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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DOCKET NUMBER
PROPOSED RULE PR 26
(53 FR 36795)

NOV 21 1989

'89 NOV 30 P3:51

The Honorable Kenneth M. Carr
Chairman
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Chairman:

Thank you for your letter regarding the Nuclear Regulatory Commission (NRC) rule for fitness-for-duty programs and requesting the expert advice of the Department of Health and Human Services (HHS). I am aware that staff at the National Institute on Drug Abuse (NIDA), a component of the Alcohol, Drug Abuse, and Mental Health Administration, have been providing advice and technical assistance to your Office of Nuclear Reactive Regulations and their contractor, Battelle Human Affairs Research Centers, for more than a year. NIDA is responsible for the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Throughout this time, HHS staff have consistently advised the NRC against: 1) the inclusion of additional drugs in the rule, 2) permitting lower cutoff levels than those specified in the Mandatory Guidelines, and 3) the inclusion of provisions to permit onsite testing. Furthermore, I am aware that the NRC was strongly advised by the Department of Justice (DOJ) against including these provisions in the final rule because it could seriously jeopardize the litigation position of the DOJ in defending the constitutional issues raised about federally mandated drug testing.

We are aware that the public comments on the NRC proposed rule were overwhelmingly in favor of lower cutoff levels for certain drugs. However, based on our experience in certifying laboratories for Federal Workplace Drug Testing Programs, it is quite apparent that many laboratories, at this time, do not have the capabilities of operating on a day-to-day basis at the lower threshold levels permitted under the NRC rule. It is for these reasons that HHS has advised the NRC in the past against permitting the use of lower cutoff levels. We are, however, looking very carefully into the maximum sensitivity levels of the assays themselves as well as the capacity of the laboratories to perform these assays at lower threshold levels. We anticipate convening a consensus conference on these and other issues which may result in making recommendations regarding changes in the cutoff levels within the next 6 months.

With regard to the question of adding barbiturates and benzodiazepines to the required test panel, the HHS Mandatory Guidelines are authorized by Executive Order 12564 and P.L. 100-71 (Section 503) which limit the Federal Workplace Drug Testing Program to Schedule I and Schedule II drugs. Few barbiturates

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and none of the benzodiazepines are included in Schedule I or II. There are hundreds of legally prescribed medications which contain small amounts of barbiturates. These drugs are widely used in the treatment of seizure disorders. Additionally, the incidence and prevalence of illicit barbiturate abuse is relatively minor compared to use of marijuana, cocaine, and the other illicit drugs. It is believed, therefore, that even those barbiturates included in Schedule II should not be included in the test battery unless there is a reasonable suspicion of barbiturate abuse.

Although you did not mention it in your letter, I am aware that your final rule includes provisions which permit the use of onsite testing. We do not recommend the use of onsite testing due to the increased probability of inaccurate and unreliable results occurring through the use of onsite testing kits, and the significant risk to individual confidentiality. We are exploring options concerning the use of onsite testing with regard to situations where there are significant safety risks such as in the nuclear industry. However, we feel that there is considerable risk to the entire Federal program by permitting the use of onsite testing, and at this time cannot condone its use.

Therefore, in terms of your request for expert advice as to the merits of including additional drugs and lowering the cutoff levels for certain drugs as specified in your letter, this Department cannot support the NRC rule. The addition of Schedule III and Schedule IV drugs is not consistent with the HHS Mandatory Guidelines, and we feel that such changes could weaken the confidence of the American public in the entire Federal drug testing program which we have worked so hard to develop.

The NRC will receive an invitation to the consensus conference mentioned above. This forum is designed to seek an update on the scientific and technical aspects of the Mandatory Guidelines. Invitees will include scientists and laboratory experts who have advised NIDA and the Department in the past, as well as interested individuals from other Federal Agencies, business and industry, and the drug testing community.

Sincerely,

Louis W. Sullivan

Louis W. Sullivan, M.D.
Secretary