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EXEMPT ORGANIZATION

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CLINICAL LABS: Importance to the Consumer

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CLINICAL LABS: DOWN THE DRAIN

Scandals in the health care industry have been reported lately with such frequency, that it is not surprising if the average consumer begins to get a little blasé. Another nursing home atrocity? Ho hum. Recently, newspapers have reported on the inadequate performance of clinical laboratories: as many as 40 to 50 per cent of laboratory test results have been shown to give erroneous results. In the context of one health scare after another, we are tempted to shrug our shoulders and say, "Well, at least this one doesn't affect me."

Unfortunately, the effect of poor clinical laboratory performance on the average individual is likely to be more direct and more harmful than many of the other publicized deficiencies. Every time people get ill, or suspect illness, and certainly every time they are hospitalized, they run a risk of faulty diagnosis or mistreatment if the laboratory sends back an incorrect report. In addition, the clinical laboratory mess hurts the consumer where it always hurts: in the pocketbook.

LAB TESTS AND YOU: ACCURACY NEXT TO GODLINESS

No matter how qualified a particular physician might be, accurate diagnosis is extremely difficult, if not impossible, if the relevant laboratory test is performed incorrectly and gives an erroneous result. All physicians, for example, use blood sugar determinations to confirm a suspected case of diabetes. Faulty testing will, at the very least, delay diagnosis and needed treatment, permitting the disease to progress with a consequent danger of developing

complications.

Even more immediately life-threatening will be an error in a test used to further the course of treatment. If cross-matching and blood typing are not performed correctly, transfusion of blood may produce a lethal reaction. Often, during treatment for an infection, bacteriological tests are necessary to identify the causative organism and thus determine the proper antibiotic. Errors in culture technique, or misinterpretation of the test, will lead to incorrect therapy and increased morbidity and mortality.

CLINICAL LABS: BIG BUSINESS

In April, 1976, the President's Council on Wage and Price Stability reported that the average American family is spending about ten per cent of its annual income on health care. The total of all health care costs in 1975 was approximately one hundred eighteen billion dollars, and something on the order of ten billion dollars of this went to pay for clinical laboratory tests. Since the clinical laboratory field has been growing at the rate of about fifteen per cent a year since 1967, it is anticipated that by the end of this decade, consumers and third-party payers will spend more than fifteen billion dollars a year on laboratory services.

To generate these revenues, some fourteen to fifteen thousand laboratories in the United States performed more than four billion diagnostic tests of human blood, urine, feces, and tissue in 1975. This equals about 20 tests for every individual in the country.

DOCTORS PASS EXAMS: EXCEPT ON TESTS

Practically all laboratory tests are ordered by a physician. The

trend in medical education in recent years has emphasized a greater reliance on laboratory testing in the diagnostic process, and this has undoubtedly influenced many doctors. But this trend has also been compounded by the recent rise in malpractice insurance rates and the consequent attention to the possibility of malpractice claims. Physicians say that they are forced to practice "defensive medicine," by which they mean that they must order every known test and x-ray so that they will be protected in court if a patient decides to sue. Unneeded tests and test results which are not heeded can however also lead to malpractice suits.

Some labs try to promote high utilization by using marketing techniques and pushing test batteries (with more kinds of tests than the patient needs). Often the high pressure sales pitch takes advantage of physician ignorance or carelessness. There is a need to educate doctors about pitfalls in testing procedures, costs, limitations and reliability.

Doctors are also usually unaware of the high cost of various testing procedures, and often expect that it doesn't make any difference because "Insurance will pay for it anyway." Of course, the consumer ultimately pays, as the cost of laboratory tests is reflected in higher health insurance premiums. In order to make physicians more conscious of laboratory costs, the House of Delegates of the Florida Medical Association passed a resolution last year which urged county medical societies to request that hospital physician staff be provided with a current list of charges for all services by the hospital.

IS THIS TEST REALLY NECESSARY?

The high cost of clinical services might be justified if it could be shown that these services directly contributed and were essential to the best medical care. However, it has been concluded by some doctors, that in observed instances only five percent of the laboratory tests ordered on a medical service had a direct relationship to the management of patients' clinical problems.

A recent study was done to see if variations in the use of laboratory tests by medical interns was related to differences in the quality of physician performance. No relationship was found! The study concluded that "Unless further studies can demonstrate a positive correlation between cost and quality of care, or unless use of the laboratory is demonstrated to increase physician productivity, a burden of proof would seem to rest with those who practice more expensive medicine."

The sole responsibility for extra and perhaps unnecessary tests does not rest exclusively with doctors. The unreliable performance of most clinical laboratories contributes significantly to the number of tests done. The physician who receives a suspicious report suggesting an erroneous test result customarily (and quite properly) re-orders the test. This duplication would be clearly unnecessary if the test had been done correctly the first time.

LAB INCOME HIGH: SO ARE PROFITS

There does not seem to be any real logic to justify the high cost of laboratory testing. Prices do vary according to the nature of the test itself, with simple chemistries costing no more than a few dollars while esoteric procedures may run up to twenty five dollars per test. But the prices charged for a given test or series of tests also vary markedly from laboratory to laboratory.

Hospitals often use their laboratories to support other services that do not easily produce so much revenue. For example, in 1969 and 1972, the General Accounting Office issued reports in-

dicating that laboratory charges averaged about 13 percent of total hospital charges while laboratory costs averaged about 10 percent of total costs, and that laboratory costs were about 78 percent of total laboratory charges. This equals about 28 percent profit.

Laboratory services seem to lend themselves to high profits and low ethics. A study done in New Jersey on some of the independent clinical laboratories, arbitrarily chosen on the basis of dollar volume billed to Medicaid, revealed substantiated evidence of sizeable kickbacks to many physicians, gross overutilization of laboratory services by those physicians receiving kickbacks, profiteering by many small laboratories, and fraudulent billing for tests not requested, not performed, or performed *free* by the New Jersey Health Department.

TESTING, TESTING: ONE BILLION, TWO BILLION

About half of the 14,000 clinical laboratories in this country are situated in hospitals; the other half are independent businesses. In addition, fifty to sixty thousand physicians maintain some type of laboratory equipment in their offices. It is estimated that the 7,000 hospital laboratories currently perform almost two billion tests a year and take in more than five and a half billion dollars (about \$2.50 per test); the more than 7,000 independent clinical laboratories perform more than one billion tests a year and take in almost three billion dollars (about \$3.00 per test); and individual doctors' offices (at most a guess) perform one billion tests a year and take in more than one and a half billion dollars (or \$1.50 per test).

More than half of all tests performed in these settings are chemical determinations in blood or urine and blood hematology or cell counting. The full range of tests, however, includes sophisticated chemical analyses, radiobioassay, pathological examination of tissues, microbiological testing and serology, immuno-hematology, and hematology. Very few laboratories have the capability to do the full-range of possible testing, while most can perform the commoner tests and procedures.

A LAB IS NOT A LAB IS NOT . . .

Income generated by hospital labs usually produces surplus income. This surplus can be used in other areas of the hospital, or go towards excessive physician (pathologist) fees. The fact that lab costs and charges for lab services have no direct relationship has cost government and consumers billions of dollars. The potential for abuse is unlimited.

The majority of tests done in a hospital laboratory are performed for in-patients of that hospital. However, 15 to 20 percent of hospital laboratory testing (about one billion dollars worth) is performed for out-patients. About half of the 7,000 hospital laboratories perform fewer than 50,000 tests per year, with corresponding revenue of less than \$200,000 per year.

Large, metropolitan hospitals commonly have laboratories equipped and staffed to perform a wide range of tests. Smaller hospitals frequently have rather primitive laboratories. Nearly three-fourths of all non-metropolitan community hospitals have fewer than 100 beds. These hospitals usually employ only one or two full-time technologists and do not staff their laboratories around the clock. Hospitals with fewer than fifty beds often do not have a special laboratory technician at all; in fact, 90 percent of these hospitals routinely farm out most of their testing procedures.

Consequently, there is a wide variation in performance among hospitals related to their size. Larger hospitals are considered to provide more and better laboratory services than smaller ones. Patients in smaller hospitals may, therefore, receive a lower level of care because of inadequate lab services. The inability of the physician to have access to a needed test can also be a threat to the patient. An incorrectly performed test can be life-threatening no matter how few or how many beds the hospital has; and erroneous tests are more likely to be most immediately dangerous to the hospital patient, who is probably more seriously ill, than the ambulatory patient. Ambulatory patients may suffer from incorrect laboratory tests, but probably not as severely. While there is usually time for a doctor to reorder less complex

tests for patients seen in an office, there will never be a chance to do a repeat cross-matching on a patient who has died of a blood transfusion of the wrong type while undergoing surgery.

LAB VOLUME VARIES

Of the 7,000 independent clinical laboratories, about 10 percent account for about 50 percent of all commercial test business. About 60 percent of independent laboratories are small and perform fewer than 50,000 tests per year per lab.

In general, independent laboratories will charge the patient less for a test than will a hospital laboratory. But there is also variation in price among different independent laboratories. The most expensive average prices are charged by the small, independent laboratories, and the least expensive prices are charged by the large independent laboratories, with the hospital laboratories somewhere in between. However, some observers say the small labs include more service in their prices (billing for the physician in some cases; transportation, speedier turn around time and better communication) than do the larger, high volume labs. The per-test price may not be the only or best basis of comparison. Also there have been reports that independent labs, especially small ones, have more need to enter into kick-back relationships with doctors which impacts on charges to patients.

OFFICE LABS: SIMPLICITY PLUS

It is impossible to say with any degree of assurance the number of doctors who perform laboratory tests in their own offices. A few surveys have been made, but these have used questionnaires sent through the mails and have had a rather low rate of response. The results, therefore, are questionable. However, there are indications that most general practitioners and internists maintain some sort of office laboratory, while in general surgeons provide these services only in smaller communities where outside laboratory services are not likely to be readily available.

Practically all physicians do urinalysis in the offices, more than

75 percent do simple blood counts, and about half examine stool samples, usually for the presence of blood or parasites. When the individual physician has these tests performed in the office it is usually for the convenience of getting an immediate result and as an adjunct to the treatment of the patients.

In group practice, where a number of different specialists practice jointly and attempt to offer patients a full range of medical care, the laboratory services are likely to be much more ambitious. While an individual physician often actually performs a test himself, the group will, in effect, own an independent laboratory.

AS GOOD AS THEY ARE

Some laboratory tests are performed to indicate the presence or absence of either normal or abnormal components in human blood, urine, stool, sputum, or tissue. They may also be able to quantify the findings in a way that has significance in diagnosing disease. A blood cell count, for example, should report how many red and white cells are in a sample of blood, and it should identify abnormal cells if present. A blood count is one of the most commonly performed laboratory tests and is a key to the diagnosis of anemias, leukemia, mononucleosis, malaria, and many other diseases if done correctly. Urine tests are used to measure how the body is functioning and to identify if there are any foreign substances present. The original methadone treatment program for heroin addiction required a urine sample from each patient before methadone was supplied. If heroin use was detected by urinalysis the program director was informed and could adjust the patient's psychological, social and medical treatment accordingly. The examples of laboratory test use are endless.

Thus, laboratory tests cannot only be very good, they can be essential to medical care. However, their very great importance to diagnosis and treatment makes it equally essential that their results be reliable and a true picture of what is going on inside any individual patient. Not all tests can do this. When a test, even when

correctly performed, gives many "false positives" or "false negatives" it is said to have intrinsic unreliability. Doctors are aware of which tests are in themselves unreliable and adjust their diagnostic dependence accordingly. But some tests will give reliable results almost all the time, if they are correctly performed. It is when these tests cannot be relied on that accurate diagnosis is impossible and correct therapy unattainable when based on laboratory results.

RESULTS IN LABS FAIL TEST

Most often, the results of a laboratory test are reported to a physician. If the findings are out-of-line with expectations the test result is ignored or another test is ordered. There is no way of knowing how often this occurs. We do know, however, that in artificial test situations, *where specimens with known qualities are sent to laboratories by official health agencies, or when an inspector watches while a test is performed, that the percentage of incorrect results is shockingly high.*

The federal Center for Disease Control (CDC) recently tested the proficiency of 22 clinical laboratories by sending specimens of urine from known drug abusers. Even though the laboratories knew they were being tested, only seventeen of them (77%) correctly identified all the drugs in the urine samples. When "blind sample" proficiency testing was used (the laboratories did not know this was government testing material but thought they were patient specimens) the record was much worse. Sixteen of the 22 laboratories scored below 60% in drug identification.

In another CDC test, not using "blind samples," 31 percent of a group of laboratories could not identify sickle cell anemia. And in yet another, four groups of laboratories incorrectly identified infectious mononucleosis at least one-third of the time, often reporting that the lab results indicated that the patient had leukemia. (Try to imagine how you would feel if you were incorrectly told that you had leukemia.)

In New Jersey, where test specimens for more than a decade have

been mailed to laboratories to test proficiency, "blind samples" are not used. Even so, 18 percent of the laboratories failed to provide an acceptable result on a simple hemoglobin determination more than 70 percent of the time. Over a period of five years, 17 percent of hospital laboratories, 33 percent of physician-directed independent laboratories, and 24 percent of non-medically directed independent laboratories gave unsatisfactory reports on bacteriological specimens more than half the time.

New York State has greatly improved the performance of clinical laboratories over the past ten

years. Yet, in September, 1975, a former New York City Health Department Commissioner of Laboratories, testified before a congressional committee and was quoted saying, "To put it in simple qualitative terms, we say, yes, the quality of laboratory work has improved. It has changed from horrible to bad."

LAB REGULATION UNEVEN

The federal government regulates part of the clinical laboratory industry through the Clinical Laboratories Improvement Act (CLIA) of 1967. This Act authorizes the Center for Disease Control to set standards and conduct profi-

ciency testing for those laboratories which operate in interstate commerce. Less than 1,000 laboratories (6 percent of the total) are now regulated by the CLIA. Laboratories participating in the Medicare program are also subject to federal regulations. About 10,000 laboratories, including those certified under CLIA are partially regulated this way. Enforcement of standards is uneven for these laboratories, as reliance is placed upon state inspection programs which vary greatly.

In addition, some states have developed their own regulations and licensure laws concerning clinical laboratories. (See Box.)

STATE LABORATORY REGULATION

1. All states, except Ohio, license hospitals. Hospital laboratories are covered under that license. (49 states)

2. The following states have hospital laboratories covered under separate hospital licensure laws: (16 states)

Alabama	Delaware	Iowa	Maine
Arizona	D.C.	Kansas	Massachusetts
Arkansas	Hawaii	Kentucky	Minnesota
Connecticut	Illinois	Louisiana	Montana

3. The following states have specific hospital laboratory laws, or requirements: (13 states)

California	Michigan	New York	Tennessee
Florida	Nevada	Oregon	Texas
Georgia	New Hampshire	Pennsylvania	Puerto Rico
Maryland			

4. The following states have laboratory laws, or requirements, for Independent Laboratories: (27 states)

Alabama	Georgia	Massachusetts	Pennsylvania
Arizona	Hawaii	Michigan	Rhode Island
California	Illinois	Nevada	South Carolina
Connecticut	Kentucky	New Hampshire	Tennessee
Delaware	Louisiana	New Jersey	Texas
D.C.	Maine	New York	Puerto Rico
Florida	Maryland	Oregon	

5. The following states have laws, or requirements, covering some, if not all, laboratory personnel: (23 states)

Alabama	Georgia	Massachusetts	Pennsylvania
Arizona	Hawaii	Michigan	Rhode Island
California	Illinois	Nevada	South Carolina
Connecticut	Kentucky	New Jersey	Tennessee
Delaware	Maine	New York	Puerto Rico
Florida	Maryland	Oregon	

6. The following states require an examination for the Medical Technologist: (6 states)

California	Hawaii	New York City
Florida	Nevada	Tennessee

7. The following states have requirements for at least the lab and/or personnel: (19 states)

Arizona	Hawaii	Nevada	Rhode Island
California	Illinois	New Jersey	South Carolina
Connecticut	Kentucky	New York	Tennessee
Florida	Maryland	Oregon	Puerto Rico
Georgia	Michigan	Pennsylvania	

However, for a state program to be meaningful, it must include (a) provisions for evaluating both hospital and independent laboratories; (b) a program to monitor labs against exacting standards, and (c) adequate funds to control the industry: New York State spends approximately \$800 and New York City \$1,200 per laboratory annually including costs for training and consultative efforts. The expenditures by some other states are as little as \$300 per laboratory. According to a statement of the Assistant Secretary, Department of Health, Education and Welfare (HEW) only Arizona, California, Connecticut, Florida, Georgia, Michigan, New York, Pennsylvania and Tennessee meet the above three criteria. This does not mean that HEW considers the programs in these states equivalent to the CLIA program. At the present time, only the New York State program is considered equivalent in quality and stringency.

CONTROLS COST \$

In many states, no matter what laws are on the books, laboratories are essentially unregulated. One health officer has testified: "In my own State of Massachusetts, it means that anyone can open a laboratory in the State of Massachusetts without a laboratory director's license; that anybody can perform tests; that no quality control has been done; that no reagent control has been done; and only if you are interested in participating in the Massachusetts voluntary proficiency testing program will anybody pay any attention to you at all."

Laboratories, of course, are not likely to voluntarily seek proficiency testing. Imposition of these techniques are expensive and laboratories are in business to make a profit. Guarantees of quality require that at least 10 percent of all tests run in many specialties will be used as controls. Thus, at least that many tests will require the expense of equipment utilization, personnel time and attention, and reagent consumption without any revenue return to the laboratory. State reagents must be discarded and new ones purchased. All this cuts in to the laboratory's profit

margin and serves to discourage voluntary participation in programs designed to maintain standards.

FEDERAL CONTROLS CUT ERRORS

Anybody who has anything to do with laboratory evaluation feels that there is no doubt that good regulations, properly enforced, can bring about substantial improvement in the quality of laboratory testing. The director of the CDC reported that annual inspections of a group of 300 laboratories, followed by consultation to improve procedures, decreased deficiencies markedly. (See Table I.)

Table I

Deficiencies on Annual Inspection (300 Laboratories)

- 1971: average of 22.2 quality control deficiencies per laboratory
- 1972: average of 14.6 deficiencies per laboratory
- 1973: average of 9.6 deficiencies per laboratory

Source: Center for Disease Control

The Center for Disease Control has administrative mechanisms to force compliance with regulations. If the laboratory does not improve after consultation, and with due notice, its license is revoked. Physicians are informed of this action and the laboratory goes out of business.

SO DOES NEW YORK STATE

New York State has had a similar experience. The federal government, in 1967, used New York's program as a model for the CLIA. Since 1972, New York has been the only State where clinical laboratories in interstate commerce are exempt from federal inspection, because it is considered that New York standards are equal to or higher than federal requirements.

New York City reports that prior to the inception of a combined program of licensing technical laboratory personnel and comprehensive proficiency testing of laboratories in 1963, that the quality of laboratory service in the City was horrifyingly substandard. For example, 85 percent of the laboratories tested were unable to isolate

and identify bacteria commonly encountered in infectious diseases. In addition, 87 percent of the laboratories repeatedly failed simple chemical tests and 18 percent could not cross-match blood accurately. By 1974, only 2 percent of the laboratories had repeated difficulty in isolating and identifying bacteria and only 0.4 percent repeatedly failed simple chemical tests. Moreover, none of the laboratories repeatedly failed to properly type or cross-match blood, identify gonorrhea smears, grow strains of pathogenic microorganisms, determine antibiotic susceptibility of bacterial pathogens, or perform syphilis serology or hematology tests correctly.

MEDICARE CONTROLS: AT MERCY OF STATES

Because laboratory regulation for Medicare disbursements is administered by individual states, it can be no better than the state machinery for laboratory regulation and inspection in general. In most instances, this means that the regulation of labs and assurance of good work are questionable. Because of this Medicare has done a poor job of identifying who performs the test, or with what level of accuracy.

In New Jersey, for example, 80 percent of Medicare reimbursement requests for laboratory services are made directly by physicians who make no notation as to the laboratory providing the services. Thus there is no assurance that these laboratory tests are being performed in certified facilities.

PROPOSED LAB LEGISLATION

The Clinical Laboratory Improvement Act of 1976 is currently before the House of Representatives. The Senate passed the Bill on April 29. Hearings were held by a Senate subcommittee in September, 1975 and by a House subcommittee in March, 1976. This House bill would essentially empower the federal government to set standards for all laboratories in much the same way it now does for laboratories operating in interstate commerce. Potential exemptions to such standards would be those laboratories maintained for three or fewer physicians which perform tests solely in connection with the

treatment of patients of those physicians, as well as laboratories in rural hospitals with 100 beds or less. The bill would require licensees of laboratories to disclose any contractual relationship with physicians and to submit a fee schedule to health planning units. It also requires HEW to set up a coordinating unit and an advisory council which includes "members of the public." If this Bill passes, it will undoubtedly contribute substantially to improved laboratory services throughout the nation.

LEGISLATIVE DEFECTS: NO COORDINATION

However, there are a few defects in the bill as presently written which might have a deleterious effect. One section prohibits states from having stricter standards for clinical laboratories than would apply at the national level. This would penalize a state like New York, which has been a leader in the field of quality control in clinical laboratories. The bill also fails to bring clinical laboratories under two quality control mechanisms required by existing federal legislation: PSRO and HSA.

Professional Standard Review Organizations (PSROs) now oversee the quality of health care and limit the excessive use of medical facilities for persons covered by federal health programs. Under the new laboratory legislation, the only time clinical laboratories would come under review by PSROs occurs when they are located in a hospital.

The Health Planning Act of 1974 gives Health Systems Agencies (HSAs) control over the quantity and distribution of health care services. HSAs, in consultation with PSROs plan for adequate provision for health care, but are not given any responsibility to control laboratories.

COSTLY TESTS: ON THE RISE

New York has an excellent program for controlling the quality of laboratory testing. But nobody seems to have any program for controlling the spiralling costs of laboratories. This is obvious from a cursory examination of the experience of Medicaid patients in New York City. From 1970 to 1975, despite the fact that the number of people eligible for Medicaid remained fairly constant, the reim-

bursement rates for each laboratory test remained frozen, and fewer than forty new tests were added to the benefit schedule auditors found that Medicaid lab costs rose from 3.7 million dollars in 1970 to more than 14 million dollars in 1975.

New York State has attempted to control the quality of Medicaid laboratory tests by refusing to pay for laboratory tests other than blood count, urinalysis or strep throat smear, unless these are performed in a regulated laboratory. The results have been, on the whole, successful. New York City has attempted to control the costs of laboratory tests for Medicaid patients by changing the manner in which these are paid for. The results have been, so far, totally unsuccessful.

LAB OWNERS FIGHT COST CONTROLS

After trying other alternatives to control costs, the City of New York introduced a program to centralize laboratory testing in each of the City's five boroughs by designating a single laboratory, chosen on the basis of competitive bidding, to process all clinical specimens susceptible to automated processing for a period of three years, with the City reserving the right to exercise an annual option to renew. Seven laboratories submitted bids. For the entire city of New York the maximum aggregate bid was \$5.7 million dollars. When this figure is compared to the more than 14 million dollars expended in 1975, the immediate savings of six to eight million dollars to the City, State and Federal governments can readily be seen. The potential savings is 50% plus.

A coalition of clinical laboratories sought and received an injunction to prevent implementation of this system. The court case was decided upon the basis that Medicaid statutes guarantee patients free choice of medical service providers. This decision was made in spite of the fact that 96 percent of all specimens are sent by physicians to a laboratory without any consultation with patients. The reality is: few, if any, patients know where their lab tests are sent. Nevertheless, New York City was unable to implement its program to control costs and quality, and laboratory services, are still purchased on a fee-for-service

basis. This will result in a loss of millions of dollars to the public.

LAB TEST CHARGES VARY WIDELY

There is a tremendous variation between charges for identical tests by each laboratory. The analysis prepared by the New York City Department of Health showed that there was an over 800% differential for some tests between the lowest price quotation and the Medicare reimbursement.

A comparison between hospital and commercial laboratory charges indicate that the differential between the highest and lowest charge can sometimes reach 1000%.

Third parties, such as Blue Shield and Group Health Insurance reimburse commercial laboratories at a fixed fee schedule. In most cases, patients are billed for the difference. With 10% of all health care costs paid to clinical laboratories, it would seem that Blue Shield and other third parties should establish non-profit laboratories which would assure their subscribers both low-cost and high-quality service. The failure of these third parties to establish experimental labs reflects their basic inability to control costs and a lack of desire to protect their subscribers against excessive charges.

The Health Insurance Plan of Greater New York has established a centralized laboratory which performs tests for its affiliated medical groups and many of the specialized tests for its affiliate, LaGuardia Hospital.

PUBLIC SUBSIDY SUPPORTS INEFFICIENCY IN PRIVATE SECTOR

Federal law prohibits government funded programs from interfering with the free choice of laboratories. This restriction is basically a government subsidy for inefficiency and poor quality. By attempting to channel laboratory work to high quality, low cost labs, New York City showed that it could reduce its lab expenditures significantly. Using these figures on a national basis, there is a potential savings for lab tests of over 5 billion dollars to the third-parties and ultimately to the consumer. This could be achieved by establishing contract or non-profit laboratories.

Of course, there are risks in creating large-scale labs. One way

to minimize these risks is the creation of government operated laboratories, much like the TVA.

DUPLICATE HOSPITAL LABS: HIGH COSTS RESULT

Hospitals and commercial labs have purchased laboratory equipment far in excess of the demand for such services. Computerized lab equipment has been installed in laboratories which have the capacity to perform lab tests for all other hospitals or physicians in the community. Rather than sharing this capacity each hospital rushes to install the most up-to-date equipment in its own labs. In New York City, eight hospitals, for example in 1975, purchased a SMAC laboratory system costing approximately one quarter million dollars each, without requesting approval of the

local health department or planning agency.

HEALTH PLANNING: NO IMPACT ON LABS

A recent study of health planning in the United States indicates that planning agencies almost never turn down proposals for laboratory systems. Hospitals in New York City have become so accustomed to receiving approval for new lab systems that they do not bother to file with the appropriate planning bodies. There seems to be no criteria developed by any planning agency regarding laboratory systems. This is surprising, since standards for evaluating a laboratory can easily be established regarding proficiency, economy, etc. Commercial labs are not even subject to planning review by the new

HSAs. There has been almost no shared service between laboratories.

QUANTITY = QUALITY?

The inordinate number of commercial laboratories is one of the prime reasons that costs are high and quality is low. An overabundance of proprietary labs has resulted in each one maximizing profits at the expense of the consumer. Just as there is an overabundance of hospital beds, there is an overabundance of commercial labs and laboratory equipment in hospitals. Each hour a laboratory system is not in operation has the same type of economic impact on costs as does each empty hospital bed; unnecessary and wasteful.

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PATIENTS AND DOCTORS SHOULD ASK THE FOLLOWING BEFORE TESTS ARE ORDERED:

1. Is this test necessary?
2. What will it show?
3. What will I do differently based on the results?
4. Will this really provide better care?
5. What will it cost?
6. Will this test avoid malpractice?

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THE COMMISSION IS A NON-PROFIT ORGANIZATION

The Consumer Commission Recommends that:

1. the federal government license, inspect and set standards for all laboratories in the United States. State standards can exceed national standards. Blind sample surveillance should be a routine part of all government inspection programs. All inspections to be unannounced and performed no less than four times each year.
2. there be full licensing of laboratory personnel and annual testing to verify maintenance and improvement of skills and technical knowledge.
3. all laboratories, including independent labs, be subject to Health Systems Agency approval; all equipment and computer systems be approved by the HSA; and all testing be subject to review by PSROs. The statistical profiles of doctor utilization of lab tests be made available to third party insurers, the professions and the public.
4. all lab equipment be subject to strict federal standards and be subject to periodic testing for quality and efficiency. All new laboratory equipment must meet federal standards of accuracy and efficiency, and before installation or use be certified by the HSA as meeting the public's need.
5. all doctors and/or technicians performing clinical lab tests be tested for proficiency on a regular periodic basis.
6. all third-party reimbursement plans, including the federal government, develop contract arrangements for low-cost high quality lab work and experiments be initiated to develop non-profit laboratory service corporations which would perform lab tests at cost, test new equipment, procedures and act as a yardstick to measure other labs.
7. as part of federal licensure, codes of ethics, publication of prices, costs, proficiency test scores, contracts, ownership and financial statements (including schedules of salaries) be made public.
8. any arrangements to induce physicians to refer lab work to a specific lab including kickbacks, percentage refunds, or any other form of payment, compensation, etc. be made illegal.
9. educational programs be set up to educate consumers and professionals of the costs, impact and quality of lab work, and its importance to patients.
10. lab and/or lab personnel who cannot meet standards of proficiency lose their licenses to operate or work in a lab until they receive retraining and pass a subsequent test.
11. the federal and state governments not farm out standard setting, regulation, inspection or enforcement to provider non-profit accreditation bodies, but instead maintain their own staffs to perform these functions, using provider and consumer advisory bodies as needed.
12. sufficient funding be realized through license and registration fees, permits, fines, inspection fees and general tax funds to ensure adequate federal supervision, monitoring and control over the lab industry.
13. all lab test results be made available to patients, on request.

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