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Control of Tuberculosis -- The Law and the Public's Health

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quadruple coronary-artery bypass surgery. He was enrolled in a double-blind trial comparing teicoplanin and cefazolin as prophylaxis against postoperative infection. The intraoperative and postoperative course was uncomplicated. On the fifth postoperative day the patient was noted to have diffuse erythema involving both arms. The erythema started about 10 cm below the shoulders and extended to the wrists. There was no blanching or warmth. There was complete sparing of the area under his wristwatch. The only other medications that he had been receiving were aspirin and an antihistamine for rhinitis.

I initially considered the possibility that he had red-man syndrome, but he had not received vancomycin, so I was quite puzzled. Then his bathrobe caught my eye. The bright red terry-cloth robe was brand-new. The patient had not been compliant with the manufacturer's instructions, and no one had ever washed it in cold water to remove the sizing.[3] The red dye from the robe had colored the patient's arms, which were still wet from a shower. The spared areas were those covered by the traditional hospital gown and the wristwatch. In fact, what appeared to be rubor was merely "robe-or." Teicoplanin was exonerated. I warn other clinicians that unwashed terry-cloth robes of the appropriate colors may also lead to pseudocyanosis, pseudojaundice, and pseudochlorosis. The most cost-effective form of prophylaxis under these circumstances is machine washing.

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LEGAL ISSUES IN MEDICINE

CONTROL OF TUBERCULOSIS — THE LAW AND THE PUBLIC'S HEALTH

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IN their history of tuberculosis, *The White Plague,* René and Jean Dubos note that the first national movement to control tuberculosis in the United States came from the Medico-Legal Society of the City of New York, a group of lawyers, scientists, and physicians devoted to solving social problems.[1] At a meeting in 1900 to organize an American Congress on Tuberculosis, the group drafted legislation designed to prevent the spread of the disease. Even though almost every state eventually passed tuberculosis-control laws, it was not the passage of legislation, or even the development of effective treatment, that led to the decline of tuberculosis in the United States, but improvement in living conditions.[1] The decline in the disease was so impressive that by the 1980s predictions were made that it would soon be eradicated.[2] With the increasing incidence of tuberculosis and the rise of multidrug-resistant tuberculosis, however, that optimism has disappeared.[2,3]

In this issue of the *Journal,* Frieden and colleagues document a dramatic increase in the prevalence of multidrug-resistant tuberculosis in New York City over the past eight years,[4] and Goble and colleagues describe the difficult and deadly nature of this disease, which in their series was associated with an almost 40 percent mortality rate over two years, even with optimal treatment.[5] There is general agreement that we should act quickly to prevent the further spread of multidrug-resistant tuberculosis[3]; there is less agreement about how this can be effectively accomplished within the law. In this essay I explore the legal aspects of public health efforts to contain the resurgence of tuberculosis.

An effective public health strategy depends in large part on properly identifying the cause of the epidemic. But causes of the current tuberculosis epidemic can be identified at a number of levels. For example, an Institute of Medicine panel concluded that multiple factors, including poverty, homelessness, substance abuse, a deteriorating health care infrastructure, and the human immunodeficiency virus (HIV) epidemic, contribute to the rise in incidence of tuberculosis.[6] The panel further concluded that two factors have probably had primary roles in the development of multidrug-resistant tuberculosis: patients' noncompliance with the 6-to-12-month regimen of antibiotic therapy required to treat the disease, and the prescription of ineffective treatment regimens by physicians.[6] This view has led to proposals, including that of Iseman and colleagues in this issue, for the routine administration of treatment to patients with tuberculosis while they are directly observed by health care providers.[7,8]

Others have argued that it is a mistake to treat tuberculosis as an isolated issue unrelated to alcoholism and drug addiction, noting that "the continued emphasis on the noncompliant patient places blame for the tuberculosis crisis on those who are ill, and diverts attention from the indifference and neglect that are the primary causes" of the resurgence of tuberculosis.[9] Similarly, former Secretary of Health, Education, and Welfare Joseph A. Califano has argued that tuberculosis must be attacked in concert with AIDS and substance abuse.[10] It has also been suggested that the tuberculosis epidemic in prisons has been fueled by our war on drugs, which has emphasized the incarceration of drug offenders in overcrowded prisons, rather than treatment of their addiction.[11]

Massachusetts has been a national leader in tuberculosis control since 1850, when Lemuel Shattuck proposed the establishment of the country's first tuberculosis case registry. The state also had the first private and community sanitarium and the first state tuberculosis hospital.[12] Nonetheless, in Massachusetts the incidence of tuberculosis, which had been declining for

70 years, increased 15 percent from 1988 to 1990.[12] The Massachusetts Commission for the Elimination of Tuberculosis has described the factors accounting for this increase as "complex and multifactorial"; among them are "poverty, homelessness, crowding in institutions, substance abuse, immigration from areas of the world where tuberculosis is still prevalent, and infection with the human immunodeficiency virus."[12] Although it recognizes that it is early in the new epidemic and that "the danger of loss of control . . . remains real," the commission believes that because the public health infrastructure for the surveillance and treatment of tuberculosis (including reporting requirements, publicly sponsored tuberculosis clinics, and a residential facility to which noncompliant patients could be committed as a last resort) remained in place and functioning during the 1980s, the tuberculosis epidemic in Massachusetts is currently under control.[12]

The State's Public Health Powers

The inherent governmental power to act to protect the public's health and safety, referred to as the "police power," resides in the individual states. Thus, public health issues have almost always been dealt with at the state level, with state departments of public health taking the lead. And the state's powers are broad. When, for example, the state's power to permit local communities to require vaccination against smallpox was challenged at the beginning of the century, the U.S. Supreme Court ruled in *Jacobson* v. *Massachusetts* that "the safety and the health of the people of Massachusetts are, in the first instance, for the Commonwealth to guard and protect. They are matters that do not ordinarily concern the National government."[13] The Court ruled as a general matter that "upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members."[13]

Actions designed to contain an epidemic will be upheld as constitutional as long as they are not arbitrary or unreasonable and are rationally related to the goal of protecting the public's health. A responsible public health approach to infectious epidemics requires surveillance, reporting, intervention, and the education of health professionals. All four must be coordinated, or their efficacy will drastically decrease.

States have the legal authority to identify infectious diseases through screening programs, and they have the legal authority to require physicians and others to report the names of persons with infectious diseases to the state. Screening and reporting are legitimate public health methods designed to protect the health and safety of citizens. Steps must, of course, be taken to protect the confidentiality of medical records and reports so that only public health officials with a legitimate need to know the identity of individual patients (such as officials responsible for monitoring or contact tracing) have access to their names.[14] More difficult legal questions are raised by treatment of disease. Although involuntary confinement should only be used as a last resort, its availability as a legal option merits discussion because it illustrates the broad scope of the state's public health powers.

Confinement of Patients with Tuberculosis

Many court cases, including *Jacobson*, provide legal authority for states to enact and enforce statutes that permit the confinement (at home, in a hospital room, or at a special facility or residence) of a patient with active tuberculosis who is a danger to others. If a state wishes to deprive such patients of their liberty on the grounds that they are a danger to others, however, the patients are now entitled to considerably more due process than they would have had at the beginning of the century. The closest legal analogy is provided by court cases that have reviewed the constitutionality of state statutes permitting the involuntary commitment of mental patients on the basis that they have a disease that causes them to be dangerous. The Supreme Court has held, for example, that illness alone is an insufficient justification for confinement, if the patient is "dangerous to no one and can live safely in freedom."[15] Nor is "mere public intolerance or animosity" sufficient "constitutionally [to] justify the deprivation of a person's physical liberty."[15] The Court has repeatedly held that "civil commitment for any purpose constitutes a significant deprivation of liberty that requires due process protection."[16] For example, the minimal standard of proof that the state must meet to commit a person involuntarily to a facility is that there is "clear and convincing evidence" of his or her dangerousness (this is less stringent than the criminal standard "beyond a reasonable doubt," but more so than the usual civil standard of "preponderance of the evidence").[15]

The following due-process rights, outlined by a West Virginia court in a case that involved the involuntary commitment of a patient with tuberculosis for treatment, are likely to be found constitutionally required by most courts:

> (1) an adequate written notice detailing the grounds and underlying facts on which commitment is sought; (2) the right to counsel and, if indigent, the right to appointed counsel; (3) the right to be present, to cross-examine, to confront and to present witnesses; (4) the standard of proof by clear, cogent and convincing evidence; and (5) the right to a verbatim transcript of the proceedings for purposes of appeal.[17]

Although these safeguards may seem impressive, in fact the only issues likely to concern a judge in a tuberculosis commitment proceeding are two factual ones: Does the person have active tuberculosis, and does the person present a danger of spreading it to others? Since it is unlikely that any case will be brought by public health officials when the diagnosis is in doubt, the primary issues will be the danger the patient presents to others and the existence of less restrictive alternatives to confinement that might protect the public equally well.

Under these circumstances, the burden of involuntary confinement will fall most heavily on the homeless and those who live in crowded, inadequate housing, because they have no place to "confine themselves"

during treatment for active tuberculosis. Since the rationale for involuntary commitment is danger to others based on the contagiousness of the patient's disease, under existing state statutes (written before multidrug-resistant tuberculosis was identified as dangerous to the public) patients have a right to be released when their tuberculosis is no longer communicable and they are therefore no longer a danger to others. The possibility of acquiring and spreading multidrug-resistant tuberculosis poses a particularly difficult problem. Even though not currently a danger to others, the patient whose tuberculosis is inactive but not yet cured might be a danger in the future if a treatment regimen that will ultimately cure the patient is not followed and if, instead, the patient takes drugs in such a way as to transform tuberculosis into a multidrug-resistant variety, which later becomes active and communicable. Because clear and convincing evidence is required to prove dangerousness, the fact that a person might be a risk to others in the future is insufficient reason alone, under current laws, for confinement until cure.

Should the Law Be Changed?

Does the existence of multidrug-resistant tuberculosis mean that state laws regarding tuberculosis should be changed to permit confinement until cure? The answer depends on the actual danger the patients pose to the public and the relative effectiveness of less restrictive treatment alternatives. In the context of antidiscrimination laws, the Supreme Court has made it clear that more than just the fear of danger is required to exclude a person with tuberculosis from the workplace. In *School Board of Nassau County* v. *Arline*,[18] the Court adopted the position of the American Medical Association as to what factual medical inquiries a court should make in determining the degree of danger posed by a tuberculosis carrier who taught schoolchildren and sought reinstatement in her job after she was fired because she had tuberculosis. Its requirements were that the following be ascertained:

> (a) the nature of the risk (how the disease is transmitted), (b) the duration of the risk (how long the carrier is infectious), (c) the severity of the risk (what is the potential harm to third parties) and (d) the probabilities the disease will be transmitted and will cause varying degrees of harm.[18]

The Court continued, "In making these findings, courts normally should defer to the reasonable medical judgments of public health officials."[18] When the teacher had active tuberculosis, there was no question that she could be excluded from the classroom.

Exclusion from crowded environments is obviously less restrictive than confinement. Nonetheless, if a state legislature concluded after hearing evidence from public health officials that such confinement was required to protect the public's health because there was no effective, less restrictive alternative available, a statute should be passed permitting confinement until cure. The hearings before the legislature could also provide useful education for the public about the epidemic and its control, as well as the opportunity to discuss alternative treatment strategies. Thereafter, if an individual patient were given a timely hearing, legal representation, and other due-process protections and if involuntary confinement were resorted to only when there is clear and convincing evidence that outpatient treatment could not effectively protect the public from that particular patient, confinement until cure would probably be found constitutional. This could be justified, even though confinement of a psychotic patient who did not consistently take medication might not be, because the time of confinement would be limited and relatively short.

Obviously, interventions short of confinement, such as periodic checkups or monitoring, or even the routine administration of therapy under direct observation, are much to be preferred. Moreover, a "technological fix" such as a slow-release implant would eliminate the need for confinement until cure altogether. It is also appropriate to use monetary and other inducements to encourage compliance with outpatient therapy, since the effective treatment of tuberculosis benefits the entire community. In no event, however, should a confined person be physically forced to take medications against his or her will, although confinement might be continued indefinitely as long as the patient continued to be a danger to the public.

Directly Observed Therapy

Current discussion is properly focusing not on confinement but on less restrictive interventions such as routine and universal use of directly observed therapy.[9,10] This "methadone maintenance" model of delivery is not now the standard of care, and a survey of state laws found only three states (Maine, Michigan, and Minnesota) that explicitly provide for such monitoring of treatment by state officials.[19] Although the data are incomplete, it appears that from 1976 through 1990, more than 80 percent of all patients with tuberculosis in the United States completed 12 continuous months of drug therapy.[5] The completion rate is much lower for New York, but it still involves a majority.[5] There is an understandable egalitarian desire to try to treat everyone in the same way by subjecting everyone to directly observed therapy. There is, however, insufficient justification for requiring this annoying and inconvenient method of treatment for patients who are virtually certain to take their antituberculosis medications and thus pose no risk to the public health. This is not a case in which there is a conflict between public health and civil rights. It is simply common sense. As Dubos and Dubos rightly observe, measures to prevent the spread of tuberculosis generally do not require legal compulsion, because they "have acquired the compelling strength of common sense."[1]

Requiring all persons to take therapy under direct observation because it is necessary for some is wasteful, inefficient, and gratuitously annoying, and it undercuts the legitimate desire to individualize treatment and to use the least restrictive and intrusive public health interventions. Moreover, in many if not most cases, reasonable discharge planning (including the provision of housing for the homeless) and coun-

seling will greatly improve voluntary compliance.[10] Of course, it can be difficult to predict some patients' degree of compliance accurately, and individualized case-management strategies and monitoring will be necessary.[12,20]

Directly observed therapy remains clearly preferable to involuntary confinement, however, and diligent and imaginative efforts to deliver therapy on an outpatient basis should be made before involuntary confinement is contemplated. Both these legal interventions, however, concentrate on the victims of social neglect, rather than on the neglect itself. This focus is understandable, since poverty is a much more difficult problem to address than the treatment of tuberculosis, but the history of the disease shows that success in controlling tuberculosis depends much more on the general standard of living than on specific medical or legal interventions.

The Federal Role

Infectious agents are likely to proliferate in the future,[6] and old scourges such as tuberculosis may continue to return in newly virulent forms as portions of some of our inner cities begin to resemble Third World countries. Public health powers are state powers. But neither an individual state nor the United States as a whole can seal its borders from worldwide pandemics. No individual state can meet the challenges of tuberculosis alone, any more than it can meet the challenges of HIV infection or influenza by itself. As we remodel our health care delivery system, we should also remodel our public health system. States should retain their primary roles in surveillance, reporting, and treatment. But public policy in matters of disease prevention and professional education requires leadership and funding at the federal level. In regard to infectious diseases specifically, the recommendations of the Institute of Medicine, which call for the United States to take the lead in establishing a global surveillance system for infectious diseases, should be implemented.[6] We should also begin our movement into the 21st century by using the tuberculosis epidemic as an opportunity to integrate public health into a national health care program. Prevention is still better than cure — and often considerably less expensive.

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BOOK REVIEWS

Occupational Disorders of the Upper Extremity

Edited by Lewis H. Millender, Dean S. Louis, and Barry P. Simmons. 308 pp., illustrated. New York, Churchill Livingstone, 1992. $59.95. ISBN 0-443-08797-0.

Very little formal training in the disposition of workers' compensation cases is provided in today's residency-training programs, no matter what the specialty. Most physicians who examine and treat patients covered by workers' compensation have learned about this area of medicine from older colleagues, from experience, and from their own mistakes. Instructional courses are offered by reputable subspecialty organizations, but the average orthopedic surgeon, neurosurgeon, or physical medicine specialist would much rather spend his or her limited continuing-medical-education time on a subject that is more exciting or related to a special interest. This book attempts to fill part of that gap in our medical-education process. The editors have brought together a group of physicians, a rehabilitation specialist, an occupational therapist, an industrial health specialist, and an attorney, all with an interest in work-related upper-extremity injuries, and have produced an overview of this complex subject.

This book is divided into four sections; if sections on low-back injuries and lower-extremity injuries were added, it could be considered a complete general guide through the maze of occupational injuries. Section I gives a historical perspective on work-related injuries and guidelines for categorizing these injuries. It also covers biomechanical studies that analyze cumulative-trauma disorders. Section II presents an overview of the workers' compensation system, including the roles of the insurance company, the employee, the employer, the state, and the attorney in workers' compensation disputes. It becomes clear to the reader why injured workers sometimes end up in the hands of attorneys. This section also discusses managed-care programs and shows how they can be of great benefit to the patient, the physician, and the employer without involving expensive legal advice. Section III provides a general approach to the diagnosis and management of occupational injuries. This material, which is laid out in "cookbook" fashion, is quite