Dragon, Karen E. (CDC/NIOSH/EID)

From: Rooney, Sarah [Sarah.Rooney@justice.org]
Sent: Thursday, September 22, 2011 12:19 PM
To: NIOSH Docket Office (CDC)
Subject: RE: Comments on NIOSH Carcinogen and Recommended Exposure Limit Policy

Good Morning,

Attached please find the American Association for Justice's comments on the NIOSH Request for Information on the Carcinogen and Recommended Exposure Limit Policy. Please let me know you if you have any questions or concerns.

Thank you.

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AMERICAN ASSOCIATION for JUSTICE
Formerly the Association of Trial Lawyers of America (ATLA®)

September 22, 2011

NIOSH -240
NIOSH Docket Office
Robert A. Taft Laboratories, MS-C34
4676 Columbia Parkway
Cincinnati, OH 45226

Re: Carcinogen and Recommended Exposure Limit (REL) Policy Assessment (NIOSH Docket -240)

Dear Sir or Madam:

The American Association for Justice (AAJ), formerly known as the Association of Trial Lawyers of America (ATLA), hereby submits comments in response to the National Institute for Occupational Safety and Health's (NIOSH) Request for Information on its Carcinogen and Recommended Exposure Limit Policy Assessment. *See* 76 Fed. Reg. 52664-65 (August 23, 2011).

AAJ, with members in the United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, promote injury prevention, and foster the disclosure of information critical to public health and safety. AAJ applauds NIOSH's efforts to update its policies regarding the classification of carcinogens. Recently, NIOSH claimed that its outdated cancer policy required it to identify asbestos as a "potential occupational carcinogen" even as other federal agencies, such as the National Toxicology Program, as well as international organizations, such as the International Agency for Research on Cancer (IARC), label asbestos a "known human carcinogen." AAJ believes that NIOSH should take a lead role in notifying workers, health care providers, and other health and safety professionals of the hazards workplace toxins pose. Any policy – relating to carcinogens or other toxins – which restricts NIOSH's ability to do so should be changed.

I. NIOSH's Cancer Policy is Out of Date

NIOSH's cancer policy is based on Occupational Safety and Health Administration's (OSHA) 1980 Policy for the Identification, Classification and Regulation of Carcinogens.[1] The OSHA policy was promulgated to distinguish between those substances which OSHA might regulate as carcinogens and those it would not

[1] 29 CFR §1990.

regulate as carcinogens. Under its cancer policy, OSHA identified two categories of carcinogens: Category 1 for which evidence of carcinogenicity is strongest; and Category 2 for which evidence of carcinogenicity was less strong.[2] OSHA established two classifications for carcinogens so each might be regulated differently.[3]

Since its promulgation in 1980, OSHA itself has never relied on this categorization scheme. No other agency of the U.S. government relies on OSHA's never utilized Cancer Policy nor does any international organization use its nomenclature. OSHA has observed that it "is aware of no instance where a toxic substance has more clearly demonstrated detrimental health effects on humans than has asbestos exposure."[4] The National Cancer Institute (like NIOSH, a division of the Department of Health and Human Services) website notes "[as]bestos has been classified as a known human carcinogen (a substance that causes cancer) by the U.S. Department of Health and Human Services, the Environmental Protection Agency, and the International Agency for Research on Cancer."[5] It is, therefore, unwise for NIOSH to rely on a largely forgotten, never used, OSHA classification scheme which requires it to identify asbestos only as a "potential occupational carcinogen." This is particularly true when the effect of such reliance is to create the illusion that NIOSH has doubts about the hazards of asbestos when an overwhelming, international consensus – which includes its parent the Department of Health and Human Services -- exists that asbestos is a known human carcinogen.

II. NIOSH Recommended Exposure Limits (RELs) Should Not Rely on the Benzene Decision.

In the Federal Register, NIOSH asks whether it should rely on a 1 in 1,000 working lifetime risk in setting RELs. The question suggests a fundamental misunderstanding of *Industrial Union Dept. v. American Petroleum Institute* (the *Benzene* decision).[6] NIOSH should not rely on the *Benzene* decision or the 1 in 1,000 risk level in setting RELs because it is not directly applicable.

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[2] 29 CFR § 1990.112(a). In addition, NIOSH's Federal Register notice is inaccurate when it suggests that the OSHA Cancer Policy has only one classification for a carcinogen.

[3] 29 CFR § 1990.111(f).

[4] 51 Fed. Reg. 22615.

[5] That National Cancer Institute and the National Institute for Health defines asbestos as a known carcinogen. *See* http://www.cancer.gov/cancertopics/factsheet/Risk/asbestos.

[6] *See Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607 (1980).

The Supreme Court, relying on section 3(8) of the Occupational Safety and Health Act[7] (OSH Act), held that OSHA must make a threshold finding that a place of employment is unsafe – in the sense that significant risks are present and can be eliminated or lessened by a change in practices.[8] There are several reasons why the *Benzene* decision should not guide NIOSH REL policy.

First, the OSH Act directs NIOSH to "describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacity or diminished life expectancy as a result of his work experience."[9] The Act does not direct NIOSH to recommend an "occupational safety and health standard," the statutory term in section 3(8) interpreted by the Supreme Court in the *Benzene* decision. Indeed, any REL policy which is tied too closely to the OSH Act definition of a section 3(8) standard would ignore the needs of other occupational health regulatory agencies. For example, the Mine Act has no provision comparable to section 3(8) and at least one court has expressed skepticism as to whether *Benzene* applies to Mine Safety and Health Administration (MSHA).[10]

Second, in *Benzene* the Supreme Court suggested that risks of 1 in 1,000 would clearly be significant, but that smaller risks might not be.[11] The Court cautioned that this not become a "mathematical straight jacket."[12] Indeed, the Court itself noted several instances when workplace hazards were so obvious that no quantification of risk would be necessary. Since *Benzene*, the Court has not consistently either quantified risk or relied on the 1 in 1,000 guidepost and the D.C. Circuit recently held that OSHA is not required to do so before it regulates. It would therefore be unwise for NIOSH to put itself in a "mathematical straight jacket" voluntarily when the *Benzene* decision requires nothing of the sort.[13]

Finally, even if the *Benzene* decision applied to NIOSH's REL policy, it requires a threshold, significant risk finding to trigger regulation. OSHA can make the finding without quantifying risk.[14] Once OSHA determines that a significant risk exists in the

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[7] 29 U.S.C. 653(8).

[8] 448 U.S. at 642.

[9] 29 U.S.C. 669(a)(3).

[10] *National Mining Association v. MSHA*, 116 F.3d 520, (D.C.Cir. 1997).

[11] 448 U.S. at 656.

[12] *Id.*

[13] 448 U. S. at 655.

[14] *National Maritime Safety Ass'n v. OSHA,* (D.C. Cir. 2011).

workplace and that a standard is "reasonably necessary and appropriate" to reduce the risk, the OSH Act requires that the Agency adopt "the most stringent standard to protect against material impairment of health bounded only by technological and economic feasibility."[15] No court has ever held that OSHA must stop regulating when risks fall below 1 in 1000 if further regulation is feasible and would ensure that more than a *de minimis* benefit to worker health.[16] It would, therefore, be inconsistent with the OSH Act for NIOSH to set a REL at the 1 in 1000 risk level. The Act requires NIOSH to identify exposure levels where no employee will suffer material impairment; NIOSH should not artificially limit its recommendations to exposure levels with quantified risks above 1 in 1000.

Further, quantitative risk assessments usually measure only some of the health effects which can harm workers. Often risk assessments gauge the magnitude of cancer risk, but do not quantify non-cancer effects of the substance in question. Any policy under which NIOSH RELs would only protect workers from measured risks greater than 1 in 1000 might fail to take into account health effects other than cancer or those effects which have not been quantified reliably. Under such a policy, NIOSH could not meet its statutory duty to recommend RELs at which workers do not face material impairment of health.

III. NIOSH RELs Should Not Be Limited by Feasibility.

NIOSH RELs should not be limited by feasibility. The Act requires that occupational safety and health standards protect workers from material impairment only "to the extent feasible."[17] The courts have held that feasibility has two components: economic and technological.[18] The Act does not direct NIOSH to take feasibility into account in recommending exposure limits. NIOSH recommendations should identify the exposure level necessary to make a workplace safe.

Of course, NIOSH might supplement its REL with information on the technology available to reduce exposures and the analytic methods available to measure them. Where NIOSH has technological expertise in control methods, NIOSH should make that expertise available to regulatory agencies, such as OSHA and MSHA. But, technology is constantly changing and the controls needed to reduce exposures in a factory are different than those needed to reduce exposures in a mine. Furthermore, NIOSH has no expertise

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[15] *American Textile Mfrg. Inst. v. Donovan*, 452 U.S. 490, 502 (1981).

[16] *Building and Construction Trades Dept. v. Brock*, 838 F.2d 1258 (D.C. Cir. 1988). *See generally*, Rabinowitz Ed., OCCUPATIONAL SAFETY AND HEALTH LAW 2d Ed., at 456-58.

[17] 29 U.S.C. 655(b)(5).

[18] *Industrial Union Dept. v. Hodgson*, 499 F.2d 467 (D.C. Cir. 1974).

in evaluating economic feasibility and has limited access to data on industry profitability. OSHA and MSHA are directed by law to evaluate recommended exposure levels in light of feasibility constraints. There is no reason that NIOSH should substitute its evaluation of feasibility for those of OSHA or MSHA. NIOSH should recommend the exposure level needed to make a workplace safe.

AAJ appreciates this opportunity to submit comments in response to NIOSH's request for information on its cancer and exposure level policies. If you have any questions or comments, please contact Sarah Rooney, AAJ's Regulatory Counsel at (202) 944-2805.

Sincerely,

Gary M. Paul, President
American Association for Justice