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PUBLIC CITIZEN

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September 6, 1995

The Honorable Donna Shalala
Secretary, Department of Health
and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Consumer Federation of America and Public Citizen
v. HHS, Civil Action No. 93-97 (GK)

Dear Secretary:

In the above-entitled case, Consumer Federation of America and Public Citizen challenged as arbitrary and capricious and contrary to law a number of regulations implementing the requirements of CLIA '88. Last week, the district court ordered the Department to issue new regulations implementing §§ 263a(f)(1)(C) and 263a(f)(4)(B)(iv) of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA '88"). On behalf of Consumer Federation of America and Public Citizen, plaintiffs in the case, we are writing to urge you not to appeal the court's decision, which directed the Department to protect the public health by strengthening these regulations.

The regulations struck down by the Court were issued in 1992, under the previous administration. As a result of industry pressure, the regulations were far weaker than those initially proposed by the Department. Now, the Department has the opportunity to strengthen the regulations and, thereby, to strengthen the protection of the public health.

In its decision, the district court judge found that HHS' criteria for categorizing laboratory tests and its categories and schedules of laboratory tests based on these criteria are arbitrary and capricious and contrary to law because HHS failed to consider the risks and consequences of erroneous results associated with such tests, as required by CLIA '88, 42 U.S.C. § 263a(f)(1)(C). Looking to the mandatory language of § 263a(f)(1)(C), the judge struck down the Department's regulations on the ground that they did not differentiate personnel qualifications for laboratory procedures on the basis of the risks and consequences of erroneous test results. She gave the Department 90 days to publish new proposed regulations on this point.

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The Court also held that the HHS regulation governing proficiency testing of cytologists is arbitrary and capricious and contrary to law because it fails to require that cytologists be tested "to the extent practicable, under normal working conditions," as required by CLIA '88, 42 U.S.C. § 263(f)(4)(B)(iv). Again, the Court gave the Department 90 days to publish a notice proposing new regulations.

Last year, to mention a highly publicized example, two Wisconsin women died from cervical cancer, after their PAP smears were read incorrectly. Would these deaths have occurred if the final regulation implementing § 263a(f)(4)(B)(iv) had complied with CLIA '88? We will never know. You, however, can ensure that we do not face this question in the future, by strengthening the regulations governing categorization of lab tests and testing of cytologists, as intended by CLIA '88.

We recognize and commend your record as a strong force in protecting consumers' health. We hope that, in connection with this case, you will act in the best interests of those you serve by proposing new regulations to implement §§ 263a(f)(1)(C) and 263a(f)(4)(B)(iv), and not appealing the Court's decision.

Sincerely,



Mark Cooper
Consumer Federation of America



Sidney Wolfe, M.D.
Public Citizen's
Health Research Group