. This research found that the median healthcare system delay is fifty-three days. (Inter-quartile range, 12-147) Id. (healthcare system delay is defined as the interval between the first date of a patient's visit with a respiratory-related diagnosis and the date on which the anti-TB medication is prescribed). Id. at 13. It also found that the median physician delay is forty-three days (Inter-quartile range, 7-138) Id. (physician delay is defined as the interval between the first date of patients' visit with respiratory-related diagnosis and the date of the sputum smear test order). Id. at 13.

Comparing the fifty-three days of delay with the fourteen-to-twenty-one days of isolation upon diagnosis, the former is undeniably a more critical factor in preventing transmission. If isolation was not beneficial, and tax payers funded the isolation of patients, taxpayers lost the chance to spend money on adopting different, potentially more beneficial strategies to prevent transmission. With public money being spent on isolation, Taiwanese society forwent opportunities to address delays in diagnosing infectious patients. Sources devoted to covering the cost of isolation should have been used to improve prompt testing, diagnosis, and treatment.

Furthermore, officials seemed neither to ground their decision-making on individualized risk assessments nor explore less restrictive measures to avert the threat patients posed to others in the review process. In terms of fairness, the lack of data makes it unknown whether certain groups of patients were disproportionately nominated by physicians. But interview results suggest that the burden of isolation was placed on those who consented hospitalization, resulting in distributing burdens to those who presented less risk to others.

Furthermore, the patient's right to be informed, which is a basic check on abuse of power, is also in jeopardy. In the notification process, hospital nurses or TB case managers, rather than public health officials, served isolation orders to patients. As routine, patients were asked to sign. Served if patients did ask what the notice was for, they would be told that the notice guaranteed their free meal and hospitalization. The practice suggests that patients might not be fully informed about the purpose of isolation, the duration of isolation, or grounds for release. The altered and simplified procedure might endanger the important procedural safeguard intended to protect the right of the patient to be notified of his or her isolation order.

Another study on healthcare system delay using a patient interview method in southern Taiwan found that median healthcare system delay was twenty-three days. See C.T. Chang, et al., Patient and Health System Delays in the Diagnosis and Treatment of Tuberculosis in Southern Taiwan, 9 (9) INT'L J. OF TUBERCULOSIS & LUNG DISEASE 1006 (2005).

³⁰⁰ In reviewing physician referrals, four respondents simply said that they respect and trust physician opinions. Interview with O7, *supra* note 111; Interview with O3, *supra* note 112; Interview with O10, *supra* note 111; Interview with O15, *supra* note 111. Respondent O6 said that they in principle approved all the referrals. Interview with O6, *supra* note 111. Four other interviewees mentioned test results, but treated the review process as routine. Interview with O1, supra note 111; Interview with O9, *supra* note 111; Interview with O13, *supra* note 111. Officials did not mention the evaluating criteria listed in the CDC's guidelines.

³⁰¹ Interview with N1, *supra* note 141.

 $^{^{302}}$ *Id*.

3. Public Health Worker Practice in Initiating Isolation

In scenarios where isolation processes were initiated by public health workers in the absence of physician referrals, interview results also suggest unwarranted implementation of the regulatory scheme in view of the five Gostin criteria. Although health officials commonly claimed that "non-compliant" or "uncooperative" patients were the main targets for isolation and described several behaviors that could be deemed uncooperative, labeling patients "uncooperative" was probably discretionary. Absent a working definition of "uncooperativeness," a requirement to undergo a risk assessment process, and documentation of the possibility and severity of risk, the isolation decisions were not fully supported by evidence.

Assuming patients with these identified behaviors presented dangers to others, the actual application of isolation did not always effectively reduce the risk of transmission and development of MDR-TB. Interviewed local health officials reported that in managing compliance issues, they tended to be unenthusiastic about using punitive measures, such as fines and isolation. They worried about backlash from isolation, which might discourage patient compliance and cause legal disputes. Therefore, patients who consistently refused treatment or failed to comply with it were in practice not actively pursued for isolation. Despite uncertainty about the size of this group, these patients may continue to pose health risks to others either because of their infectiousness or the possibility of them developing MDR-TB and subsequently transmitting it to others.

However, on the other hand, interview results revealed that uncooperative patients who were issued notices for isolation initiated by public health workers were not always cured. These patients could be persuaded, threatened, or induced by the benefits they could receive to go

³⁰³ Interview with O5, *supra* note 111; Interview with O1, *supra* note 111; Interview with O6, *supra* note 111; Interview with O8, *supra* note 111; Interview with O9, *supra* note 111; Interview with O10, *supra* note 111; Interview with O13, *supra* note 111; Interview with O15, *supra* note 111.

³⁰⁴ Interview with O5, *supra* note 111; Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O1, *supra* note 111; Interview with O12, *supra* note 111; Interview with O13, *supra* note 111; Interview with O15, *supra* note 111.

³⁰⁵ Interview with O12, *supra* note 111; Interview with O10, *supra* note 111; Interview with O15, *supra* note 111.

³⁰⁶ Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O13, *supra* note 111. Respondent O13 reported that only one out of thirteen uncooperative isolation cases in 2008 was discharged after completion of treatment. Interview with O13, *supra* note 111; Respondents O9 and O6 explained that there was management problem to keep patients remaining in isolation. Interview with O9, *supra* note 111; Interview with O6, *supra* note 111.

to the hospital for isolation, but only a small number of them stayed for the entire period of treatment.³⁰⁷ Despite efforts to convince them to stay, patients often left the hospital prematurely, and would not return until they did not feel well again or until they needed a shelter on hot summer or cold winter days. ³⁰⁸ The reasons for their noncompliance were not addressed, so these patients might continue to fail to be compliant with their course of treatment upon discharge. As a result, they will probably become infectious again and possibly develop MDR-TB.³⁰⁹

Even though confinement of uncooperative patients until they completed their treatment is theoretically an effective method to prevent transmission and development of MDR-TB, the government needs to justify the intervention by proving the reasonable cost of the intervention. As noted earlier, because of practical difficulties in managing patients with different problems and characteristics, few so-called uncooperative patients completed their treatment after isolation. The public money spent on isolating these patients did not yield the benefits originally expected. Moreover, interview results reveal that these isolated "uncooperative" patients were more correctly "unable" to be compliant because they were haunted by various social and economic problems.³¹⁰ That is why officials tended to take advantage of the financial benefits built into the isolation program that covered not only treatment but also room and board to help these patients.³¹¹ The practice suggests that to reduce the risks these patients pose to public health, public money could have been spent on providing essential social services and wide-range medical care to remove barriers that prevent patients from adhering to therapy. To the government, it may be arguable that such a system is equally costly. But to these susceptible patients, it is surely less costly than months of isolation.

Moreover, if patient non-compliance or uncooperativeness stemmed from their economic or health problems, the use of isolation may be unacceptable since less restrictive measures were not first attempted. Interview results show that in managing uncooperative patients, public health workers might have made stronger attempts to adopt less-restrictive measures, such as home visits and providing DOTS.³¹² But in confronting

³⁰⁷ Interview with O9, *supra* note 111.

³⁰⁸ *Id*.

³⁰⁹ *Id.* More than sixty percent of MDR-TB patients in Taiwan have histories of default, treatment failure or relapse. *See* Shu-Hua Huang et al., *An Introduction to Taiwan's MDR-TB Medical Care System*, 25 (2) TAIWAN EPIDEMIOLOGY BULLETIN 86, 91 (2009).

³¹⁰ Interview with O9, *supra* note 111; Interview with M1, *supra* note 143.

³¹¹ Interview with O8, *supra* note 111; Interview with O9, *supra* note 111; Interview with O12, *supra* note 111.

³¹² Interview with O5, *supra* note 111; Interview with O1, *supra* note 111; Interview with O6, *supra* note 111; Interview with O13, *supra* note 111.

patients who were unable to be compliant due to numerous problems, public health workers seemed to opt for isolation measures. This practice does not stem from ignorance of the highly restrictive, last-resort nature of isolation, as claimed in the CDC's Manual, but rather from a lack of practical and less-restrictive alternatives. Without a system to provide access to psychiatrists, social workers, alcohol abuse treatment services, or other support services public health workers have opted to use isolation as a stopgap solution to temporarily alleviate patient problems. These practices suggest that if the DOTS program were accompanied by a social welfare system providing necessary services and support, such as housing or funding, the extreme measure of depriving liberty through isolation could be unnecessary.

Furthermore, isolation initiated by public health workers seemed to be disproportionately used for socially marginalized people,³¹⁴ probably because this vulnerable group was easily persuaded to be hospitalized. However, patients who consistently refused treatment, despite being smaller in number, were not adequately convinced to receive treatment.³¹⁵ This reveals failures in targeting real hazards to public health and providing assistance to people in need, instead placing the burdens of liberty restriction on disadvantaged persons.

IV. IMPLICATIONS FOR TUBERCULOSIS PUBLIC HEALTH LAW AND POLICYMAKING

The picture that emerges from the interview results is that the regulatory scheme is not being implemented as designed. There is a significant mismatch between government confidence in isolating TB patients and the goal of reducing the burdens of the disease. This empirical study of the implementation of the TB isolation regulatory scheme highlights several lessons for TB control public health law and policymaking. The goal of the isolation regulation is to maximize public health benefits without sacrificing individual liberty. To this end, it is important to ensure that imposing isolation measures on tuberculosis patients is effective, fair, and provided with adequate procedural safeguards.

A. The Necessity of Imposing Restrictive Measures

Public health interventions should be no more restrictive than necessary to achieve their intended purposes. To contain the spread of TB

³¹³ Interview with O9, *supra* note 111; Interview with O12, *supra* note 111.

³¹⁴ Interview with O8, *supra* note 111; Interview with O9, *supra* note 111; Interview with O12, *supra* note 111; Interview with M1, *supra* note 143.

³¹⁵ Interview with O5, supra note 111: Interview with O10, supra note 111.

³¹⁶ See Tuberculosis Control Manual 2002, supra note 80, at 165-66; Tuberculosis Control Manual 2009, supra note 81, at 176-77.

and stem the rising tide of drug-resistant TB, public health authorities should be delegated a variety of powers to reduce public health threats. However, in doing this, they need clear lines of authority when limiting an individual's liberty. To ensure that removal of an individual's liberty is not beholden to mere speculation, health authorities bear a legal duty to prove that the person poses a significant risk to others and to present solid evidence that isolation is effective in reducing the risk. To these ends, legislation should first differentiate between limiting individuals' liberty in an emergency situation and a non-emergency situation. It also needs to specify criteria that must be met when issuing emergency commitment orders, orders for isolation during the period of infectiousness, and orders for detention of noninfectious patients for the purpose of treatment. Health authorities should be required to conduct risk assessment and show a significant risk that necessitates restriction on the individual's liberty.

Accordingly, an emergency isolation order may be issued if officials can provide proof that the person has active TB and is engaging in risky behavior that poses an imminent threat to the health of others. A documented history of failure to adhere to a prescribed course of treatment or the patient's expression of unwillingness to comply with prescribed treatment might justify isolation. Orders for isolating a patient during the period of infectiousness may be justified if the public health authority can demonstrate that the patient has infectious TB, and there is a substantial likelihood of transmission. ³¹⁷ Once the element of infectiousness is removed, continuing limitation of liberty to ensure treatment completion should be permitted only when the public health authority demonstrates that the patient is unlikely to complete treatment as an outpatient based on past behaviors.³¹⁸ The requirement of presenting a record of the patients' past or present behavior will help prevent a quick and easy option for using isolation and detention measures. It will also ensure that patients have been given the opportunity to complete treatment through lessrestrictive alternatives.

B. Non-Discriminatory Practice

Public health measures often target "high risk populations" due to cost-effectiveness concerns.³¹⁹ At a minimum they need to be supported by evidence proving the risks presented by the individuals or groups.

³¹⁷ For example, difficulties in adequately separating the patient from others or the patient's failure to take proper infection-control measures may increase the risk of transmission to a substantial level.

³¹⁸ For instance, public health authorities need to present a documented history of leaving a hospital prior to discharge, refusing or failing to follow a treatment regimen, failing to keep scheduled appointments for treatment, or unsuccessful repeated efforts to have the patient treated through DOTS.

³¹⁹ GOSTIN 1st ed, *supra* note 27, at 100-02, 104-07.

Unfortunately, it is too often that public health intervention measures tend to use social status as evidence of danger to others even though these are unreliable, unreasonable, and illegal bases for restriction. The Taiwan CDC's isolation policy and practice of targeting certain groups of TB patients (e.g., residents of congregate facilities or homeless people) illustrates the danger of insensitivity to social justice and an attitude based on pursuing simple solutions in response to public calls to segregate sick people.

The current Taiwanese and global TB epidemic reflects long-neglected barriers to care by vulnerable groups of people and treatment failures of the system. The rise of drug-resistant TB is not solely the product of the "irresponsible" behaviors of TB patients. It is the state's responsibility to fund cost-effective alternatives, such as improving ventilation controls in congregate settings, and provide effective services to facilitate treatment completion, such as housing. The law should acknowledge patients' rights to essential medical and social services and incorporate a working definition of "significant risk." Furthermore, health authorities should complete more epidemiological studies to provide a more complete understanding of the prevalence of TB infection and the risk of developing or reactivating the disease among different populations. In this way, public health efforts may be undertaken that are more suitable to the needs of the victims of the disease.

C. Procedural Safeguards

Persons subject to isolation should be entitled to procedural protection against illegal or abusive application. To begin with, the regulatory scheme should ensure that the right to be informed is provided to patients. Despite the legal requirement of written notification, interview results suggest that patients were often not fully informed of the purpose of isolation. ³²⁰ If they are not fully aware of the legal order, patients have little chance to defend themselves.

In addition, to ensure that decisions to restrict an individual's movement conform to evidentiary requirements and are not unnecessarily lengthy, the regulatory scheme needs to provide patients with an appropriate review system through which the court may have prompt control over the isolation process. As shown in the interview results, local health administrations retain jurisdiction over the thirty-day interval reexamination procedure. But they are unlikely to actively pay attention to possible errors or inappropriate isolation decisions. Patients subject to isolation or dentition orders need to have timely access to the courts to initiate a review procedure and ask for discharge and/or appeal.

³²⁰ Interview with N1, *supra* note 141; Interview with N2, *supra* note 238.

D. Isolation and Detention Sites

Deprivation of TB patients' liberty is not for punishment; patients are not detained based on the seriousness of their crimes but because of a calculation of risks or harms. It will raise serious ethical and legal concerns if involuntarily committed patients are confined in prisons rather than specialized hospitals dedicated to treating them. Moreover, to legitimize isolation and detention measures, health authorities need to guarantee that isolation and detention may successfully reduce spread of infection and ensure completion of treatment. To ensure the effectiveness of isolation and detention measures, designated institutions need to be able not only to provide adequate care but to also enforce restrictive orders. Unfortunately, Taiwan's hospitals designated for TB isolation fall short of this expectation due to practical difficulties in managing patients with various characteristics.

Under Taiwan's TB regulatory scheme, TB patients should be treated in designated hospitals within the Infectious Disease Control Medical Network³²¹ These hospitals are equipped with isolation rooms with negative pressure facilities built during the SARS epidemic. 322 Despite the capacity to treat patients with communicable diseases, interview results suggest that hospitals in this TB "isolation network" fail to ensure the effectiveness of isolation. 323 Some patients persistently request to go outside for "fresh air" despite the legal requirement of remaining in isolation rooms; patients would also bargain and negotiate with on-duty nurses at the isolation wards, threaten to hurt themselves or hospital employees, break equipment, or even set fire to their rooms.³²⁴ For nurses working in the isolation ward, charged with much of the dayto-day management of patients, enforcing isolation for patients with such problems exceeds their capability and job requirements. 325 It is financially impossible for these hospitals to maintain twenty-four-hour security guards at wards, not to mention that the isolation wards are for patients both voluntarily and compulsorily admitted. More importantly, some patients' length of stay is not days or weeks, but months or years. If they are not infectious, restricting their movement to the isolation rooms without opportunities for outdoor activities or educational rehabilitation programs makes the isolation site prison-like.

³²¹ TUBERCULOSIS CONTROL MANUAL 2009, *supra* note 81, at 177.

³²² CDC ANNUAL REPORT 2005, *supra* note 67.

³²³ Interview with O9, *supra* note 111; Interview with O6, *supra* note 111; Interview with O13, *supra* note 111; Interview with N1, *supra* note 141; Interview with N2, *supra* note 238.

 $^{^{324}}$ Interview with O6, *supra* note 111; Interview with N1, *supra* note 141; Interview with N2, *supra* note 238.

³²⁵ Interview with N1, supra note 141.

To sustain the legitimacy of confining TB patients, regulations need to pay attention to the suitability of isolation sites to ensure effectiveness of restriction measures. For example, when New York City revised regulations for detaining TB patients in the 1990s, it founded specialized hospitals dedicated to treating involuntarily committed patients. Two hospitals with secured wards were used to admit infectious and noninfectious patients avoiding serious ethical problems raised by the prospect of confining patients with TB in jail. Bellevue Hospital, a public city hospital, opened a twenty-one-bed unit with negative pressure facilities for the isolation of infectious patients. Patients involuntarily admitted were confined in a standard isolation room on a guarded ward.³²⁶ A civil detention ward at Goldwater Memorial Hospital was designated for noninfectious patients when all other efforts, including Commissioner's orders for directly observed therapy, were exhausted.³²⁷ Therefore, the most difficult-to-treat patients could still complete a full course of treatment. 328 The hospital provided patients with exercise classes, escorts to off-ward activities on hospital grounds, and programs addressing substance abuse, education and recreational therapy. 329

In light of the New York City approach, health authorities need to provide suitable places for isolating infectious patients during the period of infectiousness, and detaining noninfectious patients during the chronic stage of the disease. In consideration of the number of patients who may need to be isolated during the period of infectiousness, only a few treating facilities should be designated for short-term isolation. For long-term detention, the government should establish one specialized facility to improve care and offer an environment suitable to patients' needs. The mission of the facility would be to promote compliance with medical regimens in an appropriate environment. Patients should have ample

³²⁶ See COKER, supra note 16, at 100; Gasner et al., supra note 9, at 360.

³²⁷ See Gasner et al., supra note 9, at 360.

³²⁸ *Id*.

³²⁹ See Mireya Navapro, Confining Tuberculosis Patients: Weighing Rights vs. Health Risks, N.Y TIMES, Nov. 21, 1993, at A1.

³³⁰ Some hospitals, such as the Chest Hospital at Rende township in Tainan County, have been designated for treating "chronic infectious tuberculosis patients" for a decade. Since April 1995, the Department of Health's Operational Guidelines on the Detention Management of Chronic Infectious Tuberculosis Patients and "Guidelines on Subsidies to Tuberculosis Control of the Department of Health of the Executive Yuan have encouraged patients to be voluntarily hospitalized in designated hospitals by using monetary incentives. Still, in view of their long-period of infectiousness and medical needs, a specialized facility dedicated to these patients rather than a general hospital is a more appropriate venue. *See* Tuberculosis Control Manual 2002, *supra* note 80, at 149-53.

³³¹ In fact, facing hospital complaints about patient management problems, local health officials have sent patients to "preferred hospitals." Four officials this author

opportunities for recreation, exercise, and other activities as well as have access to educational and social programs. For example, alcohol addiction is the most frequently mentioned problem when managing patients under isolation. Without addressing this problem when treating TB patients, it is difficult to cure them.

With post-commitment coercive powers, the patient's rights during isolation and detention, and standards for the operation of isolation facilities should be clarified. The statutes should acknowledge the patient's right to privacy, communication, and having visitors. Medical institutions should not limit these rights without considering the patient's condition or as required for effective treatment. Limitations on the patient's movement or restraints of the body should not exceed the period of time necessary for preventing harm, and patients should be free of the use of restraint instruments or improper forms of physical or movement restrictions. Despite the possibility of indefinite confinement as long as the patient continues to pose a significant risk to the public, the patients subject to isolation should not be physically forced to take medication or receive surgery against their will. In addition, regulations must be made to ensure the safe and therapeutic nature of the facilities.

V. CONCLUSION

The use of coercive measures has been an indispensable strategy to contain communicable disease in human history. As globalization and the emergence of MDR-TB, restricting people's movement is more likely to be an important tool in the future. This article focused on the implementation of TB isolation program in Taiwan to shed light on the proper design of a regulatory scheme. Compared with other developed countries, TB poses a particular public health problem in Taiwan as

interviewed said that patients who had a history of leaving hospitals or were deemed to leave the hospital before discharge would more likely to be sent to designated hospitals in remote areas, such as Fonglin Veterans Hospital at Hualien County, Hsinwu Branch of the Taoyuan General Hospital at Hsinwu township, and the Chest Hospital at Rende township in Tainan County. Because these hospitals are located in relatively remote areas, patients have more difficulties (due to lack of transportation) and fewer incentives (such as going out to buy drinks) to leave the hospital. However, patients are allowed to have outdoor time within hospital walls to reduce the stress of isolation. Interview with O5, *supra* note 111; Interview with O9, *supra* note 111; Interview with O13, *supra* note 111.

³³² Interview with N1, *supra* note 141; Interview with M1, *supra* note 143; Interview with N2, *supra* note 238; Interview with P2, *supra* note 132. One head nurse reported that she discovered that a patient ordered a box of alcoholic drinks to be delivered to an isolation room. Interview with N2, *supra* note 238. Another head nurse said that patients would invite each other to share drinks in their rooms. Interview with N1, *supra* note 141.

evidenced by its relatively high incidence rates.³³³ The government is right to act on the problem. However, isolation measures are probably not an important factor that contributed to the decline of TB cases.³³⁴ Learning from centuries-long efforts to reduce the burden of TB, the achievement of valid health goals requires society's desire and commitment to develop a model that addresses socially produced health disparities, which are too often the sources of epidemics of serious communicable diseases. Rene and Jean Dubos have written that

[e]lucidation of the mechanisms of tuberculosis disease will long continue to require analysis by the methods of medical sciences. And the care of the stricken tuberculosis patients calls upon all the resources of medical practice. But the complete control of tuberculosis in society goes beyond medicine in its limited sense. It is a problem in social technology.³³⁵

With this vision, to bring this disease to an end requires continuous exploration of its underlying social causes and the development of strategies for helping society's most vulnerable populations resist the disease and complete treatment.

³³³ For example, in 2008, Taiwan's TB incidence rate was 62 per 100,000 people, while the U.S. rate was 4.8 per 100,000 people and that of Japan's was 22 per 100,000 people. See Centers for Disease Control, Department of Health, R.O.C. (TAIWAN), Taiwan Tuberculosis Report 2012, at 3 (2012), http://www.cdc.gov.tw/uploads/files/201303/9ea28ba2-69c7-4f27-af3b-55be5ec7e35c.pdf (last visited Apr. 25, 2013); WORLD HEALTH ORGANIZATION, United available States America **Tuberculosis** Profile, https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/ EXT/TBCountryProfile&ISO2=us&outtype=pdf (last visited Mar. 29, 2013); WORLD **HEALTH** ORGANIZATION, Japan **Tuberculosis** Profile, available at https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PRO D/EXT/TBCountryProfile&ISO2=jp&outtype=pdf (last visited Mar. 29, 2013). Moreover, while Taiwan was ranked 60th for tuberculosis prevalence in the The Global Competitiveness Report, 2006-2007, the ranking of Taiwan's tuberculosis incidence continued to drop to 65th in 2007, 82nd in 2008, and 82 nd in 2009. See Michael E Porter GlobalCompetitiveness Report 2008-2009 317 (2008),https://members.weforum.org/pdf/GCR08/GCR08.pdf (last visited Mar. 8, 2010); Klaus Schwab. The Global Competitiveness Report 2009-2010, (2009),http://www3.weforum.org/docs/WEF_GlobalCompetitivenessReport_2009-10.pdf visited Mar. 8, 2010).

³³⁴ Respondent O8 suggested that the decline of the incidence rates in the first few years of the Plan was probably due to stricter case definition. He criticized the CDC for being too eager to claim success for the Plan. In his opinion, it takes at least five years to evaluate whether control measures lead to a decrease of incidence rates. Interview with O8, *supra* note 111. Moreover, respondent P6 stated that the decline in incidence rates since 2006 was mostly because of the DOTS program, not the isolation program. Interview with P6, (Jul. 13, 2009).

³³⁵ DUBOS & DUBOS, *supra* note 51, at 226-27.

VI. APPENDIX A: INTERVIEW QUESTIONS

A. Questions to Local Health Officials ³³⁶

- 1. How long have you been in charge of tuberculosis control affairs in your department?
- 2. Could you tell me about the use of isolation to control tuberculosis in your county?
- 3. Had your department issued any isolation order prior to 2006? If yes, could you tell me how it happened?
- 4. The regulation regarding the procedure of isolation provides that medical care institutions may submit a referral to local health departments for a decision of issuance of an isolation order. Are isolation orders always issued accordingly?
- 5. Has your department ever issued an isolation order in absence of a physician's referral? If yes, could you describe the circumstances?
- 6. When you review the referrals, what factors are considered in deciding to issue an isolation order or not?
- 7. Do you give priority to any factors?
- 8. If patients receive isolation orders but refuse to submit to the designated hospital, what would happen to them?
- 9. Does every patient have a chance to join the DOTS program prior to issuance of an isolation order?
- 10. Prior to issuance of an isolation order, would any measures be taken to reduce the spread of the disease or improve compliance?
- 11. What factors would be considered when your department decides to rescind an isolation order?
- 12. From your experience, what do you think are the keys to reduce the incidence of tuberculosis in your county?
- 13. From your experience, what do you think are the greatest obstacles to successfully reduce patients with TB?
- 14. From your experience, do you see any legal problems in using isolation on TB patients?
- 15. The newly amended Mental Hygiene Act adopts a court review process in cases of emergency compulsory hospitalization. What do you think if compulsory hospitalization under the Communicable Disease Control Act adopts the same procedure?
 - B. Questions for Health Care Workers at Designated Hospitals³³⁷
- 1. When a patient presents symptoms of active TB, how do you proceed?

³³⁶ Although the questions were originally written in English, the author translated them into Chinese when she conducted the interviews.

³³⁷ Although the questions were originally written in English, the author translated them into Chinese when she conducted the interviews.

- 2. What factors would you consider in submitting a referral to the local health department?
- 3. What factors would you consider in discharging a patient under an isolation order?
- 4. What is the average length of hospitalization of patients who were subject to isolation orders?
- 5. In your experience, do patients compulsory hospitalized share any characteristics?
- 6. Could you tell me the treating process of these patients compulsory hospitalized in your hospital?
- 7. To what do you attribute the current status of epidemiology of tuberculosis?
- 8. In your opinion, what are the obstacles to patients' full compliance with the drug therapy?
- 9. What do you think about the use of isolation against patients with tuberculosis?
- 10. Do you have any comments about the law and regulations about isolation?