

LAW OFFICES  
HYMAN, PHELPS & MCNAMARA, P.C.

700 THIRTEENTH STREET, N.W.  
SUITE 1200  
WASHINGTON, D. C. 20005-5929  
(202) 737-5600  
FACSIMILE  
(202) 737-9329  
www.hpm.com

DAVID B. CLISSOLD

Direct Dial (202) 737-7545  
DClissold@hpm.com

June 1, 2011

**By Email and U.S. Mail**

Associate Director for Communications  
Office of the Director  
National Institutes of Health  
Building 1, Room 344  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Information Quality Request for Correction**

To Whom It May Concern:

- A. A detailed description of the specific material that needs to be corrected including where the material is located.**

National Cancer Institute FactSheet: Cigar Smoking and Cancer. Available at <http://www.cancer.gov/cancertopics/factsheet/Tobacco/cigars>.

- B. Specific reasons for believing the information does not comply with OMB, HHS, or agency-specific guidelines and is in error and supporting documentation, if any.**

**1. The IQA Standards**

The Information Quality Act (IQA), and IQA guidelines promulgated by the OMB and HHS explain the standards of quality for disseminations of agency information. Among other things, such disseminations must meet the standard of "objectivity." Under the HHS Guidelines:

“Objectivity” involves two distinct elements, presentation and substance. “Objectivity” includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections), and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

Most statements in this FactSheet are not referenced. However, the primary source of information used appears to be:

National Cancer Institute (1998). *Smoking and Tobacco Control Monograph 9: Cigars: Health Effects and Trends*. Bethesda, MD. Retrieved October 21, 2010, from: <http://www.cancercontrol.cancer.gov/terb/monographs/9/index.html> (“Monograph 9”).

Monograph 9 is referenced several times in the NIH FactSheet. Accordingly, the objectivity of Monograph 9 is relevant and will be discussed below.

## **2. Examples of IQA Quality Defects in the FactSheet**

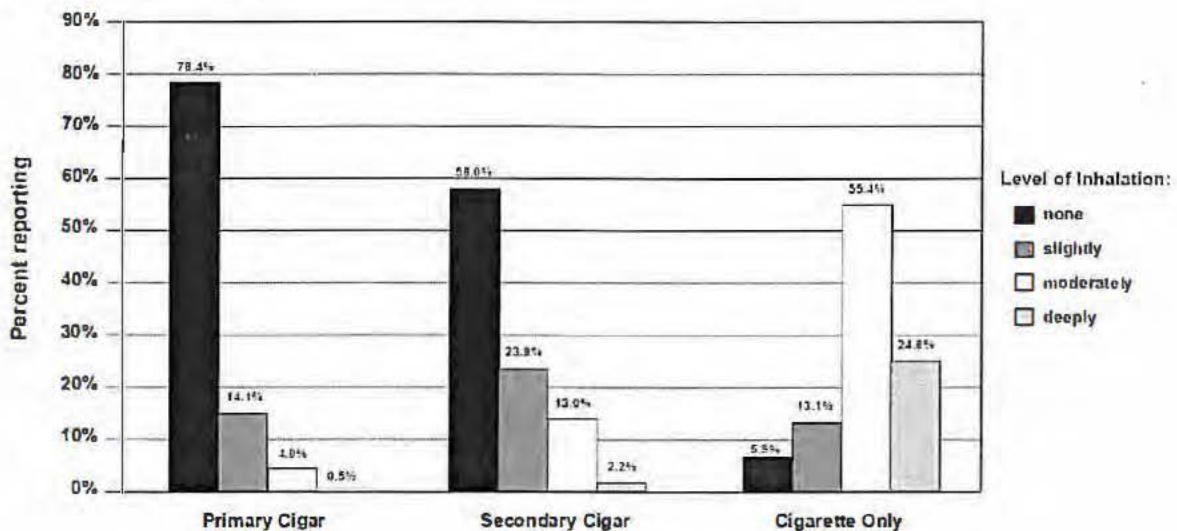
a. The FactSheet asks this question:

***How are cigars different from cigarettes? Cigarettes usually differ from cigars in size and in the type of tobacco used. Moreover, in contrast with cigarette smoke, cigar smoke is often not inhaled.***

The non-inhalation of cigar smoke is a key element in the erroneous statements made throughout the FactSheet. Since both cigars and cigarettes produce smoke that results from the burning of tobacco, it is common sense that they probably do contain the same chemical compounds. However, if the smoke from cigars is not inhaled into the lungs of smokers, then that smoke is (again by common sense), much less toxic than inhaled

cigarette smoke. Cigar smoke and cigarette smoke are in fact quite different in a number of ways, with the most important being the acidity/alkalinity (“pH”). The pH can affect the amount of nicotine that is absorbed in the buccal cavity (Armitage and Turner, 1970; Armitage et al., 1977). Buccal absorption of nicotine from American cigarettes has been considered to be negligible (Gori et al., 1986). The pH may also be a factor in the “inhalability” of cigar smoke (Hoffmann and Wynder, 1972).

Most “primary” cigar smokers (i.e., those who have never smoked cigarettes or a pipe), do not inhale (Turner et al., 1977). A comparison of inhalation rates of primary cigar smokers, “secondary” cigar smokers (i.e., those who currently smoke only cigars, but previously smoked cigarettes and/or a pipe, either in combination with cigars or exclusively), and cigarette smokers from Monograph 9 is presented below (Monograph 9, Chapter 4, Figure 1).



As shown above, approximately 80% of primary cigar smokers do not inhale, and only 0.5% inhale deeply. More importantly, according to Monograph 9, “this reduced inhalation of tobacco smoke probably explains the lower risks of coronary heart disease, COPD, and lung cancer seen among cigar smokers compared to cigarette smokers” (Monograph 9 at page 155). Thus, although the FactSheet notes a difference in inhalation between cigars and cigarettes, the important health consequences of this difference are never mentioned for context. Thus, the FactSheet is incomplete and biased in violation of the HHS Guidelines.

b. The FactSheet contains these two statements:

***“There is no safe level of exposure to tobacco smoke. If you want to reduce the health risk to yourself and others, stop smoking.”***

***“The more you smoke, the greater the risk of disease.”***

First, these statements contradict one another. If smoking more increases the risk of disease, then smoking less must reduce it. More importantly, these statements are contradicted by the data in Monograph 9. Primary cigar smokers have overall mortality rates that are very similar to those in non-smokers. Monograph 9 gives an overall mortality ratio of 1.02 for smokers of 1-2 cigars per day (Monograph 9 at Chapter 1, Table 1). These cigar smokers are at no greater risk of any disease, including lung cancer (Monograph 9 at Chapter 4, Table 7), buccal and pharyngeal cancer (Monograph 9 at Chapter 4, Table 11), cancer of the larynx (Monograph 9 at Chapter 4, Table 18), cancer of the esophagus (Monograph 9 at Chapter 4, Table 21), pancreatic cancer (Monograph 9 at Chapter 4, Table 27), coronary heart disease (Monograph 9 at Chapter 4, Table 31), COPD (Monograph 9 at Chapter 4, Table 35), or cerebrovascular disease (Monograph 9 at Chapter 4, Table 39). Monograph 9 emphasizes the relationship between the number of cigars smoked and the risk of disease, and concludes:

Most cigarette smokers smoke every day. In contrast, as many as three-quarters of cigar smokers smoke only occasionally, and some may only smoke a few cigars per year. This difference in frequency of exposure translates into lower disease risks.

(Monograph 9 at iii, emphasis added). The FactSheet does not mention this data demonstrating that occasional cigar smokers (comprising as much as 75% of the population of cigar smokers) are at no greater risk for disease than non-smokers. According to the FactSheet, cessation is the only alternative that reduces risk. Thus, the FactSheet lacks appropriate context and is both incomplete and biased within the meaning of “objectivity” in the HHS Guidelines.

c. The FactSheet also says:

***“Are cigars addictive? Yes. Even if the smoke is not inhaled, high levels of nicotine (the chemical that causes addiction) can still be absorbed into the body. A cigar smoker can get nicotine by two routes: by inhalation into the lungs and by***

***absorption through the lining of the mouth. Either way, the smoker becomes addicted to the nicotine that gets into the body.”***

This statement is not referenced. However, in contrast to such a definitive statement of effect, Monograph 9 is far more cautious about any link between cigars and addiction:

The pattern of use of cigars also sheds some light on the addictive nature of cigar smoking in comparison with other forms of tobacco use, at least for adults. The fraction of adult cigar smokers who smoke cigars every day is much smaller than the fraction of cigarette or smokeless tobacco users who use every day (Chapter 2). This suggests that cigar smoking among adults, while probably able to cause addiction to nicotine, is less likely to do so than cigarette smoking or smokeless tobacco use. Data from California, which show that the recent change in cigar use among adults is largely an increase in occasional use, also suggests that the addictive potential of cigars is lower than that for cigarettes.

(Monograph 9 at page 11, emphasis added). Elsewhere, Monograph 9 states that “Cigars . . . *may* be addictive” (Monograph 9 at iii, emphasis in the original). Moreover, Monograph 9 says that even if cigars may cause addiction, it is something lower than what is seen for cigarettes. “The pattern of cigar use in the population (infrequent use, low number of cigars smoked per day, and lower rates of inhalation compared to cigarette smokers), suggest that cigar use which begins in adulthood may be less likely to produce dependence than cigarette smoking” (Monograph 9 at 191). In contrast, the FactSheet states definitively that cigars are addictive. Thus, the FactSheet is not an objective summary of the available data regarding addiction. Moreover, the FactSheet does not reference any source for such a definitive statement, which in itself is a violation of the HHS Guidelines.

d. The FactSheet states:

***Are cigars less hazardous than cigarettes? Because all tobacco products are harmful and cause cancer, the use of these products is strongly discouraged. There is no safe level of tobacco use. People who use any type of tobacco product should be encouraged to quit.***

Cigars are less hazardous than cigarettes, so this question should be answered in the affirmative. In fact, the FactSheet itself states: “Although cigar smokers have lower rates of lung cancer, coronary heart disease, and lung disease than cigarette smokers, they have higher rates of these diseases than those who do not smoke cigars.” If cigar smokers have lower rates of disease than cigarette smokers, then cigars are less hazardous than cigarettes. Moreover, as noted above, Monograph 9 clearly concludes that people who smoke 1-2 cigars per day do not have higher rates of many diseases even when compared to non-smokers.

Instead of answering the question, however, the FactSheet states that there is “no safe level of tobacco use.” This statement is incorrect since Monograph 9 shows that there is a level of use of cigars (1-2 per day), that is not associated with a statistically greater risk of disease. Primary cigar smokers have overall mortality rates that are very similar to those in non-smokers. Monograph 9 gives an overall mortality ratio of 1.02 for smokers of 1-2 cigars per day (Monograph 9 at Chapter 1, Table 1). As explained above, an occasional smoker of cigars does not need to be encouraged to do anything, since he or she is not at increased risk of disease to begin with, including risks for lung cancer, buccal and pharyngeal cancer, cancer of the larynx, cancer of the esophagus, pancreatic cancer, coronary heart disease, COPD, or cerebrovascular disease as stated in Monograph 9. Moreover, as noted above “as many as three-quarters of cigar smokers smoke only occasionally” (Monograph 9 at iii). By not mentioning this data, the FactSheet implies that all cigar smokers are at increased risk, making the FactSheet both incomplete and biased within the meaning of “objectivity” in the HHS Guidelines.

e. The FactSheet states:

***Do cigars cause cancer and other diseases? Yes. Cigar smoking causes cancer of the oral cavity, larynx, esophagus, and lung. It may also cause cancer of the pancreas. Moreover, daily cigar smokers, particularly those who inhale, are at increased risk for developing heart disease and other types of lung disease. Regular cigar smokers and cigarette smokers have similar levels of risk for oral cavity and esophageal cancers. The more you smoke, the greater the risk of disease.***

The source of these statements is not clear, which itself is a violation of the HHS Guidelines. However, the citation appears to be to Table 10 in Chapter 4 of Monograph 9. This brings into question the quality of the data in Monograph 9. Among other quality defects, the data included in this table are very old (the oldest being a study from 1920), do

not differentiate primary from secondary cigars smokers, often combine cigar smokers with pipe smokers, have very small numbers of studies examined (a single study for esophagus), and in general show quite low relative risks for both cigar and cigarette smoking. These data simply do not support the definitive statements made in the FactSheet. There do not appear to be any definitive epidemiology data in the published literature on rates of oral, esophageal and laryngeal cancer in primary cigar smokers. In addition, discussing cancers such as these without mentioning the well-known synergistic effects of smoke with ingested alcohol (Zeka et al., 2003), seems misleading. By not noting these important limitations in the Monograph 9 table, assuming that is the source of the information in the FactSheet, the FactSheet violates the IQA and HHS Guidelines.

Moreover, Monograph 9 recognizes that these health effects are not experienced by the occasional cigar smoker (1-2 cigars per day). Monograph 9 states that “regular cigar smoking causes cancer of the lung, oral cavity, larynx, esophagus, and probably cancer of the pancreas.” (Monograph 9 at 155). However, most cigar smokers are not “regular” smokers, as Monograph 9 recognizes, stating that as many as 75% are merely “occasional” cigar smokers. The FactSheet does not recognize this important qualification, and thus, the statements regarding cancer risk are both incomplete and biased within the meaning of “objectivity” in the HHS Guidelines.

#### **Specific recommendations for correcting the information.**

The FactSheet should be withdrawn. To the extent that HHS believes the FactSheet can be corrected, it should at least reflect these two points: (1) there is no evidence to suggest that cigar smokers who smoke 1-2 cigars per day are at increased risk of any disease; and, (2) inhalation of cigar smoke (or the lack thereof), has a direct effect on risk. If HHS has definitive evidence to the contrary, the source of that data must be stated and scrutinized under the IQA.

#### **A description of how the person submitting the complaint is affected by the information error.**

The undersigned is counsel for the International Premium Cigar and Pipe Retailers Association (IPCPR). The IPCPR is a not-for-profit trade group representing premium cigar and tobacco retail shops located throughout the United States and abroad. The 1,700 retail members of the IPCPR are small businesses, and are typically family-owned and operated. IPCPR members operate more than 2,000 retail stores, employ more than 8,000 people, and sell premium cigars, tobacco pipes, loose tobacco, cigar and pipe accessories,

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and gift items related to the use and enjoyment of these products by adult Americans. IPCPR also has a direct economic relationship with more than 350 manufacturers, distributors and service providers who supply the retail members of the IPCPR and employ 7,000 more people. Aside from its economic interests, IPCPR seeks to bring reason and balance to the public debate about smoking, particularly as it pertains to cigars.

**Name, mailing address, telephone number, e-mail address, and organizational affiliation, if any, of the individual making the complaint.**

David B. Clissold  
Hyman, Phelps & McNamara, P.C.  
700 13<sup>th</sup> Street NW  
Suite 1200  
Washington, DC 20005  
202-737-7545  
dclissold@hpm.com

Sincerely,



David B. Clissold

DBC/dcp

Attachments