TESTIMONY

THE AMERICAN SOCIETY OF INTERNAL MEDICINE

BEFORE

THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

June 14, 1977

Mr. Chairman and Members of the Committee:

I am Dr. Donald Hanscom, a practicing internist in Hinsdale, Illinois. Currently I serve as Chairman of the Laboratories Committee of the American Society of Internal Medicine. With me are Dr. N. Thomas Connally, Chairman of the ASIM Government and Legislation Committee and Dr. William P. Daines, President, ASIM.

The American Society of Internal Medicine (ASIM) is a federation of 51 Component Societies of Internal Medicine. ASIM has a membership of over 14,000 members, who by training and practice standards are recognized as specialists in Internal Medicine. Most are private practice internists delivering primary *care,* sub-specialty care, or both.

From its inception 20 years ago, the American Society of Internal Medicine has been concerned with the quality of medical care. In 1967, the House of Delegates of the American Society of Internal Medicine supported a policy of individual state regulation for licensing and supervision of clinical laboratories. It stated that quality controls should be maintained through adequate testing programs for all such laboratories.

In 1967, the California Society of Internal Medicine, a component of the American Society, in cooperation with the Division of Laboratories of the California State Department of Health, helped develop guidelines for a

state-wide proficiency testing program and established a proficiency testing program for its members and others in the state. In 1968, the ASIM House of Delegates supported this California program and went on record supporting laboratory proficiency testing and quality control programs as being of primary importance to all laboratories and urged members who operated or supervised laboratories to participate in authorized testing programs. In 1973, the Board of Trustees approved continued active involvement in laboratory proficiency testing programs and agreed to assume operation of the California Society of Internal Medicine proficiency testing program.

The ASIM proficiency testing program " Medical Laboratory Evaluation--MLE" meets the requirements for Medicare certification and has been approved as a proficiency testing service by 31 State Health Departments including those in California, Illinois and Idaho where testing is required for both physician office laboratories and larger clinical laboratories. MLE has received endorsement from the American Academy of Family Physicians, the American College of Physicians, the American College of Obstetricians and Gynecologists, the California Medical Association, the Medical Association of Georgia and the Pennsylvania Medical Society. To our knowledge it is now the largest program providing service to individual physicians' offices in the country.

We believe the proposed legislation's goal of improving clinical laboratories is admirable. We would agree that no matter what level of laboratory services is currently being offered, efforts aimed at upgrading laboratory quality are highly desirable.

We have the following specific comments to make regarding portions of HR 6221,

The Clinical Laboratory Improvement Act of 1977:

1. ASIM since 1967, has made a continuing appeal that qualifications of a laboratory director and other supervisory and technical personnel be based on demonstrated proficiency of performance rather than solely on designated educational or training criteria. We are pleased to see that Section 353 (a) (2) (iv) and Section 353 (a) (2) (v) prescribe qualifications which may include licensure, training and experience requirements or any combination of such requirements for supervisory and technical personnel. We support these sections which will allow training and experience to be substituted for formal education.

2. We are pleased to see that Section 353 (b) (2) (C) permits the standard for clinical laboratories to vary on the basis of the type of test or other procedures or services performed or the purposes for which such tests, procedures or services are performed.

3. Section 353 (b) (3) (C) (ii) includes a requirement for "blind proficiency testing." We believe that blind proficiency testing if required under the national standards, would be prohibitively expensive in both money and manpower. To advocate general use of blind proficiency testing from its limited experience in drug level testing seems premature. We would like to see further demonstration of the usefulness of blind proficiency testing for assessing laboratory performance. We also believe it necessary to correlate blind proficiency testing with effective continuing education programs for improvement in areas of recognized deficiency. We therefore recommend deletion of the requirement for blind proficiency testing.

4. Sub-paragraph's (D) (i) (I) and (II) of Section 353 (c) (2) state that the national standards shall not apply to the office laboratory operated by a physician or group of physicians in which the only tests performed are performed by such practitioner in connection with the treatment of his patients. We do not believe this provision will aid in upgrading the quality of laboratory performance. Laboratories that are unable to evaluate the precision and accuracy of the testing methods they use may not be aware that some well accepted testing methods can have major inherent faults. A laboratory using such a method will be unlikely to achieve good performance even though the test may be performed in the most expert hands. We believe all laboratories will benefit from participation in an external proficiency testing program including those where the tests are performed by a physician for his own patients.

Attached is the first of a series of reports we are publishing for subscribers to the MLE program identifying significant differences in methodology for commonly performed laboratory tests. (Attachment #1, MLE Bulletin, "How Precise"),

In those laboratories subscribing to the MLE program whose testing reports have identified problems, many have remedied them by a change in equipment or procedure. We have received a number of unsolicited letters from subscribers telling us of such changes as a result o-f their participation in our program. We support the provisions in Section 353 (c) (2) (D) (ii) and (c) (2) (D) (iii) as providing appropriate allowances for physician office laboratories. Therefore, we recommend deletion of paragraph (D) (i) of Sub-section (c).

5. ASIM supports the exemption provisions of Section 353 (c) (2) (D) (iii) permitting laboratories which participate in proficiency testing to not have national standards apply to them.

6. Sub-section (n) establishes an Advisory Council. We are pleased to see it shall include representation from a variety of groups.

7. We are pleased to see that Sub-section (o) would establish the office of clinical laboratories expressly under the direct supervision of the Assistant Secretary of Health. Since clinical laboratory testing is an integral part of the delivery of medical care, regulations concerning clinical laboratories need to be considered along with other elements of the medical care delivery system and subject to the same review efforts. We believe the appropriate manner for coordination of activity and regulation relating to clinical laboratories should involve local professional standards review organizations.

8. We are not sure how to interpret Section 4 (b) (1). It adds a statement to Section 1902 (a) (23) of the Social Security Act which seems to permit the states to offer a franchise to laboratories through a competitive bidding process to provide Medicaid services in the state. The enactment of this provision would appear to exclude all other qualified laboratories from providing such services. We are concerned that if the new language is proposed to be restrictive or reduce options presently available to physicians and their patients, it would not be acceptable. Possibly, such language could encourage a separate class of care for patients covered by Medicaid programs characterized by high volume impersonalized services. Section 1902 (a) (23) as it now stands, allows an individual to choose the physician or facility he wishes to provide him with services. We believe this option should be retained and Section (4) (b) (1) deleted.

9. Heretofore, any information on laboratory tests conducted in physician offices has been in part a matter of conjecture with a limited amount of supporting data. We are pleased to see that Sections 6 and 7 of the bill identify areas for further study.

Mr. Chairman, and Members of the Committee:

The American Society of Internal Medicine appreciates this opportunity to present its' views on this issue. We will be pleased to attempt to answer any questions you may have and we wish to assure you of our continued willingness to try to assist in any manner you deem appropriate.