

in their labeling for oral hypoglycemic drugs (Bradley v. Richardson, Civil No. 72-2517 M (D. Mass. 1972)). A temporary restraining order was entered by the court on the same day. A hearing on the motion for a preliminary injunction was held before Judge Campbell on August 17, 1972, and, on August 30, 1972, he denied an injunction. Judge Campbell concluded that the plaintiffs had not demonstrated a reasonable probability of prevailing on the merits since the administrative action of the Food and Drug Administration, requiring an unencumbered warning, was a reasonable exercise of its statutory duty and the potential harm to users of the drugs was greater than any harm to the manufacturers or prescribers. Judge Campbell further observed that the Food and Drug Administration labeling requirements would not preclude physicians from exercising their best clinical judgment.

The plaintiffs filed another motion for a temporary restraining order and preliminary injunction on October 17, 1972, specifically requesting that the agency be enjoined unless the drug warning was redrafted to incorporate their views concerning the interpretation of the UGDP study. The plaintiffs argued that, without such a discussion, the labeling required by the Food and Drug Administration was misleading because it failed to reveal the existence of divergent opinion among experts, contrary to the agency's own regulation, § 1.3 (21 CFR 1.3). On November 3, 1972, the District Court issued a temporary restraining order, which became a preliminary injunction on November 7, 1972, restraining the agency from implementing the labeling.