



STATE OF CONNECTICUT
STATE ETHICS COMMISSION

ADVISORY OPINION NUMBER 81-17

State Toxicologist as Director of Private Clinical Laboratory

One of the toxicologists in the Toxicology Laboratory, Department of Health Services, has requested advice as to the ethical implications of his accepting a part-time position as a director of a private clinical laboratory.

The Toxicology Laboratory, a section of the Laboratory Division, Department of Health Services, has been established for the examination, research, and analysis of poisons, body fluids, tissues and related toxicological matters. Section 19-8, General Statutes.

A "clinical laboratory" is a facility for microbiological, serological, chemical, hemotological, immunohematological, biophysical, cytological, pathological, or other examinations of human body fluids, secretions, excretions, or tissue to provide information for the diagnosis, prevention, or treatment of human disease or for the assessment of human health. Subsection 19-9a(a), id.

Clinical laboratories are licensed and regulated by the Department of Health Services. Section 19-9a, id. Within the Department another section of the Laboratory Division, the Laboratory Standards Section, has specific responsibility for approving clinical laboratories and ensuring that they maintain the standards set forth in the Public Health Code. Licensing procedures and standards for clinical laboratories are set forth in sections 19-13-D20 through 19-13-D39, Regulations of Connecticut State Agencies. If a clinical laboratory makes certain public health laboratory examinations or tests it must also register with, and obtain a certificate of approval from, the Department of Health Services (the Laboratory Standards Section) and maintain the standards established by sections 19-4-1 and 19-13-A27 through 19-13-A35, Regulations of Connecticut State Agencies. A laboratory may not operate without a license or certificate of approval, and a license or certificate may be suspended or revoked for violation of section 19-9a, General Statutes. Subsections 19-9a(b), 19-9a(e), id.

The director of a clinical laboratory is an essential element in gaining and retaining approval to operate the laboratory. The application for a license must provide the name and qualifications of the director. Section 19-13-D22, Regulations of Connecticut State Agencies. A laboratory must reregister or relicense when there is a change of directors. Subsections 19-4-1(5)(a), 19-13-A29(b)(3), 19-13-D24(2), id. The importance of the position of laboratory director is emphasized by the fact that not only are his qualifications spelled out in the Public Health Code but also the qualifications of the interim supervisor who is in charge in the absence of the director. Section 19-13-D34,

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subsection 19-13-D36(c), id. The Public Health Code even specifies the amount of time that the director must be present and in active charge of the laboratory. Subsection 19-13-D36(d), id.

The authority and control which the Department of Health Services has over private clinical laboratories could create problems under some provisions of the Code of Ethics for Public Officials (Chapter 10, Part I, General Statutes) when a member of the Department wishes to accept a part-time position in a private clinical laboratory, particularly when the position is that of director. The problems arise when the Toxicology Section, to which the toxicologist in question is assigned, becomes involved in the exercise of the Department's responsibility to license and regulate private clinical laboratories. This is not a frequent occurrence, but those responsible for licensing and regulating private clinical laboratories do rely on the expertise of the Toxicology Section for assistance when tests and analyses performed by both a private laboratory and the Toxicology Laboratory are concerned. For example, a responsibility of the Toxicology Laboratory and of a toxicologist is to analyze body fluids for the presence of alcohol. A laboratory not currently licensed to conduct tests for alcohol in blood and urine pursuant to section 14-227a, General Statutes, would have to request the Department of Health Services' approval to carry out the tests. A toxicologist might be asked by the regulatory section for advice and assistance. If the toxicologist were director of a competing laboratory he would face a potential conflict of interest. The conflict is essentially non-existent, however, if the laboratory of which the toxicologist is director does not conduct that test. Further, the problem can be avoided by obtaining advice and assistance from another State toxicologist. Finally, the Code of Ethics for Public Officials in section 1-86, General Statutes, provides a procedure for avoiding such a conflict should the matter be referred to the toxicologist/director.

It is also possible for the toxicologist to become involved in checking questionable results from laboratories performing tests under contract with the State, or providing consultation and training to such a laboratory having problems with its analytical procedures. A contract jeopardized by inferior procedures could be made available to other laboratories. The toxicologist could be in possession of confidential information, the use or disclosure of which would constitute a violation of subsection 1-84(b) or 1-84(c), General Statutes, if used by the toxicologist/director's private clinical laboratory to compete for the contract.

This should not occur, however. A private clinical laboratory in which a Department of Health Services employee, engaged in laboratory work, holds so significant a position as director should not enter into

contracts involving the Department. This is not because of subsection 1-84(i), General Statutes, concerning contracts with the State. It is inapplicable. Any State contract would be with the laboratory owner or the laboratory, not with the State employee, a member of his immediate family, or a business with which he is associated. (The laboratory would not be a business with which the toxicologist was associated as defined in subsection 1-91(a), General Statutes. As a "director" of the laboratory he is only an employee, albeit the senior one, not the member of the board of directors identified by "director" in that subsection.) Nevertheless, there would be the appearance of a conflict of interest if a laboratory of which the toxicologist was the director entered into a contract with the Department of Health Services. Even if the open and public process specified in subsection 1-84(i), General Statutes, were employed, the public and competing laboratories could not be sure the State's interests had been properly protected if a laboratory of which the toxicologist was director were to win a State contract involving his own Department.

The Department of Health Services would have to be particularly scrupulous and thorough in licensing and regulating a laboratory of which one of its employees was director. The administrative separation between the regulatory section and the toxicologist's section seems to be sufficient to allow the Department to carry out fairly and properly its licensing and regulatory procedures in the case of such a laboratory. See Ethics Commission Advisory Opinion No. 80-17, 42 Conn. L.J. No. 20, p. 30 (Nov. 11, 1980). Potential conflicts of interests in the case of the toxicologist/director can be minimized or avoided altogether by the Department. In addition, section 1-86, General Statutes, provides a procedure when the toxicologist encounters a potential conflict of interest. There appear to be no other problems under the Code of Ethics for Public Officials. However, to maintain confidence in the contracting process, if the toxicologist were to take a position of director of a private clinical laboratory, that laboratory should not enter into any contract of any value with the State to provide services to the Department of Health Services.

By order of the Commission,

George S. Wacker, Jr.
Vice-Chairman

Dated Nov. 4, 1981

