THOMAS J. MILLER
ATTORNEY GENERAL

1305 E. WALNUT ST.
DES MOINES, IA 50319
P: 515-281-5164
www.iowaattorneygeneral.gov

IOWA DEPARTMENT OF JUSTICE
OFFICE OF THE ATTORNEY GENERAL

March 31, 2020

To: Mitchell Zeller, J.D.
Director, Center for Tobacco Products
Food and Drug Administration

CC: Stephen M. Hahn M.D., Commissioner of Food and Drugs, FDA
Anna Abram, Deputy Commissioner for Policy, Legislation, and International Affairs, FDA
Matthew R. Holman, Ph.D., Director, Office of Science, Center for Tobacco Products, FDA
David M. Murray, Ph.D., Associate Director for Prevention. Director, Office of Disease Prevention, Office of Disease Prevention, National Institutes of Health
Helen Meissner, Ph.D., Sc.M., Director, Tobacco Regulatory Science Program (TRSP), NIH
Nora D. Volkow, M.D., Director of the National Institute on Drug Abuse (NIDA), NIH

Dear Mr. Zeller,

FDA and federal government statements on smoking, vaping and COVID-19

We were surprised and disappointed to see a statement about vaping and COVID-19 from an FDA spokesman published on Bloomberg's news service: *Vaping Could Compound Health Risks Tied to Virus, FDA Says*, March 27, 2020. According to the report, this statement was in the form of "*an email Friday in response to questions from Bloomberg*". The imprecise nature of the email communication meant that the report had to be amended to stress that this assessment applied *only to those with underlying conditions*. However, the headline continues to portray vaping as an additional risk factor for COVID-19 health impacts. We wish to make three points about this regrettable episode:

1. **Process**. There are around 12 million vapers and 34 million smokers in the United States. If they are to receive information with life or death consequences, especially at this time of greatly enhanced personal pressures, they deserve better than an *ad hoc* email from an FDA spokesman sent to a single online news service. If the federal government is going to provide advice, it should be available via FDA and CDC websites, validated for its veracity and clarity, tested for unintended consequences, and made widely available through recognized and trusted health professionals.
2. **Evidence**. It is likely that many older adult vapers will have underlying conditions that increase their vulnerability and likelihood of severe or fatal COVID-19 symptoms. This is because many are former or current smokers and will have accumulated damage to their cardiovascular and respiratory systems through many years of smoking. Many will be vaping with the express purpose of reducing their smoking-related risks and/or relieving their symptoms. It is therefore particularly important

that great care is taken with advice to this group. On what basis is FDA confident that it is right to discourage people with underlying smoking-related conditions from vaping at this time, given the likely alternative for many is a return to smoking? Where is the evidence-based reasoning that advising adult smokers against vaping is appropriate for the protection of public health at any time, but especially during this COVID-19 crisis? We know of no relevant and informative evidence on vaping and COVD-19 and the evidence on smoking and COVID-19 is inconclusive and contradictory.

3. **Advice**. If FDA is going to provide advice on smoking and vaping at this time, it must do this based on recognition of the pronounced difference in risk between smoking and vaping, the difficulty that many face in quitting nicotine use completely, the risks of harmful unintended consequences, and the strong association of smoking with poverty and various forms of disadvantage. Harm reduction is a valid concept and its potential is well-established. We do not believe the FDA has any basis for making recommendations about smoking and vaping that are specific to COVID-19 at this time. At this point, therefore, we believe that advice to smokers should be consistent with the longstanding public health imperative to quit smoking using whatever methods work, and that includes by switching to vaping or other low-risk non-combustible nicotine products.

It is important that the FDA does not assert or imply, in any circumstances, an equivalence in risk between smoking and vaping. We are also concerned that FDA statements have effects outside the United States and around the world, which is another reason for taking great care. If the FDA is able to provide candid and clear advice that puts the health of millions of Americans first, and this is based on sound behavioral and biomedical insights, then it should do so, and we would welcome the agency's contribution. If, however, its communications are arbitrary and ill-conceived, spreading fear and confusion with little scientific basis and with unpredictable consequences, then it would be better if FDA and its media spokespeople did not comment further at this time.

Yours sincerely,

Thomas J. Miller
Attorney General of Iowa
Des Moines, Iowa
United States

David B. Abrams, PhD
Professor, Social and Behavioral Sciences, NYU
College of Global Public Health.
New York University.
United States

Scott D. Ballin, JD
Health Policy Consultant
Former Vice President and Legislative Counsel
American Heart Association
Washington DC
United States

Clive Bates, MA, MSc
Director, Counterfactual Consulting
Former Director, Action on Smoking and Health UK
London
United Kingdom

K. Michael Cummings, PhD, MPH
Professor, Department of Psychiatry & Behavioral Sciences
Co-leader, Hollings Cancer Center Tobacco Research Program
Medical University of South Carolina
Charleston
United States

Konstantinos Farsalinos, MD, MPH
King Abdulaziz University, Saudi Arabia
University of Patras, Greece
School of Public Health, University of West Attica
Greece

Thomas J. Glynn, PhD
Adjunct Lecturer
School of Medicine
Stanford University
Palo Alto, California
United States

Ethan Nadelmann
Founder
Former Executive Director (2000-2017)
Drug Policy Alliance
New York
United States

Raymond Niaura, PhD
Professor, Social and Behavioral Sciences
College of Global Public Health
New York University
United States

Steven A. Schroeder, MD
Distinguished Professor of Health and Healthcare
Department of Medicine,
University of California, San Francisco
United States

David Sweanor, JD
Chair of Advisory Board of the
Center for Health Law, Policy and Ethics
University of Ottawa
Canada

Kenneth Warner, PhD
Avedis Donabedian Distinguished University Professor Emeritus of Public Health and Dean Emeritus,
University of Michigan School of Public Health
United States

Daniel Wikler, PhD
Mary B. Saltonstall Professor of Ethics and Population Health
Department of Global Health and Population
Harvard T.H. Chan School of Public Health
Boston, Massachusetts
United States