CHEST
AMERICAN COLLEGE of CHEST PHYSICIANS

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June 2, 2022

Robert Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: CHEST Tobacco Regulatory Priorities and Request for Introductory Meeting

cc: Brian King, PhD, MPH
Director of the Center for Tobacco Products

Dear Dr. Califf:

On behalf of the American College of Chest Physicians (CHEST), we would like to congratulate you on your confirmation. We appreciate your prior FDA experience and perspective as a cardiologist and researcher. We are in a critical time in the space of tobacco control, including vaping and heated tobacco products, which collectively continue to impact the health of children and adults.

CHEST represents over 19,000 members who provide clinical respiratory, critical care, and sleep medicine care to patients in the United States and throughout the world. Our mission is to champion the prevention, diagnosis, and treatment of chest diseases. CHEST has been at the forefront in many of the landmark advances in tobacco control over the years, including membership in the ENACT coalition during the negotiations leading to the Attorney General's Master Settlement agreement with the tobacco industry, public recognition of the carcinogenicity of tobacco, and the banning of smoking from commercial air travel, among other initiatives. Every fellow of the American College of Chest Physicians (FCCP) takes a pledge to engage their patients in smoking cessation activities and education--the only society that requires such an oath.

As you welcome Dr. Brian King as Director of the Center for Tobacco Products (CTP), we urge you both to consider three overarching priority areas:

1. Improve transparency and accountability with the scientific community and the public;
2. Strengthen compliance monitoring and enforcement across the country; and

3. Implement CTP policy initiatives as quickly as is possible in the tightly regulated environment in which CTP functions.

Below, we propose additional detail on our recommendations.

Priority 1. Improve transparency and accountability with the scientific community and public

Specifically, CHEST recommends:

- The development of standardized safety and efficacy metrics by which emerging products can be evaluated;
- The use of independent toxicological evaluation to confirm aerosol toxicants to override the existing self-report mechanism;
- The public release of product primary application data for independent analysis by the scientific community;
- The development of a harms scale that would enable the consumer public to compare the risk of tobacco products against each other;
- The FDA post, for public understanding, the list of products that the FDA has declined to authorize;
- The development of more webinars presenting various research or analyses from within the CTP; and
- CHEST recommends more public education of the work and results from the research funded by CTP through the NIH.

Priority 2: Strengthen compliance monitoring and enforcement.

Specifically, CHEST recommends:

- The FDA to immediately include synthetic nicotine products in the existing regulatory framework;
- The development of a categorization schema to determine which products cross the threshold into medication delivery; and
- Timely and punitive action against non-compliant merchants/producers.

Priority 3: Speed the implementation of CTP policy initiatives

Specifically, CHEST recommends:

- The FDA finalize and implement the final rules related to the prohibition of menthol as a characterizing flavor in cigarettes and cigars;
- The FDA expedite premarket review of e-cigarettes, including completing public health review and issuing marketing denial orders for all nontobacco-flavored products, including menthol;
- The FDA prioritize enforcement against e-cigarette products that continue to be sold without marketing authorization for those that are flavored, have the highest market share, and/or have the highest prevalence of youth usage; and
- The public disclosure of all products that receive marketing denial orders.

Once again, on behalf of the 19,000+ clinicians represented by CHEST who care for patients affected by tobacco use, we congratulate you on assuming this role. We recognize the breadth and gravity of your charge.

We welcome the opportunity to serve as a resource to you and your staff in exploring how these priorities can be achieved. We would like to request that an introductory meeting be arranged in the coming quarter.

Sincerely,

David Schulman, MD, MPH, FCCP
President, CHEST

Frank Leone, MD, FCCP
Chair, Tobacco & Vaping Work Group