United States of America
OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION
1120 20th Street, N.W., Ninth Floor
Washington, DC 20036-3419

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SECRETARY OF LABOR
Complainant,
v.

COLUMBIA PRESBYTERIAN HOSPITAL,
Respondent,

DH & HEU LOCAL 1199,
Authorized Employee
Representative.

OSHRC DOCKET
NO. 93-0298

NOTICE OF DOCKETING OF ADMINISTRATIVE LAW JUDGE'S DECISION

The Administrative Law Judge's Report in the above referenced case was docketed with the Commission on December 1, 1995. The decision of the Judge will become a final order of the Commission on January 2, 1996 unless a Commission member directs review of the decision on or before that date. ANY PARTY DESIRING REVIEW OF THE JUDGE'S DECISION BY THE COMMISSION MUST FILE A PETITION FOR DISCRETIONARY REVIEW. Any such petition should be received by the Executive Secretary on or before December 21, 1995 in order to permit sufficient time for its review. See Commission Rule 91, 29 C.F.R. 2200.91.

All further pleadings or communications regarding this case shall be addressed to:

Executive Secretary
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Review Commission
1120 20th St. N.W., Suite 980
Washington, D.C. 20036-3419

Petitioning parties shall also mail a copy to:

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DOCKET NO. 93-0298

If a Direction for Review is issued by the Commission, then the Counsel for Regional Trial Litigation will represent the Department of Labor. Any party having questions about review rights may contact the Commission's Executive Secretary or call (202) 606-5400.

FOR THE COMMISSION

Date: December 1, 1995

Ray H. Darling, Jr.
Executive Secretary

DOCKET NO. 93-0298

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SECRETARY OF LABOR, Complainant, v. COLUMBIA PRESBYTERIAN HOSPITAL, Respondent. DH & HEU LOCAL 1199, Authorized Employee Representative	:	OSHRC Docket No. 93-298

APPEARANCES:

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Before: Chief Judge Irving Sommer

DECISION AND ORDER

BACKGROUND

This is an action to review one item of a citation alleging that Respondent, Columbia Presbyterian Hospital ("Columbia"), committed serious violations of the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-678 ("the Act") resulting from an extensive inspection which commenced on June 18, 1992. The parties have stipulated to a settlement of all allegations except item 2, which alleged that Columbia failed to comply with the standard at 29 C.F.R. § 1910.134(a)(2)[1] because its employees were given surgical masks for protection against tuberculosis bacilla ("TB") rather than respirators approved by the National Institute for Occupational Safety and Health (NIOSH) for at least dusts, mists, and fumes, known as "DMF" respirators. Columbia filed a timely notice of contest; accordingly, the Commission has jurisdiction of this proceeding. Columbia admits that it is engaged in a business affecting commerce. Therefore, Columbia is an employer under section 3(5) of the Act, and the Act applies to its work activities.

FACTS

General

Tuberculosis is an infectious disease caused by the bacteria *Mycobacterium tuberculosis*. Although it can manifest itself in a number of ways, it most commonly results in pulmonary disease, a type of pneumonia.[2] It normally is transmitted when an infected person coughs, sneezes,

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[1]This standard provides as follows:

> Respirators shall be provided by the employer when such equipment is necessary to protect the health of the employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protective program which shall include the requirements outlined in paragraph (b) of this section.

[2]The Purified Protein Derivative ("PPD") skin test is used to detect infection, although persons who are immunocompromised due to HIV (human immunodeficiency virus, also known as "AIDS") or other factors may falsely test negative even if they are infected. False positives can also occur in individuals who have been exposed to microbacteria other than TB. The commonly-used statistical measure is the "conversion rate." A "conversion" is an originally negative PPD test result which

(continued...)

or otherwise propels the organism into the air in the form of "droplet nuclei," that is, the organism surrounded by water vapor. The generally accepted range of infectious droplet nuclei is between 1 and 5 microns or micrometers (millionths of a meter) in size. Droplets larger than 10 microns are not considered a source of infection because particles of that size are trapped by the nasal passages and airways rather than entering the respiratory system. Particles in the 1-micron range are small enough to be exhaled before they can settle in the alveoli (lung tissues). According to Dr. Edward Nardel, a specialist in pulmonary medicine and Tuberculosis Control Officer for the Commonwealth of Massachusetts, the optimal size for deposition in the alveoli is 3 microns. (Tr. 90-92, 199, 1047-48, 1386-87).

Discharge of droplet nuclei by coughing results not only from the illness itself but from the necessary medical care as well. Bronchoscopy is a technique for diagnosing suspected cases of tuberculosis. It consists of inserting a fiber-optic scope down the trachea to examine the lungs and obtain tissue cultures. Aerosolized medication is a means of getting medication into the lungs. Both of these treatments may cause the patient to cough. Sputum induction is intended to make the patient cough so that sputum can be collected to evaluate the effectiveness of the medication being

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[2](...continued)
turns positive after the employee is retested; a conversion occurring within a 2-year period is said to be a "recent" conversion. (Tr. 1271, 1620, 1630).

Infection is not detectable immediately; it can take anywhere between approximately two weeks and three months for an infection to manifest itself in a positive test result. (Tr. 298-99). Moreover, once an individual tests positive, normally that individual will remain positive for life. In other words, the PPD generally speaking cannot be used to detect reinfections or as a continuing surveillance tool for a specific person. (Tr. 113).

On the other hand, infection does not equate to actual contraction of TB. The likelihood that an infected person will actually develop symptoms of the disease or become capable of transmitting it to others is highest within the first two years and decreases rapidly thereafter. The generally accepted figures in the medical community are that five percent of those infected will develop active disease within the first four years of being infected and that the percentage over the course of a lifetime is only about 10 percent. There is also preventive treatment which can forestall an infection from advancing to the symptomatic stage. (Tr. 28, 63-65, 103-04, 111-12, 114, 1367, 1571, 1578-79). The cost of curing a patient of TB can vary from as little as $2,000 for cases which are not drug resistant and can be treated without hospitalization to as much as $500,000 for strains of TB that are highly drug-resistant and require surgery. (Tr. 109-110, 1398-1400; exh. C-32).

administered and to determine whether the patient can be released from isolation. Once coughing is induced, the patient may continue coughing for some time after the treatment is completed. Even routine care such as moving the patient or changing the patient's position can cause coughing. (Tr. 95-96, 99, 101, 182, 1389-91, 1734). Patients are also given pulmonary function tests, which cause coughing. Bronchoscopies are conducted by physicians whereas respiratory therapists or other staff perform sputum induction and pulmonary function tests, and aerosol drugs may be administered by either nurses or therapists. Others who may be exposed include nurses and nursing assistants who provide the primary patient care as well as ancillary personnel such as dietary and housekeeping staff. (Tr. 99-100, 1666; exh. C-56). Although sputum induction is most commonly performed at the patient's bedside, and other treatments may be conducted at bedside if the patient is very ill, generally speaking hospitals recognize a need for negative pressure rooms or treatment booths which can capture the droplets discharged by patients induced to cough, and such requirements also appear in two documents crucial to this case, "Enforcement Guidelines for Occupational Exposure to Tuberculosis," an instruction issued by the OSHA regional office for Region II, which covers the New York City area where Columbia is located ("Region II Guidelines") and Centers for Disease Control ("CDC") of the Public Health Service *Guidelines for Preventing the Transmission of Tuberculosis in Health Care Settings, with Special Focus on HIV-Related Issues*, 39 Morbidity and Mortality Weekly Report No. RR-17 (Dec. 7, 1990) ("CDC Guidelines"). These instructions were issued in response to the outbreak of a TB epidemic in heath care facilities, primarily in the New York and New Jersey area, which occurred in 1990 to 1991. (Tr. 97-98, 200, 223, 718, 900; exh. C-3).

Actions Undertaken by Columbia

In accordance with generally accepted health care standards, Columbia had instituted both administrative and engineering controls pertaining to early detection and isolation of patients infected with TB and regular monitoring of its staff. (Tr. 111-12, 124-26, 1486-87). Its TB screening program includes periodic PPD testing of both employees and applicants for employment with appropriate recordkeeping and further diagnostic tests depending on the risk factors in the employee's work, the employee's reaction to the tests, and the employee's own

medical history and condition.[3] (Tr. 1613-27, 1631; exhs. R-17, R-18, & R-41). At the time of the inspection, Columbia's written "Tuberculosis Policy" recognized that "[e]ffective respiratory isolation of patients with suspected or confirmed infectious tuberculosis is the primary protective measure against the spread of tuberculosis to other patients and staff." To that end, the policy provided that such patients would be housed in single-bed "isolation rooms" equipped with negative-pressure ventilation, that is, an airflow into the room and away from the corridor. In addition, the air is to be vented to the outside and not recirculated within the room. Staff members must wear "the designated hospital isolation mask" when in the isolation room or when moving a patient in or out. Staff must also wear such masks when performing certain medical procedures which pose an "increased risk" of transmission of tuberculosis, including diagnostic sputum induction, administration of aerosolized pentamidine and other aerosol and cough-inducing treatments, bronchoscopy, endotracheal intubation/suctioning, and emergency dental work. (Tr. 17-18, 1293-95; exhs. C-2, C-4, & R-25). Alba Quinones, the OSHA industrial hygienist who conducted the inspection, observed Columbia staff wearing Tecnol Fluid Shield® surgical masks in isolation rooms. (Tr. 12, 22; exh. C-5).

OSHA Directives

At the time of the inspection in this case, OSHA itself had not set forth any specific guidance on the use of respirators to protect against TB. However, Region II had issued its guidelines in May 1992, the month preceding the inspection. These guidelines discuss three types of NIOSH-approved particulate filters: dust/mist filter; dust, fume, and mist filter; and high-

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[3]Although Columbia had been conducting employee and applicant testing it originally did not have procedures for collecting and recording test results from which it could develop baselines for evaluating the adequacy of its tuberculosis prevention program. It also did not specifically track high-risk exposure areas. Recordkeeping and identification of areas depending upon their level of hazard was in place and operative by May 1992, just prior to the inspection here. (Tr. 53, 1611-12, 1614-15, 1662).

efficiency particulate air ("HEPA") filter. (Tr. 354).[4] The relevant part of the guidelines states as follows:

> The dust/mist filter is tested against a silica dust challenge having a particle size of 2 micrometers. The fume filter is tested against a lead fume challenge which has a particle size range between 0.6 to 1.0 micrometer. The HEPA filter is tested against an oil mist challenge having a size of 0.3 micrometer. A respirator that receives fume approval must also pass the dust/mist test. The approved HEPA filter must pass dust/mist and fume tests. . . .
>
> If a manufacturer claims that their dust/must filter provides the same protection as the fume filter, then the manufacturer should submit this filter to NIOSH for fume approval. By the nature of the test, an approved dust/mist filter may not pass the fume test. Information regarding the particle size for the TB bacteria varies between 1 and 5 micrometers. The dust, mist, fume (DMF) respirator filters are tested for this particle size range. Consideration should be given to the use of the HEPA filter since it removes particles greater than and equal to 0.3 micrometers and is tested 100% by respirator manufacturers before sale to end users.
>
> . . . .
>
> OSHA shall require that employees must be provided with, and wear NIOSH certified Dust, Mist and Fume (DMF) respirators, or respirators affording greater protection, under the following circumstances:
>
> > 1-when entering a pulmonary isolation room occupied by a known or suspected infectious tuberculosis patient.
> >
> > 2-while performing certain high hazard medical procedures such as aerosol administration of medication (pentamidine)[,] bronchoscopy, and diagnostic sputum induction. . . .
> >
> > 3-when transporting TB disease patients.
>
> . . . .
>
> Until such time as NIOSH determines an appropriate respirator for TB, OSHA will accept a DMF or any more effective respiratory protection.

Id. at 2, 8. These guidelines in turn reference and are based on the previously mentioned CDC Guidelines (Tr. 213, 291), which state in pertinent part:

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[4]Jessica Sandler, an industrial hygienist and OSHA's expert on enforcement regarding pathogens (Tr. 855), testified that NIOSH is responsible for research for OSHA on matters for which OSHA does not have resources or capability to conduct its own research and that OSHA gives weight to NIOSH's recommendations. (Tr. 946).

> *c. Disposable PRs for filtration of inhaled air.*
>
> *1.) For persons exposed to tuberculosis patients.* Appropriate masks, when worn by health-care providers or other persons who must share air space with a patient who has infectious tuberculosis, may provide additional protection against tuberculosis transmission. Standard surgical masks may not be effective in preventing inhalation of droplet nuclei . . . because some are not designed to provide a tight face seal and to filter out particulates in the droplet nucleus size range (1-5 microns). A better alternative is the disposable PR. PRs were originally developed for industrial use to protect workers. Although the appearance and comfort of PRs may be similar to that of cup shaped surgical masks, they provide a better facial fit and better filtration capability. However, the efficacy of PRs in protecting susceptible persons from infection with tuberculosis has not been demonstrated.
>
> PRs may be most beneficial in the following situations: a) when appropriate ventilation is not available and the patient's signs and symptoms suggest a high potential for infectiousness, b) when the patient is potentially infectious and is undergoing a procedure that is likely to produce bursts of aerosolized infectious particles or to result in copious coughing or sputum production, regardless of whether appropriate ventilation is in place, and c) when the patient is potentially infectious, has a productive cough, and is unable or unwilling to cover coughs.

Id. at 12. The CDC Guidelines contain a section entitled "Recommendations" as follows:

> PRs . . . should be provided by health-care facilities and worn by persons in the same room with a patient whose signs and symptoms suggest a high potential for infectiousness and by those performing procedures that are likely to produce bursts of droplet nuclei, such as bronchoscopy, endotracheal suctioning, and administration of [aerosolized pentamidine].

Id. at 15-16. (Tr. 41). The document defines a "PR" as "a disposable, particulate respirator (respiratory protective device [face mask]) that is designed to filter out particles 1-5 microns in diameter." *Id.* at 26 (brackets in original).

Quinones testified that there are other types of particulate respirators besides DMF respirators and conceded that the CDC Guidelines do not explicitly require a DMF respirator. Quinones did not know what the term "face mask" means in this context but conceded that the Tecnol surgical mask could be characterized as a face mask. (Tr. 42, 79). Ching-tsen Bien, OSHA's supervisory industrial hygienist with responsibility for issues involving respirators (Exh. C-25), testified that when Region II issued its guidelines, "it was very clear that the respirator recommendation was an interim recommendation" and that in response to phone calls hospitals were told that the

respirator recommendation "might well change." Although the National Office, according to Bien, did not envision reducing the requirement to a lesser type of respirator, there is no evidence that health care facilities were specifically told that the requirements would likely become more stringent. (Tr. 746). Bien further gave his opinion that because the CDC Guidelines referred only to "disposable" respirators and did not even use the term "dust/mist" the CDC did not appear to understand how respirators are classified. He regarded the CDC Guidelines as "not clear" and would advise a health care facility "to consult with OSHA to verify what the CDC means." (Tr. 549-51). However, the Region II Guidelines and the CDC Guidelines referenced therein carry no indication of which—OSHA or the CDC— is to control in the event of ambiguity or uncertainty. This point is illustrated by the testimony of Dr. Melissa McDiarmid, OSHA's Director of the Office of Occupational Medicine. Dr. McDiarmid's view was that the 1990 CDC Guidelines were deficient with respect to the information it imparted "as to the type of particulate respirator that was required." (Tr. 215). She noted that the Centers for Disease Control includes a number of individual entities; NIOSH is a component of the CDC as is the Center for Infectious Disease. She was aware of situations in which health care facilities who contacted NIOSH were told that a DMF was the appropriate minimum whereas other health care providers were informed by the Center for Infectious Diseases that a DM respirator was sufficient. (Tr. 215-16).

Columbia's Response

Dr. Robert Lewy, Columbia's Senior Vice-President of Medical affairs, testified that the hospital had received and reviewed the CDC Guidelines after they were issued. (Tr. 1279). On January 8, 1992, Columbia issued a memo instructing its nursing staff that it was replacing the isolation masks then being used with the Tecnol mask because the former "do not have the 1-5 micron particle filtering capabilities necessary to adequately protect staff from some respiratory borne pathogens." (Exh. R-34). According to Lewy, Columbia felt that the Tecnol mask was appropriate based on the CDC Guidelines and in particular the CDC's emphasis on a face mask designed to filter particles of 1 to 5 microns in size. (Tr. 1282-83). Similar testimony was given by Dr. Nardel, who stated that after the 1990 CDC Guidelines were issued, Cambridge (Massachusetts) Hospital changed from simple surgical masks to a 3M face mask which he

considered identical to a DM respirator based both on information he had been given and his interpretation of the CDC Guidelines. (Tr. 984-86).

Columbia also relied on the following statements in a document issued by the state health authorities, State of New York, Department of Health, *Control of Tuberculosis in Hospitals*, Health Facilities Series H-7 (series 92-7, March 13, 1992) (exh. R-6):

> High efficiency masks and disposable particulate respirators that filter particles in the 1-5 micron range, if used properly, are likely to decrease exposure to M.tb. However, as of this writing, there are no specific masks or particulate respirators that have been proven to be effective in decreasing exposure to M.tb. The National Institute of Occupational Safety and Health (NIOSH) is currently reviewing the masks and respirators available, and can be expected to approve specific models for personal protective use against respiratory pathogens, including M.tb.
>
> The recommendations below are given to provide guidance in the interim. These recommendations can be expected to be modified in coming months, as knowledge regarding personal protective devices improves, and consensus develops on which masks or respirators to use.
>
> 1. Description of Masks
>
> a. Common surgical masks are not effective in preventing exposure to M.tb, since they do not adequately trap small aerosols and allow leakage around the mask . . . .
>
> b. High efficiency masks are now available which are effective in filtering small (1-5 microns in size) aerosolized particles, the size of TB droplet nuclei. These offer an improved fit compared to the common surgical mask, and are likely to decrease exposure to M.tb.
>
> 2. Disposable Particulate Respirators
>
> a. Particulate respirators were originally developed for industrial use to protect workers from inorganic materials, such as asbestos.
>
> b. Although the efficacy of disposable particulate respirators in protecting susceptible persons from infection with M.tb has not been demonstrated, their ability to filter out particles in the droplet nucleus range (1-5 microns) and in the submicron range has been repeatedly verified.
>
> . . . .

> d. Some of the disposable particulate respirators on the market for prevention or control of exposure to M.tb are exactly the same as the high efficiency masks described above. The distinction in these cases is the NIOSH certification as a particulate respiratory [sic], and the requirement for training and medical certification before and during use.

Id. at 10-11. The memorandum goes on to specify that hospital personnel should wear "a properly fitted high efficiency mask *or* disposable particulate respirator capable of filtering small (1-5 micron) particles" when entering rooms occupied by or otherwise having contact with infectious TB patients but should use only particulate respirators when conducting diagnostic procedures or when administering medication. *Id.* at 11-14 (emphasis added). Lewy testified that this memorandum reinforced the hospital's decision to use the Tecnol mask since it understood that that mask was capable of filtering particles of the 1- to 5-micron size. Lewy also testified that the Tecnol mask is not "a common surgical mask." (Tr. 1283-87, 1511).

Lewy believed that the instructions issued by the CDC and the state health department were sufficiently unspecific that the Tecnol mask came within those parameters, given the representations made by Tecnol. Lewy conceded that the Tecnol mask did not meet the criteria of the Region II Guidelines. (Tr. 1508). However, when it became known that OSHA Region II was considering recommending DMF respirators, the Greater New York Hospital Association ("GNYHA"), a trade association representing approximately 160 health care organizations including Columbia, wrote to the Regional Administrator questioning whether the medical/scientific community recognized DMF respirators as appropriate for TB protection and also asserting that such respirators are not practical in the patient care setting because they cannot be fitted properly and would interfere with effective communication with other staff and the patients. The Association also contended that OSHA's proposal did not give proper consideration to the existing environmental controls instituted in compliance with CDC and state health department guidance. A "TB Summit" was then convened on August 28, 1992, during the course of the inspection here, at which GNYHA and OSHA participated. The report of this conference reflects that James Stanley, the Region II OSHA administrator, reiterated OSHA's requirement for DMF respirators while the GNYHA repeated its position that less stringent respiratory protection was

appropriate in the circumstances. (Exhs. R-35, R-36, & R-38). (Tr. 1291-1302).[5] Further meetings took place, including one on October 1, 1992, between GNYHA and the state health department, which GNYHA summarized in an October 12 memorandum as follows:

> DOH officials also discussed their intention to release a revised and refined document related to the use of respiratory protection for health care workers. It would appear at this time that DOH may be headed in the direction of *clarifying* that a dust-mist *mask* (high efficiency *mask*) will not suffice but that a particular respirator (PR) will be part of the revised requirements. DOH has not yet decided whether fit-testing will be mandated for routine use although for PR use in high-risk areas it is a likely requirement. GNYHA representatives spent a significant amount of time detailing the issues related to the implementation of a fit-testing program, the complexities of the medical evaluation, the possibility that patient care would be somewhat hampered by a potential need to restrict the number of caregivers, and what protection visitors should use in the circumstance in which everyone else entering the room had been fit-tested for a dust-mist particulate respirator. Among other things, GNYHA argued that *perhaps* DOH was going further than necessary given the positive information on the environmental controls, but *should any change be required*, a significant phase-in period to allow adequate time to implement the attendant requirements should be permitted. GNYHA also raised issues on how to accommodate employees with facial hair in the PR program . . . and the reuse issues attendant to particulate respirators.

(Exh. 39) (emphasis added). This memorandum also reflected that OSHA had requested further study by NIOSH and that in response NIOSH had developed recommendations for powered air purifier respirators, which provide a filtered air supply pumped into the user's face mask, for routine care of TB patients and air-line respirators, which have their own self-contained air supply, for patients in higher-risk situations. The memorandum reflected some uncertainty as to how OSHA would react to these recommendations.[6]

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[5]The GNYHA stated that "OSHA is requiring the DMF for health care personnel (rather than the DOH-recommended DM mask)." (Exh. R-35). Lewy testified that he did not interpret this sentence to establish that the Tecnol mask did not comply with the state DOH guidance because he understood at the time that the Tecnol mask was capable of filtering out particles of one micron in size. (Tr. 1511-14).

[6]The *NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis* were issued on September 14, 1992. (Exh. R-15). These guidelines conclude, in pertinent part, that "negative-pressure, non-elastomeric, cup-

(continued...)

Columbia's conclusion that the Tecnol mask was capable of filtering particles as small as 1 micron was based on representations and data supplied by the manufacturer which Columbia's epidemiology staff had reviewed. (Tr. 1132, 1145, 1287, 1529; exh. R-34). The October 12 GNYHA memorandum caused Columbia to rethink this conclusion as it stated:

> DOH noted that many institutions were apparently using masks not considered appropriate . . . . A DOH spokesperson announced that she had personally contacted the involved company and they had agreed with her assessment that the Technol [sic] high efficiency mask is not the appropriate high efficiency type mask for the care of TB patients.

Lewy testified that because of what it regarded as "conflicting recommendations," Columbia undertook further study of the issue and developed a revised respirator policy which took effect at the end of April, 1993. Under this policy, HEPA respirators would be used in high-risk diagnosis and treatment situations—where the health care worker would be near the patient's face—and DM respirators elsewhere. (Tr. 1303-09, 1592, 1750, 1763; exh. R-40). Dr. Carlton McGregor, a staff physician at Columbia specializing in pulmonary disease, testified on June 23, 1994, that Columbia's physicians now use HEPA respirators when conducting bronchoscopies and DM respirators when visiting patients in isolation rooms. (Tr. 1735-36). In a written statement (exh. C-56), a respiratory therapist, Walter Goodmond, declared that in 1993 he began wearing a DM respirator when performing procedures such as pulmonary function tests and sputum

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[6](...continued)
shaped, disposable, particulate filter respirators (PR's) without HEPA filters (e.g., surgical masks not certified by NIOSH; NIOSH-certified dust and mist filters; NIOSH-certified dust, fume, and mist filters) cannot be relied upon to protect workers exposed to infectious tuberculosis." *Id.* at 27. At a further point in the document, the NIOSH Recommended Guidelines contain a chart entitled "Summary Comparison of Three Respirator Categories Evaluated for Protection of Health-Care-Facility Workers Potentially Exposed to Tuberculosis" which includes one column entitled "Surgical Masks Not Certified by NIOSH as Dust and Mist Masks," a second column entitled "Cup-Shaped, Disposable-Mask, Particulate Respirators (PRs) Certified by NIOSH" and another column entitled "Powered, HEPA-Filter, Halfmask Respirators and Positive-Pressure, Air-Line, Halfmask Respirators Certified by NIOSH." *Id.* at 29. Bien criticized this chart for inaccurately combining all types of particulate respirator filters together in one category. (Tr. 563). Sandler conceded that the 1990 CDC Guidelines caused confusion as to which type of particulate respirator was appropriate and that the subsequent NIOSH Guidelines further confused the issue. (Tr. 1096).

induction and when assisting physicians during bronchoscopies and "shortly thereafter" was fit tested for and began using a HEPA respirator. Another statement by John Dougherty, an electroencephalographic technician, declared that as of July 19, 1994, HEPA respirators were worn during the administration of electroencephalograms to TB patients. (Exh. C-57). Lastly, an EKG/phlebotomist technician, Evelyn Gomez, stated that she used a 3M 8715, a DM respirator (C-59), since June 1993 when treating patients in isolation rooms. (Exh. C-58).

DISCUSSION AND ANALYSIS

The Commission has issued decisions interpreting section 1910.134(a)(2) insofar as the standard requires respirators to be provided for the health of employees. Essentially, the standard demands that the employer provide respirators when a hazard exists which would be mitigated or eliminated through respirator usage. The standard leaves no discretion in the employer to evaluate or determine for itself whether there is a need for respirators in such a situation. Thus, the test the Commission has developed for measuring the extent of the employer's obligation under broadly-worded standards—whether a reasonable person would see a need for the protective measures urged by the Secretary—does not apply with respect to the requirement of section 1910.132(a)(2) for the provision of respirators where a hazardous air contaminant is present. *Pride Oil Well Serv.*, 15 BNA OSHC 1809, 1813, 1991-93 CCH OSHD ¶ 29,807, pp. 40,582-83 (No. 87-692, 1992); *Power Fuels, Inc.*, 14 BNA OSHC 2209, 2213, 1991-93 CCH OSHD ¶ 29,304, p. 39,346 (No. 85-166, 1991). These decisions, however, and the precedent on which they rely, *e.g.*, *Brock v. City Oil Well Serv. Co.*, 795 F.2d 507 (5th Cir. 1986), deal with situations in which *no* respiratory protection was provided. The situation presented here is different because Columbia was providing respiratory protection of some type, and the question is whether the respirators it had selected were of the appropriate kind. Put another way, Commission case law leaving no room for judgement or discretion on the part of the employer addresses the first sentence of the standard whereas the issue here concerns the meaning of the phrase "respirators which are *applicable and suitable* for the purpose intended" (emphasis added) in the standard's second sentence. I conclude that this language is analogous to the broad terminology of section 1910.132(a) which covers a wide

variety of types of protective equipment, *see Ryder Truck Lines v. Brennan*, 497 F.2d 230, 233 (5th Cir. 1974), or to the phrase "*appropriate* personal protective equipment" (emphasis added) in section 1926.28(a). Consistent with the well-established case law interpreting these broad standards, I hold that the burden is on the Secretary to show facts sufficient to place Columbia on notice that the Tecnol masks it was using were not appropriate for protection against TB. *Bratton Corp.*, 14 BNA OSHC 1893, 1896, 1987-90 CCH OSHD ¶ 29,152, p. 38,992 (No. 83-132, 1990). *See Trinity Indus., Inc.*, 15 BNA OSHC 1985, 1988-89, 1991-93 CCH OSHD ¶ 29,889, pp. 40,787-89 (No. 89-2316, 1982) (consolidated) (discussion of Secretary's burden of proof under a standard using the term "suitable"). As the court observed in *Diebold, Inc. v. Marshall*, 585 F.2d 1327, 1335 (6th Cir. 1978), fundamental due process dictates that regulations give adequate warning of the conduct they require. In resolving this issue, I consider not only statements made by OSHA compliance personnel but all of the surrounding circumstances, including such matters as the incidence of injury or illness and industry custom and practice as well as the employer's own understanding of the alleged hazard. *Miami Indus.*, 15 BNA OSHC 1258, 1991-93 CCH OSHD ¶ 29,465 (No. 88-671, 1991), *aff'd in part without published opinion*, 983 F.2d 1067 (6th Cir. 1992); *General Motors Corp., GM Parts Div.*, 11 BNA OSHC 2062, 1984-85 CCH OSHD ¶ 26,961 (No. 78-1443, 1984) (consolidated), *aff'd*, 764 F.2d 32 (1st Cir. 1985).

The inspection at issue occurred, and the violations are alleged to have taken place, during roughly the period from June through November, 1992. The weight of the evidence plainly shows, and I find, that this was a formative period in the investigation and development of measures to protect health care workers from contracting TB. The record well illustrates the uncertainty and conflicting guidance being issued by the various governmental bodies—OSHA, CDC, NIOSH, and the state health department—as well as the efforts of the health care community in general to arrive at an understanding of the type of respirator that would be considered appropriate. The record further reveals a paucity of effort on the part of the responsible entities to provide any assistance or guidance to the health care community in reconciling and evaluating the information and recommendations being provided. For instance, not only did the two OSHA officials intimately involved in formulating OSHA's policy, Bien and Dr. McDiarmid, recognize that the CDC Guidelines were unclear, but their testimony also indicates that health care facilities were not informed as to the

means available for clarifying those guidelines. Moreover, to the extent that health care facilities sought clarification, they were as likely to receive conflicting information in response to any such request.

I realize that Dr. McDiarmid's testimony indicates that if a health care facility had explicitly inquired of the CDC, it would have been informed of a requirement at least for a DM respirator whereas Columbia at the time in question was using a type of face mask. Leaving aside for the moment the question of whether a reference to a DM respirator would have resolved the matter in view of the fact that the 1990 CDC Guidelines generally equated face masks with particulate respirators,[7] I find as a more fundamental matter that Columbia would not have had reason to make further inquiries. I give weight to the fact that Columbia was relying on the manufacturer's representations, which had not been directly contradicted by any other source, that the Tecnol mask was adequate for particles of the size in question, as well as to Columbia's studies of its conversion rates.

In making this finding, I note that there is no question that studies of conversion rates have certain deficiencies. Individuals who have already tested positive may not be a reliable indicator of the extent of a hazard as they move from one work area to another or through the work force generally. There are also differences in the immunological resistances among individuals as well as variations in the number of patients and the severity of their condition. Lastly, it may be difficult to distinguish conversions resulting from occupational exposure. Accordingly, decline in a conversion rate does not necessarily equate to a proportional reduction in the risk of contracting TB in the occupational setting. But nevertheless, as McDiarmid herself testified, conversion rates are entitled to some weight (Tr. 171-73, 266-67), and, as Jessica Sandler, OSHA's pathogens enforcement expert noted, while conversion rates may be considered anecdotal in nature, the CDC itself relies on such data in determining when an outbreak of TB has been

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[7]The October 12 GNYHA memorandum constitutes the first clear guidance to Columbia that the Tecnol mask was not adequate fro protection against TB. The record does not specifically indicate when Columbia became aware of this memorandum.

controlled. (Tr. 1106). Dr. Nardel's view was that conversion rates are the only tool available for documenting the extent of transmission of TB. (Tr. 961, 983, 1029).

Kathleen Crowley, Director of Columbia's Employee Health Service, testified that during the May to December 1992 period the conversion rate based on annual routing testing of staff was 6 percent and 8 percent for the high-risk group which was tested at 6-month intervals. Surveillance of unprotected employees who treated TB patients before those patients were diagnosed as having TB and thus before those patients entered Columbia's TB program yielded a 10 percent conversion rate, and 6 percent converted as self-referrals. The overall rate, excluding Columbia's pool of prospective applicants for employment, was 6.4 percent. (Tr. 1617-25, 1636; exh. R-17). During the first quarter of 1993, which predates Columbia's decision to abandon the Tecnol mask, the conversion rates had substantially declined to, respectively, 4 percent, 3 percent, zero percent, and 3 percent. (Exh. R-18). A 6-month follow-up screening of its house staff alone in December 1992 showed only a 2 percent conversion rate following an overall conversion rate of 8 percent representing the prior 2-year period. (Tr. 1644-46; Exh.. R-42 & R-43). These figures are generally consistent with those given by Lewy, who testified that the overall conversion of rate of 6 percent during 1992 had declined to 3½ percent in the first half of 1993. Lewy further testified, consistent with Crowley, that Columbia's medical house staff has a lower conversion rate than the rest of the hospital employees. Since the medical house staff tends not to live in the immediate local community, Lewy concluded that Columbia's conversion rates generally reflected overall community conversion rates. Referring to figures supplied by the New York City Department of Health (exh. R-26), Lewy extrapolated an incidence rate in 1992 of 118 cases of TB per 100,000 population for the northern Manhattan area from which Columbia draws many of its staff and patients and some house staff and resident physicians. Assuming that 5 percent of conversions will develop the disease, Lewy computed a relevant community conversion rate of 2.4 percent in 1992.[8] (Tr. 1569, 1582-89, 1596).

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[8]The Secretary contends that the community conversion rate is in fact appreciably lower because the 10 percent multiplier representing the proportion of conversions that will result in contracting the disease during an individual's lifetime should be used rather than a lesser percentage when

(continued...)

Admittedly, the conversion rates among Columbia's employees during 1992 were considerably higher than 2.4 percent. However, these rates clearly were declining throughout 1992 and into 1993, a time frame which corresponds roughly to the period in which Columbia first instituted its tuberculosis policy, which included a combination of engineering controls (negative pressure isolation rooms), administrative controls (early diagnosis and isolation of TB patients and periodic testing of employees), and the use of the Tecnol mask. Indeed, Lewy testified that there were no known conversions of employees working in isolation rooms since June 1992. (Tr. 1740). Sandler, who stressed that OSHA placed heavy emphasis on early identification of TB patients, generally approved of Columbia's controls and felt that they did reduce the risk to health care workers. (Tr. 863-64, 890). As Dr. Nardel testified, most risk occurs in open wards before TB is diagnosed; once the appropriate diagnosis is made, and the patient enters an isolation room, the risk of transmission of TB is greatly reduced. (Tr. 991-92, 1002). Based on this evidence, I find that Columbia could reasonably conclude from its studies of its conversion rates that the measures it was taking to control TB transmission to employees were effective.

Nor does the record show that Columbia's knowledge and understanding or standard of conduct was at variance from an overall industry custom and practice at the time in question to use DM or DMF respirators. The Secretary presented evidence of three inspection visits ("trip reports") by CDC personnel to hospitals which had experienced outbreaks of TB. At one of these hospitals, Jackson Memorial in Miami, Florida, health care workers began using DM respirators during the post-epidemic period, that is, as of June 1990. (Tr. 136, 162, 1340; exh. C-16). Two other hospitals in New York City, Roosevelt and Cabrini, differed slightly in respirator usage among health care workers in their post-epidemic periods. At Roosevelt, workers wore Tecnol masks for routine patient care and 3M 1814 respirators during high-hazard treatment until September 1992 when nurses and physicians began using the 3M respirators exclusively when

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[8](...continued)
computing a conversion rate from the incidence of reported cases. *See supra* note 2. I disagree. Since the issue is the likelihood of contracting TB in a work environment, and since the evidence shows that that likelihood is greatest within the first few years following exposure and declines rapidly thereafter, I find that the lower multiplier is appropriate for purposes of this case.

caring for TB patients. At Cabrini, as of April 1991 workers wore "sub-micron masks" during routine care and "particulate respirators" when performing sputum induction or similar treatments. (Tr. 140-41, 160; exhs. C-18 & C-19). As previously noted, however, the hospital association in New York, the GNYHA, had a different view of the appropriate type of TB respirator. Moreover, two of Columbia's witnesses representing other hospitals did not consider use of a particulate respirator to be warranted. In addition to Dr. Nardel, who testified that face masks were used at Cambridge Hospital, Dr. Michael Iseman, chief of the Clinical Mycobacterial Disease Service at the National Jewish Center for Immunology and Respiratory Medicine in Denver, stated that there was no specific policy at that facility other than to provide surgical masks for workers dealing with TB patients. (Tr. 1338, 1355-57). It should also be kept in mind that unlike the hospitals to which the Secretary referred, there is no evidence that the CDC ever conducted an inspection visit of Columbia or that Columbia ever experienced an outbreak of TB sufficient in severity to attract the attention of the CDC.

The above is not to suggest, however, that the respirator requirements for protection against TB remained unclear after the inspection at issue here was conducted. On the contrary, new directives and guidelines have since been issued which definitively set forth the elements regarding the selection of the appropriate respirator and in particular eliminate any inconsistency between OSHA, NIOSH, and the CDC. For instance, on October 28, 1994, CDC published in the Federal Register *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities*, 59 Fed. Reg. 54,242 (1994), which contain an extensive and detailed section addressing "Performance Criteria for Personal Respirators for Protection Against Transmission of *M. tuberculosis*." This section asserts that "NIOSH-approved HEPA respirators are the only currently available air-purifying respirators that meet or exceed the standard performance criteria stated above." It further alludes, however, to revisions in the NIOSH certification procedures under which respirator filter materials would be categorized as types "A," "B," or "C" according to their efficiency, and provides that filters designated as any of those three types would comply with the standard performance criteria specified by the CDC. Lastly, the CDC publication observes that in certain high-risk conditions, such as during bronchoscopies, respirators exceeding the standard criteria may be needed. It refers the reader to information

provided by NIOSH on more protective types of negative-pressure respirators, powered-air purifying respirators, and positive-pressure airline respirators. *Id.* at 54,291. *See supra* text accompanying note 6. The revised NIOSH protocols for testing and certifying respirators have since been published on June 8, 1995. 60 Fed. Reg. 30,336 (1995). Under these new regulations, respirator certification requirements previously promulgated by the Mine Safety and Health Administration ("MSHA") as Part 11 of Title 30, C.F.R. have been superseded by a new Part 84 of title 42, C.F.R. As the preamble to the regulations explains:

> Except for the particulate-filter requirements, most requirements of the existing regulations are incorporated into the new regulations without change.
>
> The certification of air-purifying respirators under the final rule will . . . enable respirator users to select from a broader range of certified respirators that meet the performance criteria recommended by the CDC for respiratory devices used in health-care settings for protection against *Mycobacterium tuberculosis* (Mtb), the infectious agent that causes tuberculosis (TB).

Id.

Even more recently, OSHA itself issued a "revised enforcement policy for respiratory protection for occupational exposure to [TB]." This document reflects both the 1994 revised CDC guidelines and the 1995 revised NIOSH protocols noted above and states as follows:

> Under the new NIOSH criteria . . . . [t]hree classes of filter (N, R, and P) will be certified with three levels of filter efficiency (95%, 99%, and 99.97%) in each class resulting in a total of nine respirator classes. The three classes or levels of filter efficiency include the Type 100 (99.97% efficient), Type 99 (99% efficient), and the Type 95 (95% efficient). NIOSH has determined that any of these classes of respirators meet the filter efficiency criteria of the CDC for protection against TB. Based upon these criteria, the minimally acceptable level of respiratory protection for TB is the N-95 respirator. . . . Until these classes of respirators are commercially available the minimal acceptable respiratory protection meeting the criteria will remain the HEPA respirators. . . .
>
> Respiratory protection (HEPA or respirators certified under 42 CFR Part 84 Subpart K) for employees exposed to TB is required under the following circumstances:
>
> a. When workers enter rooms housing individuals with suspected or confirmed infectious TB.

b. When workers are present during the performance of high hazard procedures on individuals who have suspected or confirmed infectious TB.

c. When emergency-medical-response personnel or others transport, in a closed vehicle, an individual with suspected or confirmed infectious TB.

OSHA Memorandum from John Miles Updating Regional Administrators on TB Enforcement Policy, Dated Sept. 6, 1995, 25 BNA OSHR 584-85 (Sept. 13, 1995).

Without presuming to decide whether Columbia would have been in violation had this guidance and instructions been in effect at the time in question here, I note that the fair notice concerns addressed in this decision do not appear to be present under these revisions.[9]

FINDINGS OF FACT AND CONCLUSIONS OF LAW

All findings of fact relevant and necessary to a determination of the contested issues have been found specifically and appear herein. See Rule 52(a) of the Federal Rules of Civil Procedure.

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[9]Along with his post-trial brief the Secretary moved to amend the pleadings to allege HEPA filters as the appropriate method for abating the alleged violation. As the Secretary correctly points out in his brief, both the Secretary and Columbia adduced evidence pertaining to whether HEPA respirators are the proper type of respirator to protect against TB. *E.g.*, Tr. 331, 987, 1345, 1440. However, it is unnecessary for me to decide whether the suitability of HEPA respirators under section 1910.134(a)(2) was tried by consent. *See McWilliams Forge Co.*, 11 BNA OSHC 2128, 1984-85 CCH OSHD ¶ 26,979 (No. 80-5868, 1984). The question in this case is not the appropriateness of any particular type of respirator but rather whether Columbia could have had fair notice at the time in question of what kind of respirator was considered "applicable and suitable" within the meaning of the cited standard. I advised both parties of my concerns regarding the adequacy of the notice to Columbia when I ruled at the hearing that the Secretary would not be permitted to litigate matters that arose after the violation was alleged to have occurred. Tr. 118-23).

ORDER

Based on the Findings of Facts, Conclusions of Law, and the entire record, it is hereby ordered:

1) Item 2 of citation no. 1 is vacated.

2) The settlement agreement submitted by the parties as to the remaining items of the citation is approved, and the disposition set forth therein is incorporated as part of this order.

IRVING SOMMER
Chief Judge

DATED:
NOV 24 1995
Washington, D.C.