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EPA REJECTS WLF PETITION TO ELIMINATE “JUNK SCIENCE” FROM DETERMINATIONS REGARDING HUMAN CARCINOGENICITY

The Environmental Protection Agency (EPA) last week declined to consider a Washington Legal Foundation (WLF) petition to eliminate “junk science” from the process by which it determines whether a substance is likely to cause cancer in humans. In a petition filed pursuant to the Information Quality Act (IQA), WLF had argued that EPA guidelines for determining human carcinogenicity violate the IQA because they are not based on sound science but rather on an EPA policy judgment that extreme caution should be adopted in connection with all substances that pose any possible cancer risk.

EPA’s response asserted that because its guidelines constitute a “policy” document, it is not subject to the IQA. WLF pledged that, within the next week, it will file a petition for reconsideration of EPA’s decision. WLF filed its initial petition in August 2005 on behalf of itself and the American Council on Science and Health (“ACSH”). ACSH recently published a study, *America’s War on “Carcinogens,”* that is extremely critical of EPA’s guidelines for determining cancer risks.

EPA recently adopted Guidelines for Carcinogen Risk Assessment that provide guidance to agency personnel in making determinations that a substance is either a human carcinogen or is “likely” to be carcinogenic to humans. WLF’s petition requested that EPA comply with the IQA by eliminating “junk science” from those Guidelines. In particular, WLF requested that EPA eliminate statements that indicate that a substance may properly be labeled a “likely” human carcinogen based solely or primarily on the results of animal studies. WLF argued that such statements are scientifically unsound, noting that the great majority of toxicologists share that assessment.

WLF asserted that the Guidelines’ provisions regarding use of animal studies have led to numerous substances being deemed “likely” human carcinogens, despite the absence of evidence that the substances have caused *any* cancer in humans. WLF argued that the law permits EPA, if it so chooses, to adopt policies that err on the side of caution when faced with equivocal evidence regarding a substance’s carcinogenicity; but the IQA does *not* permit EPA to distort the scientific evidence in furtherance of such policies.

The petition was particularly critical of the Guidelines' use of "default options" in determining whether a substance is a likely human carcinogen. The Guidelines specify that a "positive" animal study (*i.e.*, laboratory rats develop tumors when exposed to massive doses of a substance) should be assumed to indicate that much smaller doses can cause cancer in humans, in the absence of scientific evidence to the contrary. EPA justifies this "default option" not on scientific grounds, but on an assertion that its mission is to protect public health – *i.e.*, when in doubt, it should err on the side of increased protection for public health.

WLF argued that Congress adopted the IQA in 2001 to prevent just such subversions of scientific integrity. WLF asserted that the IQA does not permit a federal agency to label a substance a "likely" human carcinogen in the absence of any sound evidence to support such a label. WLF argued that policymakers are entitled, if they so choose, to err on the side of caution in deciding to impose restrictions on dissemination of a substance shown to cause cancer in laboratory rats when administered in massive doses. But EPA should not be permitted to skew the policy debate by attaching scientifically-unwarranted "likely to be carcinogenic to humans" labels to substances that may very well provide significant benefits to society. WLF asserted that EPA's use of such "junk science" results in numerous false classifications of substances as likely human carcinogens.

In its response to WLF's and ACSH's petition, EPA did not contest any of WLF's allegations regarding deficiencies in the Guidelines. Rather, EPA stated, "[WLF contends] that the passages of the document which you are objecting to 'do not merely announce EPA policy' and should be viewed as 'disseminated information' subject to [EPA's IQA] guidelines. These passages do express EPA's policy and are not subject to [EPA's IQA] Guidelines." EPA's letter failed to respond to WLF's contention that policy documents are fully subject to the IQA to the extent that they contain information that is verifiable true or false.

WLF is a public interest law and policy center based in Washington, DC, with supporters in all 50 states. WLF devotes a significant portion of its resources to ensuring that public policy decisions are based on the sound application of scientific principles. In particular, WLF has regularly litigated in support of evidentiary rules that would exclude "junk science" from judicial proceedings.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's petition is posted on its website, www.wlf.org.