HCB

File
X-rays

Dear,
Thought you might find
some use for this
Tom

Meeting of the

ORC OCCUPATIONAL SAFETY AND HEALTH PHYSICIANS GROUP

in Pittsburgh, Pennsylvania

October 2, 1979

OCCUPATIONAL LUNG DISEASE, X-RAYS AND THE OSHA FORM 200

PLAINTIFF'S
EXHIBIT
AL-1686

The Necessity For Scientific Criteria

If one had to sum up in one sentence the main message that the physicians assembled in Pittsburgh gave to OSHA, it would be the following: "The most important single thing to emphasize is the necessity for the use of scientific criteria for the judgment of the existence of occupational disease." This point was made in many ways by many different people as well as the corresponding point that the substitution of political judgment for scientific judgment causes distortions that assume a life of their own.

A good example of the substitution of political standards in place of scientific judgment can be found in the history of the Black Lung Program where the medical criteria for entrance into the program has been lowered to the point that it has become, in essence, a social not a medical program! By some estimates, as few as 15% of the patients seen really meet a reasonable criteria for silicosis in a program that costs around one billion dollars per year.

An Agency's Mandate

Part of the problem that we see in occupational medicine comes from requirements that are written into an Agency's Act, requirements that say, as the attorneys are quick to remind them, that there shall be essentially no risk! No Exposure!

A Physician May Be An Anachronism

Under the modern approach to the enforcement of standards, and the determination of illness and injury, diagnosis is no longer made on the basis of a physicians judgment, but on laboratory tests. Under the zero risk, zero exposure regime with ever lower PELs, the whole game is winding up in the hands of the regulatory agencies; all that can be done now is to monitor and eliminate!

The Importance of Maintaining High Standards

It is more important than ever that occupational physicians continue to maintain high standards, to push for more research. For example, we have the problem that an individual who shows up in category 1 may 3-4 years later show up in category 2 or 3. This can be understood, but what about the large number of persons who go back to zero? We should be looking for the answer to why this happens, but if we wait for the epidemiologists to find it, we have a long wait! Epidemiologists are for the most part part not concerned. They see it only as an anamoly! It is the physicians who see these people that must push for the research to determine what is behind this phenomenon.

The Subjectivity of Judgment

Reading x-rays is a very subjective activity with many variables that can affect the outcome of any individual film reading. Whether a particular film is 1/0 or 0/1 depends

on many technical factors and two films taken on the same day, same place, with the same person can in fact be different if a different technique for shooting the film is used!

Double Reading X-Rays When Making A Diagnosis

In some situations it has been shown that 25% of lung cancers ultimately shown to have been present in an x-ray were missed when read by only a single person. When two persons read the same films, the miss rate was cut in half!

The Usefulness of Old Films

The presence of old films of an individual would be of great usefulness to those who must make a decision as to what a certain film says, but in most cases these are not available! The existence of old annual x-rays, it was pointed out, is of great value in clinical practice and many clinicians would be reluctant to make a judgment without them.

Usefulness of the Annual X-Ray

The question was asked repeatedly, does the annual x-ray really add anything to the diagnosis since this film is often not available to those doing the reading? Many thought that the annual x-ray did not really serve the employee well because it does not do anything for prevention. OSHA is very much concerned with the frequency of x-rays, since it has several standards that require them. OSHA hopes

in the future to have hearings on the usefulness of annual x-rays in view of the required exposure to ionizing radiation. OSHA felt that you probably cannot justify the use of annual x-rays for asbestosis, silicosis, etc., for most young people; because it is only after 10-15 years of exposure that lung changes will begin to show up on x-ray films.

What should be done when because of difficulty in obtaining a good film a worker must be filmed 6-7 times before a good shot is obtained? This is a big problem, and there is some question as to whether additional regulations can really address it. The place where the annual x-ray is felt by some to be most useful is precisely in those cases where the illness may have a long gestation period and where it may be necessary to go back to earlier films in order to make the most accurate possible diagnosis determining when the change really started. In this regard, preemployment films may be of some usefulness in ascertaining the condition of the lungs before beginning employment at a particular establishment.

The real key to the debate over the annual x-ray is found in the practice of tailoring the x-ray program to the individual concerned. This way the total dosage of radiation can be reduced, but we may still be able to retain a series of films for comparison when making a difficult diagnosis. The bottom line in x-ray diagnostics is mortality. If you cannot lower that, then no early detection system is any value. The man who says that by the time you are able to see cancer on an x-ray, it is already too late, is usually wrong! Some kinds

of lung cancer can be handled in such a way so as to prolong life if found early enough. Some clinicians feel that far from being used too much the regular x-ray, if used more often, could find more lung cancer and perhaps save more lives.

Screening Programs

While screening programs can be useful, so far they have not shown that they can cause a significant reduction in mortality. Also, screening programs Sputum Cell Cytology usually find squamous cell cancer, but a proper x-ray should find such a cancer first!

The kind of situations where a screeing program can be of most use would be one aimed at a man or woman, 45 years old, who smokes one pack a day or more of cigarettes. For this individual, such a program may be useful; but for most industrial occupational situations so far studied these programs have not proven to be better than x-rays.

Other Diagnostic Aids

We must not forget in the debate over x-rays that they are just one of many aids to diagnosis that are available. It is a mistake to rely on x-rays alone. For instance, in Brown Lung the x-ray is of less usefulness than with other diseases, but other tests are more valuable. Brown Lung is also associated with some chemical exposures and many would be interested in knowing what diagnostic criteria OSHA thinks should be used in these cases. Many in the textile industry do not find an increased incidence of Brown Lung to match the published incidence!

ILO Classification

The ILO Classification was designed for use by epidemiologists, and according to some, its use in isolated diagnosis is dangerous because it ignores all of the other aid to diagnosis. OSHA feels that the ILO-UC Classification's primary benefit is to aid in standardized reading of abnormalities, which is not to say that it does not have its problems because it does; but it is a beginning, a start! We may not want to classify all films, but with or without a standard, every reader still does just that. The ILO Classification System is an aid in the grey areas when making a decision.

What Is A Normal Film?

This is a very basic question and part of the ILO-UC Classification was very badly done while it was being developed. The hardest question of all is to determine what is normal and what is not! Part of the trouble comes from the fact that all of the facilities do not use the same technique, equipment, developing procedures, etc.

OSHA Form 200

This was developed to enable the Labor Department (Bureau of Labor Statistics) to have a record of accident, illness and injury occuring in the workplace. OSHA feels that it is good for the worker and for OSHA to identify potential problems that might otherwise be overlooked and that it promotes better communication between workers, the company and OSHA.

What Is Recordable On Form 200?

One of the most important points to remember according to OSHA, is that putting an illness on Form 200 does not mean that a diagnosis has been made! Other supplementary information is necessary; and if subsequent information shows that the disease is not an occupational one, the entry should be crossed out! It is not such that in the light of new evidence it cannot be changed.

A pre-existing abnormality on an x-ray in a pre-employment film does not have to be entered on a Form 200. However, for an illness of long gestation, you should go back to the earlier x-rays and look for the first signs of disease and when found, record them, noting the process by which the decision was arrived at.

Once an injury is found you do not need to record it each year, unless there have been additional exposures and more changes in the films. If there has been additional exposure and more change in the film, then the old entry should be updated. The problem is that if the same illness in the same individual results in multiple entries, it skews the accuracy of the whole system toward more illness. OSHA says that in such a case one may go back and modify the original record. Again, OSHA emphasizes that, when an entry goes on the Form 200, it is a suspicion; not a set diagnosis!

Do All Findings Have To Be Recorded?

If, for instance, some pleural thickening is found upon taking an x-ray, should this be recorded on the Form 200? OSHA answered that there is no problem in not recording this finding if it is not clear, but if at some later date it becomes clear that there is a problem related to a known exposure, then it should be recorded on the Form 200. In the end analysis, it is the decision of the physician as to whether or not there is any illness associated with the condition in question, however, the physician should be prepared to support whatever decision is made. The physician making the original diagnosis should be able to say that all of the best practices were followed and prove it!

Recording Signs and Symptons

The question was asked repeatedly as to whether one must record on the Form 200 all signs or symptons of illness as well as actual illness. OSHA answered that if the signs and symptoms are due to an abnormality due to exposure to a known agent, for instance, asbestosis then they should be recorded. It all depends on a known exposure and known symptoms related to such exposure!

Surveillance Required Under A Standard

Under these conditions, only those findings related to required surveillance need to be recorded. For instance,

if you should find high blood pressure in a worker that can be related to exposure to a known substance, it need not be recorded if there is no requirement for such in that standard. Since the blood pressure of all workers may not be monitored, it is not accurate or representative and should not be recorded for that standard.

Past Exposures and Present Illness

If you should learn that an illness in a worker is related to a past exposure that is no longer present, the illness should be recorded as beginning with the first time-lost incident that can be attributed to exposure to such substance.

Problems With Chronic Bronchitis

In a worker with this problem, when does such a condition become an occupational illness? OSHA answers that it becomes an occupational illness if there is a reasoned suspicion of exposure to a substance that can cause such conditions; for instance, asbestosis. Then it should be recorded. If you have a strong suspicion that an abnormality found on examination of an individual is related to occupational exposure, you have a duty as a physician to report such suspicion to the individual concerned.

Smoking and Asbestosis

If one should find an abnormality in an individual who is a known heavy smoker and who may possibly have had some unknown degree of exposure to asbestosis should this be recorded? If upon examination of the work history of this same individual, it is found that there was little chance for an exposure to asbestosis, should it still be recorded? OSHA answers: If an abnormality exists and if there is a reasonable assumption of such exposure, then it should be recorded. The employer has a responsibility to tell the worker the whole range of possibilities related to his diagnosis. If the physician is in some doubt as to the diagnosis, use should be made of the Form 101 and supplementary information recorded that gives all details of a suspicious case. It may turn out to be something other than what was first thought, but in any event all possibilities have been covered.

Presumptive Versus Proven Findings

There is a real problem in including presumptive findings along with proven fact in the same form. We are in fact injuring an employee by listing him or her on a Form 200 when it is only a suspicion. There can be a variety of psychological effects on the worker and the employer has in effect assumed responsibility for such disease and this cannot be eliminated even if the cause of the original suspicion disappears! OSHA says that the

Form 200 is not to be used for compensation and that the decision is to be made from supplementary information included with the Form 200.

Changing the OSHA Form 200

Yes, it can be changed, but it would be extremely difficult! There are many problems involved, and in any case the Form 101 should be used for putting down data that is only suspicious, not proven. For instance, Sputum Cell Cytology would probably not be recorded on the Form 200.

Importance of Good Equipment

It is very important to have good equipment operating up to optimum performance levels. Poor maintenance of equipment and improper technique can cause a high rate of bad films. Recently, OSHA said it found one plant where 40% of the x-rays examined were unreadable because of a combination of bad equipment and poor technique.

For instance, the ratio of beam area to film area for many x-ray setups is 60% larger than the film which means in some cases excessive exposure and often a poor film! It has been shown that some 11% of all films are so bad that they must be repeated.

FDA-Bureau of Radiological Health (BRH)

Jim Morrison of the BRH discussed with the group some of the programs that are available to the public in various areas dealing with radiological training, diagnostic radiology, nuclear medicine, quality assurance for equipment and others.

Additionally, Mr. Morrison distributed a listing of topical publications that are available from the BRH. For the information of those who may not have been present at the meeting, I have included here the listing of available publications. All that is necessary is to write to Mr. Morrison at the following address and indicate which of the publications is desired.

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DKM:jt
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