

STATUTORY DECLARATION

Fully aware that this statement can be used in a court hearing, and of the consequences of perjury, I testify under oath that my name is Dr. Gio Batta GORI, and I am the Director of the Franklin Institute Policy Analysis Center, 4701 Willard Avenue, Suite 310, Chevy Chase, Maryland 20815, U.S.A. I am a diplomate of the Academy of Toxicological Sciences and hold a Doctorate in Biological Sciences and a Master of Public Health degree. From 1968 to 1980, I founded and directed the Smoking and Health Program of the National Cancer Institute, at the Department of Health and Human Services, United States Government, and have continued my research interests in the field thereafter. As such I have acquired international recognition as an expert in scientific matters pertaining to cigarette smoking.

In 1982, I conducted studies to measure the actual smoke intake from three cigarette brands marketed in the United States. All these brands belonged to the 1 mg tar class, as defined by machine smoking standards, and were BARCLAY, CARLTON AND CAMBRIDGE. My studies utilized independent human subjects recruited from the general population, who smoked alternatively the three brands tested. Plasma cotinine, a direct metabolite of nicotine, was measured in each smoker as a direct indicator of nicotine and smoke intake. The mean plasma cotinine values across smokers for each brands, and the mean differences among brands, were clearly proportional to the standard machine analytical yields of the brands tested.

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Details of my studies on this subject have been published in an independent peer-reviewed journal "Regulatory Toxicology and Pharmacology, 3:110-120, 1983". A copy of the scientific report is attached to this declaration.

In connection with this study, I have examined a statutory declaration by Mr. Rolf Kroeger, dated December 12, 1984. Mr. Kroeger, an employee of the Reemtsma Tobacco Company in Hamburg, notes that ~~the~~ Figure 3, page 117 of my said publication gives a correlation coefficient of 0.47 between plasma cotinine levels in smokers and available daily nicotine. This coefficient, he points out, implies that only 22.9% of the variance in plasma cotinine values is explained by the available daily nicotine variable. From this, Mr. Kroeger reaches the erroneous conclusion that plasma cotinine measures are not good predictors of actual nicotine intake.

His error is a classical example of the "ignoratio elenchi" fallacy, because he mistakenly assumes that available daily nicotine is a measure of actual nicotine intake. In our paper we define available daily nicotine as $ADN = FTC(N) * CPD$, namely FTC nicotine yield multiplied by the number of cigarettes smoked daily. Therefore, available daily nicotine is an indication of what is available daily or offered to smokers under standard FTC (or DIN) conditions, but not of how much nicotine individual smokers actually intake. In fact, Figure 1, page 116 of our paper clearly shows that actual intake is not the same as the quantity offered under standard FTC conditions. On the other hand,

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plasma nicotine values are a valid indicator of actual intake of nicotine, and correlate quite well with plasma cotinine values, as Figure 2, page 117 of our paper clearly shows. Moreover, our publication gives reference to other studies that independently confirm the same excellent correlation between plasma nicotine and plasma cotinine values.

Therefore, contrary to the implication of Mr. Kroeger, plasma cotinine values are a valid representation of plasma nicotine values and, by extension, of nicotine intake in smokers.

Gio B. Gori, DSc, MPH, DATS

Chevy Chase, Maryland

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