



Commissioned Officers Association of the U.S. Public Health Service

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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Docket No. FDA-2010-N-0568
RIN 0910-AG41

The following comments are submitted on behalf of the Commissioned Officers Association of the U.S. Public Health Service, Inc. (COA), whose members are active-duty or retired officers of the USPHS Commissioned Corps. Our comments respond to the Proposed Rule published in the Federal Register on November 12. Our comments focus on the fact that all references to the U.S. Surgeon General have been inexplicably omitted from the proposed new cigarette warnings. This unwelcome development is especially baffling in light of the December, 2010 release of the nation's 30th report on smoking and health, once again published in the name of the U.S. Surgeon General. COA stands with all living former Surgeons General who, in their joint statement dated January 6, 2011 declare **“The visible and credible leadership of the Surgeon General is essential to affect the continued decline of tobacco use in our nation. Therefore, we hold that it is in the best interest of the health of the citizens of the United States, and of the world community, to include a clear attribution of the new tobacco warnings to the Surgeon General – the final common pathway of the best available public health science.”**

Federal regulators should restore the words “Surgeon General’s Warning” to all proposed cigarette labels and advertisements.

Summary statement: In each new warning label, on each cigarette pack and advertisement, regulators should restore the reference to the U.S. Surgeon General. Why? Attribution is essential. The citation of credible scientific authority is essential. There is nothing tired, stale, worn-out, or overexposed about referencing the U.S. Surgeon General on these warnings. Tacit acknowledgment of this fact came in December, 2010 with promotion and public release of the newest Surgeon General’s report, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*.

Against this backdrop, the disappearance of the U.S. Surgeon General from the new cigarette warnings is odd and misguided. It is not acceptable to dispense with the citation of credible scientific authority on urgent public health warnings. We can think of no legitimate precedent for this. The U.S. Food and Drug Administration, of all entities, should not propose or support or tolerate the casual omission of attribution. As stated by

the former Surgeons General in their January 6th letter **“Failure to attribute the tobacco warnings to the Surgeon General would represent a dramatic step backwards for the leadership, which the United States has provided in public health since 1873 when the first Surgeon General was appointed.”**

The statute itself is silent about any reason for the two-word omission in the proposed new warnings. The 40-page regulatory package is also silent. However, the statute specifically gives the Secretary of Health and Human Services flexibility to alter text and format as she sees fit. This permission occurs in several places. See, for example, Section. 201: *“The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and(b)(2) as the Secretary determines appropriate..”*

COA asks FDA regulators to comment on this entire matter, at length and in detail, in the preamble to the final rule.

We support the goals of this rulemaking. This Association strongly supports the goals of this rulemaking and the overarching purpose of the underlying statute. The Family Smoking Prevention and Tobacco Control Act, or Public Law 111-31, was approved by Congress on June 22, 2009. Its first five words are “To protect the public health...” To this end, the law increases the power and reach of the U.S. Food and Drug Administration to regulate cigarettes and other tobacco products, most importantly in the areas of labeling, advertising, marketing, sponsorship, and enforcement. This Association favors strengthening the hand of the FDA in all these areas and, in general, applauds the agency’s efforts to update and improve the warning messages on cigarette packs and advertisements.

One theme that runs through the statute and the regulatory package is the urgency of convincing young people not to start smoking in the first place. Another is the importance of helping current smokers quit. These are global public health goals, shared by many other nations. Some of them have followed America’s lead by citing the U.S. Surgeon General in their own warnings on cigarettes and other tobacco products. This is an impressive testimonial.

Reasons to restore “Surgeon General’s Warning.” The proposed new messages must be sourced. It must be crystal-clear where the stronger warnings are coming from, and on whose authority they are published. This is especially important with the graphic new warnings, the point of which is to shock and disturb and thereby attract and hold attention.

The new warnings must answer the question, “Who says?” This is particularly important if there is a chance that the new images could be dismissed or ridiculed by young people or other target populations generally thought to be resistant to warnings about the health hazards of smoking.

The potential for overkill already has been mentioned. Some initial press reports quoted experts and alluded to research suggesting that over-the-top scare messages might be self-defeating. See, for example, *The New York Times*, November 10, 2010. See also the

enclosed editorial cartoon from the *Sun-Sentinel*, which appeared in *The Washington Post* and elsewhere. The possibility that frightening messages might not be taken seriously is a sound reason to continue to source their content to the U.S. Surgeon General.

Implicit support for restoring the Surgeon General brand can be found throughout the regulatory information published in the Federal Register. It repeatedly cites the Surgeon General's reports on smoking and health. These reports have been published from time to time over nearly half a century; the most recent was released on December 9. In the public mind, they have come to link the U.S. Surgeon General with the most accurate and up-to-date scientific information available about the hazards of smoking, including the harm to non-smokers of second-hand smoke. The release of *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease* with the imprimatur of the U.S. Surgeon General continues the tradition to this day, and underscores this point.

The FDA rulemaking reflects a striking contradiction. On the one hand, FDA regulators repeatedly cite the Surgeon General's reports on smoking and health, and the FDA's parent agency, the U.S. Department of Health and Human Services, continues to compile new evidence and publish it in the Surgeon General's name. On the other hand, citation of the Surgeon General is absent from the proposed new cigarette warnings. This illogic requires an explanation.

The omission of any reference to the U.S. Surgeon General represents a departure from longstanding tradition. It represents a break with public expectations. It raises questions of legitimacy because it is not clear who is behind the blunt messages, the cartoonish typefaces, and the graphic images meant to frighten smokers and would-be smokers. Most important, the abrupt and unexplained decoupling weakens the government's credibility and dilutes the message. The effectiveness of the Surgeon General's warning is clear and unequivocal in view of the fact that since the release of the landmark *Surgeon General's Report on Smoking and Health* in 1964 the number of Americans who are smokers has been reduced from 45 percent to approximately 22 percent of the population.

There is no reason not to restore "Surgeon General's Warning." Nothing in the law says that references to the U.S. Surgeon General should or must be omitted. Nothing in the law says they cannot be restored. The law is silent. Moreover, congressional aides to the law's lead sponsor have emphasized to me personally that nothing can or should be inferred from this silence.

The statute is unusually detailed and specific in its directions to the regulators at FDA. Still, as noted above, it gives the DHHS Secretary flexibility with regard to wording and format. See Section. 201: "*The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and(b)(2) as the Secretary determines appropriate...*"

The Secretary thus has explicit congressional permission to make this change to the proposed labels. Her hands are not tied; she can restore the credibility and authority of the U.S. Surgeon General to the new cigarette warnings.

For all the reasons cited herein, this Association fully endorses and supports the recommendation of the former Surgeons General and urges the FDA to restore the Surgeon General brand to all cigarette warnings on all packages and advertisements. This can and should be done. There is no stated reason not to do so; there is no statutory impediment.

Citing the U.S. Surgeon General on cigarette warnings is part of the long and honorable history of speaking truth to the American people about smoking and health. The FDA should not break faith with this tradition.

Sincerely,

A handwritten signature in black ink, appearing to read "G. M. Farrell", with a long horizontal flourish extending to the right.

Gerard M. Farrell
Captain, U.S.N. (Ret.)
Executive Director

Enclosure

cc

VADM Benjamin
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