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Sent: Tuesday, May 06, 2003 4:07 PM
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Cc: Daniel McKeel
Subject: Comments on Proposed Rulemaking SEC and EEOICPA

To: NIOSH Docket Officer

From: Daniel W. McKeel, Jr., M.D.

Date: May 6, 2003

Subject: Comments on notice of proposed rulemaking
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The following comments are submitted per instructions in the Federal Register accompanying the March 7, 2003 proposed rule:

**Comments Of Daniel W. McKeel, Jr., M.D.
regarding the HHS Notice of Proposed Rulemaking
for Designating Classes of Employees as Members of
the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of
2000 (42 CFR Part 83), Federal Register Vol. 68, No. 45, pp. 11294-11310 (March 7, 2003)**

Below are my comments on the March 7, 2003 NIOSH Notice of Proposed Rulemaking Procedure for Designating classes of employees as Members of the Special Exposure Cohort under EEOICPA, 68 FR 11294-11310, March 7, 2003.

As a departure point, I want to strongly endorse all of the comments on pages 1 - 14 made the Government Accountability Project (GAP) which have been submitted separately. I am not affiliated with GAP in any capacity, however, I do share many of their views and applaud their scholarship and long-term interest and constructive participation in this important rule making process. In particular, I share their misgivings in both the way the scientific and Congressional underpinnings of the NIOSH proposed rule are being interpreted by both NIOSH and the Health Physics Society. I have come to these conclusions in my roles as a physician and experienced human and experimental pathologist and neuropathologist on the full time faculty (tenured Associate Professor of Pathology and Immunology) of the second-ranked U.S. Medical School, Washington University School of Medicine in St. Louis, Missouri.

My interests in this proposed rule are as an informed citizen with a long-time interest in having our country, and responsible government agencies such as DOE, address the medical harm suffered by scores of present and former workers who are now included in the EEOICPA 2000 legislation. My particular interest is in helping to secure Special Exposure Cohort (SEC) status and assistance for the former workers of the Uranium Division, Mallinckrodt Chemical Works (MCW), at their three original plants that processed enriched fissionable uranium, thorium and nuclear reactor fuels:

(a) at the downtown (Destrehan Street) plant; (b) at the Weldon Spring Nuclear Feed Materials (³Chemical²) plant in St. Charles county, Missouri;

(c) and at the Hematite, Missouri nuclear fuels facility. All three of these operations could and should be considered as one facility, because many of the approximately 3,700+ workers cycled among the various plants. Site (a) is an active FUSRAP site and site (b) is a CERCLA (Superfund) remediation site. E. Dupree-Ellis and co-authors have documented excess kidney disease and several cancers in 2,542 white male former MCW workers (Am J Epidemiol, July 2000, see full citation below). NIOSH also completed a health study on these workers in 1998. MCW workers are covered under EEOICPA.

I have been intimately involved for the past three years as a concerned citizen-participant in the CERCLA (Superfund) remediation of the Weldon Spring Site. More recently, I have been assisting former MCW workers and their survivors as a medical adviser to the United Nuclear Workers of the St. Louis Region (UNWSLR), a former MCW worker advocacy group (not a union). In this latter capacity I have become very familiar with the

difficulties these EEOICPA-targeted people are having getting dose reconstructions done and in gaining access to crucial medical records through NIOSH and DOE. This is extremely difficult to understand and is highly regrettable and deplorable performance by the concerned agencies, constituting a direct affront to the clearly stated Intent of Congress when they passed EEOICPA legislation in 2000.

That was, as put forth in the GAP comments on page 11 of 14: ³...the essential aim of the statute (i.e., timely compensation) ...² Clearly the ³timely² aim goal has not been met.

My comments concern former MCW workers, specifically and to other covered worker cohorts in general. The three major specific concerns with proposed NIOSH rule and SEC Special Exposure Cohorts, in addition to agreeing with the GAP comments and concerns, are as follows:

[COMMENT #1] AS ADDRESSED ON PAGE 11, SECTION 3 BY GAP AS A REASON RECONSTRUCTING A DOSE MIGHT BE INFEASIBLE: ³Finally, it might take too long...² My contention is that MCW dose reconstructions have already taken far more time than is reasonable in view of certain facts concerning the potential former MCW worker potential SEC.

(a) Radiation exposure doses for more than 2700 former MCW workers were published in abstract form in 1980 in the American J Epidemiology by Dr. Dupree-Ellis.

(b) Peer reviewed data for radiation exposure and mortality summary data with instructions how to access the primary data sources on 2,542 former MCW workers were published in the May, 1999 issue of the Comprehensive Epidemiologic Data Resource (CEDR) catalog by U.S. DOE. MCW data appears in summary form on pages A46-A47 and B55-B58 of the same catalog. The data sets [MCW_BRTHRDON, MCW_FB, MCW_URIN, MCW_X-RAY, MCD94A01] are available to qualified users and in anonymized form in electronic form. By making this data available, DOE by definition acknowledges that the radiation dosages for the MCW former workers that are included in the UNWSLR membership are already available. Hence minimal or no dose reconstruction time or effort should be required by NIOSH staff other than accessing the DOE-owned and controlled CEDR datasets and linking to individuals. This should be very straightforward and easy to accomplish.

(c) DOE/OARU-associated investigators led by Dr. Elizabeth Dupree-Ellis and her colleagues have published much of the MCW ³Mallinckrodt² external radiation dosage and mortality former worker data [Dupree-Ellis E, Watkins J, Ingle JN, Phillips J. External radiation exposure and mortality in a cohort of uranium processing workers. [Journal Article] American Journal of Epidemiology. 152(1):91-5, 2000 Jul 1]. NIOSH, in fact, presented a preliminary report of this Dupree-Ellis data to MCW workers in St. Louis in 1998. Obviously, the key agencies had the relevant radiation exposure data 4-5 years ago. This would not be unreasonable realizing that Weldon Spring site uranium production operations concluded thirty-five years ago in 1966! One assumes published data by OARU, DOE and NIOSH are both accurate and complete, inasmuch as no disclaimer to this assumption appeared in the peer-reviewed publications I am aware of. In fact, missing data was not discussed at all in the July 2000 Am J Epidemiology paper. Ergo, one can assume that little or no MCW data was actually missing in 2000. Why and where, then, has the MCW dose data apparently either disappeared or become inaccessible to those who need and have a legal right to have it?

Why then also, have (to date) no EEOICPA claims from MCW former workers been compensated? On the contrary, there are numerous examples known to me of MCW workers and their survivors being told by DOE or NIOSH or Mallinckrodt that they or their relatives never worked for Mallinckrodt or the contractors, their medical records have been lost, their dosage data is not available, and many other implausible excuses for the agencies failing to remit their properly (FOIA/PA, EEOICPA forms) requested personal data in a timely, EEOICPA-compliant fashion.

Logically, there must be one of several explanations: (a) the agencies that keep the records, i.e., DOE and/or NIOSH, are deliberately withholding them; (b) record keeping is very disorganized so the records are truly not accessible even to the agencies who have lost or misplaced them; or (c) the data reported in CEDR and the American J of Epidemiology by Dupree-Ellis and colleagues is other than as stated. Else, MCW radiation dose exposure information clearly IS available RIGHT NOW as an electronic data set that requires only the anonymous data set ID to be linked to specific Social Security or other information source that identifies individuals; some of these sources used already are in the Dupree-Ellis 2000 article.

I agree with GAP's suggestion that 180 days is adequate time to allow for a dose reconstruction to be made. However, in the MCW former white male worker's cases (at least 2,542 of them, at least), the radiation doses received are already available in the above mentioned sources. Thus, no dose ³reconstruction² should be

necessary since that was already done to get the data ready for the CEDR catalog and the Dupree-Ellis publications mentioned above. If there is something wrong with my logic, I would be pleased to hear of where my understanding and logic is in error.

[COMMENT #2] CONCERN WITH EXCESSIVE TIME ALREADY SPENT REACHING A DECISION WHETHER OR NOT DOSE RECONSTRUCTION CAN BE DETERMINED FOR FORMER MCW AND OTHER EEOICPA-COMPENSATED WORKERS:

a) First, I want to echo GAP's statements on page 11 of their rulemaking comments that a modified no-threshold linear risk model is the accepted international standard. Medical-scientific evidence for hormesis having a significant modifying effect on the no threshold model is very limited, and it is not clear at all how, or if, any of these postulated 'beneficial' repair mechanisms affect HUMAN radiation-induced carcinogenesis dose-response curves.

b) Second, NIOSH and the Health Physics Society (HPS) place undue emphasis on virtual modeling, maximum dose 'estimates' (e.g., dose capping) and other semi-theoretical constructs rather than hard data on actual radiation doses given and received by actual people. This is the ONLY credible exposure data in the long run. As stated in my first concern, there is considerable reason to doubt the accuracy and validity of radiation dose estimates for (at least) the former MCW workers. It is not possible to determine a priori, without organ radioactivity analyses and real (as opposed to virtual) measurements using many simplifying assumptions, where particular radionuclides will end up over time being distributed among the bodily organs in specific concentrations, as NIOSH and HPS imply can be done.

I must add a friendly reminder to those in NIOSH that physicians, specifically MD-oncologists, have the sole legal authority to order that radiation treatment be carried out for cancer treatment in today's best hospitals. Anesthesiologists, for example, may be licensed physicians, however their hospital staff privileges do not include administering curative treatment for cancer patients. Health physicists are necessary and valuable members of the care team. However, they cannot make medical diagnoses, prescribe treatments by themselves, or administer medications unless they have also graduated from medical school and been licensed by state Boards to practice medicine and surgery AND have the requisite hospital staff privileges. In my opinion, therefore, NIOSH should place far more reliance than it has done thus far, in the opinions of acknowledged expert medical and radiation MD-oncologists in considering and implementing EEOICPA regulations and the proposed NIOSH rule for assigning Special Exposure Cohort status to atomic industry workers.

c) The 10 REM threshold recommended by HPS must be viewed as serving some other inapparent agenda (expediency, service to their employers?) than scientific truth. The suggestion is simply not sustained by any available scientific evidence.

d) The epidemiologic-statistical way of looking at risk of cancer development due to nuclear/atomic weapons industry exposures may not be the optimal or correct way to evaluate EEOICPA compensation claims. Congress had the wisdom in 2000, as GAP does now, to note that such methodology might cripple the real Presidential (Bill Clinton's) and Congressional intent to provide DECADES OVERDUE compensation to workers whose basic rights to know about, and to be protected from, harm to their health. As understood today by Institutional Review Boards for human research, former workers health and safety rights were knowingly and grossly violated to the great detriment of the workers and their survivors. This is the 'heart and soul' consideration that underlies EEOICPA legislation. Rather, the old truism among practicing medical doctors should be heeded. That is, to individuals, statistical statements such 'your chance of getting pancreatic cancer are 1 in 10,000' are meaningless when the patient confronts their oncologist who has just told them that pancreatic cancer is present. The statistical chance for that person developing pancreatic cancer is 100%!

[COMMENT #3] THE ORIGINAL CONGRESSIONAL BASIS FOR ACKNOWLEDGING ONLY 22 RADIATION-INDUCED CANCERS FOR EEOICPA COMPENSATION, AND NIOSH'S AND THE HEALTH PHYSICS SOCIETY'S ATTEMPT TO FURTHER LIMIT THIS LIST FURTHER IN THE CURRENT PROPOSED RULE, IS SUBJECT TO CHALLENGE ON MEDICAL-SCIENTIFIC GROUNDS. The very concept of 'radiosensitive' and 'radioresistant' tissues in cancer causation is itself open to serious challenge in the context of EEOICPA. It only becomes an issue since DOE and NIOSH have so much trouble reconstructing accurate radiation doses, requiring them apparently to feel a need to limit economic liability under EEOICPA, an obscure mandate indeed that does not appear to be the intent of the legislation. Radiation can cause different types of cancer in almost (made every) organ and tissue type in the body -- that is established incontrovertible scientific fact documented in thousands of peer-reviewed

publications.

Radiosensitivity is a relativistic-probabilistic concept that I believe has little intrinsic merit in the context of a clear Congressional intent under EEOICPA. Yes, I am implying that Congress (unintentionally possibly) imposed unnecessarily arbitrary limits on its own legislation, and that this perhaps well intentioned short-sightedness should not be further compounded in the NIOSH proposed rule-making by more severely limiting compensable cancer types. Broad classes of cancer such as "lung cancer" should be construed broadly to include the major and minor subtypes since ALL of them can be caused by radiation, albeit with varying frequencies in a radiated population due to inherent genetic and perhaps other environmental influences.

If a former worker develops a rare cancer of "radioresistant tissue" origin that metastasizes widely, is that less a problem for him than if he/she develops a "acceptable cancer" from the Congressionally-mandated "fixed list" of 22 in his "radiosensitive" organ? Both cancers can maim or kill equally, both metastasize, both cause pain and suffering and lead to huge medical costs (dwarfing the \$150,000 award under EEOICPA) -- is this not the relevant point?

I totally agree with GAP that no rationale exists why NIOSH has any legal or moral or ethical right to further restrict the fixed list of 22 compensable cancers. It is likely that many radiation-associated cancers are, in fact, multifactorial in etiology. Radiation is one necessary factor, but individual susceptibility is determined by genetic inherited factors as well as other environmental/chemical toxic exposures (smoking included) which may add or synergize with radiation as a causative factor. These complex associations are just beginning to be unraveled in the laboratory and in the clinic. Much is not known.

The key point here is that the cancer would not have developed were it not for the additional workplace radiation exposure the worker received. In the still-ongoing Hanford nuclear worker class action lawsuit, the important legal principle was affirmed by the court that it is not necessary for claimants to establish that their particular cancer was caused by radiation. It is sufficient to establish the person worked in a higher-than-normal risk radiation exposure environment where cancer causation is likely. In other words, it is a legal and medical "given" that radiation causes and increases the risk for developing cancer. That should be enough to rebut and have NIOSH rescind any attempt to further limit the original list of 22 compensable cancers under EEOICPA. The scientific factual information is not available to them (or anyone) to do so fairly, equitably and wisely. If NIOSH is allowed to limit the list of compensable cancers further, this will establish major inequity between existing SECs and those who seek to qualify to become an SEC.

Thank you for allowing the public, and me, to participate in the rule-making process for this very important piece of legislation.

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