such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued \* after an opportunity for a hearing.' However, the Cigarette Act and the Smokeless Act both require submissions of reports or lists of ingredients to the Secretary (see 15 U.S.C. 1335a and 4403) that must be kept confidential. The agency tentatively concludes that these provisions may preclude FDA from requiring components or ingredients to be listed in all advertising and other printed matter. Therefore, FDA has decided, at this time, not to require a description of components or ingredients, but invites comment on whether it should initiate proceedings to determine whether the agency should require a listing of the component parts or ingredients of these restricted devices and the impact of the Cigarette Act's and the Smokeless Act's provisions on the agency's authority.

IOM recently recommended that a "regulatory agency should take steps to inform consumers about the meaning of statements regarding tar and nicotine yields." <sup>232</sup> Some manufacturers voluntarily disclose the quantities of tar and nicotine, as determined by the FTC method, in their labeling or advertising, and one Surgeon General's warning states, "Cigarette Smoke Contains Carbon Monoxide."

Consumers are aware that cigarettes produce tar and carbon monoxide and that they contain nicotine. Most consumers, however, do not understand the FTC rating numbers or the health implications of each constituent.<sup>233</sup> The proposed rule would not explain the FTC ratings because of the controversy surrounding the FTC method for determining tar, nicotine, and carbon monoxide

In December 1994, a conference was held under the auspices of an Ad Hoc Committee of the President's Cancer Panel (the Ad Hoc Committee) to consider the continuing usefulness of the FTC method. Although the full report is not yet available, the Ad Hoc Committee's relevant conclusions were:

The smoking of cigarettes with lower machine-measured yields has a small effect in reducing the risk of cancer caused by smoking, no effect on the risk of cardiovascular diseases, and an uncertain effect on the risk of pulmonary disease.

The FTC test protocol does not accurately reflect actual human smoking, which is not standardized, but is characterized by wide variations.

The Ad Hoc Committee recommended, among other things, that: (1) The FTC protocol be changed to

produce a range of tar, nicotine, and carbon monoxide ratings for each brand to better reflect the intensity with which each cigarette can be smoked; and (2) the range of ratings for each brand should be communicated to consumers. The Ad Hoc Committee recognized that designing the new test and determining how to convey the information to consumers would require the involvement of many agencies, including the National Institutes of Health, FDA, and CDC, and would also take time. The Ad Hoc Committee recommended against measuring other smoke constituents, but suggested that smokers be informed of "other hazardous smoke constituents" in packages and in advertising.

The FTC is considering whether and how to implement these recommendations. Until that occurs, FDA will not propose any requirements concerning tar, nicotine, and carbon monoxide ratings, but the agency requests comment on whether it should implement one of the recommendations of the Ad Hoc Committee by proposing to require manufacturers to provide information about these substances through a package insert and/or to provide information about nicotine in labeling and advertising.

In considering the design of the warning, FDA notes that research indicates that novel formats for warnings are most likely to capture the viewer's attention.<sup>234</sup> The FTC reported in 1981 on the noticeability of messages inside a rectangle, octagon, circle and arrow, and enlarged rectangle.<sup>235</sup> The report concluded that the circle and arrow and octagon were noticed and recalled more often. Recall of the message in the circle and arrow was 64 percent, whereas recall of the same message in a rectangle (the shape used in current cigarette advertising) was only 28 percent.<sup>236</sup> Other studies describe the importance that format has in conveying the information and ensuring that it is sufficiently processed.<sup>237</sup> Factors such as print size, color, contrast, graphic design, positioning (e.g. at the top of each page of advertising), shape, spacing, font style, and highlighting are all important considerations for effectively communicating information, particularly to young people.

In addition, FDA notes that several studies have demonstrated that rotating messages assists in maintaining their noticeability. FTC concluded, in its 1981 investigation of cigarette advertising practices, that a "rotational warning system would provide sufficient repetition of each message to contribute to long term recall of that

message, while decreasing the likelihood that any one message would become so familiar and so overexposed that its effectiveness would 'wear out.''' 238 The report concluded that quarterly rotated messages would assist in maintaining the novelty of the message, thus enhancing noticeability. <sup>239</sup> Additionally, the report concluded that shorter messages which are rotated are specific and concrete and are more easily converted into mental images. These messages are recalled more readily. <sup>240</sup>

The Centre for Behavioural Research on Cancer in Australia described a process of "habituation" that occurs with warnings and health messages. Under this process, a person's response to a warning or health message declines as that person increases his or her exposure to the warning or health message.<sup>241</sup> It found that habituation is greater as the frequency of exposure increases and is reduced if exposure to the stimulus is stopped for a period of time,<sup>242</sup> as can be the case if the messages are dissimilar and rotated.

The proposed regulation requires that the brief statement be readable, clear, conspicuous, prominent, and contiguous to the current Surgeon General's warning. FDA requests comments on the text and design of the brief statements, particularly in its ability to reach young people, and/or whether and what design specifications should be established. Specifically, it requests comment on how best to insure that the statement will be clear, conspicuous, and prominently displayed.

d. False or misleading labeling and advertising. Proposed § 897.36 would declare the labeling or advertising of cigarettes and smokeless tobacco products to be false or misleading if the labeling or advertisement contains "any express or implied false, deceptive, or misleading statement, omits important information, lacks fair balance, or lacks substantial evidence to support any claims made for the product." This provision would implement section 201(n) of the act, which states that labeling or advertising may be misleading based on "representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article," and section 502(q)(1) of the act, which declares a restricted device to be misbranded if "its advertising is false or misleading in any particular." FDA emphasizes that