DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

Date Dec. 23, 1996 on original →

The Honorable Alfonse M. D'Amato
United States Senate
Washington D.C. 20510-3202

Dear Senator D'Amato:

Thank you for your letter regarding the national surveillance case definition and diagnostic tests for Lyme disease. I apologize for the lateness of this response.

Lyme disease is one of several emerging infectious diseases in the United States. It is a reportable disease in all 50 States, and about 10,000 cases are reported annually by States to the Centers for Disease Control and Prevention (CDC).

CDC has developed a comprehensive, science-based, public health program for prevention and control of Lyme disease. Activities include conducting research to improve laboratory diagnosis, defining the distribution of the disease and the factors responsible for its spread, identifying risk factors for acquiring the disease, developing more effective prevention strategies, and expanding educational programs for the public and health care providers.

Enclosed are responses to the specific issues raised in your letter. Please be assured that CDC will continue to work with its partners in State and local health departments, other Federal agencies, professional organizations, private health care providers, and others to improve the timeliness and accuracy of Lyme disease surveillance data and to improve Lyme disease prevention and control programs.

I hope this information is helpful.

Sincerely,

David Satcher, M.D., Ph.D.
Director

Enclosures

RESPONSES TO RECOMMENDATIONS CONCERNING THE LYME DISEASE CASE DEFINITION AND DIAGNOSTIC TESTS

Prepared by the Centers for Disease Control and Prevention (CDC)
December 23, 1996

RECOMMENDATIONS 1 & 2

That the CDC distribute a letter to the medical community clearly stating that the CDC Case Definition for Lyme Disease is meant for statistical, not diagnostic or treatment purposes.

That the CDC stamp on the cover of the Case Definitions booklet include, in bold letters: **"FOR STATISTICAL USE ONLY, NOT FOR DIAGNOSTIC OR TREATMENT PROTOCOL".**

RESPONSE TO RECOMMENDATIONS 1 & 2

In 1990, the Council of State and Territorial Epidemiologists (CSTE) approved Lyme disease as a nationally notifiable disease and adopted a uniform national case definition for surveillance purposes. In 1993, a national panel was convened by CDC to review the Lyme disease surveillance case definition that serves epidemiologic and surveillance purposes and functions as the basis for the annual national statistical summary of Lyme disease incidence and trends. The panel recommended no changes in the definition.

CDC published and disseminated the CSTE Lyme disease case definition used by State and local health departments through its *Morbidity and Mortality Weekly Report* (*MMWR*). (Case definitions for public health surveillance. *MMWR* 1990; 39 [No. RR-13:20-22], copy enclosed). **The case definition was developed specifically for public health surveillance of cases and not for purposes of clinical diagnosis, treatment, or determination of health insurance or medical disability benefits. The following statement, "This surveillance case definition was developed for national reporting of Lyme disease; it is NOT appropriate for clinical diagnosis," is included in "Case Definitions for Public Health Surveillance."** During the spring of 1997, CDC will publish a revised report of case definitions for public health surveillance entitled "Case Definitions for Public Health Surveillance: Infectious Diseases." This report will also include the aforementioned language under the Lyme disease comment section and will be widely distributed throughout the medical community.

RECOMMENDATION 3

That Lyme Disease educational materials not be based on the Case Definitions.

RESPONSE TO RECOMMENDATION 3

The Lyme disease case definition for public health surveillance states: "This surveillance case definition was developed for national reporting of Lyme disease; it is NOT appropriate for clinical diagnosis."

Educational materials developed by CDC for the public and health care providers that include or cite the national surveillance case definition for Lyme disease note that this definition is an epidemiologic case definition intended for surveillance purposes only. Education on the criteria used for reporting cases of Lyme disease is conducted to improve the accuracy of surveillance data for public health purposes.

RECOMMENDATION 4

We urge the inclusion of "probable" and "clinically compatible" in the classification.

RESPONSE TO RECOMMENDATION 4

Cases of Lyme disease are only rarely "confirmed" by isolation of the causative agent, *Borrelia burgdorferi*; therefore, a positive serologic test result, following the recommended two-test approach, supports a physician's diagnosis of "probable," "clinically compatible" Lyme disease.

RECOMMENDATION 5

Under the "Comment" section of the Lyme Disease Case Definition there are two extraneous terms: "Exposure" and "disease endemic to county." "Exposure" speaks to having been in potential tick habitats in a county in which Lyme Disease is endemic. "Disease endemic to county" speaks to only those counties where at least two definite cases have been previously reported. These terms have nothing to do with the definition of a "late manifestation" but are in the comment section nevertheless. This misplacement leads many health care companies to conclude that the comments are part of the definition itself.

RESPONSE TO RECOMMENDATION 5

The inclusion of endemic "exposure" and "disease endemic to county" was included in the definition by CSTE under the comment section to provide clinicians with an epidemiologic basis for identifying cases and to ensure accurate geographic mapping of disease risk within States. **These elements are not used for diagnostic purposes.**

The enclosed Lyme Disease Case Report Form (CDC 52.60 REV. 1-91), used by physicians to report cases to health officials, includes the following statement: **"NOTE: It should be emphasized that this is an epidemiologic case definition intended for surveillance purposes only."** Also enclosed for your information, is the summary of cases of Lyme disease reported by State health departments to CDC during 1995 (CDC. Lyme Disease-United States, 1995. *MMWR* 1996;45:481-4).

RECOMMENDATION 6

The testing parameters need revisions as well. Currently, the CDC is supporting the use of two types of tests to confirm the disease. One such test being urged by the CDC is the Western Blot test. This is an expensive test and many insurance companies will not reimburse the cost of this test. There are, however, less expensive tests which are approved such as the "IFA" and "ELISA". Given the limitations of all of these antibody tests, however, more government required tests do not mean any better results. Since Lyme Disease is a very difficult disease to detect by any laboratory test, requiring a two test confirmation makes it that much more difficult and costly for a patient to be diagnosed properly. This two test requirement needlessly hinders Lyme Disease diagnosis. If the CDC wished this two test requirement, then payment for both tests should be reimbursable by the government.

RESPONSE TO RECOMMENDATION 6

The development and implementation of improved laboratory diagnostic tests for Lyme disease is one of CDC's research priorities. CDC collaborates with other Federal agencies, State and local health departments, the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD), CSTE, the National Committee for Clinical Laboratory Standards (NCCLS), academic research centers, manufacturers, and others in the development and standardization of Lyme disease diagnostic tests,

development of national guidelines on the use and interpretation of Lyme disease tests, and the implementation of quality assurance methodology for Lyme disease testing.

In October 1994, CDC was a cosponsor of the Second National Conference on Serologic Diagnosis of Lyme Disease. Other cosponsors included ASTPHLD, the Food and Drug Administration, the National Institutes of Health (NIH), CSTE, and NCCLS. This Conference was the culmination of a 5-year collaborative study involving ASTPHLD, CDC, and academic research centers in which a two-test approach for the laboratory diagnosis of active Lyme disease and for previous infection using a sensitive enzyme immunoassay (EIA) or immunofluorescence assay (IFA) followed by a Western immunoblot was recommended as the algorithm of choice. This two-test method provides increased accuracy over previous test approaches. CDC and NIH continue to fund research to develop improved diagnostic tests.

Recommendations from the Conference were published in CDC's August 1995 *Morbidity and Mortality Weekly Report (MMWR)*, "Recommendations for Test Performance and Interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease," (*MMWR* 1995,44:590) copy enclosed. These recommendations describe the development and use of more accurate laboratory diagnosis of Lyme disease.