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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

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STATEMENT OF
EDWARD A. DENSMORE, DEPUTY DIRECTOR, HUMAN RESOURCES DIVISION
BEFORE THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

ON THE
CLINICAL TESTING OF ANTICANCER DRUGS

Madam Chairman, we are pleased to be here today to discuss our review of the clinical testing of anticancer drugs and the regulation of that testing by the Food and Drug Administration (FDA).

On December 7, 1981, you requested that we study the adequacy of existing policy, practices, and procedures within the Department of Health and Human Services (HHS) and its sub-agencies regarding protection of humans who participate in federally sponsored trials of investigational new drugs (INDs). Because you were primarily interested in anticancer drugs, we concentrated on them.

On May 2, 1983, we sent a copy of our draft report on this review to the Secretary of HHS for comment. Pursuant to your request, a copy was also provided to you at that time. As the draft has not been fully reviewed within GAO, I would like to caution that its contents, including the proposed recommendations discussed in my statement, are subject to revision.

In addition to reviewing the FDA and National Cancer Institute (NCI) policies and procedures for monitoring and regulating clinical testing of anticancer drugs, we selected a sample of 10 investigational anticancer drugs currently undergoing testing and traced their progress through the regulatory process from the time FDA first received the IND application until our cutoff date of October 1, 1982. Six NCI-sponsored drugs and four privately sponsored drugs were chosen so that we could compare the IND review process for publicly and privately sponsored drugs. Each of the privately sponsored drugs had a different sponsor. Five drugs had been submitted to FDA before 1981 and five in 1981. We did not select any drugs submitted after 1981 because clinical testing would not have started when we began our review. As of April 1, 1983, none of our sample drugs had been approved for general marketing; all but one were still in phase I or phase II[1] testing.

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[1]In phase I, drugs are tested to determine the safe dose; in phase II, they are tested for effectiveness; and in phase III, their efficacy is compared with that of existing drugs.

THERAPEUTIC INTENT OF PHASE I TESTING

You asked that we comment on whether there is therapeutic intent--that is, an intent to help patients--during phase I testing of cytotoxic anticancer drugs. This is not an issue with most other types of phase I experimental drug studies because the persons taking the drugs are not ill, as are cancer patients. Our discussions with NCI, FDA, and medical investigators and a review of the results of phase I studies of cytotoxic anticancer drugs indicate that therapeutic intent is present in phase I. However, only a small percentage of patients make significant gains against their diseases in phase I trials.

Of the 136 phase I patient files reviewed, in only one case was someone given an experimental cytotoxic anticancer drug that the investigator did not believe could help the patient. In this case he had been eligible for and was promised the drug. Unfortunately, his physical condition deteriorated to the point where he had only a few days to live. The drug was administered with little hope of positive results because the physician did not want to destroy the patient's hope in his last few days.

In response to a request from an HHS task force, NCI reviewed the results of phase I drug testing from 1975 to 1980 and found that about 5 percent of patients in phase I studies significantly benefited from treatment, with 2-1/2 percent experiencing a complete response--meaning that their cancers at least temporarily disappeared.

More recent data from late 1979 through October 1982 showed lower percentages of patients benefiting. According to these data, less than 3 percent significantly benefited from phase I treatment, with less than 1 percent having a complete response.

The more recent data showed that 3 of the 37 drugs tested accounted for over 99 percent of the complete responses and over 60 percent of the other significant responses. Also, 99 percent of the complete responses and almost 24 percent of the other significant responses occurred in only one type of cancer--leukemia.

FDA AND NCI ARE IMPROVING PROTECTION OF PATIENTS DURING TESTING OF ANTICANCER DRUGS

FDA and NCI have made or are making a number of improvements in the way they carry out their responsibilities of assuring that patients involved in the clinical testing of anticancer drugs are protected. For example:

--NCI has increased its monitoring of clinical investigators.

--NCI has developed more specific requirements for the reporting of adverse reactions and is reporting more adverse reactions to FDA.

--NCI has increased its controls over the shipment of experimental anticancer drugs and has required investigators to do the same.

--FDA has requested congressional authority to transfer 35 staff positions from other agency programs to new drug approval.

In addition, the informed consent process was generally carried out in accordance with FDA regulations, and clinical investigators were generally complying with protocol requirements. Of the 171 patient files at the seven institutions where we checked for informed consent forms, only 1 file was missing the form. In this case, the clinical investigator could not explain why the form was missing but insisted that an informed consent form must be signed by each patient before he would administer an experimental new drug.

At another institution we found four cases in which the clinical investigators had used patient consent forms that had not been updated with the most recent information about the risk of cardiotoxicity. The clinical investigator in these cases explained that the forms used were probably the only ones available in the clinic when patients were admitted and that the risks of cardiotoxicity had been orally explained to the patients.

We also reviewed these 171 patient files to compare patient eligibility criteria and patient testing requirements as stated in the study protocols with data in the patient files. We found that most patients met eligibility requirements. An investigator who commented on those that did not meet eligibility

requirements advised us that no protocol can ever be completely followed. Other investigators indicated that flexibility is necessary in interpreting protocols, since individual cases sometimes demand individualized medical judgment.

While experimental new drugs are being tested on patients, certain laboratory tests are required to check for adverse reactions and to monitor vital signs. Although laboratory tests were not always performed on patients to the extent called for by the protocols, investigators substantially complied with most protocol requirements. Among the reasons given for the absence of certain tests were (1) patients sometimes did not keep appointments; (2) patients did not feel well enough to have tests done at the intervals specified by the protocols; (3) tests were done, but the information was misplaced; and (4) tests were apparently ordered, but were not done.

Despite the improvements noted since our 1976 review and since the November 1981 hearings by the Subcommittee on Investigations and General Oversight, we believe problems still exist and additional actions are needed to further improve the protection given patients participating in clinical studies. Some of these are discussed in the following sections of my statement.

FDA HAS NO FOLLOWUP SYSTEM TO ASSURE THAT ITS CONCERNS ARE ADDRESSED BY SPONSORS

One potentially serious problem was that FDA is allowing clinical testing to proceed without following up to determine

whether IND sponsors have complied with its recommendations regarding problems with the proposed study. For example, FDA advised NCI in a deficiency letter dated November 26, 1979, that, as the sponsor for one drug being tested, it should perform certain specific studies to monitor for cardiotoxicity and exclude patients with prior adriamycin treatment and heart disease. FDA did not follow up to determine whether these recommendations were carried out. In June 1981, when it began receiving reports of patients with cardiotoxicity problems, FDA found that protocols had not been changed to incorporate its concerns. The first reports of cardiotoxicity involved patients with prior adriamycin treatment. NCI did not issue a warning to its clinical investigators until June 1981 (more than 1-1/2 years after FDA's initial recommendation) to monitor cardiotoxicity. Protocols were still being submitted to FDA as late as December 1982 without including requirements for such monitoring.

FDA officials told us that they never know whether sponsors inform clinical investigators of FDA's concerns unless suggested changes result in revisions to protocols and/or the sponsor voluntarily notifies them of the corrective action taken. The director of the division responsible for reviewing anticancer drugs told us that his division does not have a good way of determining whether sponsors have complied with FDA requests. He said that the division's management information system does

not have this capability and reviewers' heavy workloads make it difficult for them to manually keep track of incoming correspondence.

FDA DOES NOT ALWAYS RECEIVE AND PROMPTLY REVIEW IND AMENDMENTS

Another problem was that sponsors do not always submit IND amendments to FDA for review, and when submitted, FDA frequently does not review them in a timely manner and sometimes does not review them at all. Since IND amendments can significantly change a study, FDA cannot determine whether it has any safety concerns and whether patients are adequately protected unless it reviews the amendments. This is particularly important for protocols on studies initiated after the initial IND is approved. FDA's IND regulations are unclear as to whether sponsors must submit protocols to FDA for clinical studies starting after IND approval.

We found 12 protocols involving 5 drugs that had not been submitted to FDA before clinical testing began. Only after receiving reports of adverse drug reactions did FDA realize that some of these protocols had not been submitted to it. For one drug being tested, FDA learned, after receiving a report on the death of a patient, that testing was being performed under a protocol that had not been submitted for review. NCI received this protocol on September 3, 1981, and clinical testing began in October 1981; however, FDA did not receive the protocol until

December 2, 1981. An NCI official explained that NCI had not sent this protocol to FDA earlier because of an oversight.

Human testing of another drug began at one institution under three protocols before FDA or NCI could review them. Testing under one of these protocols began on June 9, 1980, but NCI did not receive the protocol for review until August 25, 1980. NCI officials told us that they gave oral approval to start testing in January 1981. The clinical investigator completed testing under this protocol on May 1, 1981. NCI submitted the protocol to FDA on June 5, 1981.

An NCI official told us that NCI became aware, based on an inspection at this institution, that testing had begun under several protocols before NCI had approved them. NCI requested the institution to stop testing on all protocols until it could determine what other studies had begun without its approval. The official told us that NCI no longer gives oral approval to begin testing. Clinical investigators now must receive written NCI approval to start testing.

Even when sponsors submit IND amendments, FDA frequently does not review them promptly and sometimes does not review them at all. This occurs because (1) reviewers are assigned a heavy workload and review of IND amendments is given a low priority and (2) IND amendments are often misfiled and not distributed promptly to reviewers.

Although IND amendments comprise the largest percentage of workload volume, other work is assigned a higher priority to comply with regulations and internal management deadlines. FDA reviewers have expressed concern about their heavy workload, complaining that they have insufficient time to carry out their responsibilities. One FDA reviewer told us that many times they can make only a cursory review of IND amendments. Some reviewers told us that sometimes they don't review the IND amendments at all.

FDA also lacks sufficient administrative staff to process IND documents promptly. Delays in distributing and filing IND amendments hamper FDA's review process. During our review we frequently encountered problems in locating documents related to individual INDs. In many cases IND material either had not been filed, had been taken from the file room without being signed out, or had just been misplaced. FDA officials we spoke with agreed that there are problems and delays throughout the system for processing documents from the mail room to the reviewers.

In many cases documents were missing from the files or a long time was required to distribute them to reviewers. For example, FDA received an IND amendment on January 8, 1982, which included seven protocols that had been revised to incorporate restrictions to monitor for cardiotoxicity. However, the medical officer responsible for this drug did not receive this amendment until February 18, at which time he completed his

review and concluded that several protocols did not include all the required restrictions outlined in NCI's warning letter. FDA sent NCI a deficiency letter on June 3, 1982, requesting that the corrections be made. FDA officials could not explain why it took 3-1/2 months to send this deficiency letter. However, we found that FDA has generally been slow in sending deficiency letters because of delays in completing written reviews, a heavy workload, and insufficient staff to carry out its functions.

CLINICAL INVESTIGATORS AND DRUG SPONSORS DO NOT ALWAYS PROMPTLY REPORT ADVERSE DRUG REACTIONS

While adverse drug reaction reporting has improved since the 1981 congressional hearings, problems still exist in this area. The lack of specific time frames for reporting adverse reactions and the lack of a clear, generally agreed upon definition of a reportable adverse reaction may be contributing to the untimely reporting, or the nonreporting, of such reactions. In addition, when adverse drug reactions are reported, FDA does not always promptly review them.

Of the 10 drugs reviewed, we found problems in reporting adverse reactions with 5 drugs. Three of the five were NCI-sponsored drugs; the other two were privately sponsored. The reporting problems on two of the NCI drugs occurred before the start of NCI's 1981 effort to improve its adverse drug reaction reporting.

One of the NCI drugs had a similar chemical structure as a known cardiotoxic drug, and FDA had recommended earlier that NCI instruct its investigators to monitor for cardiotoxicity. However, when investigators started submitting reports of cardiotoxicity, NCI delayed sending them to FDA because of uncertainty over whether the reactions were drug related. An FDA medical reviewer later emphasized that NCI should report serious reactions immediately and that such reports should not be delayed while a sponsor determines the reaction's relationship to the drug. NCI did eventually notify all investigators of these adverse reactions and recommended that all patients be carefully monitored for cardiotoxicity, but this action was taken more than 1-1/2 years after FDA initially recommended it. By that time, NCI had received nine reports of cardiotoxicity. We also found that several months after NCI notified the investigators, one clinical investigator did not submit reports of cardiotoxicity because of doubt that this reaction was drug related.

Each of the two privately sponsored drugs had only one reported adverse drug reaction at the time our review was completed. In one case the reaction involved a severely decreased white blood count, which may have contributed to the patient's deteriorating condition and subsequent death. The investigator's delay of almost 2 months in reporting the reaction to the sponsor accounted for most of the delay in reporting

to FDA. An FDA reviewer mentioned that this sponsor has had timeliness problems in the past but has agreed to correct them.

The one adverse reaction reported for another privately sponsored drug was submitted to FDA over 2 months after it was first reported to the sponsor, largely because of miscommunication between the sponsor and the investigator. The reaction involved a death, but its relationship to the drug was uncertain. The investigator stated that when the reaction was reported to the sponsor by telephone, the sponsor apparently made no record of the telephone conversation and did not send a report to FDA. Several weeks later, the investigator submitted a written report to the sponsor, who then reported it to FDA.

While sponsors have sometimes been late in reporting adverse reactions, FDA has not always been prompt in reviewing them when they are received. In several instances, FDA did not review adverse reaction reports for days or weeks after they were submitted. For example, NCI reported adverse reactions on one drug to FDA on March 3 and March 18, 1982. These reactions, which involved a neurological disorder and hypotension, were not reviewed by the medical officer until August 11 and September 16, 1982, respectively. FDA's system for document flow appears to be a major reason why adverse reaction reports are not forwarded promptly to reviewers and, hence, why review of the reports is late.

Defining adverse reactions for investigational cancer drugs is difficult. Due to the unique, highly toxic nature of most of these drugs and the physical toll taken by the disease itself, determining whether a cause and effect relationship exists between the drug and a patient's reaction is not easy. The reporting system must rely on the clinical investigator's ability to correctly make the connection. Although FDA regulations contain requirements on the reporting of adverse reactions, wording regarding the definition of an adverse reaction is vague.

The words "alarming" and "significant" as used in the FDA regulations do not provide very definite guidance about specific types of reactions that should be reported. Such vagueness contributes to investigators having varying interpretations of what an adverse reaction is and using varying reporting criteria. On the other hand, devising a precise definition to fit all types of drug tests would be difficult. Too narrow a definition might exclude some reactions that should be reported, while too broad a definition could result in FDA being inundated with reports, which could obscure the important adverse reactions.

FDA regulations also do not provide specific guidance as to what constitutes timely reporting of adverse reactions. The word "promptly" gives no indication as to an actual reporting time frame. FDA has traditionally advocated a 15-day time frame for reporting adverse reactions, although this is not written in

the regulations. In February 1983, the Secretary of HHS proposed strengthening requirements for adverse reaction reporting to FDA by requiring specific time frames for reporting fatal or life-threatening reactions.

In 1981 NCI began to devise its own requirements which more specifically define what an adverse reaction is and when an investigator should report it. According to NCI's most recent (January 1983) adverse reaction reporting guidelines, each investigator engaged in clinical research with NCI-supplied investigational drugs is responsible for promptly reporting adverse reactions to NCI's Division of Cancer Treatment. The division's policy is to encourage investigators to submit such reports even if there is only a suspected drug effect.

FDA AND NCI NEED TO IMPROVE MONITORING OF CLINICAL TESTING

Although various aspects of NCI and FDA clinical drug study monitoring appear to be adequate, both agencies could make improvements. NCI's computerized data base, which is maintained by a contractor to provide reports on the status of the clinical studies, is not as complete or current as it could be because not all drug investigators are submitting timely or complete data. The data base, therefore, cannot be relied upon to present an accurate picture of drug study progress.

According to a report by the NCI contractor, only about half of the patient laboratory test data required by NCI's phase

I drug protocols are being submitted by the investigators, and much of the data submitted are coming in significantly late. The report also shows that data submitted on some important items, such as patient eligibility, are frequently insufficient. Although a more recent report shows some improvement, further progress should be made to ensure that the data base provides an accurate, up-to-date overview of NCI's drug studies. NCI has recognized the need to improve investigators' data reporting to its contractor and is planning an experiment using computer terminals to improve the reporting.

As of March 1983, NCI was not making site visits to monitor how some of its investigators were performing their clinical drug studies. Site visits by drug sponsors to monitor their investigators' performance are an important means of determining whether patients are adequately protected during IND clinical drug tests. As of March 1983 the site visit monitoring procedures for NCI's phase I cytotoxic drug studies were generally good, and NCI was requiring frequent site visits by a contractor to these phase I investigators. However, some of NCI's phase II and III drug studies are not visited at all, while others may not be visited often enough. NCI has recognized for some time the need to expand its site visit monitoring to more of its drug studies and has made plans to do so.

Although NCI has good controls over its process for handling drug requests from its investigators, as of March 1983

it did not have adequate controls to ensure that drug shipments are received and used by investigators only for authorized purposes.

NCI has begun to implement improved drug accountability controls over its investigators, but several problems remain. For example, no way has been developed to verify investigator drug disbursements to satellite locations, and site visits to phase II and III investigators may not be frequent enough to determine whether the investigators are carrying out their recordkeeping responsibilities and are making only authorized disbursements of their drug supplies.

Since 1976 FDA has recognized the need to improve the monitoring of clinical studies. To meet that need FDA developed proposed sponsor-monitoring regulations in 1977 but has not implemented them. We believe FDA should finalize its sponsor-monitoring regulations to provide greater assurance that sponsors are monitoring clinical studies to the extent considered necessary to assure patient safety.

Because FDA regulations do not specify what information should be included in sponsors' drug progress reports to FDA, sponsors have not always submitted reports that give FDA meaningful information on the progress of the drug study. To ensure that progress reports are informative, FDA should establish minimum acceptable drug study progress reporting requirements. FDA should require detailed information on (1) the number of

patients treated under each protocol; (2) toxicities encountered, including adverse reactions; and (3) drug dosage levels attained, including maximum tolerated dose levels and dose limiting toxicities.

PROPOSALS TO THE SECRETARY OF HHS

We are making a number of proposals to the Secretary that we believe will result in even greater protection of patients during testing. These include proposals that FDA:

--Establish a formal followup system so that FDA can know whether IND sponsors respond to its recommendations to improve patient safety.

--Revise its regulations to require sponsors to approve and submit all clinical protocols for FDA review before clinical testing begins.

--Develop a system for identifying major IND amendments and more promptly distributing them to reviewers.

--Give sponsors more precise guidance as to what types of adverse reactions should be reported and when they should be reported, particularly in cases in which the reaction's relationship to the drug is uncertain.

--Urge sponsors, if they have not already done so, to establish definite time frames for clinical investigator reporting of reactions which will allow the sponsors time to meet FDA's reporting requirements.

--Instruct sponsors to label or otherwise highlight adverse reaction forms or mailing envelopes so that adverse drug reactions will be recognized and can be dealt with immediately upon their arrival at FDA.

--Issue final sponsor-monitoring regulations.

--Establish specific requirements for information to be included in progress reports submitted by sponsors of drug studies.

We are also proposing that NCI:

--Advise FDA in a timely manner of actions taken or to be taken on FDA's concerns.

--Review the need for and usefulness of its drug study data base. If needed, NCI should require clinical investigators to submit data in a more timely and complete manner; if not needed, NCI should terminate the effort.

--Ensure that NCI's site visit monitoring includes all NCI investigators; devise a procedure to verify investigators' drug disbursements to their satellite locations or require that drug shipments be made directly to these locations by NCI; and if possible within allocated resources, increase the frequency of site visits to monitor investigators' performance.

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Madam Chairman, this concludes my statement. We will be pleased to answer any questions you or other members of the Committee may have.

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UNITED STATES GENERAL ACCOUNTING OFFICE

WASHINGTON, D.C. 20548

FOR RELEASE ON DELIVERY
TUESDAY, JUNE 21, 1983

STATEMENT OF

KENNETH A POLLOCK

DEPUTY ASSOCIATE DIRECTOR

BEFORE THE

DEFENSE SUBCOMMITTEE

COMMITTEE ON APPROPRIATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

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Mr. Chairman and Members of the Subcommittee:

We appreciate the opportunity to appear here today to discuss opportunities for improving the management of the Defense Department's computer systems. I have with me today Mr. Greg McDonald from our Dallas office, and Mr. Fred Chasnov from our National Security and International Affairs Division. At the conclusion of my prepared remarks, we will address any questions you may have.

The Department of Defense is the largest consumer of computer hardware and services in the Government. During the past fiscal year DOD spent more than $4.3 billion to acquire and operate general purpose computer systems and an estimated $ 7.4 billion on embedded systems, which are integrated into and form a part of a larger system, such as a weapons system. Expenditures for both general purpose and embedded computer systems are expected to experience continued growth in coming years and the costs for embedded systems will be substantial.

Our message today in both areas, is that, through greater management attention to its computer resources, DOD can reduce its costs and increase the effectiveness of its computer support. Let me first address the area of general purpose computer systems.

The Department of Defense will account for almost 60 percent of the $1.1 billion the Government will spend to lease general purpose computer equipment this year. Our work indicates that millions of these dollars can be saved if managers will seek and apply existing alternatives to current computer leasing practices.

The Federal Government retains computers, whether they are owned or leased, longer than the private sector. As a result, agencies tend to retain costly, obsolescent equipment and, when that equipment is leased for such prolonged periods, to pay rents that have exceeded original purchase prices, in some instances by 300 to 400 percent.

Leasing is an appropriate acquisition method under a variety of circumstances, but managers must evaluate each acquisition or renewal -- whether for computers or other property -- on its own merits, considering

--Advancements in technology,
--Intended systems life, and
--Sound financial management principles.

Just as we would not advocate purchase as the only appropriate acquisition alternative in all types of procurements, we would also suggest that on-going leases should be periodically analyzed and evaluated, and changed when necessary, to insure that agencies are continuing to meet their data processing needs at the lowest overall cost to the Government. In our work, both within DOD and elsewhere, we have not found this kind of systematic, recurring evaluation of installed equipment leases.

For example, at eight Defense data processing installations, we found

--Known savings opportunities that were bypassed because purchase funds were not readily available,

--Excessive rents paid and ownership opportunities that were missed because leased equipment contracts were not monitored

--Obsolete equipment that continued to be leased when it could have been bought for a fraction of a single year's rent.

When we analyzed the leases on more than 225 computer components installed at these installations, we found, in 93 % of the cases, that outright purchase, refinancing the existing lease through a third party, or acquiring a used substitute in the open market, would be less expensive than continuing the equipment's present lease. Savings expectations generally ranged between 30 and 60 percent, but in several instances they were dramatic--reducing cash flows by as much as 90 percent.

Continuing the current lease arrangement was most economical in only 7 % of the cases. These 7% fell into the following categories:

--Exceptionally low lease prices,
--Short term projects, and
--Lease-to-ownership plans.

I would like to briefly share with you some examples from our work at Defense installations which, I feel, will illustrate the problems we are finding:

--Between 1974 and 1982 the Air Force paid more than $29 million in rent on a Burroughs system at its Manpower and Personnel Center that sold new for $10 million. A communications controller at the San Antonio Data Service Center has been paid for 5 times over in rent and an 11-year old optical page reader at Ft. Lee, Virginia, has been paid for more than 3 times over. Similar conditions existed at each of the eight sites we visited.

--The Air Force Systems Command, Armament Division, Directorate of Computer Sciences, Eglin AFB, Florida, spent $241,000 more than necessary on its CYBER 176 computer because it did not have purchase funds allocated for this purpose in 1981 and had to lease until 1982 rather than buy at an optimum time.

--The Army has paid almost $13,000 in unnecessary rent on an Ampex memory increment installed on a Ft. Lee, Virginia, computer under a GSA mandatory requirements contract. The Army was unaware that it could have owned the equipment with no additional charge by exercising an option in March 1981. The Navy paid more than $100,000 in unnecessary charges for a similar Ampex unit under the same contract.

--The Military Airlift Command is spending about $230,000 annually to lease old IBM punch card equipment that could be bought for a few months rent. At the same time GSA is excessing government-owned like machines, in prime condition, to non-government users. Six of the Defense installations we visited were leasing old punch card machines, some of which had been under lease for up to 23 years.

There are a variety of cost effective alternatives to continuing the present leasing contracts, and in our analysis we considered:

--exercising purchase options, taking advantage of accrued purchase option credits

--acquiring title to the equipment, as above, but selling the equipment to a third party and leasing it back (at a lower monthly lease cost than paid at present)

--buying similar equipment on the used market, and terminating the present lease

--leasing similar equipment from a dealer in used equipment, and terminating the present lease

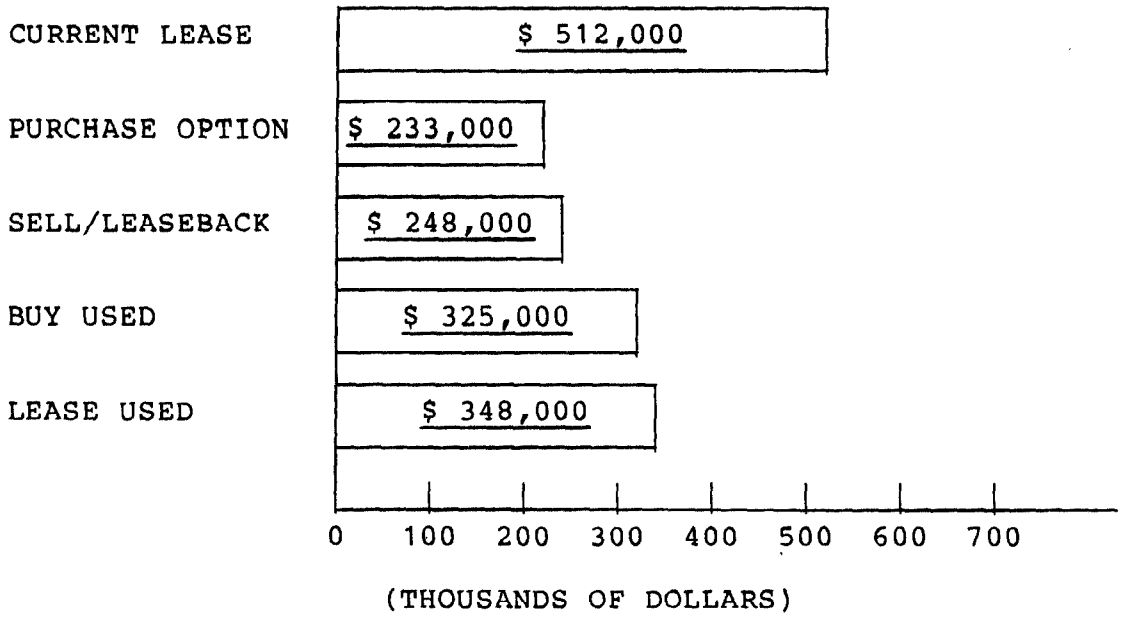
These alternatives were little known or little used at the installations we visited. The most obvious of these alternatives is converting leased equipment to purchase, where appropriate. This could involve additional appropriations, but should result in economies.

Notwithstanding installation managers' perceptions that purchase monies were generally not available within DOD, the Office of the Secretary of Defense has been somewhat successful in budgeting purchase money for lease conversions when requested. This fiscal year, OSD honored Army requests for $8.6 million to buy leased ADP equipment. The General Services Administration's ADP Revolving Fund may be used for purchase opportunities if money is available within the Fund and certain eligibility criteria are met.

Sell/Leaseback, a transaction where the government's purchase option is exercised by a third party who then leases the equipment back to the government, has resulted in substantial savings in the few instances in government where it has been used. For example, in 1980 the Department of Energy's Livermore Labs refinanced a leased CRAY computer through a sell/leaseback transaction that resulted in both a two-year saving of more than $2 million and government ownership of the computer at the end of the lease term.

Substantial savings can also be realized if agencies will give greater consideration to acquiring equipment in the used computer market or substituting a lower cost used item for installed, leased equipment. For example, a Digital RP-06AA disk drive would cost $34,000 if purchased new under GSA schedule contract and more than $15,000 per year to lease. The same drive, used, is advertised for sale at about $12,000.

This chart (below) provides a graphic comparison of the three-year costs for one component--an IBM 4341 computer.



As you can see, in this instance, any available alternative selected results in a lower overall cost than continuing the present lease. We found this to be the case for 159 of the 225 leased components we reviewed, about 70%. For 210, or 93% of the components reviewed, there was at least one lower cost alternative. Only 15 of these components (7% of the 225 reviewed) did not have at least one available alternative at less cost than their present rental contracts.

Alternatives such as these could be immediately pursued by the Services. They were not doing so because (1) the installations we visited were not systematically analyzing their leased computer inventory for cost effective alternatives, (2) the information necessary to perform such analyses was not readily available (and in some instances was impossible to reconstruct from existing records), or (3) purchase was perceived as the only opportunity and money may not have been available.

We found unreliable equipment inventory records at all but one of the Defense installations we visited. For example, we found discrepancies in recorded model numbers, serial numbers, purchase prices, rental rates and installation dates. In some instances, contract terms and conditions were not available. None of the installations or command elements we visited tracked the Government's accumulated purchase option credits, and the accounting records needed to accurately reconstruct credit information on equipment more than 5 years old were not retained.

In December 1980 we reported [1] on the state of obsolescence in Federal Government computer installations and urged immediate actions to reduce the Government's use of old computer technology. In recommending lease restructuring, purchase conversions, or used replacements we are not suggesting that installations retain old

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[1] Continued Use of Costly, Outmoded Computers in Federal Agencies Can Be Avoided, AFMD-81-9, December 15, 1980.

equipment any longer than necessary. Rather, we are saying that managers should periodically evaluate equipment costs and attain the most economic arrangements possible for the remaining period of the systems life.

To recap, we believe that the Services are paying far more than necessary for leased general purpose computer hardware. There are available lower cost options for retaining installed leased equipment, but those alternatives are not being aggressively pursued.

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I would like to switch gears at this point, and turn from the subject of leasing general-purpose computers to the subject of acquiring embedded computer systems. Embedded computers are specially designed or configured and (1) acquired as part of a total weapons package, or (2) integrated into a command center, and thus are "embedded" in such a structure.

Chart 1 shows the estimated 1980 and forecasted 1985 and 1990 annual costs for DOD's general purpose and embedded computers. Much of the growth in DOD computer usage that I mentioned at the beginning of my statement is expected to take place in the embedded systems area. We prepared this chart from an October 1980 study by the Electronic Industries Association, which used DOD budget data,

interviews with experts in industry and Government, market surveys, periodicals, and other reports for its 10 year forecast of DOD computer hardware costs and the cost of labor-intensive software and services. Analysis of this chart shows that:

--DOD computer costs will increase substantially in all categories, although embedded computer costs will become increasingly dominant; and

--software costs for embedded computers will increase to more than two-thirds of total computer costs.

Chart 2 shows hardware and software percentage cost trends from 1955 to 1985 for computers in general. This chart was developed from a widely published graph by a recognized software expert. Notice that the hardware cost percentage is decreasing while the software cost percentage is increasing, particularly the maintenance portion which is expected to make up about 60 percent of total costs by 1985.

Software maintenance consists of modifying existing operational software while leaving its primary functions intact. Software maintenance costs are expected to eventually contribute roughly 70 percent of the overall cost of software. The lower percentages shown in this chart for software maintenance reflect the fact that additions to the inventory of code via development will occur at a greater rate than code will become obsolete for some time.

Chart 3 applies and extrapolates development and maintenance software percentage cost trends (chart 2) to the forecasted costs of hardware and software for DOD embedded computer systems (chart 1) to show possible cost trends of DOD's embedded computers.

Assuming these trends apply, an analysis of the chart shows that

--hardware costs will increase but continue to decline as a percentage of total costs,

--software development costs will increase while remaining nearly constant as a percentage of total cost, and

--software maintenance costs will increase rapidly and continue to increase as a percentage of total cost.

Let me turn now to the area of computer system development, in particular the development of command and control systems which for the most part are embedded systems. Command and control is "the exercise of authority and direction by a properly designated commander over assigned forces in the accomplishment of his mission" (JCS Publication 1). Automation provides a means of augmenting a commander's capability to direct and control resources in today's complex, high-speed military world. Other automated systems

can also be used for control, such as embedded control elements of individual weapons. The embedded control elements of weapons are generally not involved in human control, but in physical control. In fact, their very purpose is to eliminate the human from the loop as much as possible rather than further his role in it.

Command and control systems which provide information to aid commanders in reaching decisions have proven difficult to develop and effectively implement. I would like to describe four examples of command and control system development efforts which indicate some of the problem areas, including:

--Identifying user needs,
--Responsive system designs,
--Software development techniques, and
--Inserting new hardware technology.

We believe that substantial improvements in the command and control system development process are required to efficiently provide commanders the information necessary to more effectively direct military forces to deter and counter potential adversaries.

The four examples I will describe include the World Wide Military Command and Control Information System (or WIS, formerly known as WWMCCS ADP) intended to support the National Command Authorities (the President and Secretary of Defense), Joint Chiefs of Staff, and Commanders-in-Chief of the unified and specified commands. The other examples are system development efforts by each of the Services for automated tactical operations centers to

support field commanders. All of these efforts to date have been unsuccessful in fielding systems which satisfy operational users.

The first example is the WWMCCS ADP program which completed installation of 35 standard systems at 26 sites in 1973. The use of standard computers in this system permitted the development of standard software, procedures and training. However, as early as 1974, DOD realized the standard computers selected would be unable to provide many of the capabilities desired and would need to be replaced. After many studies, DOD started planning for the replacement system in 1978. Currently, after nearly 5 years, a definitive set of objectives, comprehensive plan and effective systems architecture or blueprint have not been completed. Consequently, the modernized WIS is not expected to be operational until 1990 at the earliest, 16 years after this need was first identified.

The second example is an Army command and control development effort. In 1958, the Army established a project office to develop an Army Tactical Operations Center intended for use in Europe. A prototype was assembled and delivered to Ft. Leavenworth in 1963, where it was tested for 2 years. Following this effort, several other developments were attempted in succession to meet the need for a Tactical Operations System (TOS). In 1972, a new TOS project was started primarily using existing hardware. Tests in 1977 revealed substantial software and system design problems.

Also in 1977, the Commander-in-Chief of the U.S. Army Europe expressed an urgent operational requirement for a TOS, so develop-

ment of a division level TOS continued. By 1979, the Defense Systems Acquisition Review Council approved initiation of engineering development for the division level TOS. GAO strongly criticized this development effort in 1979, which led to a reduction in funding for the division level TOS. By 1979, about $93 million had been spent on TOS and major defects remained. Currently, the SIGMA project, employing several by-products from the recent TOS effort,is under development, 25 years after the initial need was identified.

My third example is the Navy's Tactical Flag Command Center (TFCC) which is a shipboard command and control system intended to provide the tactical commander at sea with information from on-shore and task force sources, pertaining to the state of U.S. forces and the location and probable intention of enemy forces. In 1972, the Navy began to prepare a Request-for-Proposal, using the results of a large number of analytical studies as a basis for requirements. An Interim TFCC was then evaluated in 1975 but the results were not conclusive. Following a lengthy competition, the Navy awarded a development contract for TFCC in 1977. After the design phase was completed, initial operating capability cost estimates had tripled. Cost increases, schedule delays, and disagreement within the Navy over TFCC functional requirements, all combined to cause rejection of the proposed development.

The Chief of Naval Operations approved a development program but encouraged that it be revised to accelerate deployment to the fleet. In response, the Navy restructured the development to use an existing testbed developed as a 1975 proof-of-concept demonstration in over-the-horizon targeting called OUTLAW SHARK. A limited procurement of six shipboard and two shore-based systems was approved and these systems should be installed by 1984.

Because OUTLAW SHARK employed non-standard computers and software, the Navy started a parallel activity to redesign the hardware and software for TFCC using Navy standard computers and a high order language. This would reduce future software maintenance costs and enable addition of new capabilities. Although partial fielding of TFCC will have been accomplished within 12 years from initial needs identification, evaluations of engineering development models have indicated that these systems do not have many of the the command and control decision aids needed to support the embarked flag staff.

The fourth example is an Air Force effort to develop a similar system, Tactical Air Control Center Automation (or TACC AUTO), for its mobile tactical air control systems. The requirement for TACC AUTO was based on a required operational capability statement

approved in 1967. Delays in the development project were caused by uncertain specifications, software development problems, cost overruns and eventually, disenchantment with computer hardware which was deemed obsolete before the TACC AUTO software could be developed. Although the system was judged a conditional success after testing, the serious problems encountered in the program led to its termination. The Air Force had spent about $80 million on this development. After 16 years, this required operational capability statement remains unfulfilled in the field.

The case histories I have just outlined illustrate the difficulty and complexity in providing automated assistance to support command and control. Every major command and control software development project is likely to experience problems at some stage, and the earlier these problems are diagnosed, the less costly the solution will be. What can we learn from these examples?

First, it is important to more completely identify objectives and user needs before beginning software development.

Second, system designs need to be more responsive to user needs and have the flexibility to incorporate new capabilities.

Third, the software development process needs to be improved by capitalizing on proven state-of-the-art software development techniques and tools such as high order languages and modular and structured programming.

Finally, we believe that provisions should be made during development for inserting new hardware technology for growth potential, and to postpone or avoid obsolescence during the system life-cycle.

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In closing, we appreciate this opportunity to participate in these hearings, and at this time, we will try to answer any questions you may have.

CHART 1

ESTIMATED AND FORECASTED COSTS OF DOD COMPUTERS

ALL COMPUTERS

	1980		1985		1990	
	COST (BILLIONS)	PERCENTAGE	COST (BILLIONS)	PERCENTAGE	COST (BILLIONS)	PERCENTAGE
GENERAL PURPOSE						
HARDWARE	$ .8	12	$ 1.5	8	$ 2.7	6
SOFTWARE	1.8	27	2.9	16	5.1	11
EMBEDDED						
HARDWARE	1.3	19	2.8	15	5.9	13
SOFTWARE	2.8	42	11.2	61	32.1	70
TOTAL	$ 6.7	100	$18.4	100	$ 45.8	100

CHART 2

HARDWARE-SOFTWARE COST TRENDS

ALL COMPUTERS

PERCENT OF TOTAL COST

	1955	1970	1985
HARDWARE	83	30	13
SOFTWARE			
DEVELOPMENT	11	33	24
MAINTENANCE	6	37	63
SUBTOTAL	17	70	87
TOTAL	100	100	100

CHART 3

COST TRENDS APPLIED TO FORECASTED

RISING ANNUAL DOD EMBEDDED COMPUTER COSTS

	HARDWARE		SOFTWARE				TOTAL	
			DEVELOPMENT		MAINTENANCE			
YEARS	COST (BILLIONS)	PERCENTAGE	COST (BILLIONS)	PERCENTAGE	COST (BILLIONS)	PERCENTAGE	COST (BILLIONS)	PERCENTAGE
1980	$1.3	32	$ .8	19	$2.0	49	$ 4.1	100
1985	2.8	20	3.1	22	8.1	58	14.0	100
1990	5.9	15	8.7	23	23.4	62	38.0	100