DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

April 1988

Dear Colleague:

This letter will cover a number of topics in the areas of tobacco/smokeless tobacco, fluoridation, infection control, plus other areas of interest.

Please note that we have introduced, as a new feature of the "Dear Colleague" letter, a removable fact sheet, which has been inserted in the middle of the letter. The topic for this particular letter is tobacco and health and includes both tobacco and smokeless tobacco. The box at the bottom of the second fact sheet is provided for you to insert any information you wish, for example, a contact person, address, etc. We plan to produce fact sheets on other areas of oral health as a permanent part of the "Dear Colleague" letter.

Two other areas are covered in tobacco/smokeless tobacco: symptoms of tobacco and smokeless tobacco withdrawal; risk of head and neck cancer from smoking and smokeless tobacco; and the availability of the "Report to Congress--1986 Comprehensive Smokeless Tobacco Health Education Act."

The fluoridation section contains information on the basic training course and advanced workshop; an update on the availability of fluoride chemicals; use of the colorimeter in analyzing fluoride content of public well water; effects of fluoride on mouse sperm morphology; oral health status of 13-year-old children in Alberta, Canada; caries prevalence in Northern Scotland before and after defluoridation; and fluoride and root surface caries.

The following topics are covered in the infection control section: WHO's statement on dentists' professional and ethical responsibilities for HIV-positive and AIDS patients; the prevalence of antibody to HIV and HBsAg; a joint advisory notice from the Departments of Labor and Health and Human Services concerning hepatitis B virus and HIV; a regulatory program for bloodborne infectious diseases; proposed rulemaking for occupational exposure to hepatitis B virus and HIV; and risk to dental professionals from occupational exposure to HIV.

Other items of interest concern the National Oral Health Conference to be held May 10-12 in Indianapolis, Indiana; classification of dental devices by FDA; proposal of exemptions for some dental devices by FDA; consumption of soft drinks; and a description of mechanisms for reporting malfunctions of dental equipment.

We welcome any contributions and/or comments you may have with regard to this letter. With your assistance, we can continue to provide the most

current information concerning the prevention of oral diseases and the promotion of oral health.

Sincerely yours,

Lawrence J. Furman, D.D.S., M.P.H.
Chief, Dental Disease Prevention
Activity
Center for Prevention Services

TOBACCO/SMOKELESS TOBACCO

SYMPTOMS OF TOBACCO AND SMOKELESS TOBACCO WITHDRAWAL

The following is taken from an abstract from Hatsukami, DK, Gust, SW, Keenan, RM. Physiologic and Subjective Changes from Smokeless Tobacco Withdrawal. Clinical Pharmacology and Therapeutics 41(1):103-107, January 1987:

Withdrawal symptoms were compared in 16 male smokeless tobacco chewers and 11 cigarette smokers (6 men) during a 6-day period. The smokeless tobacco chewers averaged >two tins/week for <7 years, whereas cigarette smokers consumed an average of >26 cigarettes/day for <9 years. After using smokeless tobacco or cigarettes for 3 days, chewers abstained from tobacco for 3 days and smokers for 5 days. Changes for both tobacco chewers and smokers included increases in craving for tobacco ($p \leq 0.001$ and $p \leq 0.01$. respectively), heart rate ($p \leq 0.01$), orthostatic pulse change ($p < 0.01$ and $p \leq 0.05$, respectively), confusion on the Profile of Moods States (POMS) ($p \leq 0.05$), eating ($p < 0.01$ and $p < 0.05$, respectively), number of sleep interruptions ($p \leq 0.05$ and $p \leq 0.01$, respectively), and total scores on a withdrawal symptoms checklist for both self-rated ($p \leq 0.05$ and $p < 0.001$, respectively) and observed ($p \leq 0.01$) measures. Anger and hostility measures were higher for cigarette smokers ($p \leq 0.01$), but not chewers. Cigarette smokers, but not chewers, had increased tension and anxiety ($p \leq 0.01$), decreased vigor on POMS ($p \leq 0.01$), and weight increases ($p \leq 0.05$). No difference was shown between smokers and chewers in baseline saliva cotinine levels. Although withdrawal symptoms occur from smokeless tobacco deprivation, these symptoms are quantitatively less severe than in cigarette withdrawal.

RISK OF HEAD AND NECK CANCER FROM SMOKING AND SMOKELESS TOBACCO

The following is taken from an abstract from Stockwell, HG, Lyman, GH. Impact of Smoking and Smokeless Tobacco on the Risk of Cancer of the Head and Neck:

The relationship between tobacco use and the risks of cancers of specific sites within the head and neck region was assessed in a case-control study of 2,351 cases and 8,285 controls from the Florida Cancer Data System. Relative risk of squamous cell cancers of the head and neck increased with number of cigarettes smoked/day and was higher among women than men at each level of consumption. Odds ratios were 7.4 vs. 4.1 for light smokers (<20); 14.4 vs. 10.7 for moderate smokers (20-40); 34.2 vs 6.5 for heavy smokers (>40); 7.9 vs. 3.6 for ex-smokers; and 6.6 vs. 4.2 for cigar, pipe, or snuff users. Risks varied for each site. Smoking cigarettes was associated with increased risk of cancer of the lip, tongue, mouth and gums, pharynx, nasopharynx, nasal cavity, and larynx. No association was observed between neoplasms of the salivary glands in smokers; however, snuff users were five times as likely as nonusers to develop cancer of the salivary glands. Smokeless tobacco users also experienced elevated risks of cancers of the mouth and gums, pharynx, and larynx. Cigar and pipe smokers had higher risks of cancers of the tongue, pharynx, and larynx.

Reference:

The above articles appeared in the July-August issue of the Smoking and Health Bulletin, a publication of the Office of Smoking and Health, Center for Health Promotion and Education, Centers for Disease Control. Further information about this bimonthly publication, as well as the Office's bibliographic search and retrieval services, may be obtained from:

CDC, CHPE, OSH
Technical Information Center
Parklawn Building, Room 116
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-1690

REPORT TO CONGRESS - 1986 COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT

As of the issuance of this "Dear Colleague" letter, copies of the Report to Congress under the Comprehensive Smokeless Tobacco Health Education Act of 1986 (PL-99-252) have either been or will soon be distributed to key individuals and organizations by the Dental Disease Prevention Activity (DDPA). Some copies are still available from DDPA, but supplies are limited, and requests should be limited to one copy. Requests should be sent to:

Dental Disease Prevention Activity
Freeway Park, Room 424 (E-09)
Centers for Disease Control
Atlanta, Georgia 30333

FLUORIDATION

FLUORIDATION BASIC TRAINING COURSE AND ADVANCED WORKSHOP

The Dental Disease Prevention Activity (DDPA), Center for Prevention Services, Centers for Disease Control, and the State of Tennessee periodically conduct a training course on the basic engineering aspects of community water fluoridation. The course has been designed primarily for State-employed engineers and/or technicians who are involved with community or school water fluoridation. However, other personnel, i.e., State, county, and local dental directors, fluoridation program managers, and others involved in fluoridation programs have benefited from the course.

The 5-day training course includes the areas of fluoridation and public health, fluoride chemicals, fluoride equipment, equipment installation, system design, and school fluoridation. The instructional methods include lectures, group discussions, and hands-on training. Each Basic Fluoridation Engineering Course is limited to 20 attendees, but will be cancelled if there are fewer than 15 potential attendees.

The following dates have been set for the Basic Fluoridation Engineering Course in 1988:

August 15-19

CDC and the State of Tennessee have also established an annual Advanced Fluoridation Engineering Workshop for those individuals who are more technically involved in fluoridation in order to provide information about the most recent advances in equipment, operation, and maintenance, both from equipment manufacturers and each other. Only graduates of the Basic Fluoridation Engineering Course are eligible to attend this workshop. The Advanced Fluoridation Engineering Workshop is unlimited in size, but will be cancelled if there are fewer than 20 potential attendees.

The following dates have been established for the annual Advanced Fluoridation Engineering Workshop in 1988:

October 24-28

Both the basic course and the advanced workshop will be held at the Tennessee State Department of Health's Operator Training Center in Murfreesboro, Tennessee, which is located 35 miles southeast of Nashville. Attendees will stay in Nashville on Sunday night and remain in Murfreesboro for the rest of the week. Transportation will be provided daily to and from the training facility. There is no fee or registration charge for either course, but transportation to and from Nashville and lodgings costs will be borne by each attendee or the sponsoring organization.

All interested parties should contact DDPA as early as possible to register. Details will be provided to registrants 1 1/2 months prior to each course. For further information and/or to register for either the

basic course or advanced workshop, contact Tom Reeves or Darrell Sanders, Fluoridation Engineers, at the following address:

Dental Disease Prevention Activity
Center for Prevention Services
Freeway Park, Room 424, M.S. E-09
Centers for Disease Control
Atlanta, GA 30333
Telephone: (404) 639-1833
FTS: 236-1833

UPDATE ON AVAILABILITY OF FLUORIDE CHEMICALS

Presently, an oversupply of hydrofluosilicic acid exists, and is selling in some large cities for as low as 2¢/gallon. The immediate supply for the future (next 1-1 1/2 years) looks very good. However, it is anticipated that production shortages will eventually occur again and it is suggested that cities begin to increase their storage capacities now--some cities are already doing this.

Reference:

Thomas G. Reeves, Chief Fluoridation Engineer, DDPA, CDC.

USE OF COLORIMETER IN ANALYZING FLUORIDE CONTENT OF PUBLIC WELL WATER

The following is taken from the study, "The Use of a Colorimeter in Analyzing the Fluoride Content of Public Well Water":

Water samples taken from 110 public wells in Ohio were analyzed for fluoride content using both an ion-specific electrode and a colorimeter. Analyses were also performed on selected known interfering substances in the water. Sixty percent of the samples differed by >0.1 ppm fluoride, with a mean difference of +0.14 ppm. Prescriptions for dietary fluoride supplementation based on the colorimetric results would have been incorrect 44.6 percent of the time. Sulfate levels had a significant ($P<0.05$) effect on the accuracy of the colorimetric results. Without prior distillation, the colorimetric method is unsatisfactory for determining fluoride concentration of well water.

Reference:

Brossock, GE, McTigue, DJ, Kuthy, RA. "The Use of a Colorimeter in Analyzing the Fluoride Content of Public Well Water," Pediatric Dentistry, Vol. 9, No. 3, 204-7, September 1987.

EFFECTS OF FLUORIDE ON MOUSE SPERM MORPHOLOGY

The following is taken from the study, "Effects of Fluoride on the Mouse Sperm Morphology Test":

Little information and much confusion has existed regarding the genotoxic effects of fluoride. The purpose of the above study was to examine the spermatogenic influence of sodium fluoride (NaF) on the germ cells by mean of the mouse sperm morphology test. Male mice of genotype $B_6C_3F_1$ were obtained at about 8 weeks of age and maintained on a low-fluoride diet (<0.2 ppm F) and distilled water ad libitum throughout the experiment. At approximately 13 weeks of age, the animals were randomly assigned to eight groups. Group I was intubated with the Maximum Tolerable Dose (MTD) of NaF (70 mg/kg). Groups II through VI received NaF by stomach intubation at doses of 35, 20, 10, 1, and 0.1 mg/kg, respectively. Group VII served as a negative control and was intubated with distilled water. Group VII, the positive control, was exposed to a known mutagen, cyclophosphamide (20 mg/kg, i.p.). The mice were treated daily for 5 days and killed by cervical dislocation 35 days after the first exposure to chemicals. Slides of sperm from the cauda epididymides were prepared and blindly scored for morphological abnormalities. Testes weight was recorded and the femurs were saved for fluoride (F) analysis. Analysis of bone F demonstrated the effective absorption of fluoride following incubation. Counts of abnormal sperm and weights of the testes for the mice exposed to NaF doses up to the MTD were not significantly different from those of the negative control. The results of this study showed that NaF did not have adverse effects on mouse sperm morphology.

Reference:

Li, Y, Dunipace, Stookey, GK. "Effects of Fluoride on the Mouse Sperm Morphology Test," Journal of Dental Research, Vol. 66, No. 9, September 1987.

ORAL HEALTH STATUS OF 13-YEAR-OLD CHILDREN IN ALBERTA, CANADA

The following is taken from the paper, "Oral Health Status of 13-Year-Old-Children in Alberta, Canada:"

A survey of the dental health of 13-year-old children in Alberta, Canada, was completed in 1978. A new survey was undertaken in 1985 in order to examine the pattern of dental disease.

After a stratified multi-staged sampling of students was undertaken, 3,117 were selected, all of whom would be 13-years-old at the time of examination. The children were examined for a variety of oral conditions, but this paper's discussion is confined to the findings on dental caries, periodontal disease, and oral hygiene status.

A dramatic improvement in oral health was shown over the period 1878-1985; the caries-free children now comprise 24 percent of the community sampled compared with 7.5 percent in 1978, and the mean DMFT

has declined from 4.74 in 1978 to 3.09 in 1985, a 35 percent reduction. The periodontal assessments included the new CPITN index as well as Greene and Vermillion's oral hygiene index for comparison with the 1978 survey; the OHI(S) index showing little change (0.81 in 1978 and 0.89 in 1985). Overall findings show a dramatic reduction in dental disease, which is discussed in relationship to the availability of fluoride through various agents and the recommendations of the World Health Organization that a level of 3 DMFT be achieved in the world population of 12- to 13-year-olds by the Year 2000.

Reference:

Lizaire, AL, Hargreaves, JA, Finnigan, PD, Thompson, GW. "Oral Health Status of 13-Year-Old School Children in Alberta, Canada," Journal of the Canadian Dental Association, No. 11, 1987.

CARIES PREVALENCE IN NORTHERN SCOTLAND BEFORE AND AFTER DEFLUORIDATION

The following is taken from the study, "Caries Prevalence in Northern Scotland Before, and 5 Years After, Water Defluoridation":

Clinical and radiographic examination of 106 5-6-year-old children who had been born and raised in the fluoridated town of Wick were compared with 126 similar subjects 5 years after Wick's water was defluoridated in 1979. During the intervening period, the mean dmft index rose by 27% and the mean dmfs value by 39.6%; there was a 10.1% reduction in the number of caries-free children, in spite of some shift in socioeconomic class patterns. Furthermore, this caries increase has occurred when there is a reported overall reduction in caries nationally and when fluoridated dentifrice has been universally available. Thus, any suggestion that the caries pattern is improving to such an extent that a water fluoridation policy might now be questioned is not borne out by this data. It is to be hoped that the Wick defluoridation decision will soon be reversed, to the benefit of present and future generations.

Reference:

Stephen, KW, McCall, DR, Tullis, JI. "Caries Prevalence in Northern Scotland before, and 5 Years after, Water Defluoridation," British Dental Journal, 1987:163:324

EXPOSURE TO FLUORIDE-ADEQUATE WATER ON ROOT CARIES IN ELDERLY

The following is taken from the study, "Impact of Exposure to Fluoride-Adequate Water on Root Surface Caries in Elderly":

Residents aged 60 years and over in two sets each of matched fluoride-adequate and fluoride-deficient communities were asked to participate in a free oral health screening. Root caries was recorded only for the mandibular six anteriors, since these are the most frequently retained teeth. The patterns of tooth loss varied little between exposure groups, although more teeth were retained in every tooth

category in the groups exposed to fluoride-adequate water as opposed to those with no exposure to fluoride-adequate water. By controlling for age and socioeconomic status, the difference in number of carious root surfaces for the mandibular six anteriors between older persons exposed to fluoride-adequate water for a minimum of 8 years and those with no exposure was significant at the p less than 0.5 level (analysis of covariance). The results indicate that fluoride may have a significant positive impact on the oral health status of elderly persons, but further studies are needed to clarify both the mode of action (topical and/or systemic) and the length of exposure needed to produce clinical differences in caries rates.

Reference:

Brustman, B. "Impact of Exposure to Fluoride-Adequate Water on Root Surface Caries in Elderly." Gerodontics 1986:2:203-207.

FLUORIDE AND ROOT SURFACE CARIES

The following is taken from the article "Fluoride and Root Surface Caries":

Carious lesions on the surfaces of the roots of teeth (root surface caries) tend to be much less frequent than carious lesions of the crowns of the teeth (coronal caries.) Root surface caries have not received much clinical or investigative attention until recently because of the relatively low percentage of individuals with lesions and the small number of lesions per affected individual. Additionally, relatively little is known about the etiology or prevention of root surface caries. Because of the increasing numbers of individuals in the 60-year and older categories and the increased ability to maintain natural dentitions to advanced ages, a real possibility exists that root surface caries will become a more common disease entity than in previous generations. Therefore, investigation of root surface caries has become more popular, more intensive, and better financed.

The direct relationship between the ingestion of optimal amounts of fluoride during tooth development and the frequency of coronal caries is well-known; however, epidemiologic studies on fluoride and root surface caries have only been reported recently. The referenced article reports on the results of several of the latter studies. The overall conclusion appears to be that elevated levels of fluoride in the drinking water result in reduced prevalences of carious lesions on the surfaces of the roots of teeth.

Reference:

"Fluoride and Root Surface Caries," Nutrition Reviews, Vol. 45, No. 4, April 1987.

INFECTION CONTROL

WHO STATEMENT: DENTISTS' PROFESSIONAL AND ETHICAL RESPONSIBILITIES FOR HIV-POSITIVE AND AIDS PATIENTS

The following is taken from a World Health Organization statement, "Dentists' Professional and Ethical Responsibilities for HIV-Positive Patients and Patients with AIDS":

Hardly ever has a disease received such wide-spread interest from the mass media as the acquired immunodeficiency syndrome (AIDS). One explanation for this phenomenon is the alarming increase in the number of persons infected with the human immunodeficiency virus (HIV) and the number of AIDS patients. As of April 1, 1987, 45,700* AIDS cases were reported to the World Health Organization's (WHO) Special Programme on AIDS from 102 countries throughout the world. AIDS and HIV infection constitute a priority public health problem of global importance.

Dentists all over the world will, therefore, have to prepare themselves for delivery of oral health care to patients who are infected by HIV. WHO recommends that dentists participate actively in the global and national AIDS prevention and control programs. The following is a summary of the oral health section of WHO's Special Program on AIDS:

- Examination of the oral cavity for detection and diagnosis of those oral manifestations often seen in AIDS patients and those who are positive for HIV. When possible, patients should be referred to an oral medicine unit for further diagnosis, if the findings suggest an underlying immunodeficiency.

- Providing ordinary oral health care to individuals who are positive for HIV. Treatment of oral mucosal lesions may preferably take place in dental departments of hospitals or at dental colleges.

- Upgrading of the oral health team's knowledge with regard to infectious diseases, their transmission, and the necessary hygienic procedures for infection control when providing oral health care.

- Education of dental clients regarding HIV transmission and its prevention.

WHO considers that dentists have a professional and human obligation to treat and care for persons infected with HIV. In this way, the dental community can, together with other health care workers, psychologists, social counselors, etc., support the infected and the diseased.

*As of March 7, 1988, the total number of reported AIDS cases in the United States is 55,167.

Reference:

Oral Health Unit, World Health Organization. "Dentists' Professional and Ethical Responsibilities for HIV-Positive Patients and Patients with AIDS," AIDSM 870415.

PREVALENCE OF ANTIBODY TO HIV AND HBsAg

The following is taken from the article, "Prevalence of Antibody to Human Immunodeficiency Virus and Hepatitis B Surface Antigen in Blood Samples Submitted to a Hospital Laboratory":

Laboratory workers and other health care personnel who handle clinical specimens are at increased risk for hepatitis B virus (HBV) infection. Recent reports have also documented that health care personnel exposed to infected blood also have a small risk of infection by human immunodeficiency virus (HIV), the etiologic agent of acquired immunodeficiency syndrome (AIDS). The above study was undertaken to analyze the prevalence of of hepatitis B surface antigen (HBsAg) and antibody to HIV, respectively in blood specimens submitted to the clinical chemistry laboratory of an urban teaching hospital, and to correlate the results with biohazard labeling.

All clinicians, nurses, and other hospital personnel who collected clinical specimens were instructed to affix biohazard labels to the containers of specimens from patients known or suspected to be infected with any pathogen potentially transmitted via blood or secretions. This policy was made known to staff at the time of employment and at subsequent periodic in-service training sessions on infection control practices. A total of 508 specimens was collected for these tests and the results were limited to 506 specimens for which both HBsAg and antibody to HIV were determined and for which biohazard label information was recorded.

Hepatitis B surface antigen, HIV antibody, or either of these were present in 32 (6.3%), 15 (3.0%), and 44 specimens (8.7%), respectively. Ten (67%) of 15 specimens with HIV antibody and nine (28%) of 32 with HBsAg bore biohazard labels. Among 473 unlabeled specimens, HIV antibody was present in five (1.1%), HBsAg was present in 23 (4.9%), and 27 (5.7%) contained either or both of these markers. All clinical and laboratory personnel should be vaccinated against hepatitis B and should handle all blood specimens as if they were from infected persons, regardless of biohazard labeling. By fostering complacency in handling unlabeled specimens, the use of biohazard labels may paradoxically increase the risk that health care workers will be exposed to HIV and hepatitis B virus.

Reference:

Handsfield, HH, Cummings, J, Swenson, PD. "Prevalence of Antibody to Human Immunodeficiency Virus and Hepatitis B Surface Antigen in Blood Samples Submitted to a Hospital Laboratory," Journal of the American Medical Association, December 18, 1987, Vol. 258, No. 23.

EDITORIAL NOTE: Upon reviewing the synopsis of the above article, the following comment was made by Dr. Bryan D. Hardin, Acting NIOSH AIDS Coordinator, Centers for Disease Control:

"This study demonstrates the futility of attempting to discriminate positive from negative, or high from low hazards, samples of biological

materials. The study demonstrates that when that is done, risks may indeed be increased. The proper conclusion is that universal blood and body fluid precautions must be practiced with ALL biological specimens, without regard to the known, suspected, or imagined status of the patient. Consequently, ALL biological specimens should be labeled 'BIOHAZARD.'"

JOINT ADVISORY NOTICE - DEPARTMENTS OF LABOR AND HEALTH AND HUMAN SERVICES - HEPATITIS B VIRUS AND HUMAN IMMUNODEFICIENCY VIRUS

The following is taken from a joint cover letter and joint advisory notice issued by the Department of Labor (DOL) and the Department of Health and Human Services on October 30, 1987, which was sent to approximately 500,000 employers. The letter was co-signed by William E. Brock, Secretary of Labor, and Otis R. Bowen, M.D., Secretary of Health and Human Services. The letter states, in part:

> Dear Health-Care Employer:
>
> We are writing to you about a serious health-care problem that faces all Americans but is particularly acute for health-care workers. That problem is potential exposure to hepatitis B virus (HBV), human immune deficiency virus (HIV), which causes acquired immunodeficiency syndrome (AIDS), and other blood-borne diseases.
>
> Fortunately there are reasonable precautions which can be taken by health-care workers to prevent exposure to HBV, HIV, and other blood-borne infectious diseases. Precautions for HBV and HIV have been published by the Centers for Disease Control (CDC) on several occasions.
>
> DOL joins HHS in urging the widest possible adherence to the appropriate precautions as exemplified by the CDC guidelines and the joint advisory notice. All health-care workers who may be exposed to HBV or HIV should receive training and should utilize appropriate precautions.
>
> The dangers of HBV and HIV are very real, but you can prevent or minimize those dangers for health-care workers through the utilization of the appropriate precautions recommended by the CDC.

Reference:

Federal Register, Vol. 50, No. 210, October 30, 1987.

BLOOD-BORNE INFECTIOUS DISEASES - REGULATORY PROGRAM

Many health care workers (HCWs) are exposed to blood and body fluids from patients who have active blood-borne infections or are carriers of these infections. Such exposure presents a potential risk of disease for HCWs. One such disease, hepatitis B, has been shown to present a substantially increased risk for HCWs. Data indicate that of the

approximately 250,000 cases of hepatitis B diagnosed in the United States each year, approximately 5.5 percent, or 15,000 cases, are among HCWs. It has been estimated that 222-265 HCWs die each year as a result of hepatitis B and associated complications. About half of the Nation's 5 million HCWs are at increased risk from exposure to blood-borne infectious diseases. OSHA's personal protective equipment standard, 29 CFR 1910.132(a), provisions for general housekeeping, 29 CFR 1910(a)(1) and waste disposal, 29 CFR 1910.141(a)(ii) along with Section 5(a)(i) of the Act: requiring employers to provide employment and a place of employment free of recognized hazards. . .will be used to reduce some, but not all, of the hazards of blood-borne diseases. In 1983, OSHA issued voluntary guidelines for reducing the occupational risk of hepatitis B infection. In September 1986, OSHA was petitioned by the American Federation of State, County, and Municipal Employees and other unions for the issuance of an emergency temporary standard to protect workers from occupational exposure to blood-borne infectious diseases, such as hepatitis B and acquired immunodeficiency syndrome (AIDS).

For further information, contact:

Mr. Charles E. Adkins
Director, Health Standards Programs
Department of Labor, OSHA
200 Constitution Avenue, N.W.
Room N3718, FPB Building
Washington, D.C. 20210

Reference:

Federal Register, Vol. 52, No. 206, October 26, 1987.

PROPOSED RULEMAKING FOR OCCUPATIONAL EXPOSURE TO HEPATITIS B VIRUS AND HUMAN IMMUNODEFICIENCY VIRUS

The Occupational Safety and Health Administration (OSHA) has announced the initiation of a rulemaking process for reducing occupational exposure to hepatitis B virus (HBV) and human immunodeficiency virus (HIV or AIDS virus) under section 6(b) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655.

Examples of occupations with potential for exposure include physicians, nurses, dentists, laboratory personnel, etc. Although OSHA has no standard that was designed specifically to reduce occupational exposure to these viruses, there are a number of existing regulations that apply to this hazard. An example is 29 CFR 1910.132 (personal protective equipment) which requires employers to provide: protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, and protective shields and barriers "wherever it is necessary by reason of hazards of processes or environment" encountered in a manner capable of causing injury or impairment in the function of any part of the body through physical contact. In addition, section 5(a), the General Duty clause of the Act, requires that each employer: "furnish to each of his employees

employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."

The Departments of Labor (DOL) and Health and Human Services (HHS) have formed a working group to develop an extensive and far reaching plan regarding blood-borne diseases in the workplace. Pursuant to this plan, and in order to provide immediate protection in the health care workplace against HBV and HIV, the Departments are taking the following steps: (1) Currently implementing a targeted inspection program under the OSHA Act to examine actual work practices among HCWs at risk from exposure to blood-borne diseases; (2) DOL and HHS have issued a Joint Advisory Notice (52 Federal Register 41818, October 30, 1987) to ensure that health care and other affected employers are fully aware of the applicable guidelines regarding blood-borne diseases; (3) DOL and HHS will jointly begin an extensive educational effort which targets HCWs, involving as many interested employer and employee organizations and governmental agencies as possible, and emphasizing education, training, and technical assistance.

OSHA will require adherence to existing regulations and will apply the General Duty clause in order to protect HCWs from the risks of blood-borne diseases. In addition, a careful assessment of the extent to which actual work practices conform to the guidelines, as well as the reasons for any difference between practice and guidelines, is an essential starting point for the development of a proposed standard. OSHA intends to use information gathered in these targeted inspections as one part of a program to assess actual work practices.

HHS, which will continue to play a primary role in developing consensus recommendations and guidelines for protecting against HBV and HIV infections in the workplace, will be reviewing the various guidelines already issued in this area to determine if the need exists for updating. OSHA will also work with HHS to develop additional materials intended for worker education that can be easily reproduced and distributed. There is agreement that education and training are important to assure optimum use of available protective measures.

OSHA will also be working with other Public Health Service agencies, local agencies, universities, hospitals, and State and local health care departments in an effort to provide both health employers and workers with the latest information on blood-borne diseases. This will be useful in the country's overall response to address these infectious diseases.

When a final Federal standard is promulgated, the 25 States and Territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard or amend their existing State standard, if not as effective as the Federal standard, within 6 months. These States or Territories are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington, and Wyoming. (In Connecticut and New York, the plan covers only State and local government employees.) The final Federal standard should be completed by October 1988.

For further information, contact:

Mr. James F. Foster
Occupational Safety and Health Administration
U.S. Department of Labor, Office of
Information, Room N-3647
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Reference:

Federal Register, Vol. 52, No. 228, November 27, 1987

RISK TO DENTAL PROFESSIONALS FROM OCCUPATIONAL EXPOSURE TO HIV

The following is taken from a presentation, "Risk to Dental Professionals from Occupational Exposure to Human Immunodeficiency Virus (HIV): Followup.":

Dental professionals with occupational exposure to blood and saliva contaminated with HIV may be at risk for infection. To evaluate the magnitude of risk, the authors enrolled 304 dental professionals without established risk factors for AIDS in a prospective cohort study beginning in January 1986. Sixty percent were dentists; the remaining were dental hygienists and dental assistants. At 12-month intervals, each dental professional completed a questionnaire and was tested for HBsAg and anti-HBs and antibody to HIV by ELISA (reactive sera confirmed with immunofluorescent assay and Western blot).

Sixty-five percent of dental professionals provided care to patients with risk factors for AIDS. Thirty-six percent provided care to AIDS/ARC patients (duration of exposure $\geq$1 year is 74 percent). Twelve dental professionals reported 55 needlesticks to blood/saliva from AIDS patients. A total of 79 dental professionals had either needlestick, splash, or both exposures from patients with AIDS or other HIV infection. None of the 304 dental professionals had HIV antibody at enrollment; none have acquired antibody during the first 12 months followup interval. In contrast, 23 percent non-immunized dental professionals had anti-HBs. Of 36 dental professionals with exposure to blood/saliva from patients infected with hepatitis B, two acquired new infection (5.6 percent/year). Thus, dental professionals appear to be at low risk for occupational infection with HIV despite intensive exposure over time.

Reference:

Gerberding JL, Nelson K, Greenspan D, et al., "Risk to Dental Professionals (DP) from Occupational Exposure to Human Immunodeficiency Virus (HIV): Followup," Abstracts of the 1987 Intrascience Conference on Antimicrobial Agents and Chemotherapy, New York, New York, October 4-7, 1987.

ADDITIONAL NOTEWORTHY ITEMS

FDA CLASSIFIES DENTAL DEVICES

The Food and Drug Administration (FDA) classified 110 dental devices into one of three regulatory categories in a final rule published in the Federal Register on August 12, 1987. FDA placed 53 devices into class I, 42 devices into class II, and 10 devices into class III.

Regulatory classes are assigned according to the extent of control necessary to assure the safety and effectiveness of each device. Class I devices are required to meet only the general controls applicable to all devices. Class II provides for the future development of one or more performance standards (in addition to general controls) to assure the safety and effectiveness of the device. Class III devices are those for which general controls are not enough to assure safety and effectiveness and for which insufficient information exists to develop a performance standard. A manufacturer of a class III device must submit a premarket approval application proving the safety and effectiveness of the device.

FDA originally proposed the classifications for 185 dental devices in 1980. In this final rule, FDA has grouped 89 of the proposed devices into 22 generic categories, eliminating the need for 67 separate classifications.

The regrouping results in 118 generic types of dental devices. FDA is postponing for now its final classification of 10 generic types of electrically-powered dental devices pending review of additional data on electrical safety. The 10 devices are: mechanical denture cleaner, dental handpieces and accessories,dental chair with or without operative unit and accessories, powered toothbrush, AC-powered dental amalgamator, fiber optic dental light, heat source for bleaching teeth, and boiling water sterilizer.

For more information on the preceding articles, refer to the August 12, 1987, Federal Register, pages 30082-30106 and 30120-30123 respectively, or contact Gregory Singleton, D.D.S., Office of Device Evaluation (HFZ-470), CDRH, 8757 Georgia Avenue, Silver Spring, MD 20910, telephone (301) 427-7555.

FDA PROPOSES EXEMPTIONS FOR SOME DENTAL DEVICES

The Food and Drug Administration (FDA) has proposed to exempt, with some limitations, 23 dental devices from the requirement of premarket notification (510[k]).

The dental devices proposed for exemption from 510(k)s are: electrode gel for pulp tester, dental x-ray film holder, mercury and alloy dispenser, dental amalgam capsule, resin applicator, articulator, facebow, endodontic paper point, endontic silver point, gutta percha, dental hand instrument, abrasive device and accessories, saliva absorber, base plate shellac, prophylaxis cup, rubber dam and accessories, dental floss, impression tube, massaging pick or tip for oral hygiene, silicate

protector, manual toothbrush, disposable fluoride tray, and preformed impression tray.

Reference:

Medical Devices Bulletin, Vol. 5, No. 9, September 1987.

SOFT DRINK CONSUMPTION IS UP

According to the National Soft Drink Association, there has been an increase in consumption of soft drinks (66 cans [12-oz. units]) per person) in the United States. In 1980 the average consumption was 420 cans per person and rose to 486.2 cans per person in 1985. Additionally, diet soft drinks account for 21 percent of today's market.

Information concerning soft drink calories, nutrients, and ingredients may be obtained from:

National Soft Drink Association
1101 16th Street, N.W.
Washington, D.C. 20036
Telephone: (202) 463-6770

MALFUNCTIONS OF DENTAL EQUIPMENT OR OTHER PROBLEMS

Malfunctions of dental equipment, defective gloves, or problems with other items should be reported to:

Device Monitoring Branch
Center for Radiological Health, HFZ-343
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910

FOR YOUR INFORMATION

The Dental Disease Prevention Activity (DDPA) "Dear Colleague" letter is developed by DDPA, Center for Prevention Services, Centers for Disease Control. Articles and/or written comments should be sent to:

Ms. Betty Ballinger
Technical Information Specialist
Dental Disease Prevention Activity
Freeway Park, Room 424, E-09
Centers for Disease Control
Atlanta, Georgia 30333
Telephone: (404) 639-1830
FTS: 236-1830