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August 19, 2003

VIA OVERNIGHT MAIL

Information Quality Guidelines Staff
Mail Code 28220T, U.S. EPA
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Re: Request For Correction of Information

Dear Sir/Madam:

We write to express serious concerns about the quality, accuracy, completeness, and currency of information contained in a 1986 EPA publication entitled "Guidance for Preventing Asbestos Disease Among Auto Mechanics" (the "Gold Book").¹ We have four fundamental concerns:

- The statements in the Gold Book were based on inadequate and inappropriate scientific data and literature at the time of its original preparation;
- The Gold Book is now seventeen years old and is badly outdated in light of significant scientific studies published since 1986;
- The Gold Book's origins, preparation, funding, review, and approval are largely undocumented; and
- The Gold Book is routinely used to convey the misperception that EPA has conducted a complete analysis of the scientific and medical literature

¹ EPA also issued, at roughly the same time it issued the Gold Book, the following related materials: (1) a fact sheet entitled "Controlling Brake Dust to Protect Your Health ... What Every Auto Mechanic Should Know, EPA-560-OPTS-86-003 (Sept. 1986); and (2) a videotape, and accompanying poster, both entitled "Don't Blow It!"

and has concluded that brake mechanic work is in fact hazardous and that as a direct result brake mechanics are at increased risk of contracting an asbestos-related disease, including mesothelioma, from such exposure.

Pursuant to EPA's Data Quality Act Guidelines (the "Guidelines"), all information disseminated by EPA is now subject to the following performance goals:

- Disseminated information should adhere to a basic standard of quality, including objectivity, utility, and integrity.
- The principles of information quality should be integrated into each step of EPA's development of information, including creation, collection, maintenance, and dissemination.
- Administrative mechanisms for correction should be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into EPA's information resources management and administrative practices.²

Accordingly, pursuant to the Guidelines, we respectfully request that EPA discontinue disseminating the Gold Book and post a caveat on EPA's website to the effect that the 1986 Gold Book is no longer current from a scientific perspective. In the alternative, we request that EPA engage in an analysis of the scientific information contained in the Gold Book and update it so that it reflects a complete assessment of the extensive medical and scientific literature on the subject, particularly given the development since 1986 of a significant body of scientific data showing no increased asbestos-related health risks associated with brake work.³

I. THE GOLD BOOK IS INFORMATION DISSEMINATED TO THE PUBLIC

The Guidelines apply to all information that the agency disseminates to the public. "Information" includes "any communication or representation of knowledge such as facts or data, in any medium or form." In addition, dissemination occurs when EPA "initiates or sponsors the distribution of information to the public." EPA "initiates a distribution of information if EPA

² See Guidelines at 3.

³ In pointing out the deficiencies of the Gold Book, it is not our intent to argue the merits of an alternative scientific position or to convince EPA that brake repair work is in fact safe (even though we do believe that the weight of the prevailing scientific evidence supports such a position). Nor do we mean to criticize the content or effect of the portions of the Gold Book that seek to provide guidance to brake workers as to basic industrial hygiene practices for work in dusty environments. In fact, since 1994, OSHA has imposed the Gold Book's recommended work practices as a matter of regulation.

prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position."⁴

Clearly, the Gold Book meets these threshold requirements. First, it is "information." In it, EPA sought to communicate information to auto mechanics concerning the hazards allegedly associated with friction products, such as brake linings and clutch facing, and provides general guidance concerning recommended work and safety practices. Second, there is no question that EPA is responsible for distributing the Gold Book to the general public. The Gold Book was prepared in June 1986, apparently under the auspices of EPA's Asbestos Action Program. It bears EPA's name, logo, and address. It is currently listed on EPA's website and is available to the public free of charge through EPA's TSCA Assistance Office.

II. AS "INFLUENTIAL SCIENTIFIC INFORMATION," THE GOLD BOOK IS SUBJECT TO A HEIGHTENED STANDARD OF QUALITY

The Guidelines recognize a higher standard of quality for "influential information" that is disseminated to the general public. The term "influential information" means "that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions." EPA presumptively considers, among other things, some "policy documents" or "guidance" to be within the class of information considered "influential."

Moreover, to the extent that policy and/or guidance documents contain "scientific" information, the Guidelines state that such information "should adhere to a rigorous standard of quality" and that EPA "recognizes that influential scientific . . . information should be subject to a higher degree of quality" than other types of disseminated information. Specifically, EPA states that "[a] higher degree of transparency about data and methods will facilitate the reproducibility of such information by qualified third parties, to an acceptable degree of imprecision."⁵

The more rigorous standard of quality that applies to "influential scientific information" should be applied to the Gold Book. First, the Gold Book is "influential information." In essence, it is an educational tool intended to raise awareness of the potential occupational hazards facing auto mechanics and to prevent asbestos disease by recommending certain work safety practices. To the extent that its purpose was to impact and ultimately change work place behavior and practices in an entire industry, it is clear that this type of information is "influential" in terms of its scope and intended effect.

Second, the Gold Book provides auto mechanics information that purportedly is derived from "scientific" sources. The Gold Book discusses a broad range of scientific and medical issues

⁴ See Guidelines at 15.

⁵ *Id.* at 19-21.

relating to whether brake workers face an increased risk of asbestos-related disease as a result of exposure to asbestos-containing friction products. It is extensively footnoted and contains four pages of references, conveying the impression that it is based upon scientific data.⁶

For these reasons, the Gold Book should be scrutinized under the heightened quality standard that applies to EPA disseminated materials that contain “influential scientific information.”

III. THE GOLD BOOK FAILS TO COMPLY WITH THE GUIDELINES

The purpose of the Guidelines is “to ensure and maximize the quality, including objectivity, utility and integrity of disseminated information.” “‘Objectivity’ focuses on whether the disseminated information is being presented in an accurate, clear, complete and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. “‘Utility’ refers to the usefulness of the information to the intended users.”⁷ The Gold Book fails to meet these quality standards.

A. Gold Book Relies on Inadequate/Inappropriate Data and Literature

In essence, the Gold Book makes sweeping conclusions about the risks of asbestos disease among auto mechanics and brake workers. Specifically, the Gold Book concludes that exposure to friction products causes asbestos-related diseases, such as mesothelioma, lung cancer, and asbestosis, and suggests that brake mechanic workers have an increased risk of developing an asbestos-related disease. In reaching these conclusions, the Gold Book relies almost exclusively on a handful of case reports. While the authors of the Gold Book may have attempted to gather information available at the time regarding risks to brake workers, case reports do not reflect the best available science and do not constitute a sufficient basis to draw firm conclusions regarding causation. Rather, they simply describe isolated cases of diseases in certain individuals and as such have limited utility. While case studies can serve a useful purpose in developing working

⁶ See Gold Book at 13-16.

⁷ See Guidelines at 15.

hypotheses for further investigation, it is an accepted scientific proposition that a proper causation assessment must be based on appropriate epidemiological studies.⁸

The use of case reports in the Gold Book is particularly problematic. Among the cited sources are several unpublished case reports referenced in an 1984 book, and a British television show called "Alice: A Fight for Life."⁹ At the same time, the Gold Book did not mention a number of epidemiological studies published before 1986 that found no greater risk of mesothelioma to brake mechanics workers than to the general population.¹⁰ Thus, the Gold Book reflected – even at the time it originally was published – at best an incomplete and selective assessment of the overall scientific and medical literature.

B. Gold Book is Outdated

Even had the Gold Book cited and relied upon the best available scientific information on the issue of asbestos and brake workers at the time it was published in 1986, it has since been rendered hopelessly outdated. Even the newest information in the Gold Book is now over seventeen years old. Its content is inconsistent with more recent pronouncements made by EPA and OSHA. For example, the Gold Book, somewhat loosely describes asbestos fibers as "germs," and suggests that small asbestos fibers that cannot be measured are nonetheless hazardous:

⁸ An example of the pitfalls of reliance on case reports to draw firm conclusions regarding causation occurred in the scientific literature relating to brake mechanics after the publication of the Gold Book in 1986. In 1991, researchers reported several cases of malignant mesothelioma in garage mechanics at a clinic in Germany. Based on those cases, and with no information on the size of the underlying population at risk, the authors concluded that there was "increased incidence of mesothelioma among car mechanics exposed only to chrysotile." See *Woitowitz, et al.*, "Chrysotile Asbestos and Mesothelioma," *Am. J. Ind. Med.* 19:551-53 (1991). In 1994, the same researchers performed a complete epidemiological study of mesothelioma risks to garage mechanics. Based on the strength of the 1994 epidemiologic study, the authors reversed their 1991 findings, concluding "[f]rom these results there is no evidence that car mechanics are exposed to increased risk of mesothelioma even if they do brake repairs." See *Woitowitz, et al.*, "Mesothelioma Among Car Mechanics?" *Ann. Occup. Hyg.*, 38:635-38 (1994).

⁹ See Gold Book 2 & fn. 20-21.

¹⁰ See McDonald, *et al.*, "Malignant Mesothelioma in North America," *Cancer*, 46:1650-56 (1980) ("no increase in risk was found in garage workers, certainly exposed to chrysotile from brake linings"); Teta, *et al.*, "Mesothelioma in Connecticut, 1955-1977, Occupational and Geographic Associations," *J. Occup. Med.*, 25:749-56 (1983) (relative risk of mesothelioma for "automobile repair and related service" less than 1); Spirtas, *et al.*, "Mesothelioma risk related to occupational and other asbestos exposure: preliminary results from a case-control study," *Am. J. Epidemiol.*, 122:518 (1985) (mesothelioma risk for workers engaged in brake lining installation and repair same as for general population).

Like germs, asbestos fibers are small enough that they can remain and accumulate in the lungs. . . . Most of the smaller fibers will not show up with the methods commonly used for measuring asbestos levels in the air, such as the method used to determine compliance with OSHA asbestos standard, since most asbestos fibers in brake dust are too small to be measured by these methods.¹¹

However, OSHA continues to adhere to the methodology in use in 1986, which counts only fibers greater than 5 microns. And, a 1999 risk assessment commissioned by EPA concluded that:

“Short fibrous structures (less than 5 [microns]) do not appear to contribute to risk.”

“In fact, there is no positive evidence from any of the studies reviewed that suggests short structures do contribute measurably to risk.”

“Results from several injection and implantation studies . . . and other mechanism studies . . . also suggest a reason that short structures do not contribute substantially to disease: they are efficiently cleared from lung tissue relative to longer structures.”

“. . . the asbestos exposure index recommended in this report excludes consideration of structures shorter than 5 [microns].”¹²

In addition, a number of major epidemiological studies published since 1986 have found that there is no increased risk of mesothelioma among brake mechanic workers above that of the general population.¹³ These studies, along with those published prior to the issuance of the Gold Book, are summarized in a 2001 “meta-analysis” synthesizing *all* of the epidemiological studies conducted between 1980 and 2000. The meta-analysis concluded that “clearly there is no

¹¹ See Gold Book at 1.

¹² *Final Methodology for Conducting Risk Assessments at Asbestos Superfund Sites, Part 2: Technical Background Document*, Interim Version, at 5-41 (EPA Feb. 15, 1999).

¹³ See *Woitowitz, et al.*, “Mesothelioma Among Car Mechanics?” *Ann. Occup. Hyg.* 38:635-38 (1994) (“[f]rom these results there is no evidence that car mechanics are exposed to an increased risk of mesothelioma even if they do brake repairs”); *Teschke, et al.*, “Mesothelioma Surveillance to Locate Sources of Exposure to Asbestos,” *Can. J. Pub. Health*, 88:163-68 (1997) (“[a]s with vehicle mechanics in the occupational analysis, a history of brake lining installation or repair had a risk below 1.0” and “[b]rake installation and repair did not appear to be associated with mesothelioma”); *Agudo, et al.*, “Occupation and Risk of Malignant Pleural Mesothelioma: A Case-Control Study in Spain,” *Am. J. Ind. Med.*, 37:159-68 (2000) (figures presented by authors show no increased risk of mesothelioma among vehicle mechanics in Spain).

evidence to support or even suggest an association between an increased risk of mesothelioma and exposure to brake linings and clutch facings among garage mechanics.”¹⁴

Scientific and medical study of asbestos-related diseases other than mesothelioma in brake workers likewise has progressed since 1986. For example, authors of the Gold Book wrote that “[t]he extent of risk of lung cancer among mechanics is not now known.” They speculated, nonetheless, that “given the known lung cancer risk among other groups exposed to asbestos, caution is necessary.”¹⁵ In the intervening years, a number of published studies have found no increased risk of lung cancer among brake mechanic workers.¹⁶ Likewise, since 1986 a number of researchers have looked at brake workers and asbestosis and concluded that auto mechanics face no increased risk of asbestosis.¹⁷

The overwhelming weight of the scientific evidence – including significant scientific development that has occurred after the Gold Book’s publication in 1986 – supports the proposition that brake usage and work does not cause asbestos-related disease. However, as stated above, our request that EPA withdraw the Gold Book is not based upon our belief that the medical and scientific literature shows that auto mechanics do not face an increased risk of asbestos-related disease. Indeed, there are some who find fault with the prevailing weight of the medical evidence, and there continues to be debate on these difficult and often emotionally-charged issues. But one thing is certain: the continued availability of a seventeen year old EPA guidance document that did not consider the best available science at the time it was issued in 1986 and does not reflect the significant development of the medical and scientific evidence since 1986 unfairly impacts the debate in far-reaching and fundamental ways.

¹⁴ See Wong, “Malignant Mesothelioma and Asbestos Exposure among Auto Mechanics: Appraisal of Scientific Evidence,” *Reg. Toxic. & Pharm.*, 34:170-77 (2001).

¹⁵ See Gold Book at 2 (emphasis added).

¹⁶ See Lerchen, *et al.*, “Lung Cancer and Occupation in New Mexico,” *JNCI*, 79(4):639-45 (1987); Benhamou, *et al.*, “Occupational risk factors of lung cancer in a French case-control study,” *British J. of Ind. Med.*, 5:231-33 (1988); Vineis, *et al.*, “Proportion of Lung Cancer in Males Due to Occupation in Different Areas of the United States,” *Int’l J. of Cancer*, 41:851-56 (1988); Hansen, “Mortality of auto mechanics, A ten-year follow-up,” *Scan. J. Work Environ. Health*, 15:43-46 (1989); Gustavsson, *et al.*, “Lung cancer and exposure to diesel exhaust among bus garage workers,” *Scand. J. Work Environ. Health*, 16:348-54 (1990); Morabia, *et al.*, “Lung cancer and occupation: results of a multicentre case-control study,” *British J. of Ind. Med.*, 49:721-27 (1992); Wong, “Considerations of Specificity in Assessing the Relationship Between Asbestos and Cancer,” *Am. J. of Ind. Med.*, 23:521-23 (1993).

¹⁷ See Marcus, *et al.*, “Asbestos-associated lung effects in car mechanics,” *Scand. J. Work Environ. Health*, 13:252-54 (1987); Raitel, *et al.*, “Health Hazards From Fine Asbestos Dusts: An Analysis of 70,656 Occupational Preventive Medical Investigations From 1973 to the End of 1986,” *Int. Arch. Occup. Environ. Health*, 61:527-41 (1989).

C. Gold Book's Origins, Preparation, Funding, Review, and Approval Are Almost Entirely Undocumented and Cannot be Verified or Evaluated

Given its continued availability, and the recent focus on the quality of the information being disseminated by EPA, it is surprising that EPA is able to produce virtually no documentation regarding the origins, preparation, funding, review, and approval of the Gold Book. In response to FOIA requests on these subjects, EPA located only a small number of internal documents, all of them prepared in 2000, consisting essentially of e-mails and information fact sheets. The documents reflect a largely unsuccessful internal effort by EPA to reconstruct as much as possible about the history of the Gold Book. No original source documents were ever located, and the documents that were located provided little information about even the most basic background or history of the Gold Book.¹⁸

As to the Gold Book itself, EPA was able to provide virtually no information. While it appears that the Gold Book essentially was authored by a single EPA official, there is no information or detail about how the Gold Book was researched or prepared, whether there was any consultation with or involvement of medical experts, what persons or entities were involved in funding the publication, or whether the Gold Book was ever subjected to any internal or external peer or other review or comment. Nor is there any information about who at EPA reviewed or authorized the publication of the Gold Book.

The materials located by EPA suggest that, with the advent of revised OSHA regulations issued in 1994 with respect to workplace exposure to asbestos – which specifically applied to brake and clutch workers and workers engaged in the manufacture of friction product materials and set new standards, controls, and work procedures – the Gold Book became less important from the standpoint of worker training and education. Thus, though EPA continues to make the Gold Book available to the public, an EPA official has noted internally that “these materials are all dated 1986 or thereabouts [and that as a result] [s]ome of their content is likely out-of-date from a regulatory perspective, although the general guidance remains useful.”¹⁹

IV. THE IMPACT OF THE GOLD BOOK

Hundreds of American companies have been confronted with asbestos personal injury litigation. Thousands of those cases allege disease from exposure to asbestos-containing friction products. In the highly-charged environment of such litigation, the Gold Book has been used to try to sway jurors, who are told that it represents EPA's current position and thinking on the question of whether asbestos-containing friction products are dangerous to users. In the courtroom, the Gold

¹⁸ The documents do indicate that the Asbestos Action Program, which apparently oversaw the preparation of the Gold Book, was abandoned by EPA at some unknown point in time.

¹⁹ See EPA FOIA Response.

Book is routinely portrayed as a thoroughly researched, up-to-date, and definitive EPA statement that friction products are indeed hazardous and cause asbestos-related disease.

While clearly the intent of the Gold Book was not to constitute a definitive scientific statement on these issues, either at the time it was prepared and certainly not now in light of the development of the scientific literature since 1986, jurors inevitably are heavily swayed by the impression that EPA's "official position" is that friction products are hazardous. The impact of such an argument is particularly powerful both because of EPA's status as a respected agency charged with protecting safety and health and because whether auto mechanics face a risk from asbestos in friction products is precisely the question the jurors are being asked to answer.

Outside the courtroom, the continuing availability of the Gold Book, and its alarmist and inflammatory tone, hinders a fair-minded assessment of the hazards, if any, posed to users of asbestos-containing friction products. EPA's implicit endorsement of the statements in the Gold Book gives it undue (and unnecessary) weight in any discussion of the matter. Wittingly or not, EPA is a participant in the debate on these issues through the continuing availability of the Gold Book.

V. REQUESTED ACTION

In light of the fact that it no longer contains adequate or current information regarding the hazards, if any, posed by the use of asbestos-containing friction products, EPA should discontinue any further dissemination of the Gold Book. At the same time, EPA should notify the public, through EPA's website or otherwise, that the Gold Book is outdated from a scientific and regulatory perspective. Should EPA believe that it should continue to provide guidance in this area, EPA should update the Gold Book to reflect a complete analysis of the state of medical science.²⁰

VI. CONCLUSION

We appreciate very much the opportunity to be heard on a matter considered to be of fundamental importance. We would be pleased to provide any supplemental information or answer any questions that would assist EPA in its consideration of this request. We look forward to your response in accordance with the Guidelines.

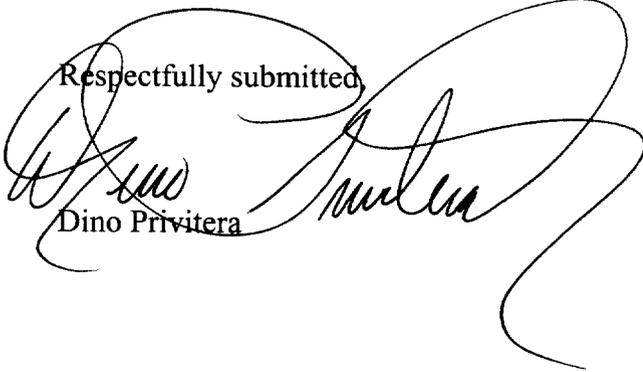
²⁰ In the event that EPA undertakes a substantive reevaluation of the Gold Book, we would request the opportunity to submit a more complete presentation of the medical and scientific evidence regarding auto mechanics and the use of asbestos-containing friction products.

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Morgan Lewis
C O U N S E L O R S A T L A W

Thank you for your attention to this matter.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'Dino Privitera', is written over the typed name. The signature is highly cursive and loops around the typed text.

Dino Privitera