UNIVERSITY OF CALIFORNIA SAN FRANCISCO

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA • SANTA CRUZ

STANTON A. GLANTZ, PhD Professor of Medicine (Cardiology) American Legacy Foundation Distinguished Professor of Tobacco Control Director, Center for Tobacco Control Research and Education

530 Parnassus Suite 366 San Francisco, CA 94143-1390 Phone: (415) 476-3893 Fax: (415) 514-9345 glantz@medicine.ucsf.edu

Comment on

Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match...

FDA-2014-N-1051-0843

August 15, 2015

The FDA has posted amendment for a modified risk tobacco product (MRTP) application submitted on June 10, 2014, by Swedish Match North America Inc. for 10 snus smokeless tobacco products specifically to seek comments on the amendments to the originally filed applications. The FDA stated in its press release that "After filing the applications for scientific review—the first MRTP applications to reach this milestone—FDA requested clarifying and other information from the company and received several amendments in response" and is requesting public comment on these amendments.

The FDA has, however, reeducated the amendments so extensively for "trade secrets and confidential commercial information" that there is nothing of substance remaining upon which for the public to make an informed comment.

The law allows the FDA to waive claims of trade secret when it deems it in the public interest to do so. These extensive redactions are particularly unjustified because, as we pointed out in our paper based on previously secret tobacco industry documents, "Cigarette company trade secrets are not secret: An analysis of reverse engineering reports in internal tobacco industry documents released as a result of litigation," the companies routinely reverse engineer each others' products, so the "trade secrets" are not really secret from their competitors.

The paper also reviews the legal authority that the FDA has to make this information public.

In any event, the FDA's current practice makes this solicitation of public input in its evaluation process a joke.

In issuing whatever final decision it makes on the Swedish Match MTTP application, the FDA cannot claim meaningful public engagement in this part of the process.

¹ Velicer C, Lempert LK, Glantz S. Cigarette company trade secrets are not secret: an analysis of reverse engineering reports in internal tobacco industry documents released as a result of litigation. *Tob Control*. 2014 Jun 11. pii: tobaccocontrol-2014-051571. doi: 10.1136/tobaccocontrol-2014-051571. [Epub ahead of print]