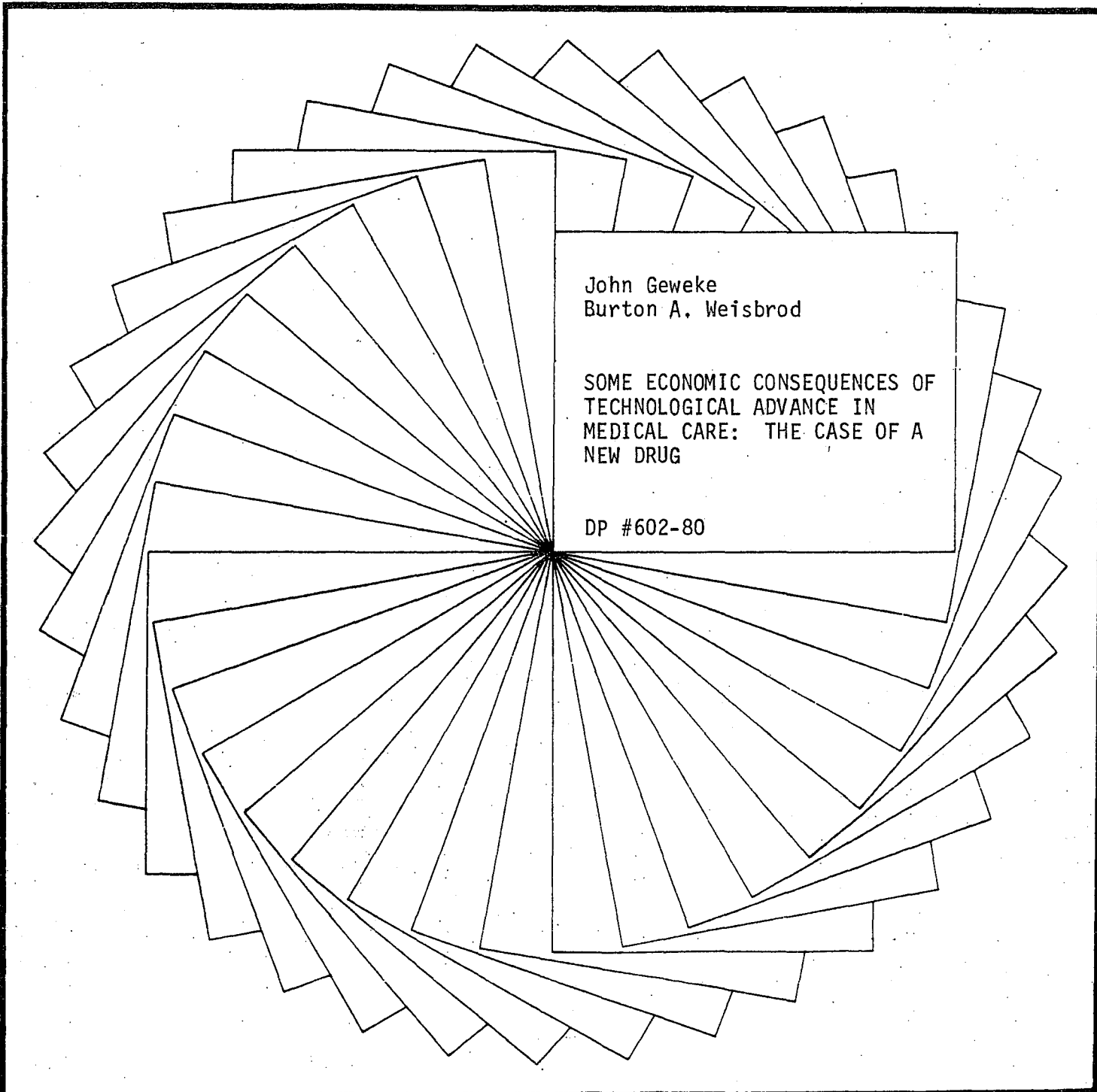




Institute for Research on Poverty

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TECHNOLOGICAL ADVANCE IN
MEDICAL CARE: THE CASE OF A
NEW DRUG

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MEDICAL CARE: THE CASE OF A NEW DRUG

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Abstract

This paper has two goals: (1) to develop a methodology for examining the economic consequences of any medical care innovation, and (2) to apply that methodology to the case of a new drug. Specifically, we attempt to determine the effects on medical care expenditures of a new drug, cimetidine, used for the treatment of duodenal ulcers. Using the health care expenditure records of 1206 individuals participating in the Texas Medicaid program between September 1977 and July 1978, we have found that the new drug therapy appears to reduce treatment expenditures compared to the average of other technologies. Total health care expenditures with an associated diagnosis of duodenal ulcer are from 40 percent to 63 percent lower, and days hospitalized are from 15 percent to 33 percent lower. Estimating the effects of health care innovation on medical expenditures is not equivalent to undertaking a social benefit-cost analysis. However, since reduced expenditures reflect both savings in resource costs and increases in social benefits resulting from improved health, it is likely that the reduction we found does reflect net social benefits from the new treatment mode.

I. Introduction

How should a technological change be evaluated? Conceptually, we would like to know whether the present value of its discounted future net benefits is or is not greater than zero. An innovation that imposes increased social costs compared with the counterfactual is not ipso facto inefficient. Neither is an innovation necessarily efficient if it imposes decreased social costs. Both costs and benefits, and their time streams, must be examined.

The "technology" of medical care encompasses such labor and capital inputs as surgeons and surgical capital, equipment for diagnoses and treatment, and drugs. Given the variety of input combinations available and their expansion over time, given the development of expensive new types of inputs, and given the widespread use of public and private "insurance" arrangements that provide incentives for inefficient choice, it is understandable that concern is growing about the rate of increase of medical care expenditures. Whether that concern reflects implicit recognition of allocative inefficiency or of the income redistributions occurring through the governmental tax-transfer system, the facts of political and economic pressure to reduce expenditures for health care are clear.

Thus, notwithstanding the economists' social perspective that treats costs and benefits even-handedly, government policymakers have become increasingly concerned about the effects of innovations on costs alone; this is especially so in the medical care area. It has become a matter of considerable concern that the percentage of GNP devoted to

medical care has continued to rise, from 3.5 percent in 1929 to 5.3 percent in 1959 and to 9.1 percent in 1978 (Table 1). Numerous mechanisms have been discussed and utilized for the expressed purpose of "cost control": deductibles and copayment in health insurance, prepaid group practice (HMO's) and regional hospital planning councils in the organization of health-care delivery, and prospective reimbursement and second surgical opinions to induce efficiency in the face of health insurance that frequently confronts physicians and patients with zero private marginal costs of care. Now the Carter administration seeks to impose a "cap" -- a constraint on the rate of increase in each hospital's total annual expenditures. Somehow, rising total expenditures have come to be regarded as "bad," irrespective of the (admittedly hard-to-measure) benefits. For decades the percentage of GNP devoted to automobiles, by contrast, has grown, but this never came to be perceived as a "problem," let alone a reflection of allocative inefficiency.

This paper seeks to accomplish two goals: (1) to develop a methodology for examining the consequences of any new medical care technology, and (2) to apply that methodology to the case of a new drug, cimetidine, used in the treatment of duodenal ulcers (DU). The selection of a drug, rather than some other health-care input, and of the one specific drug that we consider was determined by data availability. With small modifications, however, the data could be exploited to examine the expenditure consequences of other medical innovations, whether a drug or not.

The question of whether a particular medical input--drug or other--causes medical expenditures to increase or decrease has obvious policy relevance, given the current political emphasis on

Table 1

HEALTH CARE EXPENDITURES IN THE U.S., 1929-1978

| Year | Percent of GNP | Dollar Amounts (in billions) |
|------|----------------|---------------------------------|
| 1929 | 3.5 | \$ 4 |
| 1950 | 4.5 | 13 |
| 1960 | 5.3 | 27 |
| 1970 | 7.6 | 75 |
| 1975 | 8.6 | 131 |
| 1978 | 9.1 | 192 |

Source: Statistical Abstract of the United States 1979, p. 97.

"cost containment." Individual states now make decisions, for example, on whether to approve payments for particular drugs and other specific health resources used by Medicaid patients; and the approval process involves consideration of the aggregate expenditure effects.

Our methodology, dictated by the twin desires to be conceptually correct and operationally relevant, is a simplification of the benefit-cost framework, in which benefits from a new technology consist only of reductions in costs, and, indeed, reductions in only those costs that are reflected in explicit payments for health resources.

Measuring net benefits by reductions in costs alone results in biased estimates of net benefits, but in general we cannot determine the direction of bias. If, for example, a new medical technology were to be both more effective in enhancing good health and also less costly than the technology it replaced, a focus on costs alone would understate its net social benefits. Similarly, if the new technology were more effective but also more costly, then disregard of the increased effectiveness would lead to the false conclusion that the new technology brought negative net social benefits. If, on the other hand, the new technology were both less effective and less costly, then measuring its net benefits by the reduction in cost would overstate the net benefits.

Measurement of increased effectiveness is fraught with complexity. If a medical-care innovation reduces pain and suffering we would have a difficult time valuing those benefits. If the innovation led to a strengthening of the body's defense mechanisms, so that there were subsequent improvements in health status, this would also seem to be difficult to assess; under some circumstances, however, such benefits

would appear as reductions in medical care expenditures and thus will be captured by the cost-based approach. What will be overlooked is the value that the affected persons place on their improved health and/or longevity; reduced medical care expenditures are generally an underestimate of this value.

In the preceding paragraphs we have used the terms "costs" and "expenditures" synonymously. In some contexts this produces misleading conclusions, as in discussions of "inflation" of medical care "costs," which confuse increases in total expenditures on medical care with increases in the prices of a constant-quality set of inputs. To some extent this confusion of costs with expenditures is present in the operational model we set forth here. Ideally, we would measure changes in both benefits and costs. Insofar as we omit some forms of benefits, we are in effect estimating changes in expenditures on a commodity, health status, that is of varying quality, not the cost of producing a commodity of constant quality. This is another way of seeing the possible bias resulting from the systematic omission of those benefits that are not captured by reductions in expenditures. Any observed changes in expenditures, in short, do not necessarily imply a change in the cost of purchasing a given level of health.

Another variable in the present-value formulation, we shall call it V , is the "lifetime" of the innovation. Determination of its magnitude is complicated, for that depends on future research and innovation; the length of life of an innovation will be a function of when some other medical advance will make that innovation economically obsolete. Although difficult to determine, this variable is likely to be of

critical importance. An innovation that would be initially more costly than another may be far less costly, as well as more beneficial, in later years; the number of those "later years" can be crucial to a determination of the present value of the prospective innovation.

The other key variable in V is the discount rate. For a long-lived innovation the value selected for the discount rate can have a great effect on V .¹

Drugs generally used in the treatment of duodenal ulcers include antacids, antidepressants, anticholinergics, and cimetidine. Antacids neutralize the acid in the upper gastrointestinal tract which irritates and prevents the healing of duodenal ulcers. Antidepressants are used to control anxiety, which can exacerbate the symptoms of DU. Anticholinergics block the effect on acid secretion of the stimulant acetylcholine, rather than neutralizing the acid which is produced as the antacids do. However, in order to be effective nearly toxic doses are required; these invariably lead to adverse reactions such as dry mouth, blurred vision, and retention of urine.

The drug cimetidine was granted a conditional use permit by the Food and Drug Administration (FDA) in September 1977, for use in the treatment of duodenal ulcer and a few other, much rarer, disorders of the upper gastrointestinal tract. It is fundamentally different from antacids, because it blocks the production of acid. It differs from the anticholinergics, because it blocks the effect of histamine, which is required for acid secretion. Unlike the anticholinergics, its undesirable side effects appear to be negligible.²

Cimetidine is manufactured by Smith, Kline and French Laboratories under the trade name Tagamet. The manufacturer claims that the drug promotes rapid ulcer healing and effective symptom relief to a degree unparalleled by clinically acceptable doses of other currently available drugs. This claim seems to be borne out by independent pharmacological studies³, but there are no prospective studies on the question of whether or not treatment with cimetidine results in increased ulcer recurrence when the drug is discontinued. Thus more data are required for an assessment of long-term therapy with cimetidine, but the drug appears to be effective in the short-term treatment of DU.

Although symptoms may subside and healing may occur within the first week or two after treatment with cimetidine begins, that treatment should be continued for four to six weeks. Under the conditions of its approval by the Food and Drug Administration, treatment periods are not to exceed eight weeks. Few side effects in excess of those found with placebos have been reported in clinical trials. Sufficient indication for its use is the presence of DU based on a thorough physical examination of the patient and the considered professional opinion of the examining physician.

Tagamet is generally more expensive than other currently available drugs in the treatment of DU. In terms of price per dose, Tagamet is about three times as expensive as anticholinergics, fifteen times the cost of sedatives, and thirty times that of antidepressants. One week of therapy using Tagamet costs \$8.40, at 30¢ per 300 mg. tablet. In terms of effectiveness, however, it is less clear that Tagamet is more

costly; it appears that the cost of the recommended daily dosage of Tagamet is similar to the cost of a quantity of antacid that has approximately the same short-term effect.

The outline of this paper is as follows. Having set the stage in the section above--that is, having presented a structure for evaluating a new or proposed medical care technology--we turn in Section II to survey previous research that estimates social costs of ulcers and the change in social costs resulting from use of cimetidine. Sections III, IV and V present, respectively, our methodology for measuring the change in social costs resulting from the new drug, the data base, and our findings.

II. Social Costs of Duodenal Ulcer Disease

There is a substantial literature devoted to the estimation of the social costs of various diseases, and to ulcers and duodenal ulcers in particular. Much less attention has been given to the impact of changes in medical technology on these costs, the question to which this paper is ultimately addressed. Before describing our approach to this question, we summarize what is known about the social costs of DU and briefly describe a preliminary estimate of the likely impact of cimetidine on these costs.

Traditionally, social costs associated with any disease have been classified as direct and indirect. Direct costs are the uses of resources in medical care of the disease in question which have been diverted from other uses. They include hospital care, physicians' services, drug therapy, nursing home expenses, etc. Indirect costs are those resulting from the loss of current and future productivity due to disability caused by the disease. Measurement of indirect costs is fraught with well-known conceptual problems relating to the valuation of human life

and nonmarket activities, and the forecasting of future productivities and interest rates. None of these conventional measures includes the pain, discomfort and suffering incurred by the patient and his family and associates which are social costs but very difficult to quantify and even more difficult to value.⁴

As we proceed with our examination of the effect of a new medical input on expenditures, the following should be noted: (1) as pointed out above, a change in expenditures is not equivalent to a change in net costs (costs minus benefits); (2) the change in expenditures bears no particular relationship to a change in real production costs for the producers involved, or to the profits of the firm(s) that developed or produced the good involved.

A duodenal ulcer is any tissue death that results in a crater on the mucous membrane of the duodenum, which is the first ten to twelve inches of the small intestine. Its immediate physiological cause is unknown. It is a chronic, recurrent disease characterized by sporadic episodes of acute symptoms. Pain due to DU is usually not localized; it may occur daily, or may be periodic, lasting for seven to ten days followed by periods of no pain, and may be very intense. A commonly used analogy is that gastric acid dripping on an open ulcer is like boiling water being poured onto a burn. Current techniques for diagnosis are expensive, unpleasant for the patient, and time-consuming.

In the treatment of DU the patient is "managed" through symptomatic relief by diet control and liberal use of antacids while the ulcer heals itself, usually in six to eight weeks. While most DU patients respond well without surgery, recurrence of the disease for those patients is common. Only about 25 percent of patients with newly diagnosed DU will eventually require surgery and of these, only 10 to 25 percent will experience permanent remission of all symptoms. Even if the treatment seems effective and the symptoms abate, the sporadic and recurrent nature of ulcer pain requires that the patient be monitored over a considerable period of time to determine whether the ulcer is dormant or has indeed healed.

An important social characteristic of DU is that it seems to be a "lifestyle" disease. That is, certain ways of living and kinds of activities may increase the overall occurrence of DU in the population. (Lung cancer, coronary disease and obesity are other examples of lifestyle diseases.) Although they no longer consider the characterization of the "ulcer personality" as hard-driving, ambitious, over-achieving, and competitive accurate, psychiatrists have observed that many ulcer patients need to be dependent, but fight that need.

A pattern of regular living with few emotional upsets is therefore a key factor in the long-term management of DU patients. This pattern may, of course, be very difficult to bring about. Ulcers which refuse to heal may eventually lead to various complications--among them minor or major bleeding. The mortality rate for bleeding from a DU is about 10 percent; for massive bleeding it is 14 to 25 percent.

If such conditions develop, hospitalization of the patient is invariably required, and frequently surgery. However, there are other reasons why a provider may hospitalize a DU patient: a long history of DU which is not responsive to medical management; a home environment unlikely to reinforce compliance with a therapeutic regimen; or a job which makes therapeutic compliance a practical impossibility.

Most social cost estimates have been undertaken for peptic ulcers, which include all ulcer diseases of the digestive system, rather than for duodenal ulcers alone. Robinson Associates have estimated that 68 percent of peptic ulcer social costs should be ascribed to duodenal ulcer; this figure permits at last some rough inferences about social costs of duodenal ulcer disease from social cost studies of peptic ulcers.⁵

The results of earlier studies are reviewed and updated by von Haunalter and Chandler.⁶ They estimate that, in 1975, 4 million United States residents suffered from some form of ulcer disease, 6,840 deaths were attributed to ulcer, and 77,000 persons were disabled. Their total social cost estimate for 1975 is \$2.6 billion. Of this total, direct costs account for slightly less than half, but are increasing at a faster rate than indirect costs. The largest single cost component is morbidity, divided fairly evenly between those disabled by ulcer and those temporarily absent from work. The reduced productivity of those ulcer sufferers who work at a slower pace is not included because of the near impossibility of measuring this loss.

The only effort to date to evaluate the likely impact of the introduction of cimetidine on the social costs attributed to duodenal ulcer is contained in the study by Robinson Associates cited above; it was commissioned by Smith Kline & French Laboratories. In that study, 23 of the physicians who conducted clinical trials of cimetidine for the Food and Drug Administration were asked to describe in detail their drug treatment regimens for various types of DU patients with and without the availability of cimetidine. They were asked to evaluate both regimens according to the following criteria: frequency of repeat episodes, frequency of patient visits to physician, likelihood and frequency of hospitalization, likelihood of surgery, frequency of diagnostic X-rays and endoscopies, amount of missed work, and likelihood of death from ulcer complications. These estimates were then combined with information from secondary sources on indirect costs and costs of various forms of treatment, and cost reductions resulting from the availability of cimetidine were computed for each type of DU patient. The physicians were also asked to estimate a penetration rate for cimetidine--that is, the proportion of each type of patient which would be treated with cimetidine when the drug was being used by most of the physicians in the U.S. who would eventually do so.

The findings of this study are summarized in Table 2. At the average estimated penetration rate of 80 percent, a reduction of \$645 million, or 29 percent, in health care costs for DU was estimated. The drug cost component was estimated to increase by 40 percent, but decreases in all other components were estimated. The authors of the study claim

Table 2

COSTS OF DUODENAL ULCERS, COMPUTED FOR 80 PERCENT CIMETIDINE USAGE
FOR YEAR 1977

| Cost Component | National Costs (in millions of dollars) | | National Per-Patient Costs | | |
|-------------------------|---|------------|----------------------------|-----------|----------------------|
| | DU Costs | Reduction | DU Costs | Reduction | Percent Reduction |
| <u>DIRECT COSTS</u> | | | | | |
| Hospital Care | \$474 | \$ 258 | \$ 225 | \$ 123 | 35% |
| Physicians & Related | 139 | 47 | 66 | 23 | 26 |
| Drug Therapy | 119 | -34 | 57 | -16 | -40 |
| Nursing Home | 11 | - | 5 | - | 0 |
| Other Professional | <u>2</u> | <u>-</u> | <u>1</u> | <u>-</u> | <u>0</u> |
| Total direct costs | 745 | 271 | 351 | 130 | 27 |
| <u>INDIRECT COSTS</u> | | | | | |
| Mortality | 201 | 44 | 96 | 21 | 18 |
| Morbidity | 602 | 329 | 286 | 156 | 35 |
| Absenteeism | 307 | 148 | 146 | 70 | 33 |
| Long-term disability | <u>295</u> | <u>181</u> | <u>140</u> | <u>86</u> | <u>38</u> |
| Total indirect costs | 803 | 373 | 381 | 177 | 32 |
| <u>GRAND TOTAL</u> | 1547 | 645 | 732 | 307 | 29 |

Source: Robinson Associates, Inc., "The Impact of Cimetidine on the National Cost of Duodenal Ulcers," (Bryn Mawr, PA: Robinson Associates, 1978), pp. 2-3.

that the sample of 23 physicians represents a carefully selected group of experienced respondents offering highly technical information on a subject with which they were more familiar than any other physicians in the United States; thus a high degree of confidence may be placed in their assessments. The study provides no quantitative assessment of the confidence which can be placed in these estimates, however. The authors do imply that the 40 percent increase in "drug therapy" costs associated with usage of cimetidine (Table 2) are offset by an enormously greater decrease in every other form of direct and indirect cost of ulcers.

III. Methodology

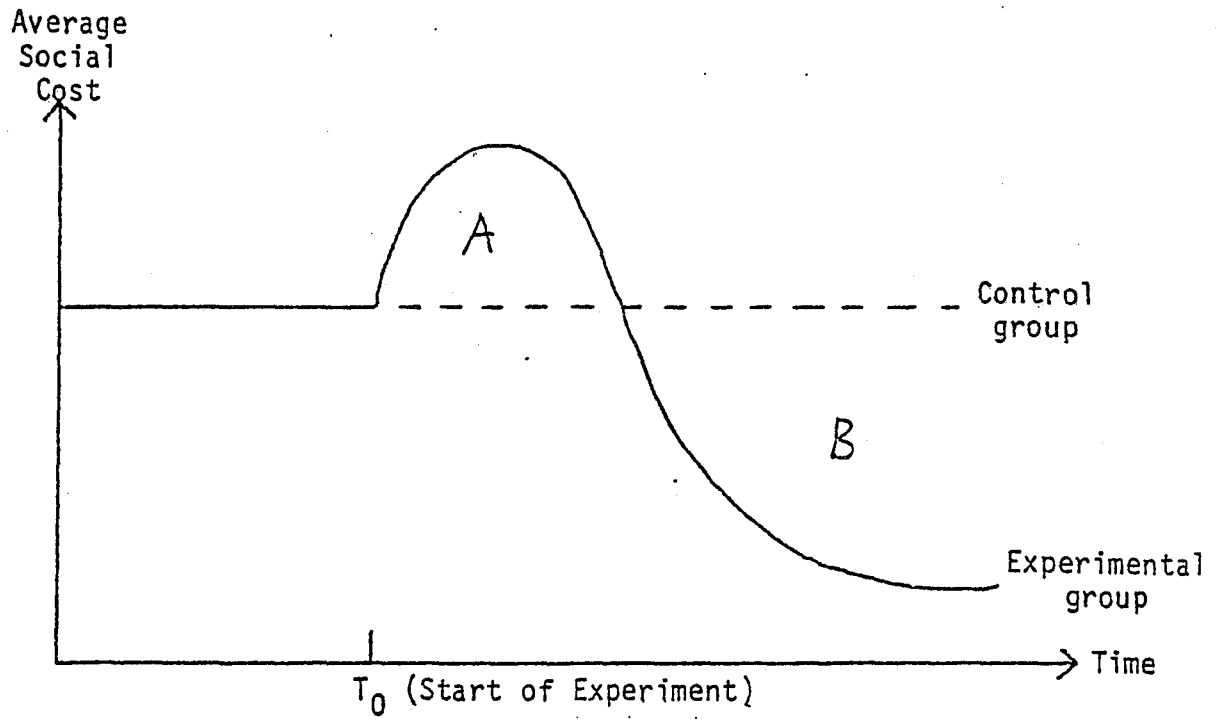
The methodology developed here for measuring the socioeconomic costs and benefits of the introduction of a new drug is general enough to be used in the evaluation of any new drug, although we focus specifically on cimetidine. In the introduction of any new drug it is all but impossible to evaluate economic and social effects--as distinguished from medical effects--within a controlled experiment framework. Besides the inherent political and ethical problems, the costs of designing and monitoring such an experiment plus the cost of introducing yet another delay in the introduction of new drugs are apt to be prohibitive. For the foreseeable future, inferences about socioeconomic effects must therefore be drawn in nonexperimental settings, often using data bases that were constructed for other purposes. These problems are paramount in the evaluation of cimetidine, and we

believe that they are likely to be of overriding concern in the introduction of other drugs and medical techniques as well. Thus methodology devised here to cope with the problems of nonexperimental design should be applicable in other cases.

A Hypothetical Experiment. To highlight the difficulties in making inferences about socioeconomic effects in nonexperimental settings, imagine that a controlled experiment could be constructed in which duodenal ulcer patients and providers were randomly assigned to three groups: group 1, in which the key treatment variable, cimetidine, was not available; group 2, in which cimetidine was mandated; and group 3, in which cimetidine was available, but its use was not mandatory. Group 1 might be termed the control group, C; groups 2 and 3, the experiment groups, E_1 and E_2 . In many controlled experiments in the health area, only groups C and E_1 are compared. This approach can be quite misleading if the most effective therapy is to use the experimental variable (cimetidine in this case) only some of the time. Our group E_2 patients would use or not use cimetidine, depending on provider judgments. Clearly the more interesting experiment is a comparison of groups C and E_2 .⁷

The social costs associated with each of the two groups, C and E_2 , would be monitored over a period of time. One possible relationship of the social cost paths of the two groups is illustrated in Figure 1. During the pre-experimental period, social costs for the two randomly chosen groups are the same, because of the controlled nature of the experiment. Early in the experimental period some patients in E_2 would

Figure 1
HYPOTHETICAL COSTS PER PATIENT,
EXPERIMENTAL AND CONTROL GROUPS



be treated with cimetidine, and perhaps other therapies as well. Since cimetidine treatment normally lasts about eight weeks, drug therapy costs per patient for the experimental group might be expected to be higher early in the experimental period. As the experiment proceeds, however, it could be hypothesized that the social costs associated with the E_2 group would be lower than those of the control group. In the case of a chronic disease like DU, complete measurement of social costs might well require an experimental period of many years. The net social cost saving from the introduction of cimetidine would simply be the difference between the area marked "B" and that marked "A" in Figure 1, after appropriate discounting for passage of time.

This hypothetical experiment has two attractive features in common with any well-designed experiment, one of these is always absent in nonexperimental situations and the other is likely to be absent. The first is that the "fairness" of the trial is guaranteed by random assignment of patients and providers. But in the actual introduction of any new drug, assignment is made by the actors themselves -- primarily providers, but to varying degrees the patients, as well. There are two problems here. First, we have no practical way of knowing whether those providers and patients that use the new technology differ in important ways from those who do not use it. It could be that as soon as the new drug is approved for conditional use by the FDA all providers have access to the drug and are fully aware of how it should be used in conjunction with other treatments; but this case is rather implausible. It might also be that in the new technology all patients

receive the drug just introduced; but this case is also unlikely. If neither of these polar cases prevails, systematic differences between the "experimental" and "control" groups are likely to exist. In particular, patients whose social costs are higher may well be proportionately more important in one group than the other. The obvious bias which this nonproportional representation introduces in measurements of the type illustrated in Figure 1 is an example of the selectivity bias which can exist whenever inferences are made in nonexperimental settings under the (erroneous) assumption of random assignment.

The second attractive feature of our hypothetical experiment is that extensive measures of socioeconomic well-being may be made, provided the control and experimental groups are kept small enough that the costs of measurement are not prohibitive. In nonexperimental situations this is usually not the case, although it could be: intensive measurements on a randomly selected subpopulation could be made, as is done for the general population by the Bureau of the Census and the Bureau of Labor Statistics each month. As a matter of fact, however, most of the existing measures have been made for the entire population. Like the data discussed in the previous section they have insufficient coverage and detail because they are collected for other purposes.

Making Inferences From Nonexperimental Data. It seems unlikely that either of the two polar cases just discussed would prevail in practice, and in the introduction of cimetidine there is some evidence that they did not. The FDA certified effectiveness of the new drug only in the

case of DU and some hypersecretory conditions which are rare by comparison. In our sample, however, we were able to associate only about one out of every 14 prescriptions of cimetidine with a DU diagnosis. It is clear that providers' behavior and the FDA certification restrictions cannot both reflect optimal use of the drug, thus ruling out the first case.⁸ In the other polar case, in which all DU patients receive cimetidine, the penetration rate should increase towards unity and the ratio of DU patients treated with cimetidine to those not treated should increase without bound. Table 3 shows, however, that this decidedly was not the case for the Texas medicaid sample.

The medicaid data, being nonexperimental do not permit separate analyses of the E_1 and E_2 groups discussed above. We know only that some providers prescribed cimetidine to some patients, and so we have an approximation to group E_2 . There is no group E_1 , for which cimetidine therapy was mandatory. (It is also notable that we can distinguish between those cimetidine users for whom duodenal ulcers were diagnosed, and other users of the drug.)

We identify all duodenal ulcer patients who received cimetidine between September 1, 1977 and June 30, 1978 as the T group, all other patients who received treatment (but not cimetidine) for duodenal ulcer during that period as the F group. We control for selectivity bias within the limitations imposed by the data base. Given a sufficiently large sample, we would restrict our attention to those patients with indications of an "active ulcer" diagnosis in the period P, September 1, 1977 to June 30, 1978;

Table 3

USE OF CIMETIDINE
SEPTEMBER 1977 - JUNE 1978

| | Distribution of Prescriptions n=530 | Ratio of Cimetidine- Treated Patients to New DU Patients Not So Treated ^a n=1206 |
|----------------|---|--|
| September 1977 | .057 | 0.698 |
| October 1977 | .100 | 0.946 |
| November 1977 | .098 | 1.182 |
| December 1977 | .134 | 1.164 |
| January 1978 | .098 | 0.839 |
| February 1978 | .160 | 1.308 |
| March 1978 | .075 | 0.571 |
| April 1978 | .087 | 0.719 |
| May 1978 | .094 | 0.667 |
| June 1978 | .096 | 0.375 |

^aA "new" DU patient is one whose first indication of DU in the period September 1977 - June 1978 occurred in the month indicated.

a patient is assumed to have an active ulcer problem if (1) any treatment is provided for duodenal ulcer as a primary or secondary diagnosis, or (2) he or she is treated with an anti-ulcer drug and has a diagnosis of DU during the preceding year. The timing of indicators of socioeconomic cost for each patient is measured relative to the first indication of an active ulcer problem within the sample period for those in group F, and relative to the prescription of cimetidine for those in group T. This "point of reference" is the analogue of the start of the experiment in a controlled environment; it corresponds to the point T_0 in Figure 1. For group F, the point of reference is chosen to be the first indication of ulcer (rather than September 1, 1977) because if the date were chosen, some patients with no active ulcer problem at the reference point would be included in F, whereas all patients in T do have an active ulcer problem at the time cimetidine is prescribed. Presumably there would then result a downward bias in the measurement of social costs for group F relative to group T, and an upward bias in the estimated cost-reducing effects of cimetidine.

Samples F and T are then subdivided to control for all measured factors which might affect real treatment costs. The divisions are made conditional on two groups of variables.

The variables in the first group are demographic: the sex, race, and age of each patient is known, and our subsample may be further divided conditional on these variables. There is an obvious and large

potential for selectivity bias if demographic factors are ignored. (And as we shall see below, even if all demographic groups were identical with respect to the relevant medical factors and if they were proportioned in the same way between F and T, there would still be reason to separate them in assessing social medical care costs.)

The second group of variables consists of those associated with the "severity" of a given disease. Under nonexperimental circumstances, we can never measure adequately all those factors that would be controlled implicitly in a randomized experiment. Even in the experiment contemplated above, providers may (even subconsciously) take into account unmeasured or unmeasurable dimensions of a patient's health in deciding whether or not to prescribe cimetidine. There is no way to account for nonrandom factors which affect assignment to groups F and T but are uncorrelated with measured variables. The best that one can do is to account adequately for the variables that are measured.

In the present study, there are available four specific variables which, it is reasonable to assume, are associated with potentially nonrandom assignment and which, in turn, are related to social costs. All relate to a specified period before the reference point, which we shall call the "presample period"; they are (1) number of indications of sickness; (2) care; (3) days hospitalized; and (4) indications of other disease. Each may be positively correlated with medical care

costs over the presample period and over the sample period whether cimetidine was prescribed or not. Failure to account for these variables could introduce a potentially very large source of selectivity bias: one has only to conjecture polar situations in which providers prescribe cimetidine only to patients at death's door or, alternatively, those in which cimetidine is given only to those who are relatively healthy or are on no other medication and consequently unlikely to suffer complications.

In principle, selectivity bias would be minimized by evaluating treatment costs controlling for each of these factors using a very fine categorization, but this can lead to more cells than observations. We tested for the existence of selectivity bias for each of seven dimensions (sex, race, age, indications of sickness, expenditures on health care, days of hospitalization, and indications of other disease) by testing the hypothesis that the proportion receiving cimetidine is unaffected by variations in that dimension in the presample period. In our results, we control for selectivity bias by subdividing the sample only in those cases where such bias appeared to be substantively and statistically significant. Once this initial subdivision was made, we tested for selectivity bias within each subsample and made further subdivisions only where there was evidence, within a subsample, of selectivity bias conditional on another dimension. The subsamples so selected are the populations within which treatment costs associated with the new technology incorporating cimetidine and the old are compared.

Measurement of Social Cost Variables. Having subdivided our sample in this way, we have now approximated the conditions of controlled experiments undertaken on each of a number of groups of patients. The proportion of patients in each subsample receiving cimetidine is in general not the same; this indeed, necessitated the subdivision of the original sample to reduce selectivity bias. Within each group, we monitor indicators of social cost in the fashion anticipated in Figure 1. The subdivisions and testing procedures outlined above provide some assurance that the paths of measurable treatment cost variables in the presample period are about the same for the F and T groups in each subsample, as they would be expected to be in a randomized experimental design.

At this point, further division of the sample may be desirable. For example, tests for selectivity bias may indicate no need to dissociate young males from older females, but it is quite conceivable that the two groups might respond very differently to cimetidine and non-cimetidine-based treatments in the sample period. Since the socioeconomic implications of the ability to control a chronic disease indefinitely are very different for the two groups, they would be analyzed separately. In the interests of manageability, however, we treat groups separately only if separation is necessary to reduce (and, we hope, eliminate) selection bias, or if groups with different socioeconomic characteristics behave in the sample period in ways that are statistically significantly different.

For each group, we estimate the mean and standard deviations of paths of the form shown in Figure 1. For continuous variables like health care expenditure, the quantity estimated is the expected value for a patient in the group at a particular time relative to the reference point. For categorical variables like "no days hospitalized" the estimated quantity is a probability. From the nature of our sample, it is obvious that the position of the path is estimated with less accuracy as one moves to the right of the reference point, especially for group T, because the sample becomes thinner. Means and probabilities for the whole 10-month sample period are also estimated. By weighting the numerical importance of each group treated separately, we then arrive at estimates of magnitudes associated with treatment costs.

IV. Data Base

All the data used in this study are taken from Medicaid claims in the state of Texas for the period September 1976 through June 1978. The data were collected originally for accounting purposes, and were made available to us by Pracon, Inc., of Fairfax, Virginia, an independent consulting firm. Pracon and Systemetrics, Inc., of Santa Barbara, California, converted the data from its original form to a format more suitable for studying the health care experience of individual patients.

The basic organizational unit from which our files were constructed is the claim. A claim is a bill submitted to the state of Texas for a medical service or drug. In some cases, claims are amended after their original submission; in that case the amended claim was used.

Associated with each claim is a patient identification number; an identification number for the provider (for example, a physician or pharmacy); a primary and in some cases secondary diagnosis if the claim is for hospital, physician, or nursing home services; the date of the claim; the date on which the service was rendered; the nature of the service performed by the physician (for example, surgery or consultation); the length of stay for hospital and nursing home claims; the amount filled, in the case of drug claims; and the size of the claim. Demographic information -- sex, race and age -- about each patient is provided, as is detailed information about the provider: for example, specialty in the case of physicians and whether a hospital is profit, nonprofit, or a unit of an institution.

Perhaps the most attractive feature of this data base is the detailed medical information about the period in which health care costs are incurred as well as the point in time at which they are billed. Together with patient identification numbers, this information makes possible a detailed reconstruction of that portion of a patient's health care history which was paid for by the state. But although we believe that this data set constitutes the best nonexperimental evidence yet assembled for the evaluation of innovations in medical technology, it is not without its shortcomings. Those which are most important in limiting the kinds of questions which can be addressed, or in evaluating the results presented here are listed:

1. The only aspects of patients' experiences that are known to us are those that entail a claim. In particular, there is no direct information on morbidity outside of institutions. At most, we can make rough guesses about the implications for work experience of days hospitalized and of various diagnoses and drug prescriptions.
2. Only those direct costs billable to the state Medicaid system are known. In general, there is no way of knowing the nature or magnitude of health care costs not publicly paid. For patients over 65 the problem is significant, because many of their health care costs are paid by Medicare. For those under 65, Medicaid generally pays all health care bills when the recipient is eligible.
3. In the case of DU, there is little information available about the severity of the illness. Diagnoses are recorded using the International Classification of Diseases, which provides eight gradations of severity for DU, but most providers use the code for a ninth classification in which severity is unspecified. Hence we have little information about a potentially important source of selectivity bias.

4. For drug claims, no diagnosis is indicated. Hence it is not possible to get reliable information on the drug therapy component of direct costs for cimetidine and non-cimetidine-based treatments.
5. Deaths are not recorded in our data set. If patients in one group had higher mortality experience, we would observe lower expenditures on medical care for that group.

It should also be noted that our data are limited to Medicaid patients. We do not believe that they constitute a biased sample of the entire DU population in terms of the expenditure effects of cimetidine, but we cannot be certain.

From the original file of about 12 million claims, the sample S was constructed as described in the previous section. This sample is restricted to those individuals who were eligible for the Medicaid program during the entire period September 1976 through June 1978. Sample T is composed of the individuals in S with a DU diagnosis on some claim during September 1976 through June 1978 who also had a claim for cimetidine from September 1977 through June 1978 inclusive. Sample F is composed of the individuals in S with a DU diagnosis on some claim during September 1976 through June 1978 inclusive who had either a claim with a DU diagnosis or a claim for an ulcer prescription (but not cimetidine) during that period. For the latter group, "ulcer prescription" is defined by the National Drug Commission codes; base dating begins with the first such claim or prescription between September 1977 and June 1978. There are 1206 individuals in Sample S; 530 of them are in Sample T.

V. Findings

In this section we report our estimates of the changes in certain public expenditures and other measures of costs which may be ascribed to the introduction of the new medical technology which incorporates cimetidine. After briefly discussing selectivity biases evident in the data, we treat total health care expenditures, hospital and physician expenditures for duodenal ulcer, and days of hospitalization. All three measures can be disaggregated in various ways, but a careful discussion at this level of detail is beyond the scope of this paper.⁹

By any number of measures, it appears that the new drug has been administered to patients who exhibited more illness in the preceding 12 months than did those patients treated with older therapies (Table 4). Patients treated with cimetidine were hospitalized almost 50 percent more days than those who were not, in the preceding 12 months--7.46 days compared to 5.14--and their total health care expenditures for this period were significantly higher, \$1506 compared to \$1293.

A close examination of monthly expenditure and hospitalization records reveals that much of the difference between the two groups' presample histories occurs in the single month immediately preceding the base date. This difference may be accounted for by the environment in which cimetidine is prescribed, and our definition of the base date. For patients who receive cimetidine, any immediately preceding duodenal ulcer therapy is by definition in the presample period, whereas for patients who do not receive cimetidine, our sample is so constructed that there can be no duodenal ulcer therapy in the immediately preceding

Table 4
TESTS FOR SELECTIVITY BIAS

| Variable | Sample T (n=676) | | Sample F (n=530) | | "t" |
|---|------------------|--------|------------------|------|----------|
| | Mean | S.D. | Mean | S.D. | |
| Days hospitalized, -12/-1 | 7.46 | 111.00 | 5.14 | 9.57 | -3.84*** |
| Total expenditures, -12/-1 | 1506 | 2224 | 1293 | 1945 | -1.72* |
| Drugs | 125 | 110 | 111 | 109 | -2.18** |
| Outpatient | 74.8 | 181 | 44.9 | 118 | -3.28*** |
| Hospital | 674 | 1314 | 499 | 1096 | -2.45** |
| Physicians | 278 | 1476 | 231 | 370 | -1.88* |
| Physician and hospital expenditures with DU diagnosis, -12/-1 | 117 | 376 | 60.5 | 219 | -3.07 |
| Days hospitalized, -12/-2 | 5.33 | 9.57 | 4.44 | 8.51 | -1.69* |
| Total expenditures, -12/-2 | 1280 | 2014 | 1138 | 1826 | -1.26 |
| Drugs | 113 | 102 | 100 | 100 | -2.20** |
| Outpatient | 65.6 | 162 | 38.2 | 100 | -3.41*** |
| Hospital | 542 | 1177 | 434 | 1005 | -1.68* |
| Physicians | 241 | 431 | 203 | 338 | -1.63 |
| Physician and hospital expenditures with DU diagnosis, -12/-2 | 61.5 | 316 | 54.7 | 212 | -0.42 |

Significance Levels: *10%
 ** 5%
 *** 1%

month--only therapy with other diagnoses--unless the treatment occurred during September 1977. There exists, however, a selectivity bias problem independent of how the first presample month should be treated. For the first 11 months of the presample period, cimetidine patients still exhibited greater health problems in the seven dimensions exhibited in Table 4, although the differences are smaller than when the first presample month is included and are significantly different at the 10 percent level in only four instances.

Examination of demographic variables turned up no significant differences between the two groups. Expenditures associated with the treatment of duodenal ulcer in the first 11 months of the presample period averaged only a few dollars per month per patient, and were not significantly different for the T and F samples. Both health care expenditures and days of hospitalization in the presample period affected the probability that a given patient would be treated with cimetidine. Because of the size of the sample, stratification was attempted only on total health care expenditures in the first 11 months of the presample period.

Because of the special behavior of the history of health care in the first presample month in the T and F samples, we have treated this month in two different ways in reporting our results. In essence, the question is whether treatment received immediately prior to a cimetidine prescription is an integral part of the new technology which incorporates cimetidine. If it is, then expenditures incurred in the first presample month should be associated with cimetidine, and comparing

expenditures for the T and F samples beginning with the base date would lead to a downward bias in the expenditure estimate for the T sample. In all likelihood, expenditures in the first month of the presample are part of the new technology for some patients treated with cimetidine--for example, those whose newly diagnosed ulcer was confirmed by an endoscopy--but are not for others--for example, those for whom the new technology was used after other methods failed. In the estimates reported below, we compare samples T and F for three months, -1 through +2, for two months -1 and +1, and for the single month +1. The cost of the treatment of therapy incorporating cimetidine relative to that not incorporating cimetidine is probably overstated for the first two groups of months and understated for the last.

In Tables 5, 6, and 7, we report mean total health care expenditures, hospital and physician expenditures on persons with a diagnosis of duodenal ulcer, and days of hospitalization, for several interesting subperiods of the presample and postsample periods. In all cases we eliminated from the sample patients over 65, since expenditure records for patients eligible for Medicare are incomplete. In each table the sample has been stratified by those patients with less than \$300 total health care expenditures in the first 11 months of the presample period (Group A), those with \$300 to \$1,000 expenditures (Group B), and those with more than \$1,000 (Group C). Overall means have also been computed, by weighting groups A, B, and C by their proportionate representation in the entire sample of patients under 65.

It is perhaps worth emphasizing that the overall means for T and F are not the simple means. The simple means would reflect that proportionately more patients in sample T had high presample health care

expenditures; thus, the simple means do not control for the selection bias which is inherent in the data. On the other hand, patients with high (and intermediate, and low) presample health care expenditures are of equal importance in the overall means for samples T and F.

All groups and samples show high levels of mean expenditures and mean days of hospitalization immediately following the base date, followed by a decrease which is sometimes sharp but usually does not return to presample levels (see, for example, Figures 2-5, for expenditures). In the first month or two of the sample period, almost all patients exhibit levels of expenditures which are high relative to their presample expenditures, but in the latter months of the sample period a few patients have high expenditures while many (in some instances, most) have no expenditures at all in a given month; this is reflected in standard deviations greater than the mean for all but one entry for the months +2/+4, +5/+7, and +8/+10 in Tables 5 and 6. As discussed above, the data on which Table 6 is based are less reliable than those for Tables 5 and 7, because diagnostic information is often not reported by hospitals and physicians.

Systematic and significant differences emerge only early in the sample period, and of the three groups, only for Group A, which had the lowest presample health care expenditures. For the patients who received cimetidine, overall health care expenditures (Table 5) were 32 percent lower in months -1/+2 (which we have argued provides a lower bound on relative costs) and 51 percent in month +1 (the upper bound). Hospital and physician expenditures with an associated diagnosis of duodenal

Table 5
HEALTH CARE EXPENDITURES

| Control Group a/ | Month | T Sample | | | F Sample | | | "t" |
|------------------|--------|----------|-------|--------|----------|--------|--------|---------|
| | | n | Mean | S.D. | n | Mean | S.D. | |
| A | -12/-2 | 149 | \$113 | \$93.5 | 206 | \$95.3 | \$90.1 | -1.83* |
| | -1/+1 | 149 | 504 | 781 | 206 | 745 | 1460 | 2.00** |
| | +1 | 149 | 325 | 658 | 206 | 663 | 1404 | 3.01*** |
| | -1/+2 | 139 | 569 | 781 | 190 | 835 | 1432 | 2.15** |
| | +2/+4 | 116 | 316 | 580 | 151 | 313 | 772 | -0.02 |
| | +5/+7 | 57 | 264 | 570 | 81 | 154 | 337 | -1.30 |
| | +8/+10 | 10 | 79.6 | 68.7 | 31 | 202 | 434 | 1.51 |
| B | -12/-2 | 97 | 543 | 184 | 127 | 594 | 196 | 1.99** |
| | -1/+1 | 97 | 449 | 709 | 127 | 481 | 866 | 0.31 |
| | +1 | 97 | 305 | 593 | 127 | 359 | 711 | 0.61 |
| | -1/+2 | 92 | 587 | 770 | 119 | 576 | 889 | -0.09 |
| | +2/+4 | 65 | 335 | 540 | 95 | 383 | 719 | 0.48 |
| | +5/+7 | 37 | 205 | 383 | 64 | 459 | 790 | 2.16** |
| | +8/+10 | 16 | 150 | 215 | 18 | 511 | 806 | 1.82* |
| C | -12/-2 | 132 | 3432 | 2581 | 149 | 2951 | 2265 | -1.65 |
| | -1/+1 | 132 | 900 | 1204 | 149 | 736 | 938 | -1.25 |
| | +1 | 132 | 511 | 913 | 149 | 423 | 678 | -0.90 |
| | -1/+2 | 125 | 1114 | 1316 | 140 | 1068 | 1292 | 0.78 |
| | +2/+4 | 101 | 878 | 1272 | 117 | 863 | 1170 | -0.08 |
| | +5/+7 | 44 | 694 | 1109 | 76 | 598 | 832 | -0.49 |
| | +8/+10 | 10 | 929 | 1088 | 33 | 691 | 1432 | -0.55 |
| OVERALL | -12/-2 | 378 | 1310 | 1480 | 482 | 1159 | 1300 | -1.57 |
| | -1/11 | 378 | 619 | 926 | 482 | 673 | 1167 | 0.76 |
| | +1 | 378 | 381 | 737 | 482 | 506 | 1047 | 2.05** |
| | -1/+2 | 356 | 752 | 986 | 449 | 844 | 1264 | 1.16 |
| | +2/+4 | 282 | 505 | 862 | 363 | 511 | 910 | 0.09 |
| | +5/+7 | 138 | 389 | 758 | 189 | 378 | 660 | -0.14 |
| | +8/+10 | 36 | 376 | 544 | 82 | 442 | 957 | 0.47 |

^aPatients under 65 with less than \$300 total health care expenditures in months -12/-2 of the presample period constitute Group A; \$300 to \$1000, Group B; over \$1000, Group C.

Significance Levels: * 10%
** 5%
*** 1%

The Overall Means are computed by weighting groups A, B, and C by their proportions in the population: .413, .260, and .327, respectively.

Table 6
HOSPITAL AND PHYSICIAN EXPENDITURES, FOR DU

| Control Group ^a / | Month | T Sample | | | F Sample | | | "t" |
|------------------------------|--------|----------|--------|--------|----------|--------|--------|---------------------|
| | | n | Mean | S.D. | n | Mean | S.D. | |
| A | -12/-2 | 149 | \$4.39 | \$22.6 | 206 | \$3.55 | \$14.9 | -0.39 |
| | -1/+1 | 149 | 173 | 514 | 206 | 447 | 1257 | 2.81 ^{***} |
| | +1 | 149 | 108 | 445 | 206 | 438 | 1258 | 3.47 ^{***} |
| | -1/+2 | 139 | 196 | 533 | 190 | 439 | 1261 | 2.37 ^{**} |
| | +2/+4 | 116 | 51.2 | 170 | 151 | 36.3 | 217 | -0.62 |
| | +5/+7 | 57 | 95.2 | 357 | 81 | 7.91 | 45.1 | -1.83 [*] |
| | +8/+10 | 10 | 0 | 0 | 31 | 23.6 | 116 | 1.12 |
| B | -12/-2 | 97 | 47.7 | 127 | 127 | 61.7 | 142 | 0.77 |
| | -1/+1 | 97 | 124 | 293 | 127 | 146 | 435 | 0.43 |
| | +1 | 97 | 98.0 | 271 | 127 | 144 | 435 | 0.98 |
| | -1/+2 | 92 | 139 | 304 | 119 | 136 | 364 | -0.06 |
| | +2/+4 | 65 | 51.5 | 207 | 95 | 23.2 | 104 | -1.01 |
| | +5/+7 | 37 | 4.93 | 22.6 | 64 | 14.5 | 79.0 | 0.90 |
| | +8/+10 | 16 | .849 | 3.39 | 18 | 25.8 | 109 | 0.96 |
| C | -12/-2 | 132 | 166 | 603 | 149 | 143 | 409 | -0.35 |
| | -1/+1 | 132 | 167 | 918 | 149 | 197 | 505 | 0.55 |
| | +1 | 132 | 97.4 | 339 | 149 | 187 | 498 | 1.79 [*] |
| | -1/+2 | 125 | 167 | 386 | 140 | 211 | 517 | 0.78 |
| | +2/+4 | 101 | 60.2 | 228 | 117 | 42.2 | 241 | -0.56 |
| | +5/+7 | 44 | 29.2 | 170 | 76 | 63.6 | 364 | 0.70 |
| | +8/+10 | 10 | 0 | 0 | 33 | 8.90 | 35.6 | 1.43 |
| OVERALL | -12/-2 | 378 | 68.5 | 351 | 482 | 64.3 | 245 | -0.20 |
| | -1/+1 | 378 | 158 | 638 | 482 | 287 | 886 | 2.48 ^{**} |
| | +1 | 378 | 102 | 372 | 482 | 279 | 885 | 3.97 ^{***} |
| | -1/+2 | 356 | 171 | 436 | 449 | 236 | 882 | 2.42 ^{**} |
| | +2/+4 | 282 | 54.2 | 200 | 363 | 34.8 | 203 | -1.21 |
| | +5/+7 | 138 | 50.2 | 244 | 189 | 27.8 | 214 | -0.86 |
| | +8/+10 | 36 | .221 | 1.73 | 82 | 19.4 | 95.1 | 1.82 [*] |

^aPatients under 65 with less than \$300 total health care expenditures in months -12/-2 of the presample period constitute Group A; \$300 to \$1000, Group B; over \$1000, Group C.

Significance Levels: * 10%

** 5%

*** 1%

The Overall Means are computed by weighting groups A, B, and C by their proportions in the population: .413, .260, and .327, respectively.

Table 7
DAYS OF HOSPITALIZATION

| Control Group ^a / | Month | T Sample | | | F Sample | | | "t" |
|------------------------------|--------|----------|------|------|----------|------|------|---------------------|
| | | n | Mean | S.D. | n | Mean | S.D. | |
| A | -12/-2 | 149 | 0.19 | 0.12 | 216 | 0.14 | 1.06 | -0.34 |
| | -1/+1 | 149 | 2.41 | 3.99 | 206 | 4.02 | 6.18 | 2.97 ^{***} |
| | +1 | 149 | 1.49 | 3.39 | 206 | 3.68 | 5.48 | 4.36 ^{***} |
| | -1/+2 | 139 | 2.51 | 3.74 | 190 | 4.50 | 6.61 | 3.45 ^{***} |
| | +2/+4 | 116 | 1.18 | 2.92 | 151 | 1.31 | 3.54 | 0.32 |
| | +5/+7 | 57 | 1.22 | 3.37 | 81 | .703 | 2.15 | -1.03 |
| | +8/+10 | 10 | 0 | 0.00 | 31 | .806 | 2.18 | 2.06 ^{**} |
| B | -12/-2 | 97 | 2.04 | 5.38 | 127 | 2.21 | 2.75 | 0.28 |
| | -1/+1 | 97 | 2.23 | 4.02 | 127 | 2.64 | 5.06 | 0.67 |
| | +1 | 97 | 1.36 | 3.26 | 127 | 2.00 | 4.21 | 1.28 |
| | -1/+2 | 92 | 2.86 | 4.32 | 119 | 3.48 | 6.86 | 0.79 |
| | +2/+4 | 65 | 2.35 | 6.06 | 95 | 2.30 | 6.13 | -0.04 |
| | +5/+7 | 37 | 0.70 | 2.41 | 64 | 1.89 | 3.97 | 1.86 [*] |
| | +8/+10 | 16 | 0 | 0 | 18 | 3.00 | 7.12 | 1.78 [*] |
| C | -12/-2 | 132 | 14.4 | 12.1 | 149 | 13.2 | 11.9 | -0.81 |
| | -1/+1 | 132 | 4.71 | 6.33 | 149 | 3.47 | 5.99 | -1.68 [*] |
| | +1 | 132 | 2.59 | 4.74 | 149 | 2.10 | 4.12 | -0.92 |
| | -1/+2 | 125 | 5.69 | 6.79 | 140 | 4.65 | 7.05 | -1.22 |
| | +2/+4 | 101 | 3.82 | 6.54 | 117 | 3.25 | 6.03 | -0.65 |
| | +5/+7 | 44 | 3.77 | 7.50 | 76 | 1.73 | 3.34 | -1.70 [*] |
| | +8/+10 | 10 | 3.90 | 6.75 | 33 | 1.48 | 3.34 | -1.09 |
| OVERALL | -12/-2 | 378 | 5.32 | 7.44 | 482 | 4.95 | 6.98 | -0.74 |
| | -1/+1 | 378 | 3.11 | 4.89 | 482 | 3.48 | 5.85 | 1.01 |
| | +1 | 378 | 1.82 | 3.85 | 482 | 2.73 | 4.75 | 3.10 ^{***} |
| | -1/+2 | 356 | 3.64 | 5.07 | 449 | 4.28 | 6.82 | 1.53 |
| | +2/+4 | 282 | 2.35 | 5.20 | 363 | 2.20 | 5.18 | -0.05 |
| | +5/+7 | 138 | 1.92 | 4.96 | 189 | 1.35 | 3.11 | -1.19 |
| | +8/+10 | 36 | 1.28 | 3.86 | 82 | 1.60 | 4.34 | 0.40 |

^aPatients under 65 with less than \$300 total health care expenditures in months -12/-2 of the presample period constitute Group A; \$300 to \$1000, Group B; over \$1000, Group C.

Significance Levels: * 10%

** 5%

*** 1%

The Overall Means are computed by weighting groups A, B, and C by their proportions in the population: .413, .260, and .327, respectively.

Figure 2

AVERAGE TOTAL HEALTH CARE EXPENDITURES
PERSONS UNDER 65
\$0 - \$300 EXPENDITURES IN PRESAMPLE

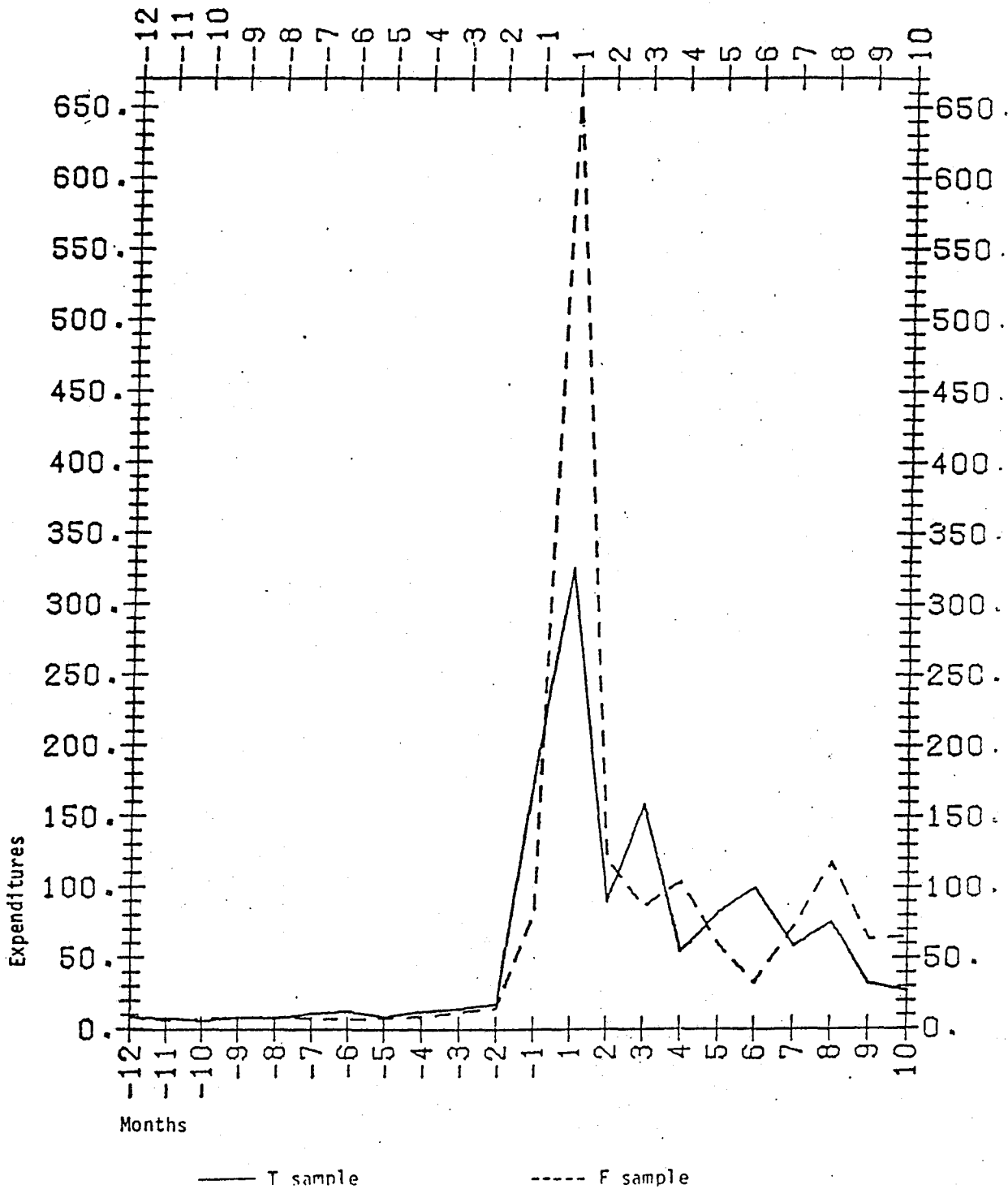


Figure 3

AVERAGE TOTAL HEALTH CARE EXPENDITURES
PERSONS UNDER 65
\$300 - \$1,000 EXPENDITURES IN PRESAMPLE

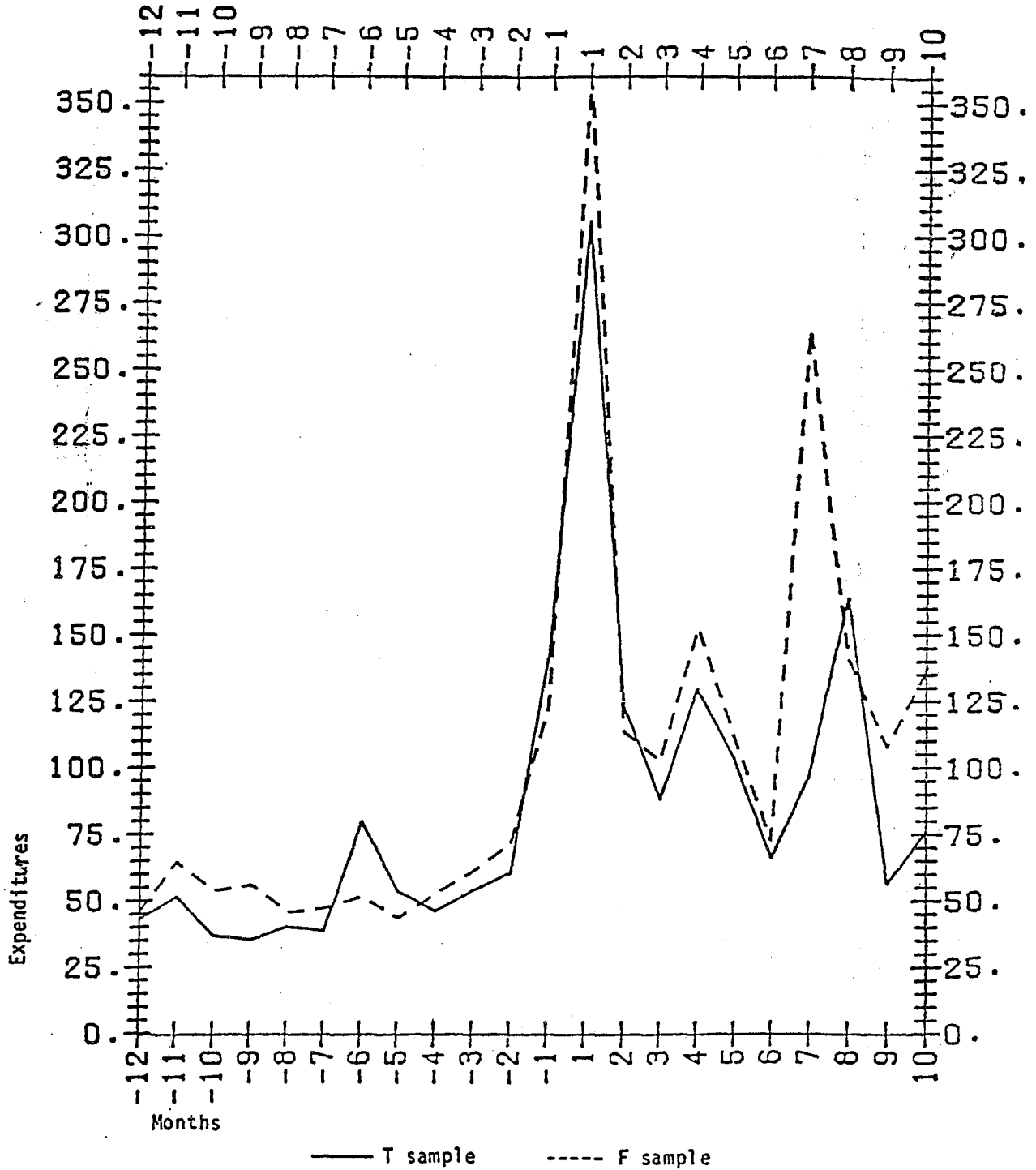


Figure 4

AVERAGE TOTAL HEALTH CARE EXPENDITURES
PERSONS UNDER 65
\$1,000+ EXPENDITURES IN PRESAMPLE

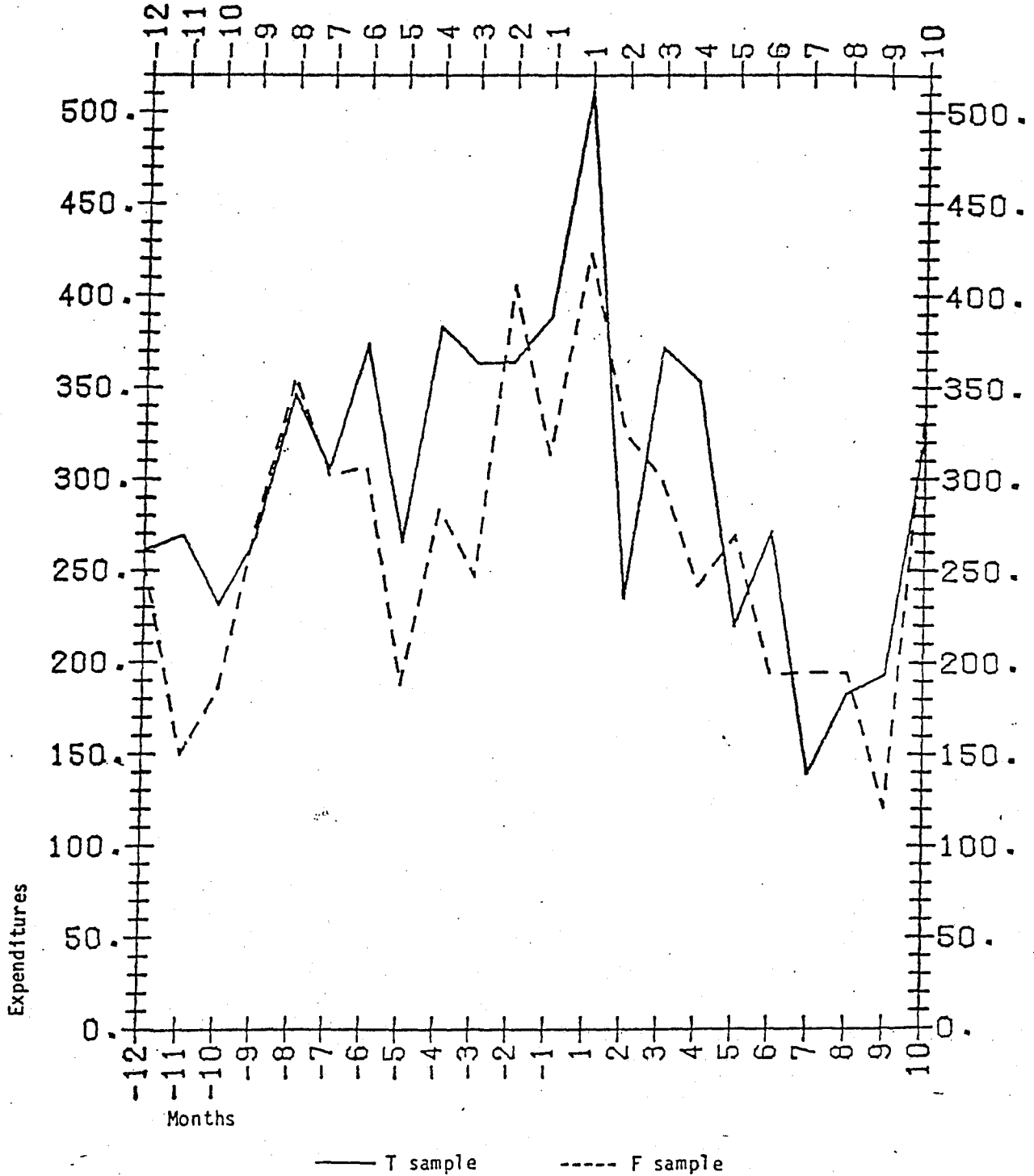
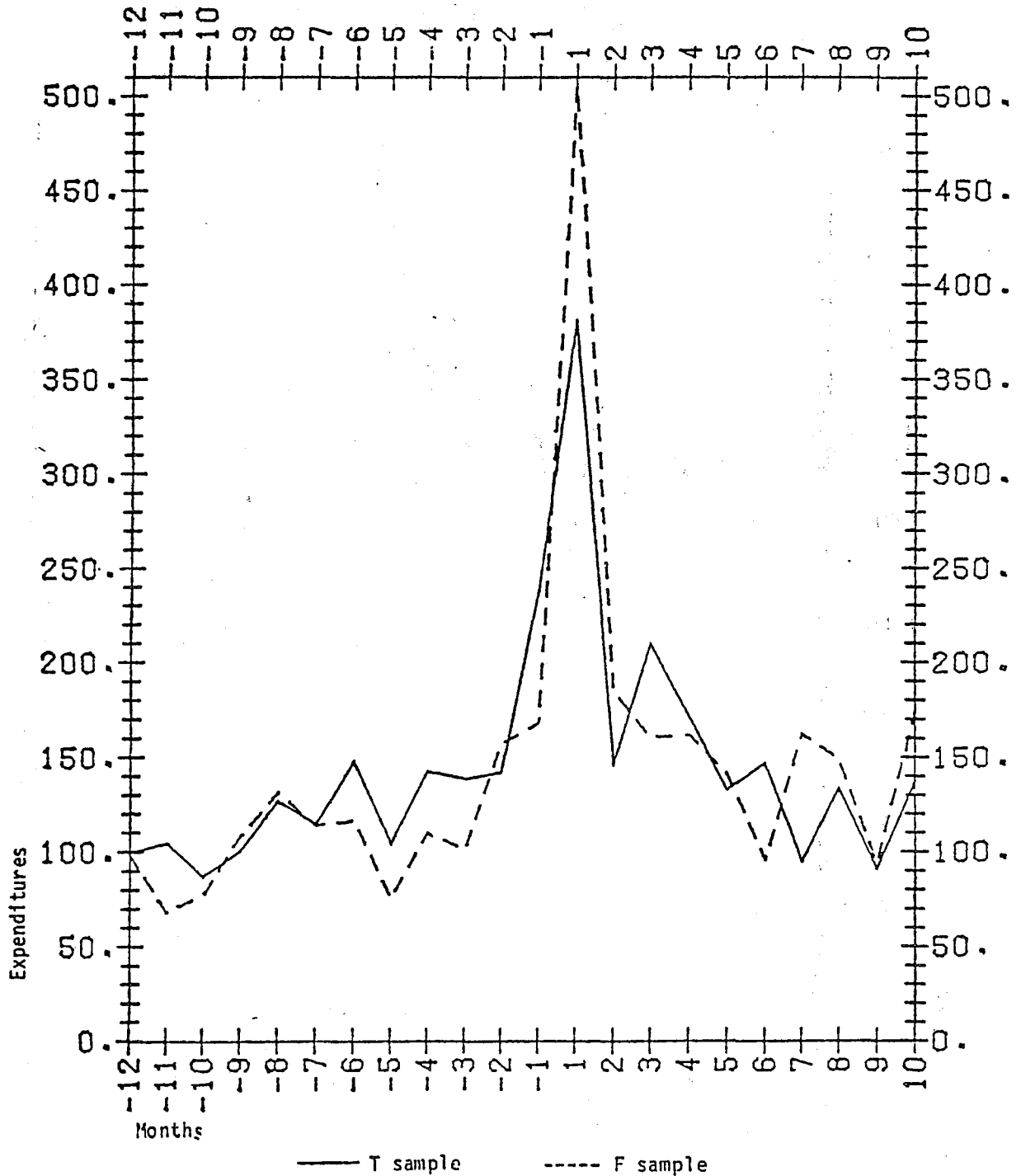


Figure 5

AVERAGE TOTAL HEALTH CARE EXPENDITURES
PERSONS UNDER 65



Total health care expenditures are obtained from Figures 2, 3, and 4 by weighting the groups by their proportions in the population: .413, .260, and .327, respectively.

ulcer (Table 6) were 55 percent lower in months $-1/+2$ and 75 percent lower in month $+1$, while mean days of hospitalization (Table 7) were 44 percent lower in months $-1/+2$ and 60 percent lower in month $+1$. In the latter months of the sample period differences in expenditures and hospitalization for the two samples are for the most part statistically insignificant. These differences are small arithmetically as well, and do not appear to result from the fact that the sample becomes smaller as we move further beyond the base date.

For the two groups with higher presample-period health care expenditures, groups B and C, differences between the T and F samples during the sample period are mostly statistically insignificant. Perhaps the technology that incorporates cimetidine does not, in fact, reduce health care costs for those patients with more severe health problems. On the other hand, the proportionate reduction in total health care expenditures would be less to the extent that "more severe health problems" implies afflictions other than duodenal ulcer; hospital and physician expenditures associated with the treatment of duodenal ulcer may be difficult to define or may be recorded less reliably in this case. There is some evidence that this is so: total health care expenditures for the groups with high presample expenditures are in the sample period about the same as--or higher than--those for the groups with lower presample expenditures (Table 5), but their recorded expenditures for hospital and physician treatments associated with diagnoses of duodenal ulcer are about the same (Table 7).

In spite of the statistically insignificant differences for groups B and C, the differences in overall means for samples T and F are significant for month $+1$, and for months $-1/+1$ and $-1/+2$ as well

in the case of hospital and physician expenditures associated with a diagnosis of duodenal ulcer. The significance of these differences may be attributed to the contribution of group A, the fact that the signs of the differences for groups B and C are generally the same as those for group A, and the larger sample which results when the groups are combined. Overall health care expenditures (Table 5) range from 11 percent less (in months -1/+2) to 25 percent less (for month +1). Hospital and physician expenditures associated with a diagnosis of duodenal ulcer are from 40 percent to 63 percent less, days hospitalized from 15 percent to 33 percent less.

An alternative presentation of our findings is provided in Table 8, where we have controlled for presample health care expenditures by regression on total health care expenditures in the -12/-2 period rather than by stratification. Significant differences between the T and F samples again emerge early in the sample period, most strikingly in the first month. In each case the new technology seems to have the most favorable impact for those patients with the lowest presample total health care expenditures, as shown by comparison of estimated intercepts. For example, total health care expenditures in the first month are \$212 less for the T sample (\$211) than the F sample (\$423) among patients with no health care expenditures in the presample period. This differential declines as presample total health care expenditures increase, and becomes negative when these expenditures exceed \$2700, which is well above the mean expenditure level of \$1200. For hospital and physician expenditures associated with the treatment of duodenal ulcer the "break-even" point is \$20,000, well outside the range of our sample, and for days of hospitalization it is \$4700, which is exceeded only for a few observations in the entire sample.

For later months in the sample period there are some interesting and significant differences in expenditures between the T and F samples (Table 8, HCE and DU HCE dependent variables). In most cases the cimetidine-based technology is relatively more advantageous for patients with low presample expenditures. The only exception worthy of note is total health care expenditures in the +2/+4 period, in which the entire regression and the slope coefficients alone are significantly different and the situation is reversed; the "breakeven" level of presample expenditures here is \$1200. Days hospitalized are directly related to health care expenditures in the presample period for both samples, and the incremental effect is once again greater for the T sample than for the F sample in the periods +5/+7 and +8/+10. In both cases, however, days hospitalized tend to be lower for the F than for the T sample, even when presample health care expenditures are set to zero -- that is, the intercept for T is larger than for F. The pattern for days of hospitalization shown in Table 8 is consistent with the interpretation that the cimetidine technology provides a substitute for surgery in many cases,⁸ while in some others it merely postpones surgery to a later date.⁹

VI. Conclusion

We have set out a methodology for assessing the effect on total health care expenditures of a change in medical technology, and we have applied the methodology to a new drug, cimetidine. Governments at all levels -- federal, state, local -- are increasingly concerned with rising medical

Table 8

COST MEASURES CONTROLLING FOR PRIOR HEALTH CARE EXPENDITURES BY REGRESSION ^{a/}

| Dependent Variable ^{b/} | Months | T Sample | | F Sample | | "F" ^{d/} | | |
|----------------------------------|--------|----------|----------------------------------|-----------------|----------------------------------|-------------------|-----------------|-----------|
| | | n | Intercept Slope _{c/} | n | Intercept Slope _{c/} | | | |
| HCE | -1/+2 | 500 | 407 (9.47) | 236 (13.2) | 633 | 516 (9.58) | 213 (8.65) | 1.16 |
| | +1 | 530 | 211 (6.33) | 106 (7.65) | 676 | 423 (9.33) | 27 (1.31) | 7.31 *** |
| | +2/+4 | 395 | 276 (6.09) | 160 (8.71) | 533 | 199 (5.22) | 222 (12.6) | 3.07 ** |
| | +5/+7 | 187 | 203 (3.73) | 140 (6.17) | 345 | 205 (5.21) | 158 (8.44) | 0.30 |
| | +8/+10 | 51 | 116 (1.32) | 220 (3.90) | 136 | 170 (2.03) | 187 (5.92) | 0.08 |
| DU HCE | -1/+2 | 500 | 161 (8.13) | -2.56 (0.31) | 633 | 269 (6.64) | -8.28 (0.44) | 3.01 ** |
| | +1 | 530 | 43.1 (5.63) | -1.85 (0.26) | 676 | 266 (6.78) | -10.6 (0.58) | 8.52 *** |
| | +2/+4 | 345 | 47.5 (4.62) | .080 (0.02) | 533 | 28.3 (3.24) | -.661 (0.16) | 1.57 |
| | +5/+7 | 187 | 34.4 (1.86) | 6.82 (0.88) | 345 | 23.0 (2.00) | -.171 (0.03) | 0.94 |
| | +8/+10 | 51 | .375 (1.14) | -.096 (0.45) | 136 | 14.5 (1.95) | -1.36 (0.48) | 0.82 |
| DH | -1/+2 | 520 | 3.98 (12.6) | .634 (4.84) | 633 | 4.52 (13.4) | .260 (1.62) | 1.34 |
| | +1 | 530 | 1.73 (8.15) | .266 (2.94) | 676 | 3.62 (13.6) | -.136 (1.10) | 14.42 *** |
| | +2/+4 | 345 | 1.87 (6.32) | .380 (3.16) | 533 | 1.25 (5.14) | .478 (4.25) | 1.37 |
| | +5/+7 | 187 | 1.65 (3.69) | .334 (1.82) | 345 | 1.28 (5.92) | .059 (0.60) | 2.82 * |
| | +8/+10 | 51 | 1.49 (1.43) | 1.08 (1.62) | 156 | 1.09 (2.81) | .075 (0.51) | 3.55 ** |

^{a/} Ratios of coefficients to standard errors ("t" statistics) are reported in parentheses. The control variable is total health care expenditures in the -12/-2 period, measured in dollars.

^{b/} HCE denotes total health care expenditures; DU HCE, hospital and physician expenditures for DU; DH, days hospitalized.

^{c/} Coefficients have been scaled by a factor of 1,000.

^{d/} For a test of the hypothesis that intercept and slope coefficients for the T and F samples are the same.

Significance Levels: * 10%
 ** 5%
 *** 1%

care expenditures and, thus, they are often preoccupied with the effect on those expenditures of any change in the health care system, whether it be a change in technology, administrative arrangements, input prices or anything else. At the same time, as we emphasized in the introduction to this paper, identification of the effect of some activity on expenditures is not generally equivalent to determination of whether it would or would not pass a social benefit-cost test of economic efficiency, let alone a test of its net contribution to social welfare.

In our estimation work we relied on medicaid records for the state of Texas as the basis for determining the expenditure effects of a new drug, cimetidine, recently approved by the Food and Drug Administration for treating duodenal ulcers. Medicaid is available largely to the poor; thus our data all apply to this population. We are aware of no reason to believe that findings for this population cannot be generalized to the nonpoor population, but we cannot be certain that the two populations are essentially identical in the expenditure-effects of the new drug.

We have found that the introduction of cimetidine resulted in a large and statistically significant decrease in hospital and physician expenditures for the treatment of duodenal ulcers for a substantial portion of our sample, and smaller but insignificant decreases for the other portion. Whether the new technology is more or less efficacious than the old, and whether it has affected morbidity and mortality rates

are questions which cannot be addressed using our data base. Whether or not it affects public expenditures for the treatment of this chronic disease over longer periods of time is a question which could be answered with more data of the type used here.

In this study we concentrated on the impact of cimetidine on three broad measures of resources devoted directly to health care: total health care expenditures, hospital and physician expenditures for duodenal ulcers, and days hospitalized. These measures can be disaggregated to provide more detail on the composition of expenditures under the old technology and the new. In Tables 9 and 10, we provide examples of this decomposition for that part of the sample and that period for which differences in the two technologies seem to be the greatest: patients with low presample total health care expenditures, in the period immediately surrounding their treatment for duodenal ulcer. As discussed earlier, expenditure differentials for the first sample month alone (disaggregated in Table 9) probably overstate the short term impact of cimetidine, while those for the last month of the presample and the first two months of the sample period (disaggregated in Table 10) probably understate it. Whichever estimates are used, however, the same conclusions emerge about the way in which expenditures are reduced by the new technology. The reduction in mean (per capita) total health care expenditures for persons treated with cimetidine -- between \$265 (Table 10) and \$338 (Table 9) -- is accounted for almost entirely by a reduction in those hospital expenditures resulting from the treatment of duodenal ulcer, between \$242 and \$330. By contrast,

Table 9

DECOMPOSITION OF HEALTH CARE EXPENDITURES, CONTROL GROUP A, MONTH +1

| | T Sample (n = 149) | | F Sample (n = 206) | | Percent Reduction, T over F | "t" |
|--------------------|-----------------------|------|-----------------------|------|-----------------------------------|-----------------------|
| | Mean | S.D. | Mean | S.D. | | |
| Total Expenditures | 325.80 | 658 | 663.42 | 1406 | 57% | 3.02 ^{***} |
| Hospital | 190.60 | 520 | 512.36 | 1308 | 63% | 3.19 ^{***} |
| Physician | 80.41 | 145 | 117.95 | 195 | 32% | 2.08 ^{**} |
| Drugs | 29.66 | 12.9 | 11.32 | 8.37 | -162% | -15.19 ^{***} |
| Outpatient | 15.80 | 40.7 | 15.02 | 36.5 | a/ | -0.18 |
| Nursing Home | 4.05 | 49.4 | 0.32 | 4.62 | a/ | -0.91 |
| Other | 5.26 | 17.4 | 6.43 | 20.0 | a/ | 0.58 |
| DU Expenditures | 108.63 | 445 | 438.32 | 1258 | 75% | 3.47 ^{***} |
| Hospital | 84.81 | 402 | 404.18 | 1225 | 79% | 3.49 ^{***} |
| Physician | 23.81 | 65.8 | 34.14 | 116 | a/ | 1.06 |

^a Reduction is statistically insignificant at the 10% level.

Significance Levels: * 10%

** 5%

*** 1%

Table 10

DECOMPOSITION OF HEALTH CARE EXPENDITURES, CONTROL GROUP A,
MONTHS -1/+2

| | T Sample (n = 149) | | F Sample (n = 206) | | Percent Reduction, T over F | "t" |
|--------------------|-----------------------|------|-----------------------|------|-----------------------------------|-----------|
| | Mean | S.D. | Mean | S.D. | | |
| Total Expenditures | 569.76 | 781 | 835.22 | 1432 | 35% | 2.15** |
| Hospital | 336.03 | 601 | 602.81 | 1322 | 44% | 2.45** |
| Physician | 129.68 | 165 | 165.41 | 213 | 22% | 1.70* |
| Drugs | 50.50 | 27.3 | 23.18 | 18.3 | -118% | -10.20*** |
| Outpatient | 28.99 | 54.2 | 26.97 | 101 | a/ | -0.23 |
| Nursing Home | 8.83 | 104 | 0.34 | 4.81 | a/ | -0.95 |
| Other | 15.70 | 47.1 | 16.47 | 47.1 | a/ | 0.14 |
| DU Expenditures | 196.95 | 533 | 439.26 | 1261 | 55% | 2.37** |
| Hospital | 164.12 | 495 | 402.28 | 1242 | 59% | 2.39** |
| Physician | 32.83 | 66.7 | 36.97 | 101 | a/ | 0.44 |

^a Reduction is statistically insignificant at the 10% level.

Significance Levels: * 10%

** 5%

*** 1%

the difference in drug costs between the two groups, between \$18 and \$27, is trivial. This decomposition suggests the conjecture that cimetidine has been a substitute for surgery in many cases. If this conjecture is correct, then morbidity and mortality due to treatment, and the accompanying pain and suffering of patients, relatives and others are very probably lower in the new technology than in the old. At the same time, we cannot rule out the possibility that use of cimetidine serves primarily to postpone surgery beyond the 10-month sample period covered by this research, rather than to eliminate it, although we are aware of no evidence suggesting this outcome.

This new medical care technology, cimetidine, has substitutes in the forms of both surgery and conventional antacids. From the narrow viewpoint of minimizing government expenditure the question is, which alternative or combination involves the lowest level of expenditure. We have not compared all possible treatment combinations, but what we have found is that using cimetidine does appear to reduce expenditures on treatment of duodenal ulcers compared to the average of other treatment technologies not employing cimetidine.

It would be tempting to conclude that cimetidine is "cost effective" compared with non-cimetidine-using alternatives. It is likely that this is a correct conclusion -- subject to two qualifications: (1) longitudinal extension of our data might conceivably show a reversal of the cimetidine therapy's cost advantage, and (2) the efficacy (or more generally, the benefits) of the various treatment modes and the accompanying health states -- morbidity,

mortality, pain and suffering -- have not been measured explicitly in our in vivo study (as distinct from a laboratory setting); thus we cannot be certain that the efficacy of the cimetidine technology is at least as great as that of the others.

It seems inappropriate, however, to end on a note of reservation. Regarding point 1, above, our evidence is that the cost advantage in favor of the cimetidine therapy is not likely to be reversed. Regarding point 2, it seems likely that a therapy that produces a decrease in hospitalization and in medical care expenditures is also bringing about an improvement in the state of patients' health, both because treatment is itself productive of discomfort and disruption of normal work and leisure activities, and because people who experience a decrease in involvement with the medical care system may be presumed to have improved their health status.

In short, the apparent expenditure-reducing effect of cimetidine therapy, while measuring only (average) resource costs, seems to reflect a favorable benefit-cost relationship. In general, a change in expenditures on a commodity is of dubious worth as an index of the net benefits. Reduced expenditures on medical care and specifically on duodenal ulcer therapy, however, reflect both savings in resource costs and increases in social benefits resulting from improved health and the decreased demand for medical attention.

Footnotes

¹A sensitivity analysis of the effects of a number of variables on V can be found in Burton A. Weisbrod, "Costs and Benefits of Medical Research: A Case Study of Poliomyelitis," Journal of Political Economy, 79 (1971), 527-544.

²The nature and therapeutic application of cimetidine cannot be discussed in detail here. For further discussion see Charles T. Richardson, "Effect of H₂-Receptor Antagonists on Gastric Acid Secretion and Serum Gastrin Concentration," Gastroenterology, 74 (November 1978) pp. 366-370; and Daniel H. Winship, "Cimetidine in the Treatment of Duodenal Ulcer," Gastroenterology, 74 (November 1978), pp. 402-406, and see the Appendices below.

³See the studies by Richardson and Winship, note 2.

⁴For a recent attempt to measure these "intangible" effects, in the context of a randomized experiment in treating the mentally ill, see Burton A. Weisbrod, "A Guide to Benefit-Cost Analysis, As Seen Through a Controlled Experiment in Treating the Mentally Ill," University of Wisconsin Institute for Research on Poverty, Discussion Paper 559-79, 1979.

⁵Robinson Associates, The Impact of Cimetidine on the National Cost of Duodenal Ulcers (Bryn Mawr, PA: Robinson Associates, 1978).

⁶George von Haunalter and Virginia V. Chandler, Cost of Ulcer Disease in the United States (Menlo Park, CA: Stanford Research Institute, 1977).

⁷Even E₂, however, is subject to shortcomings as a model of reality. In reality, all DU patients for whom cimetidine is the medically

preferred therapy will not obtain it--because physicians misdiagnose, or the patient fails to seek medical advice, or to heed it. Similarly, some patients will actually receive cimetidine, even though it is not the medically preferred therapy for their particular set of problems.

⁸We might further expect that if the FDA proscription on use of the drug beyond an initial eight-week period reflected the consensus of practitioners, then eventually the number of cimetidine prescriptions would decline, as the stock of patients with DU at the time of the drug's introduction was treated once and only those with new ulcers were treated with cimetidine. Certainly there is no evidence that this occurred in the ten months for which we have data (Table 3), although such a decline might occur beyond the sample period.

⁹The interested reader is referred to another paper by the authors now in progress.

¹⁰J.D. Elashoff and M.I. Grossman, "Trends in Hospital Admissions and Death Rates for Peptic Ulcer in the United States from 1970 to 1978," Gastroenterology (forthcoming).

¹¹More detail on this point is provided in another paper by the authors now in progress.