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PUSH TO GET EXCEPTIONS, ADJUSTMENTS FOR CLINICAL RESEARCH IN DRG REGULATIONS GAINING MOMENTUM

The effort to win support in Congress and the Administration for cancer clinical research related exceptions and adjustments to the impending Diagnosis Related Group reimbursement regulations was picking up momentum this week:

—The first wave of what may turn out to be a flood of letters from

(Continued to page 2)

In Brief

KRAKOFF TO HEAD NEW M.D. ANDERSON DIVISION, TWO OTHER APPOINTMENTS MADE IN REORGANIZATION THERE

IRWIN KRAKOFF, director of the Vermont Regional Cancer Center, has been named head of the new Div. of Medicine at M.D. Anderson Hospital & Tumor Institute. Krakoff's appointment, which takes effect Sept. 1, follows two other appointments in a reorganization announced by Univ. of Texas Cancer Center President Charles LeMaistre. The new division is composed of four existing departments: Cancer Prevention, chaired by Guy Newell; Clinical Immunology, chaired by Evan Hersh; Developmental Therapeutics, chaired by Emil Freireich; and Internal Medicine, chaired by Thomas Haynie. Eugene McKelvey, who directs the Cancer Information Dissemination & Analysis Center for diagnosis and therapy which screens literature for NCI's International Cancer Research Data Bank, has been appointed associate vice president for research. He will be responsible for insuring that all clinical research programs meet the regulations of both M.D. Anderson and outside regulatory bodies, Frederick Becker, VP for research, said. McKelvey will continue to run the CIDAC operation. Also, Athony Mastromarino was named assistant vice president for research. Krakoff has been professor of medicine and pharmacology at the Univ. of Vermont College of Medicine since 1976, along with his duties at the cancer center, and will hold those appointments at the UT Cancer Center. . . . **THADDEUS DOMANSKI**, who has been at NCI for more than 16 years, currently as chief of the Chemical & Physical Carcinogenesis Branch in the Div. of Cancer Cause & Prevention, will retire Aug. 1. DCCP Director Richard Adamson has suggested that Domanski's friends and colleagues may wish to contribute letters for a volume being compiled for presentation after his retirement. They should be addressed to Domanski and sent to Mrs. Marjorie Suttora, NCI, Landow Bldg. Rm. 8C29, Bethesda, Md. 20205. . . . **DANIEL GRISWOLD** has been appointed director of the Chemotherapy Research Dept. at Southern Research Institute. He succeeds Frank Schabel, who has retired from administrative duties. . . . **JOHN INGALL**, medical director of the Michigan Cancer Foundation, has been elected to a four year term as chairman of the Executive Board of the London based World Federation for Cancer Care.

DEVITA: IT WOULD BE NICE TO HAVE EXCEPTIONS, BUT MORE DATA NEEDED

(Continued from page 1)

members of the Assn. of Community Cancer Centers hit Washington, pleading with the Health Care Finance Administration to heed congressional intent in the legislation creating DRGs to make special provision for institutions involved in clinical research, and asking Congress to make certain its mandate is being carried out.

—ACCC members were preparing to buttonhole their representatives when they return home for the August congressional recess, and were initiating discussions with congressional staff members.

—Members of the National Cancer Advisory Board were due to receive this week copies of the resolution drafted by the Board's Committee on Cancer Control & the Community. The resolution asks HCFA to establish institution specific rates for comprehensive and specialized cancer centers with NIH peer reviewed core grants or clinical program project grants, and to establish rates at least double the average reimbursement for cooperative group members and Community Clinical Oncology Program institutions. The resolution would require those institutions to contribute at least 25 patients a year to protocol studies to be eligible for the special rates. NCAB members were asked to vote on the resolution by mail within seven days of receiving it.

ACCC's position differs from the NCAB resolution in one respect—the association is asking for the double reimbursement rate for all hospitals with oncology units and which contribute at least 25 patients a year to clinical research.

As evidence of the intent of Congress to permit exceptions for institutions involved in clinical research, ACCC dug out from the *Congressional Record* a discussion between Sen. Quentin Burdick (D.-N.D.) and Sen. Robert Dole (R.-Kan.) during debate on the bill which included the provision which says the HHS secretary "may" make those exceptions and adjustments:

Burdick: I hope we can clarify a concern I have about the Diagnosis Related Groups, or DRGs. I am concerned that the proposed system will not take into consideration the costs at those institutions which have research costs associated with the care of their patients.

As you may know, the Senate Appropriations Committee, on which I serve, has a long history of supporting community based cancer centers. In fact, the Labor-HHS Appropriations Subcommittee has included report language in two of the last three years directing the National Cancer Institute to continue this effort. In part because of this interest, the Institute is establishing closer links between community physicians and hospitals and the larger cancer centers. Two examples of this outreach are the regional cancer research groups and the Community Clinical Oncology Program. These kinds of programs are allowing patients at the local level to participate in and benefit from NCI research. In the upper Midwest, we have a fine program developing in which community based physicians and hospitals are involving their patients in cooperative research programs which benefit not only the patients, but the larger body of medical knowledge. This research does not involve excessive additional costs, but it sometimes requires a greater intensity of care, more careful monitoring, additional testing or slightly longer hospital stays.

I feel strongly that this kind of cooperative, community based research should continue so that citizens from all parts of the country can share the benefits of NCI research. I would hate to see the prospective reimbursement system limit this or reduce the opportunity for participating for medicare patients. I would hope that the secretary will have the flexibility to recognize the additional research related costs that may be involved in these cases, and that she will have the authority to make appropriate adjustments for them.

Dole: I fully understand your concerns about this and share your belief in the importance of community based research. We have no intention of discouraging legitimate research from taking place. Under the terms of our bill, the secretary will have the authority to take the intensity of these cases into consideration in making the adjustments to the standard DRGs.

The issue is not whether the secretary has the authority to make adjustments but whether in fact that authority will be used to permit continuation of cancer clinical research.

In what may have been a trial balloon, HHS informally advised NIH last month that it was considering making either no exceptions or extremely limited ones. That would constitute abandonment of the secretary's discretionary authority and ignoring the intent of Congress.

ACCC, and perhaps other organizations as well as individuals, have been gathering information on the cost of cancer care and patient costs involved with clinical trials, as ammunition to convince HCFA, the HHS secretary, and members of Congress that they have a case for exceptions or adjustments.

NCI executives have cited the need for more information on costs before going along with either the NCAB resolution or the ACCC position. Director Vincent DeVita repeated that concern this week.

"Until we see the data, we can't assume (DRG reimbursement) will not be adequate," DeVita told ***The Cancer Letter.*** "There are a lot of unknowns. We need a lot more information than we have now."

DeVita said he agrees that "the concept of DRGs is not bad. It is unrealistic to expect that it will be implemented in a perfect way the first time around. However, I don't believe that it will be harmful to cancer patients or cancer research. My inclination is that it would be nice for all institutions involved in clinical research to have exceptions."

DeVita said he did not agree that the financial impact on clinical research would amount to billions of dollars. "I've heard those figures being tossed around, and they are outlandish." He said that "we've always accepted what third party payers have paid" for patient care when the patients are entered on NCI supported protocols. When the protocols call for additional steps above standard care, NCI pays those additional costs. DeVita said he expects that practice to continue with DRGs. "I happen to think that routine cancer care is halfway technology, it is labor intensive and costs are unpredictable."

In discussing DRG issues with HCFA and with HHS, DeVita said, "I haven't found anyone to be intractable, but there are a lot of unanswered questions."

It was suggested by HCFA officials in discussions with ACCC and representatives of the Assn. of American Cancer Institutes and the American Society of Clinical Oncology that if clinical research increases patient care costs above that of the average, then NCI should pick up those additional costs.

"If clinical research is the reason costs go up, then we do pay it," DeVita said. However, "if the costs are underestimated (and the difference between the reimbursement and actual costs is due to that underestimation and not to research), we do not."

As for paying any additional money for clinical trials, "we can't absorb any increases," DeVita said. "Our budget is stretched as thin as it can be. If we find ourselves in a hole (as the result of DRG limits), that possibly could make the case to get exceptions."

What about going to Congress for a supplemental appropriation to pay for additional clinical research costs imposed by DRG?

NCI knows what the cost of doing clinical research is. If DRG reimbursement does not pay the full cost of patient care, that would be due to a miscalculation, DeVita said. Payment for those costs "should be from the agency which is supposed to fund it," namely, HCFA.

DeVita said he did not think DRG is a threat to CCOPs, although it possibly could hamper them in their efforts to become involved in clinical research, perhaps more than other institutions because of their relative lack of experience.

Some disagreement exists, even among some ACCC members, over the severity of the threat.

John Travis, Topeka radiotherapist and a member of the ACCC board, strongly disagreed with the NCAB proposal of limiting exceptions to institutions with NIH grants or recognition. Along with colleagues from St. Francis Hospital, Travis sent this letter to HHS Secretary Margaret Heckler:

"A great many of us in community cancer practice are deeply concerned that the Health Care Financing Administration will misapply your authority to except from DRG guidelines certain costs of clinical cancer care and research. Proposed regulations could create a situation in which large numbers of cancer patients were deprived of needed access to modern care and support.

"Several years ago, there was a national initiative to coordinate, organize, and concentrate expensive facilities and scarce technical and professional skills in selected institutions within a given area or region. Our institution, among others, responded in what we believed to have been an exemplary manner: St. Francis Hospital and Medical Center assumed the burden of space allocation, capital investment, and personnel support to sustain the enrollment of 1,300 new cancer patients annually and the treatment with radiation therapy of approximately 1,000 patients per years as the regional resource for such treatment. Now the spectre has been raised that new federal reimbursement regulations will not recognize these added specific costs except in those relatively few institutions designated as comprehensive cancer centers or Community Clinical Oncology Program centers by the National Cancer Institute; these categories of institutions comprise only a fraction of the community hospitals and centers offering state of the art, sophisticated cancer patient care in the U.S. today.

"The Assn. of Community Cancer Centers, the American College of Surgeons, the Patterns of Care Study of the American College of Radiology, the American Society of Therapeutic Radiologists, and the American Society of Clinical Oncology are worthy organizations, each capable of offering a major contribution to reasonable standards by which community cancer programs can be effectively judged. We urge you to look toward this broader perspective in setting criteria for reimbursement in this area. We do not believe that either the National Cancer Institute or the Health Care Financing Administration possesses the capability to fairly and effectively dictate or regulate by reimbursement the practice of cancer medicine or to control the access to such care."

On the other hand, Herbert Kerman, former ACCC president and still a board member, and principle investigator for the CCOP in Daytona Beach, said he was "not really worried" about the DRG impact on his CCOP.

The impact of DRG reimbursement will "depend on your mix of patients and on the number of Medicare patients you have," Kerman said. If necessary,

patient workup could be adjusted to use less expensive procedures."

Another current member of the ACCC Board said he doubted that DRG in the long run would adversely affect cancer care or clinical research. "We're paying far too much now for drugs. Maybe if we simply told the pharmaceutical companies that we aren't going to buy any more adriamycin or whatever from them unless they cut the cost in half, they just might do that. If they don't, we'll give our patients something else."

Still another ACCC Board member said, "Perhaps one result of DRG will be that institutions will be forced to stop doing clinical research which ought not to be doing research in the first place."

ACCC President William Dugan and a majority of the Board, however, are supporting the attempt to influence the writing of DRG regulations now, and if that fails, to seek relief through legislation.

In an effort to supply some hard data on costs, ACCC has undertaken a survey of its members. One result from that survey includes information from 40 hospitals relating to intensity of patient care as determined by nursing hours.

The 40 hospitals saw a total of 33,000 new cancer patients in 1982. They have a total of 23,000 beds, 1,146 of them dedicated oncology beds. They put a total of 1,782 patients on formal clinical trials in 1982.

Seventeen of the 40 are CCOP members, 27 are involved in the cooperative group outreach program, and eight are affiliated with cancer center outreach programs.

Thirty-two of the hospitals saw 1,000 or fewer patients, nine had from 1,000 to 2,000, and one had from 2,000 to 3,000.

Five of the 40 did not put any patients on clinical trials last year; 21 placed between one and 20 patients on trials, and 16 had more than 21 on trials.

Together, the 40 hospitals plan to enter 2,399 patients onto clinical trials in 1984, 600 more than they did in 1982.

The survey asked for the specific number of nurse hours per patient in the oncology units and in the medical-surgical units.

One of the 40 reported that the oncology unit used fewer nurse hours per patient than the med-surg unit. Four reported no difference. All the rest reported significantly higher levels of nurse hours per patient, with a mean score of 146 percent of oncology unit hours over that of the med-surg units.

Nurse hours per patients are considered as the key factor in the level of intensity of cancer care, and are one of the main cost factors.

Forty-two percent of the respondents said they put less than 25 patients onto clinical trials in 1982 and would not increase that number of 1984. Twenty-one percent reported fewer than 25 on trials last year but said they planned to increase the number to more than 25 in 1984 (seven of those are CCOP members). Thirty-five percent had more than 25 patients on clinical trials in 1982 and planned to continue at that rate next year.

Thus, only 56 percent of the 40 hospitals participating in the survey would qualify for the double DRG reimbursement sought by ACCC—with oncology units, and with at least 25 patients on clinical trials.

Lee Mortenson, ACCC executive director, pointed out that there are only from 300 to 500 hospitals, of the 7,000 in the U.S., which have oncology units. Applying the 56 percent to that number would mean that from 150 to 250 hospitals would qualify.

"That's a relatively small number, certainly not enough to break up the DRG program," Mortenson said. "That's all we're asking for."

DCCP BOARD COMMITTEE FINISHES ITS RADIATION TABLE RECOMMENDATIONS

A committee of the Board of Scientific Counselors of NCI's Div. of Cancer Cause & Prevention has completed its recommendations for development of radioepidemiological tables, a task surrounded with controversy which was mandated by the Dept. of Health & Human Services by the Orphan Drug Act (P.L. 97-414).

The committee concluded that, while it is feasible to develop tables attributing the risk of site specific cancer to degree of exposure, that effort is fraught with uncertainties, especially so with low level radiation.

That provision was written into the Act on the demand of Sen. Orrin Hatch (R.-Utah), some of whose constituents were exposed to atomic testing fallout and who are seeking (or their survivors are seeking) compensation for malignancies they contend were caused by that exposure.

The Act directed HHS to:

1) Conduct scientific research and prepare analyses necessary to develop assessments of the risks of thyroid cancer associated with thyroid doses of iodine 131; develop methods to estimate the thyroid doses of iodine 131 received by individuals from nuclear fallout; and develop assessments of the exposure to iodine 131 received by individuals from the Nevada atmospheric nuclear bomb tests.

2) Prepare a report concerning these activities to be transmitted to Congress within one year of enactment of P.L. 97-414.

3) Devise and publish radioepidemiological tables that estimate the likelihood that people with any radiation related cancer who received specific radiation doses before the onset of the cancer developed the disease as a result of such exposure. The tables must show the probability of causation for each cancer associated with receipt of doses ranging from

1 millirad to 1,022 rads in terms of sex, age at time of exposure, time from exposure to disease onset, and such other categories as the HHS secretary, after consultation with appropriate scientific experts, determines to be relevant.

4) With publication of radioepidemiologic tables, the secretary must include an evaluation of the credibility, validity, and degree of certainty associated with the tables; and a compilation of formulae that yields such probabilities. The tables and formulae must be updated at least every four years based on the best available scientific data.

HHS turned this hot potato over to NCI, and a Committee on Development of Radiation Tables was established by the DCCP Board. William Haenszel of the Illinois Cancer Council was chairman, and other members were Victor Bond, Brookhaven National Laboratory; Pelayo Correa, Louisiana State Univ.; Joseph Rall, National Institute of Arthritis, Diabetes, and Digestive & Kidney Diseases; and Arthur Upton, New York Univ. David Howell of DCCP was executive secretary.

The committee's specific charge was to recommend how best to answer these questions:

- What are the scientific issues involved in the creation of the compensation tables?
- What should be the composition of any supervising committee taking responsibility for the creation of the tables or for reviewing tables produced elsewhere?

The committee's report follows:

"Central to section 7 of P.L. 97-414 is the issue of compensation. The section itself is a consequence of hearings by the Senate Committee on Labor & Human Resources concerning compensation of individuals for cancer that may have been caused by fallout from U.S. weapons tests in the 1950s and early 1960s. However, the committee recognizes that the tables may be involved in litigation that reaches far beyond this particular exposure and, therefore, wishes to make several points that are generally applicable to creation and analysis of the tables.

- "The committee endorses the use of the concept of attributable risk in preparation and review of the tables. This use is not new; British Nuclear Fuels Ltd. is presently using the general principle of attributable risk in considering compensation for union members who have developed cancers alleged to be radiation related. Furthermore, an adequate data base on risk of site specific cancer for the general U.S. population is available. However, the committee feels it essential that in computing attributable risk, the influence of a number of patient variables be taken into account as much as feasible. For this and other reasons to be discussed later in this report, it is essential that uncertainties in the tables be clearly identified. Indeed, the President, in signing P.L. 97-414, directed the secretary, HHS to 'complete the tables to the extent that may be possible and scientifically responsible in light of the analysis also mandated by Section 7, which required him to assess the credibility, validity, and degree of uncertainty associated with such tables. The committee recognizes and fully agrees with the necesssity for doing so.
- "The committee urges that the tables be prepared by one group of experts and reviewed in a fashion that is acceptable and credible, politically and scientifically, by a separate group which is independent of the first.
- "The committee recommends that the task force or committee creating the tables be organizationally attached and responsible to the Office of the Assistant Secretary for Health. It is also important that adequate and appropriate support be provided to that group to permit it to accomplish its task in a timely manner. This is particularly urgent because of the deadline imposed by P.L. 97-414 (January 1984).
- "The membership of the oversight committee reviewing the tables should represent the disciplines necessary to assure that the tables are useful and scientifically valid instruments. The committee might therefore comprise experts in radiation biology, statistics, risk factors and their significance, iodine-131 exposure and risk of thyroid cancer, radiation dosimetry, cancer epidemiology, and law. It might also include an actuary and an expert on compensation. All of these individuals should be recognized authorities in their fields since the tables should represent the efforts of the best judgment that can be mustered.
- "The oversight group should be organized as a standing committee since it will be responsible for the periodic revisions of the tables mandated by P.L. 97-414. Furthermore, it should be convened by and attached to the Office of the Assistant Secretary for Health, HHS, and should be involved in activities concerning the tables at the earliest feasible stage. This is particularly important since the implications of the tables go beyond the problem of radiation related cancer, potentially touching upon broader issues of compensation involving exposure to asbestos and hazardous wastes as well as illnesses of coke oven workers, asphalt workers, roofers, and others.

"In addition to these general recommendations, the committee recognizes that there are a number of specific scientific issues that will have to be settled before the tables are created.These are:

"1) The types of cancer that are regarded as radiogenic.

"Specification of the tumors that are regarded as radiogenic is clearly one of the issues that must be addressed and should be part of the duties of the committee overseeing the creation of the tables. It should be borne in mind, however, that the influence of radiation is not yet clearly enough established for cancer in a number of organ sites to permit the cre-

ation of tables for them. These categories might be identified in the text accompanying the tables.

"2) Risk coefficients representing the radiation hazard.

"Those who develop the tables will probably have to rely heavily on pre-existing, up to date tables devised by other expert groups. It is essential, however, that the tables be regularly revised to include new knowledge.

"3) Other environmental and host variables will be acknowledged to influence the tabled probabilities of radiation causation.

"The selection of ancillary risk factors should be part of the task of the expert oversight committee. Again, the developers of the tables will have to rely upon already existing information.

"However, the text accompanying the tables should explain their shortcomings and uncertainties with regard to specific variables. This is important because knowledge about the interaction of these variables with radiation is scanty, although research is continuing and new findings must be included in future revisions of the tables.

"4) Relative biological effectiveness (RBE) of iodine-131 exposure to the thyroid.

"An authoritative risk number for protracted internal radiation from ^{131}I does not presently exist. Moreover, the so called 'natural incidence' of thyroid cancer is greatly understated in the scientific literature. The committee which produces the tables must therefore be concerned with this as well as with the RBE for ^{131}I. Although P.L. 97-414 makes ^{131}I a special case, the committee does not feel that there is a scientific basis for singling out this isotope since dose rate and protraction of exposure are also potentially important in cancers other than that of the thyroid, such as those of the bone marrow, breast and lung. In any event, the effect of ^{131}I exposure represents another complex area where there is considerable uncertainty, and a range of estimates and/or a qualifying statement accompanying the table will be essential.

"5) Site specific and age specific minimal latent periods; and limiting dates for the disappearance of radiogenic cancers.

"The committee feels that these factors, which go hand in hand, are issues which both the committee preparing the tables and the oversight committee will have to consider. The committee also points out that determination of either minimal latent period or a maximum latent period beyond which cancer does not occur is very difficult. However, the tables should be appropriately revised with regard to both factors as experience accumulates.

"6) Special consideration to be given to type of cancer.

"The committee feels that simply specifying anatomic sites of cancer in the tables is not sufficient; where feasible, histology should also be addressed. Although specific risk coefficients for given histologic types of cancer may not always be available, the committee recommends that the various types of lymphomas and leukemia should be specifically considered.

"7) Range of exposure to be considered in the tables.

"Although P.L. 97-414 specifies that an exposure range of .001-1,000 rads is to be considered, the committee feels that the lower extreme is unreasonable and scientifically meaningless since it represents a fraction of yearly exposure to background radiation. The committee suggests that the committees preparing and overseeing the tables might more fruitfully consider a lower level of exposure in the vicinity of 1 rad.

"8) Consideration of linear energy transfer (LET).

"Since LET is known to influence risk per rad, and high LET exposure is not uncommon (e.g., alpha irradiation to the lungs of uranium miners), this factor also will have to be taken into account in preparing the tables."

The committee which will compile the tables has been appointed and has had two meetings. It is chaired by Rall and includes Gilbert Beebe, Charles Land and Oddvar Nygaard of NCI; David Hoel of the National Institute of Environmental Health Sciences; Seymour Jablon of the National Academy of Sciences; Upton; and Warren Winkelstein of the Univ. of California (Berkeley). A separate NAS committee will review the recommendations of Rall's committee.

PRICE INCREASE EFFECTIVE WITH JANUARY 1984 ISSUES FOR THE CANCER LETTER

Effective with subscriptions starting Jan. 1, 1984, and thereafter, the subscription rate for ***The Cancer Letter*** will be $150 a year in the U.S., Canada, and Mexico, and $175 a year elsewhere. The higher rate for subscriptions outside of North America covers part of the cost of overseas airmail.

MACFARLANE, FRELICK OF NCI TO SPEAK AT ELM'S "CCOP SURVIVAL" SEMINAR

Two more NCI staff members, both playing key roles in the Community Clinical Oncology Program, were added to the list of speakers for the seminar, "Final Agenda: How to Survive CCOP," July 31-Aug. 6.

Dorothy MacFarlane and Robert Frelick, CCOP program directors, will speak during the six day meeting designed for representatives of the institutions which will participate in CCOP. Another added to the speaker list (published last week in ***The Cancer Letter***) will be Eleanor McFadden, who is with the

statistical office of the Eastern Cooperative Oncology Group.

NCI, incidentally, is not associated with organizing or promoting the seminar. Elm Services Inc. of Rockville, Md. is the sponsor.

MacFarlane sent the following notice to "all successful CCOP applicants":

"Most of you have received notification of a workshop sponsored by Elm Services. As a courtesy, some NIH and NCI staff will be participating in this workshop as they could in response to a request from any group, especially one composed of those recommended for funding for an NCI program. However, the workshop is neither sponsored nor endorsed by the NCI. Furthermore, neither registration fee nor travel support to attend this meeting may come either directly or indirectly from funds awarded by NCI for support of your CCOP.

"Representatives from the Grants Administration Branch of NCI plan to visit each CCOP which has not had previous federal funding before or shortly after awards are made. They should be able to answer your questions about administration and management of federal funds.

"In addition, NCI is planning a workshop for all CCOPs this fall. Topics to be covered will include use of microcomputer, investigational drug use requirements, CCOP evaluation, clinical epidemiology of clinical trials, DRGs—questions and issues, potential future cancer control activities for CCOPs, local and regional data bases helpful in cancer control activities, future CCOP participation in large scale clinical trials, reporting needs, standard patient log, and site visits by research bases and program staff."

For further information on the Elm seminar, contact Elm, 11600 Nebel St., Suite 201, Rockville, Md. 20852, phone 301-984-1242. The seminar will be held in the Key Bridge Marriott Hotel, Rosslyn, Va., across the Potomac River from Washington.

MANVILLE SEEKING PARTNER IN ASBESTOS INJURY SUITS – THE U.S. GOVERNMENT

An "intensive review" of government documents, including recently declassified ones, reveals that during World War II, the U.S. government was aware that shipyard workers involved in the massive wartime shipbuilding program were being exposed to dangerous levels of asbestos dust from asbestos products deemed essential for defense, the company which supplied most of that asbestos has charged. These hazardous shipyard working conditions were not corrected by the Navy nor made known to asbestos manufacturers, the company said.

The charges were presented in a suit filed this week by Johns-Manville Corp., a wholly owned subsidiary of Manville Corp. against the U.S. in which Johns-Manville claimed breach of express and implied in fact wartime contracts. The suit, filed in the U.S. Claims Court in Washington D.C., claims damages as the result of Johns-Manville's manufacture and supply of strategic asbestos containing insulating and fireproofing materials for the U.S. during World War II.

"Johns-Manville's decision to sue the federal government follows a year long review of now declassified wartime documents. The documents demonstrate that the U.S. government is responsible for injured shipyard workers and, thus, should share with the asbestos industry in the social and financial responsibility for properly compensating the injured wartime shipyard workers," according to Dennis Markusson, Manville's assistant corporate counsel.

The suit claims that the government breached its contract with Johns-Manville for the responsibility of the occupational safety and health of its wartime shipyard workers. Government hygiene studies of the working conditions in shipyards throughout the war indicate that the government chose not to require compliance with its own health and occupational standards, the suit contends.

According to Manville officials, the government specified asbestos during World War II because of its life saving qualities aboard ships, but the government also allowed excessive exposures to asbestos to endanger the lives of shipyard workers. As early as 1939, the U.S. Navy knew that it was not complying with known occupational standards. In March 1941 a memo from the medical officer in charge of the Navy's Div. of Preventative Medicine to Admiral McIntire, the Navy's surgeon general and President Roosevelt's personal physician, states, "(i) Asbestosis. We are having considerable amount of work done in asbestos and from my observations, I am certain that we are not protecting the men as we should. This is a matter of official report from several of our Navy yards."

Another shipyard study in September, 1941 recommends, "The conditions in this shop present a very real asbestosis hazard and immediate steps should be taken to segregate the dusty processes into well ventilated areas." But the Navy apparently did not implement that recommendation. A followup study two years later in the same shop measured dust counts between six and 10 times higher than the known and accepted government standard for 'safe' exposure levels.

In seeking relief, Johns-Manville also claims the U.S. controlled the supply and use of strategic asbestos fiber during World War II. Johns-Manville contends the government purchased, sold, or supplied fiber, primarily African fiber, to manufacturers who, in compliance with wartime regulations and contracters, were required to manufacture insulating and fireproofing materials used in government combat vessels.

John McKinney, chairman and president of Manville Corp., said: "The practical effect of these wartime regulations and contracts upon Johns-Manville was such that our entire business was essentially being operated for the direct benefit of the U.S. government with criminal sanctions if we did not do so. Although almost half of the asbestos lawsuits against Manville are shipyard workers, the government has not shared any of the responsibility. Yet the government has accepted responsibility in other health related areas. It's time for the government to acknowledge and accept responsibility for these war related injuries."

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-37595-07
TITLE: Development and production of parenteral dosage forms
DEADLINE: Approximately Oct. 19

(This replaces the announcement of the same RFP which appeared last week in **The Cancer Letter.**)

The Pharmaceutical Resources Branch of the Developmental Therapeutics Program, DCT, NCI, is seeking a contractor to provide staff and a facility for the manufacture and production of parenteral dosage forms for investigational use in man. The products prepared will be used for NCI sponsored clinical trials throughout the world.

Contractor selected must prepare all products in accord with FDA's Current Good Manufacturing Practices regulations and NCI's product specifications.

Contractor selected shall be experienced in the preparation of sterile freeze-dried dosage forms and sterile liquid filled products. The capability to develop and manufacture other pharmaceutical dosage forms, i.e., sterile suspensions, dry fills, large volume parenterals, etc., is desirable, but not essential.

As a minimum requirement, contractor's facility must be registered and approved by FDA for manufacture of sterile parenteral pharmaceuticals. The Contractor must be currently engaged in sterile parenteral manufacturing involving freeze drying, liquid filling and ampuling. The contractor will be required to have operational equipment and capabilities for all production and quality control tasks at the time of contract award.

The government will provide the new drug substance and contractor shall provide all other materials used in the manufacture, testing, packaging and labeling of the formulated parenteral dosage products. Annual workload estimates for development and production are, respectively, 1,040 hours of technical staff time and 10 production assignments. Most development products will involve preparation of sterile freeze-dried products requiring only familiarization studies with an existing formulation. Small batch development (preproduction) runs will be required before each new production. Approximately eight freeze dried productions and two liquid filled productions will be required annually. Contractor will be responsible for the quality control testing of all formulation components including the active ingredient, excipcipients, container closure system as well as the finished product.

Contractor will not be responsible for the shelf life surveillance of the dosage forms since a separate contract resource will perform this task. All products will be labeled and packaged according to specifications supplied by the government. Label preparation may be subcontracted, but labeling must be performed at the contract site.

It is anticipated that the government will award a single contract on an incrementally funded basis. Each increment will be for a period of one year and the total contract will be awarded for a five year period.

CONTRACT SPECIALIST: Helen Kelly
RCB, Blair Bldg. Rm. 228
301-427-8737

RFP CANCELLATION
RFP NCI-CM-37577-25
TITLE: Development and marketing of SR-2508 as a radiosensitizer

RFP has been canceled by NCI. Reissuance is anticipated in August 1983.

NCI CONTRACT AWARDS

TITLE: Development and production of pharmaceutical dosage forms
CONTRACTOR: Univ. of Iowa, $991,384.

TITLE: Analysis of chemicals and pharmaceutical formulations
CONTRACTORS: Research Triangle Institute, $1,282,024; Midwest Research Institute, $1,613,061; SRI International, $1,905,750.

TITLE: Largescale isolation of antitumor agents from natural sources
CONTRACTOR: Polysciences Inc., Warrington, Pa., $899,786.

TITLE: Preparation and updating of clinical protocol summaries
CONTRACTOR: Informatics Inc., Rockville, Md., $94,201.

TITLE: Prime contractor for performance of protocol toxicology studies, 53 months
CONTRACTOR: Battelle Memorial Institute, Columbus, Ohio, $11,654,110.

The Cancer Letter _Editor Jerry D. Boyd

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