The original documents are located in Box 46, folder "President - Medals Inaugural Medals (2)" of the Philip Buchen Files at the Gerald R. Ford Presidential Library.

THE FRANKLIN MINT

FRANKLIN CENTER, PENNSYLVANIA 19063

March 27, 1975

Senator Mark O. Hatfield
Chairman
Inaugural Medal Committee
Washington, D. C.

Dear Senator Hatfield:

On January 31, 1975, we forwarded a preliminary royalty check of $23,745 to you from sales of the Official Gerald R. Ford Presidential Inaugural Plate Program.

Now that the final accounting is completed, I am pleased to enclose a supplemental royalty check of $605.

Again, let me say that The Franklin Mint has been proud to participate in this important program.

Sincerely yours,

Charles L. Andes
President

THE FRANKLIN MINT

FRANKLIN CENTER, PENNSYLVANIA 19063

Statement of Royalties Due

As of February 23, 1975

Sales Program: The Official Gerald R. Ford Inaugural Plate

Contract Date: October 10, 1974

Solid Sterling Silver Inaugural Plate "Gross Receipts Realized"	$226,000.00	
Total Royalties earned at 10%		$22,600.00
Solid 18 Karat Gold Inaugural Plate "Gross Receipts Realized"	$ 35,000.00	
Total Royalties earned at 5%		$ 1,750.00

Less: Royalties previously paid by The Franklin Mint

Check No.	Date	Amount	
2322	01/30/75	$23,745.00	(23,745.00)

Total Royalties due the Inaugural Medal Committee $ 605.00

Check No. 2488 Date: 3/20/75

Sales Accounting
March 17, 1975

MEDALLIC ART COMPANY
OLD RIDGEBURY ROAD · DANBURY, CONN. 06810 · (203) 792-3000

August 6, 1975

~~American Cancer Society~~

Gerald Ford - Presidential Inaugural Medal Sales

Accounting for Sales thru June 30, 1975

Silver Sales	468,098.05	
Bronze Sales	86,188.07	
	554,286.12	
Royalty Due 10%		55,428.61
Gold Sales	391,363.00	
Royalty Due (See Attached)		17,667.08
		73,095.69
Less Sets @ No Charge		
ANA	198.00	
Smithsonian	198.00	
Less Medals to:		
Pres. Ford (21/2 "14K)	506.00	
Mrs. Ford (1 1/4" 18K)	147.00	
Less Medals to Inaugural Medal Committee		
Silver Content 55.66to	255.48	
10 @ $10.00	100.00	1,404.48
Total Royalties Due		71,691.21

MEDALLIC ART COMPANY
OLD RIDGEBURY ROAD · DANBURY, CONN. 06810 · (203) 792-3000

August 6, 1975

Royalties on Gold Medal Sales

Gold Cost: Shipment #1 195.50
Shipment #2 177.75
Shipment #3 184.05

557.30 = $185.76 Avg. Spot per T.O.

1 Medal = 3/4 t.o. fine gold = $185.76 @ .75 = $139.32

Sold				Gold Cost	Net	10%
26	@	$395	10,270	3622.32	6647.68	664.77
227	@	375	85,125	31625.64	53499.36	5349.93
514	@	237	121,818	71610.48	50207.52	5020.75
774	@	225	174,150	107833.68	66316.32	6631.63
			391363.00	214692.12	176670.88	17667.08

Pres. medals

June 11, 1975

Dear Senator:

We are examining the procedures by which the President may designate those charities to which he recommends the Inaugural Medal Committee direct royalties from the sale of inaugural items and the possible tax consequences to the President of such designations. In order to determine whether designated royalties would constitute taxable "income" to the President, it is necessary for us to have additional information regarding the establishment and operation of the Committee. Insofar as possible, we would appreciate your providing us answers to the following questions:

First, was the President's approval for the formation of the Inaugural Medal Committee sought because it was legally necessary for, or financially advantageous to the Committee's operation?

Second, were the commemorative items advertised and promoted as having the President's formal endorsement?

Finally, was the Committee's commitment to let the President designate charities accorded to him for any value received?

Again, my sincere thanks for any guidance which you can provide us with respect to the above-cited questions.

With best regards,

Sincerely,

(S)

William E. Casselman II
Counsel to the President

Honorable Mark O. Hatfield
United States Senate
Washington, D.C. 20510

WEC:bw

MAY 8 1975

MEMORANDUM FOR HONORABLE WILLIAM E. CASSELMAN II
Counsel to the President

Re: Inaugural Medal and Inaugural Plate.

You have asked our advice concerning the appropriate procedures by which the President may make charitable designations of the royalty proceeds accruing from the sale of the medals and plates marketed in the name of the Inaugural Medal Committee by the Medallic Art Company and The Franklin Mint respectively, and the tax consequences to the President, if any, of such designations.

As to your first question, there is no established procedure for making such designations. We would think that a letter from the President to the Inaugural Medal Committee expressing his preferences would suffice. In light of the tax discussion below, the letter should avoid any implication that the President is directing a disposition of funds to which he has any claim or over which he possesses any legal right of control.

The question as to tax consequences is difficult to answer without a comprehensive knowledge of the facts involved. It is possible, of course, for payment to a third person, even to a charity, to constitute "income" to the President, if that payment is made at the President's request in order to discharge a legal obligation to him, or as compensation for some service or benefit he had rendered or conferred. On the basis of the facts we know, this does not appear to be the situation in the present case; but the matter can be determined with certainty only by discussions with the principals involved. Pending such further investigation, we must condition our opinion upon the accuracy of the following factual premises:

As we understand the situation, the Inaugural Medal Committee was formed with the "approval" of the President to make arrangements for an "Official Presidential Medal". We take it that Presidential approval was sought only because it seemed courteous and appropriate to advise the President of, and obtain his consent to, an enterprise which was being formed by friends and former colleagues to honor his inaugural--and that there was not involved the obtaining of any consent from the President which was legally necessary for, or financially advantageous to, the Committee's operation. (There was, in our opinion, no legal necessity to obtain the President's consent to reproduction of his image or signature. There might have been somefinancial advantage to the Committee if his "endorsement" was to be featured in the advertising or promotion of the project, but we do not understand that this was intended or occurred.) We presume that the Committee's commitment to let the President designate charities was prompted by similar sentiments--not accorded to him for any value received, but merely out of a sense of appropriateness that any profits from an enterprise meant to honor his inauguration should be given to a charity which he personally favored.

All of the material you have forwarded to us is consistent with the foregoing analysis. The one item which gives us some pause is Senator Hatfield's description of the President's original consent as "going to the re-formation of the Committee to do an Official Presidential Medal". We are not clear on what makes a medal an "official" medal. If the phrase was meant to imply that the medal would be advertised and promoted as having the President's formal endorsement, the premises of our opinion would be eliminated. If the phrase was meant to imply that the President would publicly object to the striking of a commemorative medal by any other group, the same result would follow. The totality of the material you forwarded, however, does not support that view of the matter, and we take it that the "officialness" of the medal merely referred to its issuance by a committee chaired by a United States Senator, and numbering among its members other senators and representatives and a former chairman of the Inaugural Committee. This point in particular, however, might warrant further investigation.

"Gross income" is defined in section 61 of the Internal Revenue Code, 26 U.S.C. § 61. The only portions of the definition which could conceivably be relevant for present purposes are "(1) Compensation for services including fees, commissions and similar items", and "(3) Gains derived from dealings in property." On the factual premises described above, it is clear that neither of these provisions would apply.

The Tax Division of this Department has informally concurred in the above views concerning the tax aspects of this matter. You might wish, however, to consult the Internal Revenue Service in order to place the matter beyond doubt.

Antonin Scalia
Assistant Attorney General
Office of Legal Counsel

MARK O. HATFIELD
OREGON

United States Senate

WASHINGTON, D.C.

June 12, 1975

Mr. William E. Casselman II
Counsel to the President
The White House
Washington, D.C. 20500

Dear Mr. Casselman:

In response to your letter of June 11, I am writing in an effort to provide additional information on the Inaugural Medal Committee.

First, the President's approval for the formation of the Inaugural Medal Committee was not sought because it was legally necessary, nor because it was financially advantageous to the Committee's operation. All of the proceeds from the sale of the medal will be donated to charity. The sole reason for requesting the President's initial approval was as a matter of courtesy to the President. The Inaugural Medal Committee felt that notifying the President and receiving his acquiescence was the proper way to proceed with the establishment of the Committee.

Second, the commemorative medals are not advertised and promoted as having the President's formal approval. Rather, the advertisements for the medals merely reflect the President's acquiescence or general approval of the committee's work.

Finally, the Committee decided that as a matter of propriety the President should be given the opportunity to designate the charities which would receive royalties. The Committee's commitment to have the President designate these charities was not accorded to him for any value received or to be received. The members of the Committee simply agreed to abide by the President's choice of charities.

I sincerely hope that this additional information will serve to clarify the role of the Committee vis-a-vis the President. If any further questions arise, please do not hesitate to contact me.

Kindest regards.

Sincerely,

Mark O. Hatfield
United States Senator

MOH:scj

MARK O. HATFIELD
OREGON

United States Senate

WASHINGTON, D.C.

August 11,1975

Mr. William E. Casselman III
Counsel to the President
The White House
Washington, D.C. 20500

Dear Mr. Casselman:

In accordance with our earlier telephone contact, I am enclosing the final accounting for royalties from the Medallic Art Company and Franklin Mint.

Incidentally, the royalty payments from Franklin Mint have not been sent to the committee, as indicated in the letter. These payments along with those from Medallic Art will be paid directly to the designated charity or charities under the direction of the Inaugural Committee. The amount of total royalties, however, is accurate.

If you desire any other information, please do not hesitate to let me know.

With kindest regards.

Sincerely,

Mark O. Hatfield
United States Senator

MOH:scs
Enclosures

THE WHITE HOUSE

WASHINGTON

August 26, 1975

MEMORANDUM FOR: PHILIP W. BUCHEN

FROM: JAY T. FRENCH

Attached is a copy of pertinent correspondence and material from Senator Hatfield identifying five breast cancer projects to which royalties from the sale of medals might be donated. As of this time, neither the Inaugural Medal Committee nor the President has further designated some or all of these projects to receive the royalties. I suggest that in your letter to Senator Hatfield acknowledging receipt of the final accounting, you invite the Committee's further recommendations with respect to the division of the royalties among some or all of the five projects.

A new draft letter to Senator Hatfield is attached at Tab A.

DRAFT

Dear Senator Hatfield:

Thank you very much for your letter of August 11 to William Casselman enclosing a final accounting of royalties from the sale of inaugural medals.

In reviewing your earlier correspondence with Mr. Casselman, I note that the Committee has identified five specific breast cancer projects to which these royalties might be donated in accordance with the President's desires. Because the total amount of royalties has now been determined, I would like to further solicit the Committee's recommendations with respect to the division of these royalties among some or all of the five projects. Based upon the Committee's recommendations, I will inform the President of the final accounting and seek his approval of the distribution of the royalties.

Also, I would like to inquire whether you believe it would be appropriate for the Committee to issue a press release on the final disposition of the royalty payments after the President has made his decision.

Your kind assistance is these matters is appreciated.

Sincerely,

Philip W. Buchen
Counsel to the President

The Honorable Senator Mark O. Hatfield
United States Senate
Washington, D.C. 20510

President

medals

THE WHITE HOUSE

WASHINGTON

September 3, 1975

Dear Senator Hatfield:

Thank you very much for your letter of August 11 to William Casselman, in which you enclosed a final accounting of royalties from the sale of inaugural medals.

In reviewing your earlier correspondence with Mr. Casselman, I note that the Committee has identified five specific breast cancer projects to which these royalties might be donated in accordance with the President's desires. Because the total amount of royalties has now been determined, I would like to solicit the Committee's recommendations with respect to the division of these royalties among some or all of the five projects. Based upon the Committee's recommendations, I will inform the President of the final accounting and seek his approval for distribution of the royalties.

Also, I would like to know whether you believe it would be appropriate for the Committee to issue a press release on the final disposition of the royalty payments after the President has made his decision.

You and your Committee have had remarkable success in this worthwhile project, and we all very much appreciate your generous and effective efforts.

Sincerely,

Philip W. Buchen

Philip W. Buchen
Counsel to the President

The Honorable Mark O. Hatfield
United States Senate
Washington, D. C. 20510

MARK O. HATFIELD
OREGON

United States Senate

WASHINGTON, D.C.

September 18, 1975

The President
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Attn: Mr. Jay French
Assistant Counsel

Dear Mr. President:

I am writing to recommend a recipient for the royalties realized from the sale of the Ford Presidential Inaugural medal and plate.

During our meeting on December 10, 1974, you indicated a desire to donate at least the first $100,000 of royalty proceeds from the inaugural medal towards research in breast cancer. In response to our discussion, I contacted the National Cancer Institute in an effort to identify specific projects which needed additional funding. Then in the latter part of February, I sent you a summary of five specific breast cancer projects which were outlined by Dr. Frank J. Rauscher, Jr., of the National Cancer Institute.

I now have a final accounting of the royalties from both the Medallic Art Company and The Franklin Mint. The total amount of the proceeds is $97,000. In view of this figure, I recontacted the National Cancer Institute. They still feel that the five projects which were originally recommended are highly meritorious. Due to the amount of the proceeds available and to the lack of continuation of funding, however, they suggest that the funds be used to sponsor an International Conference on Breast Cancer. I would also like to recommend that the proceeds be used to sponsor this conference. As the enclosed material from NCI indicates, such a conference would be timely and greatly beneficial in educating both professionals and the public.

I hope that this additional information along with my suggestion will be of assistance to you. If you feel that this conference should receive our support, please let me know. The committee will be available to announce the designation of the recipient or to help in any other way. In any event, should you desire any more information, please don't hesitate to contact me.

Sincerely,

Mark O. Hatfield
United States Senator

MOH:scs

It is proposed that proceeds from the sale of President Ford's inaugural medals be used to sponsor an International Conference on Breast Cancer to be held in Washington, D.C. and sponsored by the National Cancer Program, National Cancer Institute. Breast cancer is the number one cancer killer of women throughout the United States and the world. There have been recent scientific advances in the early detection, diagnosis and treatment of breast cancer that warrant widespread dissemination throughout this country and the world. A similar, though smaller, conference was held on the NIH campus in September, 1974, entitled Advances in Breast Cancer--A Report to the Profession (Attachment). This conference was well received and highly publicized. Scientific knowledge has continued to accrue such that a larger, international conference would be both timely and meaningful in educating both lay and professionals in these advances. Such a conference would serve to partially fulfill our international mandate under the National Cancer Act of 1971 and 1974 and would foster our formal and informal bilateral agreements with the USSR, Japan, France, Germany, Poland, Egypt, etc. The Conference would add to the humanitarian attitude of this Nation on behalf of all nations who share the human destruction caused by breast cancer. It is suggested that Mrs. Betty Ford, Mrs. Happy Rockefeller, and other lay leaders, be invited to participate in the conference.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

NATIONAL CANCER INSTITUTE
PRESS SUMMARY

September 30, 1974

FOR RELEASE Tuesday, Oct. 1, A.M.'s

For further information
Contact William S. Gray
Robert M. Hadsell
(301) 496-6641

A Report to the Profession from the Breast Cancer Task Force

Breast cancer is the major cause of death due to cancer among women in the United States. This year there will be an estimated 89,000 new cases and 32,500 deaths from breast cancer in this country.

Because of this grave health problem and because the extent of traditional surgical treatment for the disease has been questioned, a sustained effort has been mounted by the National Cancer Institute's Breast Cancer Task Force to improve the diagnosis and treatment of this dreaded disease.

What has emerged from this effort and will be reported today, is a significant step forward in earlier diagnosis and more effective treatments for both localized and advanced disease. It should be emphasized that these findings are tentative and do not, by themselves, represent major breakthroughs. More time and more study will be needed to document long-term results and to improve our techniques.

However, it should also be emphasized that encouraging trends have emerged from enough different studies to justify confidence in the preliminary findings. In short, we know that it is best to find breast cancer in its earliest, and therefore most curative stages. In cooperation with the American Cancer Society, we have demonstrated a significant

improvement in our capability to accomplish this goal. At the same time there is preliminary evidence that more effective treatments have been developed for both early and advanced disease. If this evidence is sustained by the passage of time, and we have confidence that it will be, it should be possible to improve substantially both the cure and survival rates from cancer of the breast, and with less disfiguration than results from radical mastectomy.

BREAST CANCER DETECTION

Early detection of breast cancer before it has spread to other parts of the body increases a patient's chance for long-term survival and cure. Patients whose axillary (armpit) lymph nodes are free of cancer (negative nodes) at the time of breast cancer diagnosis have a 5-year survival rate of about 75 percent, and about 65 percent of these patients are alive after 10 years. In contrast, women with breast cancer in the axillary nodes (positive nodes) have a 5-year survival rate of about 50 percent, and only about 25 percent will live 10 years.

In the U.S. at present, patients have negative, cancer-free nodes in about 45 percent of newly-diagnosed breast cancer cases. A real hope that this rate may be improved--with a corresponding increase in survival rates--comes from the breast cancer screening demonstration program sponsored jointly by the ACS and the National Cancer Institute. Dr. William Pomerance, Chairman of the Breast Cancer Task Force's Diagnosis Committee, reported that about 75 percent of the women with breast cancer, detected so far by the screening program, had negative nodes.

The ACS-NCI program involves 27 breast cancer screening projects, where up to 270,000 women of ages 35 years and older will be screened annually with a physical examination, X-rays (film mammography or xeroradiography), and thermography. The first projects established began screening women in mid-1973; all 27 centers will be operating by the end of 1974. About 75,000 women have been screened to date. When comprehensive data have been compiled, it is expected that about 775 breast cancers will have been detected among these women, a rate of 10.5 cases per 1,000 women screened, or about 1,000 cases per 100,000 women screened.

The combination of physical examination and X-ray mammography in breast cancer screening has been shown to decrease breast cancer death rates. A group of 31,000 women screened for breast cancer by the Health Insurance Plan of Greater New York in a NCI-supported study have had a one-third reduction in breast cancer deaths over a 5-year follow-up period as compared with 31,000 women given their usual comprehensive medical care in their medical groups. One-third (44 out of 132) of the breast cancers detected in the screening program were found by X-ray mammography before the tumors were large enough to be detected physically. Only one of these 44 women died of breast cancer during the 5-year period, indicating that early detection led to substantially more effective treatment.

BREAST CANCER TREATMENT

Breast cancer presents usually as disease limited to the breast and axillary nodes without clinical evidence of metastatic disease. Surgery has been the main weapon against cancer of the breast for the past six or more

decades. The standard approach to surgery has been radical mastectomy. Radical mastectomy means removal of the breast, underlying pectoral muscles and axillary lymph nodes. Recently, less radical procedures have been recommended, but supporting data from controlled clinical studies has not yet been available in the United States.

Primary Breast Cancer

Dr. Bernard Fisher of the University of Pittsburgh, Chairman of the National Surgical Adjuvant Breast Project (NSABP), has directed a large clinical study involving surgeons, radiotherapists and pathologists at 34 institutions attempting to determine the optimal treatment for primary breast cancer. This study, supported by NCI grants and the Breast Cancer Task Force, has involved 1,700 patients.

For patients with operable disease limited to the breast, the study compares radical mastectomy, total mastectomy (removal of breast only) and total mastectomy plus radiation therapy to the chest. For patients whose disease involves the breast and axillary nodes, radical mastectomy is compared with total mastectomy combined with postoperative radiotherapy.

The results after two years indicate that in each group the various options are essentially equivalent. Thus, for disease limited to the breast, a total mastectomy with or without radiation therapy is equivalent to the radical procedure. For patients with disease in the breast and axillary nodes, total mastectomy with postoperative radiotherapy is equivalent to radical mastectomy. While the long-term follow-up data necessary to obtain survival characteristics are not yet available from this study, similar trends from early stages of

other studies have been borne out by long term follow-up and are thus considered predictive. The major impact of these results is to provide scientific information for practicing surgeons to determine the most effective type of operation for each patient and, in addition, to set the stage for planned clinical studies of less surgery (segmental mastectomy), a procedure where only part of the breast is removed.

Early Chemotherapy

Historically more than 50 percent of breast cancer patients die with metastatic disease. Previous studies have indicated that the presence of cancer in the axillary nodes carries a dire prognosis. More than 75 percent of patients with one or more positive nodes will have recurrent disease at 10 years and most of the patients will die of their disease. Thus, the presence of axillary gland involvement predicts the presence of metastatic disease.

To combat this clinical situation a second study, sponsored by the Breast Cancer Task Force and done jointly by the NSABP and members of the Eastern Cooperative Oncology Group and the Central Oncology Group, is investigating the addition of postoperative systemic chemotherapy in women who have had modified or radical mastectomy and shown to have positive axillary nodes. To date 250 patients have been entered on a double-blind randomized study receiving either a placebo or L-phenylalanine mustard (L-PAM), an oral anticancer drug, for five days by mouth every six weeks for two years.

The study has been underway about 24 months and involves 37 institutions. Data concerning the results of the study to date, presented by Dr. Fisher, have been analyzed independently by Dr. Carole Redmond of the University of Pittsburgh and Dr. Marvin Zelen of the Statistical Laboratory of the University of New York at Buffalo. The data indicate that the recurrence rate is significantly reduced for women receiving the L-PAM. This was particularly striking for women who were premenopausal where only 1 of 30 patients receiving L-PAM recurred, whereas 11 of 37 recurred after surgery alone. The investigators have recommended that the study be terminated for the premenopausal group of patients because of these dramatic results. For postmenopausal patients the failure rates are also reduced in the L-PAM treated group, but not as markedly. For this reason, that part of the study involving postmenopausal women is under further review.

Dr. Paul P. Carbone, Chairman of the Breast Cancer Task Force Treatment Committee, also reported that similar studies employing combination chemotherapy regimens are being done at the National Cancer Institute of Milan, Italy, the Mayo Clinic, the University of California at Los Angeles, and the Cleveland Clinic. The study at the Milan Cancer Institute has accrued 100 patients who are receiving the three-drug combination of cytoxan, methotrexate and 5-fluorouracil. Results are consistent with the L-PAM study.

The importance of these postoperative chemotherapy trials is that patients with breast cancer and axillary node metastasis can receive drug therapy to treat the subclinical metastases before they become

clinically obvious and lethal. From two previous clinical studies and from experimental data in animals, this combined approach of surgery and chemotherapy offers the best chance of survival.

The L-PAM treatment is a simple program with minimal side effects and can be widely used. With these encouraging results Dr. Fisher and the NSABP investigators are planning an additional study using a two-drug combination and a combination of L-PAM with C. Parvum, an immuno-stimulant.

Advanced Disease

Dr. Carbone reported preliminary results from several other studies of patients with metastatic disease indicating that combinations of drugs are more effective than single drugs. In a study sponsored by the Eastern Cooperative Oncology Group a three-drug combination produced 53 percent response (shrinkage of tumor by 50 percent or more) as compared to 19 percent with L-PAM alone. Patients receiving the combination regimen had more complete responses and longer survivals than patients treated with the single agent.

Similar improved results with combination therapy are reported in a study by Dr. David Ahmann and his co-workers at the Mayo Clinic. Drs. John Horton, the Albany Medical College of Union University, and Thomas Dao, Roswell Park Memorial Institute, have reported improved results with the combination chemotherapy of cytoxan, fluorouracil and prednisone as compared to adrenalectomy and adriamycin alone.

Dr. Douglass Tormey and co-workers at the National Cancer Institute, have demonstrated improved results by incorporating adriamycin into a three-drug combination using cytoxan and fluorouracil.

In several ongoing research studies, immunostimulants such as BCG and C. Parvum are being added to chemotherapy to determine whether treatment results can be improved.

While management of the advanced disease patients has improved, the likelihood of eliminating all cancer cells is highest when the numbers of cancer cells are small. This is most likely to occur when the patient first presents with cancer. An objective of the Breast Cancer Task Force is to develop therapeutic programs utilizing effective local treatment in combination with safe, easily administered systemic anticancer drug combinations.

Hormone Receptors

Removal of the ovaries in premenopausal women and the removal of the adrenals or pituitary are forms of breast cancer therapy to which approximately 30 percent of women respond. Administration of androgens or estrogens can also induce tumor regression. These responses occur in 20 to 40 percent of patients.

Dr. William McGuire, of the University of Texas at San Antonio and member of the Breast Cancer Task Force Treatment Committee, described the role of hormone receptors (specific cell proteins) in predicting response to these endocrine treatments for breast cancer. The laboratory determination of whether an individual patient has a hormone receptor can be used to predict whether she will respond to hormone therapy. The importance of this test is that it differentiates between patients who would benefit from hormone therapy and those who would not. These latter patients can then be placed on other therapies without delay.

Approximately 50 percent of biopsies of breast cancer are found to contain the receptors. The response rate to endocrine treatments by patients with positive endocrine receptor (ER) tests was markedly higher than that in ER negative patients. For ER positive patients 52 percent responded compared to 4 percent responses in patients who were ER negative. Thus the estrogen receptor assays can be helpful to predict the results of endocrine therapy and increase the likelihood of predicting response. The challenge of the future is to incorporate endocrine therapy into the treatment strategy with chemotherapy for those patients who are ER positive. For the ER negative patients two approaches appear possible. These patients can be treated directly with non-hormonal methods obviating the delay of less effective measures. Secondly, there may be ways to uncover or alter the hormone receptors to make them sensitive.

Several studies are being sponsored by the Breast Cancer Task Force to combine hormonal approaches with chemotherapy. Two studies, one at the Mayo Clinic and the other through the Eastern Cooperative Oncology Group, are studying ways to combine combination chemotherapy with oophorectomy in premenopausal women. Another approach being done at Emory University by Dr. Charles Vogel combines estrogens with a three drug combination of cytoxan, fluorouracil and adriamycin.

Dr. Tormey, Chief of the NCI Medical Breast Cancer Service, reported on studies of biologic markers--substances found in the blood or urine that correlate with the presence of tumor. Ideally, levels

of these substances should correlate with the amount of tumor in the patient and change in parallel with the response of tumors to therapy.

Out of eight biologic markers tested, three, human chorionic gonadotrophin (HCG), carcinoembryonic antigen (CEA), and a transfer RNA nucleoside (N^2N^2-diemthylguanosine), were found to be present in abnormal amounts. Using these markers, 63 patients (97 percent) in a group of 65 were found to have abnormal levels of at least one of these markers. In a group of 15 post-operative patients found to have positive nodes, 10 (67 percent) had elevated levels.

SUMMARY

At the present time, the two-year report from the Breast Cancer Task Force indicates that less than radical surgery is acceptable for the treatment of primary breast cancer. Moreover, the trends of other studies involving surgery and chemotherapy for women with breast cancer and positive axillary nodes show that the recurrence rate can be significantly reduced. This in turn indicates that we can successfully treat sub-clinical metastasis. The advances in the treatment of early and advanced breast cancer, coupled with progress in earlier detection and diagnosis, should lead to significant improvements in cure rates and survival.

It should be emphasized that this report does not include results from other research studies conducted by the NCI, cooperative groups and individual institutions.

Room 110

THE WHITE HOUSE

WASHINGTON

Date: Monday

September 25, 1975

Dear Mark:

I want to take this opportunity to thank you for your initiative and dedicated efforts as Chairman of the Inaugural Medal Committee. I [redacted] appreciate Committee's your effective leadership in carrying out the purposes ~~of the Committee~~. ~~I find it~~ most gratifying for me to know that my oath of office ceremony will be commemorated by the designation of the royalty payments from the sale of Inaugural Medals for such a worthy charitable cause.

I hope that whatever good derives from this contribution will make you feel that your time and energy on the project were well placed.

With warmest personal regards,

Sincerely,

The Honorable Mark O. Hatfield
United States Senate
Washington, D.C. 20510

THE WHITE HOUSE

WASHINGTON

September 25, 1975

Dear Mr. MacNeil:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath taking ceremony by a special contribution to such a worthy charitable cause.

~~I want to~~ Many thank~~s~~ To you for your part in the success of this effort~~, and express the~~ so hope that you found it a personally satisfying experience.

Sincerely,

Mr. Neil MacNeil

_____

_____

_____

Get proper names, addresses & salutations for comm. members mentioned Hatfield

Inaugural Medals

THE WHITE HOUSE

WASHINGTON

November 5, 1975

Dear Mark:

On behalf of the President, I thank you very much for your letter of September 18, in which you informed him of the Inaugural Medal Committee's decision to use the proceeds of the sale of inaugural medals to sponsor an international conference on breast cancer. President Ford was particularly pleased that the Committee had decided upon this use of the proceeds.

If you believe it would be appropriate, the Committee should make a public announcement of its decision.

With much appreciation for all your good work on this project,

Sincerely,

Philip W. Buchen
Counsel to the President

The Honorable Mark O. Hatfield
United States Senate
Washington, D. C. 20510

THE WHITE HOUSE

WASHINGTON

November 5, 1975

Dear ~~Senator~~ Mark ~~Hatfield~~:

On behalf of the President, I ~~would like to~~ thank you very much for your letter of September 18, in which you informed him of the Inaugural Medal Committee's decision to use the proceeds of the sale of inaugural medals to sponsor an international conference on breast cancer. President Ford was particularly pleased that the Committee had decided upon this use of the proceeds. If you believe it would be appropriate, the Committee should make a public announcement of its decision.

With much appreciation for all your good work on this project,

Sincerely,

Philip W. Buchen
Counsel to the President

The Honorable Mark O. Hatfield
United States Senate
Washington, D. C. 20510

Tuesday 11/4/75

2:00 Jay called. Said he had a call from Senator Hatsfield's office ; the Senator doesn't know whether a charity has been selected.

Jay said he drafted a letter to Senator Hatfield advising him of the President's decision -- in the vein that we didn't want to appear to be dictating what charity the proceeds should go to.

I pulled the attached from your "hold" file, but don't see Jay's draft letter to Hatfield.

THE WHITE HOUSE
WASHINGTON

October 3, 1975

Copy sent to Jay. If you need talking points for Senator Hatfield, Jay will be happy to provide them.

shirley

See attached memo to Pres.

THE WHITE HOUSE

WASHINGTON

October 3, 1975

ADMINISTRATIVELY CONFIDENTIAL

MEMORANDUM FOR: PHILIP W. BUCHEN

FROM: JAMES E. CONNOR JEC

SUBJECT: Inaugural Medal Committee

The President reviewed your memorandum of September 26 on the above subject and approved the following option:

"Favor an International Conference on Breast Cancer"

The recommended letters of appreciation to the Committee Members were signed. Copies are attached for your file.

Please follow-up with appropriate action.

cc: Don Rumsfeld

WHITE HOUSE

WASHINGTON

October 2, 1975

Dear Mark:

I want to take this opportunity to thank you for your initiative and dedicated efforts as Chairman of the Inaugural Medal Committee. I appreciate your effective leadership in carrying out the Committee's purposes.

It is highly gratifying for me to know that my oath of office ceremony will be commemorated by the designation of the royalty payments from the sale of inaugural medals for such a worthy charitable cause. I hope that whatever good derives from this contribution will make you feel that your time and energy on the project were well placed.

Sincerely,

Jerry Ford

The Honorable Mark O. Hatfield
United States Senate
Washington, D.C. 20510

WHITE HOUSE

WASHINGTON

October 2, 1975

Dear Bob:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Jerry Ford

The Honorable Robert Griffin
United States Senate
Washington, D.C. 20510

WHITE HOUSE

WASHINGTON

October 2, 1975

Dear Phil:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Jerry Ford

The Honorable Philip A. Hart
United States Senate
Washington, D.C. 20510

WHITE HOUSE

WASHINGTON

October 2, 1975

Dear Al:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Jerry Ford

The Honorable Elford Cederberg
House of Representatives
Washington, D.C. 20515

HITE HOUSE

WASHINGTON

October 2, 1975

Dear Mrs. Clain-Stefanelli:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Jerry Ford

Mrs. E. Clain-Stefanelli
Smithsonian Institution
1000 Jefferson Drive, SW.
Washington, D.C.

WHITE HOUSE

WASHINGTON

October 2, 1975

Dear Mr. Dusterberg:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Jerry Ford

Mr. Richard B. Dusterberg
First National Bank Building
Fourth and Walnut Streets
Cincinnati, Ohio 45202

WHITE HOUSE

WASHINGTON

October 2, 1975

Dear Dr. Crain:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Jerry Ford

Dr. Darrell C. Crain
1234 19th Street, NW.
Washington, D.C.

ITE HOUSE

WASHINGTON

October 2, 1975

Dear Bill:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Jerry Ford

The Honorable J. Willard Marriott, Sr.
Marriott Corporation
5161 River Road, NW.
Washington, D.C. 20016

WHITE HOUSE

WASHINGTON

October 2, 1975

Dear Mike:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Dr. Michael Radock
Vice President
University Relations and Development
University of Michigan
1028 Administration Building
Ann Arbor, Michigan 48104

WHITE HOUSE

WASHINGTON

October 2, 1975

Dear Mr. MacNeil:

I am deeply grateful to you for the valuable support you provided to Senator Mark Hatfield on the Inaugural Medal Committee.

I was greatly pleased by the Committee's decision to commemorate my oath-taking ceremony by a special contribution to such a worthy charitable cause.

Many thanks to you for your part in the success of this effort. I hope that you found it a personally satisfying experience.

Sincerely,

Jerry Ford

Mr. Neil MacNeil
Time, Inc.
888 16th Street, NW.
Washington, D.C. 20006

THE WHITE HOUSE

WASHINGTON

September 26, 1975

MEMORANDUM FOR THE PRESIDENT

FROM: PHILIP W. BUCHEN P.W.B.

SUBJECT: Inaugural Medal Committee

On August 11, Senator Hatfield, Chairman of the Inaugural Medal Committee, forwarded to you a final accounting of royalty payments from the sale of inaugural medals (see Tab A). These payments from the Franklin Mint and the Medallic Art Company total approximately $97,000.

In a subsequent letter dated September 18, Senator Hatfield sought your reaction to the Committee's tentative determination to use the proceeds to sponsor an International Conference on Breast Cancer (see Tab B). The Conference was suggested to the Inaugural Committee by the National Cancer Institute (National Institutes of Health) and would be similar to a conference held in September 1974.

Additionally, in his letter, Senator Hatfield noted five breast cancer projects which had been identified earlier by the National Cancer Institute as meritorious. However, in light of the amount of the royalty payments and the lack of continuity of funding, these five projects are less desirable than the proposed International Conference.

Below are appropriate options for you to mark indicating your reaction to the Committee's preliminary determination. I will inform Senator Hatfield of your reaction, and I will suggest that any announcement of the final determination be made by the Committee.

Favor (an International Conference on Breast Cancer _____

Do not favor _____

Other project _____

In order for you to express appreciation for the Committee's efforts, an appropriate letter to each member of the Committee has been prepared for your signature by the Editorial Office. I recommend that you sign these letters in Tab C.

MARK O. HATFIELD
OREGON

United States Senate

WASHINGTON, D.C.

August 11,1975

Mr. William E. Casselman III
Counsel to the President
The White House
Washington, D.C. 20500

Dear Mr. Casselman:

In accordance with our earlier telephone contact, I am enclosing the final accounting for royalties from the Medallic Art Company and Franklin Mint.

Incidentally, the royalty payments from Franklin Mint have not been sent to the committee, as indicated in the letter. These payments along with those from Medallic Art will be paid directly to the designated charity or charities under the direction of the Inaugural Committee. The amount of total royalties, however, is accurate.

If you desire any other information, please do not hesitate to let me know.

With kindest regards.

Sincerely,

Mark O. Hatfield
United States Senator

MOH:scs
Enclosures

THE FRANKLIN MINT

FRANKLIN CENTER, PENNSYLVANIA 19063

March 27, 1975

Senator Mark O. Hatfield
Chairman
Inaugural Medal Committee
Washington, D. C.

Dear Senator Hatfield:

On January 31, 1975, we forwarded a preliminary royalty check of $23,745 to you from sales of the Official Gerald R. Ford Presidential Inaugural Plate Program.

Now that the final accounting is completed, I am pleased to enclose a supplemental royalty check of $605.

Again, let me say that The Franklin Mint has been proud to participate in this important program.

Sincerely yours,

Charles L. Andes
President

THE FRANKLIN MINT

FRANKLIN CENTER, PENNSYLVANIA 19003

Statement of Royalties Due

As of February 23, 1975

Sales Program: The Official Gerald R. Ford Inaugural Plate

Contract Date: October 10, 1974

Solid Sterling Silver Inaugural Plate "Gross Receipts Realized"	$226,000.00	
Total Royalties earned at 10%		$22,600.00
Solid 18 Karat Gold Inaugural Plate "Gross Receipts Realized"	$ 35,000.00	
Total Royalties earned at 5%		$ 1,750.00

Less: Royalties previously paid by The Franklin Mint

Check No.	Date	Amount	
2322	01/30/75	$23,745.00	(23,745.00)

Total Royalties due the Inaugural Medal Committee $ 605.00

Check No. 2488 Date: 3/20/75

Sales Accounting
March 17, 1975

MEDALLIC ART COMPANY
OLD RIDGEBURY ROAD · DANBURY, CONN. 06810 · (203) 792-3000

August 6, 1975

~~American Cancer Society~~

Gerald Ford - Presidential Inaugural Medal Sales

Accounting for Sales thru June 30, 1975

Silver Sales	468,098.05		
Bronze Sales	86,188.07		
	554,286.12		
Royalty Due 10%			55,428.61
Gold Sales	391,363.00		
Royalty Due (See Attached)			17,667.08
			73,095.69
Less Sets @ No Charge			
ANA		198.00	
Smithsonian		198.00	
Less Medals to:			
Pres. Ford (21/2 "14K)		506.00	
Mrs. Ford (1 1/4" 18K)		147.00	
Less Medals to Inaugural Medal Committee			
Silver Content 55.66to		255.48	
10 @ $10.00		100.00	1,404.48
Total Royalties Due			71,691.21

MEDALLIC ART COMPANY

OLD RIDGEBURY ROAD · DANBURY, CONN. 06810 · (203) 792-3000

August 6, 1975

Royalties on Gold Medal Sales

Gold Cost: Shipment #1 195.50
Shipment #2 177.75
Shipment #3 184.05

557.30 = $185.76 Avg. Spot per T.O.

1 Medal = 3/4 t.o. fine gold = $185.76 @ .75 = $139.32

Sold				Gold Cost	Net	10%
26	@	$395	10,270	3622.32	6647.68	664.77
227	@	375	85,125	31625.64	53499.36	5349.93
514	@	237	121,818	71610.48	50207.52	5020.75
774	@	225	174,150	107833.68	66316.32	6631.63
			391363.00	214692.12	176670.88	17667.08

MARK O. HATFIELD
OREGON

United States Senate

WASHINGTON, D.C.

September 18, 1975

The President
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Attn: Mr. Jay French
Assistant Counsel

Dear Mr. President:

I am writing to recommend a recipient for the royalties realized from the sale of the Ford Presidential Inaugural medal and plate.

During our meeting on December 10, 1974, you indicated a desire to donate at least the first $100,000 of royalty proceeds from the inaugural medal towards research in breast cancer. In response to our discussion, I contacted the National Cancer Institute in an effort to identify specific projects which needed additional funding. Then in the latter part of February, I sent you a summary of five specific breast cancer projects which were outlined by Dr. Frank J. Rauscher, Jr., of the National Cancer Institute.

I now have a final accounting of the royalties from both the Medallic Art Company and The Franklin Mint. The total amount of the proceeds is $97,000. In view of this figure, I recontacted the National Cancer Institute. They still feel that the five projects which were originally recommended are highly meritorious. Due to the amount of the proceeds available and to the lack of continuation of funding, however, they suggest that the funds be used to sponsor an International Conference on Breast Cancer. I would also like to recommend that the proceeds be used to sponsor this conference. As the enclosed material from NCI indicates, such a conference would be timely and greatly beneficial in educating both professionals and the public.

I hope that this additional information along with my suggestion will be of assistance to you. If you feel that this conference should receive our support, please let me know. The committee will be available to announce the designation of the recipient or to help in any other way. In any event, should you desire any more information, please don't hesitate to contact me.

Sincerely,

Mark O. Hatfield
United States Senator

MOH:scs

It is proposed that proceeds from the sale of President Ford's inaugural medals be used to sponsor an International Conference on Breast Cancer to be held in Washington, D.C. and sponsored by the National Cancer Program, National Cancer Institute. Breast cancer is the number one cancer killer of women throughout the United States and the world. There have been recent scientific advances in the early detection, diagnosis and treatment of breast cancer that warrant widespread dissemination throughout this country and the world. A similar, though smaller, conference was held on the NIH campus in September, 1974, entitled Advances in Breast Cancer--A Report to the Profession (Attachment). This conference was well received and highly publicized. Scientific knowledge has continued to accrue such that a larger, international conference would be both timely and meaningful in educating both lay and professionals in these advances. Such a conference would serve to partially fulfill our international mandate under the National Cancer Act of 1971 and 1974 and would foster our formal and informal bilateral agreements with the USSR, Japan, France, Germany, Poland, Egypt, etc. The Conference would add to the humanitarian attitude of this Nation on behalf of all nations who share the human destruction caused by breast cancer. It is suggested that Mrs. Betty Ford, Mrs. Happy Rockefeller, and other lay leaders, be invited to participate in the conference.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

NATIONAL CANCER INSTITUTE
PRESS SUMMARY

September 30, 1974

FOR RELEASE Tuesday, Oct. 1, A.M.'s

For further information
Contact William S. Gray
Robert M. Hadsell
(301) 496-6641

A Report to the Profession from the Breast Cancer Task Force

Breast cancer is the major cause of death due to cancer among women in the United States. This year there will be an estimated 89,000 new cases and 32,500 deaths from breast cancer in this country.

Because of this grave health problem and because the extent of traditional surgical treatment for the disease has been questioned, a sustained effort has been mounted by the National Cancer Institute's Breast Cancer Task Force to improve the diagnosis and treatment of this dreaded disease.

What has emerged from this effort and will be reported today, is a significant step forward in earlier diagnosis and more effective treatments for both localized and advanced disease. It should be emphasized that these findings are tentative and do not, by themselves, represent major breakthroughs. More time and more study will be needed to document long-term results and to improve our techniques.

However, it should also be emphasized that encouraging trends have emerged from enough different studies to justify confidence in the preliminary findings. In short, we know that it is best to find breast cancer in its earliest, and therefore most curative stages. In cooperation with the American Cancer Society, we have demonstrated a significant

improvement in our capability to accomplish this goal. At the same time there is preliminary evidence that more effective treatments have been developed for both early and advanced disease. If this evidence is sustained by the passage of time, and we have confidence that it will be, it should be possible to improve substantially both the cure and survival rates from cancer of the breast, and with less disfiguration than results from radical mastectomy.

BREAST CANCER DETECTION

Early detection of breast cancer before it has spread to other parts of the body increases a patient's chance for long-term survival and cure. Patients whose axillary (armpit) lymph nodes are free of cancer (negative nodes) at the time of breast cancer diagnosis have a 5-year survival rate of about 75 percent, and about 65 percent of these patients are alive after 10 years. In contrast, women with breast cancer in the axillary nodes (positive nodes) have a 5-year survival rate of about 50 percent, and only about 25 percent will live 10 years.

In the U.S. at present, patients have negative, cancer-free nodes in about 45 percent of newly-diagnosed breast cancer cases. A real hope that this rate may be improved--with a corresponding increase in survival rates--comes from the breast cancer screening demonstration program sponsored jointly by the ACS and the National Cancer Institute. Dr. William Pomerance, Chairman of the Breast Cancer Task Force's Diagnosis Committee, reported that about 75 percent of the women with breast cancer, detected so far by the screening program, had negative nodes.

The ACS-NCI program involves 27 breast cancer screening projects, where up to 270,000 women of ages 35 years and older will be screened annually with a physical examination, X-rays (film mammography or xeroradiography), and thermography. The first projects established began screening women in mid-1973; all 27 centers will be operating by the end of 1974. About 75,000 women have been screened to date. When comprehensive data have been compiled, it is expected that about 775 breast cancers will have been detected among these women, a rate of 10.5 cases per 1,000 women screened, or about 1,000 cases per 100,000 women screened.

The combination of physical examination and X-ray mammography in breast cancer screening has been shown to decrease breast cancer death rates. A group of 31,000 women screened for breast cancer by the Health Insurance Plan of Greater New York in a NCI-supported study have had a one-third reduction in breast cancer deaths over a 5-year follow-up period as compared with 31,000 women given their usual comprehensive medical care in their medical groups. One-third (44 out of 132) of the breast cancers detected in the screening program were found by X-ray mammography before the tumors were large enough to be detected physically. Only one of these 44 women died of breast cancer during the 5-year period, indicating that early detection led to substantially more effective treatment.

BREAST CANCER TREATMENT

Breast cancer presents usually as disease limited to the breast and axillary nodes without clinical evidence of metastatic disease. Surgery has been the main weapon against cancer of the breast for the past six or more

decades. The standard approach to surgery has been radical mastectomy. Radical mastectomy means removal of the breast, underlying pectoral muscles and axillary lymph nodes. Recently, less radical procedures have been recommended, but supporting data from controlled clinical studies has not yet been available in the United States.

Primary Breast Cancer

Dr. Bernard Fisher of the University of Pittsburgh, Chairman of the National Surgical Adjuvant Breast Project (NSABP), has directed a large clinical study involving surgeons, radiotherapists and pathologists at 34 institutions attempting to determine the optimal treatment for primary breast cancer. This study, supported by NCI grants and the Breast Cancer Task Force, has involved 1,700 patients.

For patients with operable disease limited to the breast, the study compares radical mastectomy, total mastectomy (removal of breast only) and total mastectomy plus radiation therapy to the chest. For patients whose disease involves the breast and axillary nodes, radical mastectomy is compared with total mastectomy combined with postoperative radiotherapy.

The results after two years indicate that in each group the various options are essentially equivalent. Thus, for disease limited to the breast, a total mastectomy with or without radiation therapy is equivalent to the radical procedure. For patients with disease in the breast and axillary nodes, total mastectomy with postoperative radiotherapy is equivalent to radical mastectomy. While the long-term follow-up data necessary to obtain survival characteristics are not yet available from this study, similar trends from early stages of

other studies have been borne out by long term follow-up and are thus considered predictive. The major impact of these results is to provide scientific information for practicing surgeons to determine the most effective type of operation for each patient and, in addition, to set the stage for planned clinical studies of less surgery (segmental mastectomy), a procedure where only part of the breast is removed.

Early Chemotherapy

Historically more than 50 percent of breast cancer patients die with metastatic disease. Previous studies have indicated that the presence of cancer in the axillary nodes carries a dire prognosis. More than 75 percent of patients with one or more positive nodes will have recurrent disease at 10 years and most of the patients will die of their disease. Thus, the presence of axillary gland involvement predicts the presence of metastatic disease.

To combat this clinical situation a second study, sponsored by the Breast Cancer Task Force and done jointly by the NSABP and members of the Eastern Cooperative Oncology Group and the Central Oncology Group, is investigating the addition of postoperative systemic chemotherapy in women who have had modified or radical mastectomy and shown to have positive axillary nodes. To date 250 patients have been entered on a double-blind randomized study receiving either a placebo or L-phenylalanine mustard (L-PAM), an oral anticancer drug, for five days by mouth every six weeks for two years.

The study has been underway about 24 months and involves 37 institutions. Data concerning the results of the study to date, presented by Dr. Fisher, have been analyzed independently by Dr. Carole Redmond of the University of Pittsburgh and Dr. Marvin Zelen of the Statistical Laboratory of the University of New York at Buffalo. The data indicate that the recurrence rate is significantly reduced for women receiving the L-PAM. This was particularly striking for women who were premenopausal where only 1 of 30 patients receiving L-PAM recurred, whereas 11 of 37 recurred after surgery alone. The investigators have recommended that the study be terminated for the premenopausal group of patients because of these dramatic results. For postmenopausal patients the failure rates are also reduced in the L-PAM treated group, but not as markedly. For this reason, that part of the study involving postmenopausal women is under further review.

Dr. Paul P. Carbone, Chairman of the Breast Cancer Task Force Treatment Committee, also reported that similar studies employing combination chemotherapy regimens are being done at the National Cancer Institute of Milan, Italy, the Mayo Clinic, the University of California at Los Angeles, and the Cleveland Clinic. The study at the Milan Cancer Institute has accrued 100 patients who are receiving the three-drug combination of cytoxan, methotrexate and 5-fluorouracil. Results are consistent with the L-PAM study.

The importance of these postoperative chemotherapy trials is that patients with breast cancer and axillary node metastasis can receive drug therapy to treat the subclinical metastases before they become

clinically obvious and lethal. From two previous clinical studies and from experimental data in animals, this combined approach of surgery and chemotherapy offers the best chance of survival.

The L-PAM treatment is a simple program with minimal side effects and can be widely used. With these encouraging results Dr. Fisher and the NSABP investigators are planning an additional study using a two-drug combination and a combination of L-PAM with C. Parvum, an immuno-stimulant.

Advanced Disease

Dr. Carbone reported preliminary results from several other studies of patients with metastatic disease indicating that combinations of drugs are more effective than single drugs. In a study sponsored by the Eastern Cooperative Oncology Group a three-drug combination produced 53 percent response (shrinkage of tumor by 50 percent or more) as compared to 19 percent with L-PAM alone. Patients receiving the combination regimen had more complete responses and longer survivals than patients treated with the single agent.

Similar improved results with combination therapy are reported in a study by Dr. David Ahmann and his co-workers at the Mayo Clinic. Drs. John Horton, the Albany Medical College of Union University, and Thomas Dao, Roswell Park Memorial Institute, have reported improved results with the combination chemotherapy of cytoxan, fluorouracil and prednisone as compared to adrenalectomy and adriamycin alone.

Dr. Douglass Tormey and co-workers at the National Cancer Institute, have demonstrated improved results by incorporating adriamycin into a three-drug combination using cytoxan and fluorouracil.

In several ongoing research studies, immunostimulants such as BCG and C. Parvum are being added to chemotherapy to determine whether treatment results can be improved.

While management of the advanced disease patients has improved, the likelihood of eliminating all cancer cells is highest when the numbers of cancer cells are small. This is most likely to occur when the patient first presents with cancer. An objective of the Breast Cancer Task Force is to develop therapeutic programs utilizing effective local treatment in combination with safe, easily administered systemic anticancer drug combinations.

Hormone Receptors

Removal of the ovaries in premenopausal women and the removal of the adrenals or pituitary are forms of breast cancer therapy to which approximately 30 percent of women respond. Administration of androgens or estrogens can also induce tumor regression. These responses occur in 20 to 40 percent of patients.

Dr. William McGuire, of the University of Texas at San Antonio and member of the Breast Cancer Task Force Treatment Committee, described the role of hormone receptors (specific cell proteins) in predicting response to these endocrine treatments for breast cancer. The laboratory determination of whether an individual patient has a hormone receptor can be used to predict whether she will respond to hormone therapy. The importance of this test is that it differentiates between patients who would benefit from hormone therapy and those who would not. These latter patients can then be placed on other therapies without delay.

Approximately 50 percent of biopsies of breast cancer are found to contain the receptors. The response rate to endocrine treatments by patients with positive endocrine receptor (ER) tests was markedly higher than that in ER negative patients. For ER positive patients 52 percent responded compared to 4 percent responses in patients who were ER negative. Thus the estrogen receptor assays can be helpful to predict the results of endocrine therapy and increase the likelihood of predicting response. The challenge of the future is to incorporate endocrine therapy into the treatment strategy with chemotherapy for those patients who are ER positive. For the ER negative patients two approaches appear possible. These patients can be treated directly with non-hormonal methods obviating the delay of less effective measures. Secondly, there may be ways to uncover or alter the hormone receptors to make them sensitive.

Several studies are being sponsored by the Breast Cancer Task Force to combine hormonal approaches with chemotherapy. Two studies, one at the Mayo Clinic and the other through the Eastern Cooperative Oncology Group, are studying ways to combine combination chemotherapy with oophorectomy in premenopausal women. Another approach being done at Emory University by Dr. Charles Vogel combines estrogens with a three drug combination of cytoxan, fluorouracil and adriamycin.

Dr. Tormey, Chief of the NCI Medical Breast Cancer Service, reported on studies of biologic markers--substances found in the blood or urine that correlate with the presence of tumor. Ideally, levels

of these substances should correlate with the amount of tumor in the patient and change in parallel with the response of tumors to therapy.

Out of eight biologic markers tested, three, human chorionic gonadotrophin (HCG), carcinoembryonic antigen (CEA), and a transfer RNA nucleoside (N^2N^2-diemthylguanosine), were found to be present in abnormal amounts. Using these markers, 63 patients (97 percent) in a group of 65 were found to have abnormal levels of at least one of these markers. In a group of 15 post-operative patients found to have positive nodes, 10 (67 percent) had elevated levels.

SUMMARY

At the present time, the two-year report from the Breast Cancer Task Force indicates that less than radical surgery is acceptable for the treatment of primary breast cancer. Moreover, the trends of other studies involving surgery and chemotherapy for women with breast cancer and positive axillary nodes show that the recurrence rate can be significantly reduced. This in turn indicates that we can successfully treat sub-clinical metastasis. The advances in the treatment of early and advanced breast cancer, coupled with progress in earlier detection and diagnosis, should lead to significant improvements in cure rates and survival.

It should be emphasized that this report does not include results from other research studies conducted by the NCI, cooperative groups and individual institutions.