Press Release: May 29, 2024 US FDA Decision: No Regulations for LED Products

On May 24, 2024, the US Food and Drug Administration rejected four Soft Lights Foundation petitions to regulate LED products. (<u>https://www.softlights.org/wp-content/uploads/2024/05/Final-Response-Citizen-Petitions-FDA-2022-P-1151-FDA-2023-P-0233-FDA-2023-P-3828-FDA-2023-P-3879.pdf</u>)

In summary, the FDA's position is that the FDA should not regulate LED products, that the FDA has no intention of regulating LED products, and that the FDA will not collaborate with any other federal agency to regulate LED products.

This FDA ruling has major policy and constitutional implications. As noted in a history of the 1968 Radiation Control for Health and Safety Act, one of the reasons that Congress passed the law directing the FDA to regulate electromagnetic radiation from electronic products was to provide federal regulatory oversight that was previously handled at the local and state level. (https://dash.harvard.edu/bitstream/handle/1/8846732/Tran06.pdf).

Since the FDA is the only federal agency with Congressional authority to regulate LED products, the FDA ruling means that all other federal agencies, including NHTSA, DOE, OSHA, CPSC, EPA, Access Board, FAA, FHWA, and others are blocked from publishing regulations for LED vehicle headlights, LED street lights, LED light bulbs, LED flashing lights on emergency vehicles, LED office lights, LED appliance indicator lights, or any other LED product, even if those LED products cause harm.

The FDA's decision to not regulate LED products thus pushes regulation of LED products to state and local governments, which is likely an unconstitutional shift of regulatory authority from federal agencies to state and local agencies, and a clear violation of the Congressional mandate codified in 21 U.S.C. 360ii.

Without an intervention by Congress or the Courts, municipalities, businesses, manufacturers, and employers are each now forced to develop and publish their own policy for LED products to ensure the health, safety, and civil rights of the public and the protection of the environment, and a failure by an entity to establish the necessary health, safety, and civil rights policies in relation to the entity's use or manufacture of unregulated and unsafe LED products makes the entity liable for tort or discrimination claims due to negligence or a failure to provide a duty of care.

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