Federal Communications Commission
Washington, D.C. 20554

January 26, 2021

Mark J. Langer, Clerk
United States Court of Appeals
for the District of Columbia Circuit
333 Constitution Avenue, N.W.
Washington, D.C. 20001

RE: *Environmental Health Trust, et al. v. Federal Communications Commission*, Nos. 20-1025 and 20-1138 (oral argument held January 25, 2021)

Dear Mr. Langer:

This letter responds to Judge Henderson's request, made at oral argument yesterday, that the FCC submit information regarding the establishment, membership, and current status of (1) the Food and Drug Administration's Technical Electronic Product Radiation Safety Standards Committee (Committee) and (2) the Radiofrequency Interagency Work Group (Work Group).

(1) The Committee was established by the Radiation Control for Health and Safety Act of 1968. Pub. L. No. 90-602, 82 Stat. 1173, 1179 (1968) (codified at 21 U.S.C. § 360kk). *See* 21 C.F.R. §§ 14.120-130. Under the statute, the Committee is to be consulted before the FDA "prescrib[es] any standard under this section." 21 U.S.C. § 360kk(f)(1)(A); *id.* at § 360kk(a)(1)(A) ("The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety."); 21 C.F.R. § 14.120 (Committee established "to provide consultation before the [FDA] prescribes any performance standard for an electronic product."). Neither the Act nor the Committee Charter, a copy of which is attached, provides for a Committee role when the FDA acts, as here, to "(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of

the hazards and control of electronic product radiation; and (B) make such recommendations relating to such hazards and control as [it] considers appropriate." 21 U.S.C. § 360ii(b)(1); *see* FCC Br. at 23.

In this case, the FCC, by Notice of Inquiry, sought the views of interested members of the public and expert federal agencies on the issue of whether it should reexamine its radiofrequency emission limits. JA 161-363. It specifically sought the views of the Director of the FDA's Center for Devices and Radiological Health, Dr. Jeffrey Shuren. JA 8184. No statute or regulation required the FCC to seek out the views of the Committee, or otherwise intrude into the process by which the FDA (or any other federal agency) decides to formulate its views on a matter upon which the FCC has sought comment. Indeed, FDA regulations generally prohibit federal employees from conferring with the Committee directly. 21 C.F.R. § 14.31(d). It is therefore unsurprising that the Committee was not a part of any argument advanced by any party in the agency proceeding below or by petitioners in the briefing of this case. *See* 47 U.S.C. § 405 (requiring parties to provide the Commission with an opportunity to pass on an argument before obtaining judicial review).

The Committee consists of 15 members, five from industry, five from the government (Federal, State, or local), and five from the general public, one of whom must be a representative of organized labor. 21 U.S.C. § 360kk(f)(1)(A); 21 C.F.R. § 14.127. As the FDA's website discloses, the Committee last met on October 25 and 26, 2016. https://www.fda.gov/advisory-committees/technical-electronic-product-radiation-safety-standards-committee/past-meeting-materials-technical-electronic-product-radiation-safety-standards-committee. The FDA website lists the Committee roster; there are 10 current vacancies. https://www.fda.gov/advisory-committees/technical-electronic-product-radiation-safety-standards-committee/roster-technical-electronic-product-radiation-safety-standards-committee; *see* 21 C.F.R. § 14.124(c) ("Ten members constitute a quorum").

As set forth in our brief, in declining to initiate a rulemaking to consider new radiofrequency limits to protect against non-thermal effects, the FCC relied on Dr. Shuren's April 24, 2019 letter, the FDA's assessment that the "'totality of the available scientific evidence continues to not support adverse health effects in humans caused by exposures at or under the current radiofrequency energy exposure limits,'" and the according views of other agencies and recognized

standard-setting bodies. FCC Br. at 24-25, 27-28 (internal quotations and citations omitted). Moreover, Dr. Shuren's letter was not confined to cell phones. In particular, Dr. Shuren explained that the "FDA is responsible for the collection and analysis of scientific information that may relate to the safety of cell phones *and other electronic products*. As part of our ongoing monitoring activities, we have reviewed the results and conclusions of the recently published rodent study from the National Toxicology Program in the context of *all available scientific information*, … and concluded that no changes to the current standards are warranted at this time… [T]he available scientific evidence to date does not support adverse health effects in humans due to exposures at or below the current limits." JA 8187 (emphases added).

(2) Through the Work Group, Federal Communications Commission (FCC) and FDA staff maintain a "continuing dialogue … regarding the ongoing research into the possible health effects of [radiofrequency] emissions." JA 8184 (Mar. 22, 2019 Letter from Julius P. Knapp, Chief, OET, FCC, to Dr. Jeffrey Shuren, M.D., J.D., at 1). The Work Group, the charter of which we have also attached, was established in 1995. In addition to representatives from the FDA and FCC, the Work Group is composed of officials from the Environmental Protection Administration, National Cancer Institute, National Institute on Occupational Safety and Health, National Institute of Environmental Health Sciences, National Telecommunications and Information Administration, and Occupational Safety and Health Administration. *Id.* "The purpose of the Work Group is to provide a forum to address public health, environmental, occupational, and regulatory issues pertaining to [radiofrequency] radiation and to provide a basis for technical and policy coordination among member agencies in their approach to evaluating exposures to radiofrequency energy." *Id.* As this Court has recognized, the views of the Work Group do not "represent the official policy or position of members agencies," *EMR Network v. FCC*, 391 F.3d 269, 271 (D.C. Cir. 2004), nor can the Work Group supplant the FCC's ability to initiate a Notice of Inquiry, as it did in this case, to gather the views of interested expert agencies.

Sincerely,

/s/Ashley S. Boizelle
Ashley S. Boizelle
Deputy General Counsel
Federal Communications Commission

Charter of FDA Technical Electronic Product Radiation Safety Standards Committee

U.S. FOOD & DRUG ADMINISTRATION

C H A R T E R

Committee's Official Designation

Technical Electronic Product Radiation Safety Standards Committee

Authority

The Technical Electronic Product Radiation Safety Standards Committee is a permanent statutory committee established pursuant to the provisions of the Radiation Control for Health and Safety Act (21 USC 360kk) and is also governed by the provisions of Pub.L. 92-463, as amended (5 USC App. 2), which sets forth standards for the formation and use of advisory committees.

Objectives and Scope of Activities

The Commissioner of Food and Drugs is charged with the administration of the Radiation Control for Health and Safety Act of 1968. This Act creates the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and requires the Commissioner to consult with the Committee before prescribing standards for radiation emissions from electronic products.

Description of Duties

This Committee provides advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products and may recommend electronic product radiation safety standards to the Commissioner for consideration.

Agency or Official to Whom the Committee Reports

The Committee provides advice and consultation to the Commissioner of Food and Drugs.

Support

Management and support services shall be provided by the Center for Devices and Radiological Health, Food and Drugs Administration.

Estimated Annual Operating Costs and Staff Years

The estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is $10,781. The estimated person years of staff support required is 0.20, at an estimated annual cost of $43,125.

FDA U.S. FOOD & DRUG ADMINISTRATION

Designated Federal Officer

FDA will select a fulltime or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each Committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives.

The DFO will approve and prepare all meeting agendas, call all the Committee and subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest and chair meetings when directed to do so by the official to whom the Committee reports. The DFO shall be present at all meetings of the full committee and subcommittees.

Estimated Number and Frequency of Meetings

Meetings shall be held approximately once every other year. Meetings shall be open to the public except as determined otherwise by the Commissioner or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public.

Duration

Continuing

Termination

Unless renewed by appropriate action prior to its expiration, the charter for the Technical Electronic Product Radiation Safety Standards Committee will expire two years from the date it is filed.

Membership and Designation

The Committee shall consist of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to four years.

Voting members will include five members selected from governmental agencies, including State and Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor. A quorum shall consist of 10 members, of which at least 3 shall be from the general public, 3 from the government agencies, and 3 from the affected industries.

FDA U.S. FOOD & DRUG ADMINISTRATION

Subcommittee

Temporary subcommittees consisting of two or more Committee members may be established by the Commissioner or designee as needed to address specific issues within their respective areas of expertise.

Subcommittees make preliminary recommendations to the full Committee regarding specific issues for the full Committee's consideration. Subcommittees must not provide advice or work products directly to the agency. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping

Meetings of the Committee and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date

December 24, 2020

Approved:

December 16, 2020
Date

|S|
Russell Fortney
Director, Advisory Committee Oversight
and Management Staff

U.S. Food & Drug Administration
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Radiofrequency Interagency Work Group

Radiofrequency Interagency Work Group

Environmental Protection Agency
Federal Communications Commission
Food and Drug Administration
National Cancer Institute
National Institute for Occupational Safety and Health
National Institute of Environmental Health Sciences
National Telecommunications and Information Administration
Occupational Safety and Health Administration

Charter

The Radiofrequency Interagency Work Group (RFIAWG) is composed of select individuals from civilian federal agencies that have regulatory or public health responsibilities to evaluate and control the risk to the public, workers, and the environment from the use of specific RF devices and products, or from exposure to non-ionizing electromagnetic radiation and fields, or have responsibility for regulation and management of the use of the radiofrequency electromagnetic spectrum.

The purpose of the RFIAWG is to provide a forum to address public health, environmental, occupational, and regulatory issues pertaining to radiofrequency radiation and to provide a basis for technical and policy coordination among member agencies in their approach to evaluating exposures to RF energy. The RFIAWG may address the development of non-ionizing electromagnetic radiation exposure standards, guidance, or guidelines for advancing public understanding of the implications of exposure on human health as well as the prudent use of specific devices, products or technologies. The RFIAWG provides a forum for discussion and coordination of specific RF radiation-related activities and policies of the member agencies that could affect other federal agencies represented in the Group. The Work Group also provides a forum to discuss emerging issues and research and to help address the need for long-range federal strategies. Members of the RFIAWG maintain currency with the latest research and studies in the field from both the private and public sectors and at the national and international levels in order to make informed recommendations to their agencies. It is intended that such coordination and discussion will lead to a more coordinated federal approach to addressing potential health, environmental, and occupational issues associated with existing and proposed technologies that emit non-ionizing electromagnetic energy.

The RFIAWG was originally established in 1995, by formal invitation from the Environmental Protection Agency to other agencies having legislative and executive responsibilities on this topic. The agencies currently participating are the Environmental Protection Agency, the Federal Communications Commission, the Food and Drug Administration, the National Cancer Institute, the National Institute for Occupational Safety and Health, the National Institute of Environmental Health Sciences, the National Telecommunications and Information Administration in the Department of Commerce, and the Occupational Safety and Health Administration in the Department of Labor.

26 January 2012