

PROGRESS REPORT

Contract for: Research Services directed toward the development  
of a combined agent for Disease Prophylaxis and Contraception.

Contract No. AID/csd - 2822

July 15, 1973

January 1, 1973 - June 30, 1973

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REPORT SUMMARY

- A. 1. Research Services Directed Toward the Development of a Combined Agent for Disease Prophylaxis and Contraception - AID/csd - 2822
- 2. Principal Investigator: John C. Cutler, M.D., Director, Population Division  
Contractor: Graduate School of Public Health, University of Pittsburgh  
Mailing Address: Fifth & DeSoto Streets, Pittsburgh, PA 15261
- 3. Contract Period: (as amended) June 30, 1970 to June 30, 1975
- 4. Period covered by Report: January 1, 1973 to June 30, 1973
- 5. Total A.I.D. funding of contract to date: \$ 581,198
- 6. Total expenditures and obligations to date: (6/70 to 6/73) \$ 385,356
- 7. Total expenditures and obligations for reporting period: (1/73 to 6/73) \$ 80,015
- 8. Estimated expenditures for next six months: (7/73 to 12/73) \$ 84,110
- 9. Budget available end of original contract period: \$ 195,842

B. Narrative Summary of Accomplishments and Utilization

- 1. During the present reporting period, the principal accomplishments have been:
  - (a) Acquisition of participants for the initial human field trial at Allegheny Health Department; (b) A new agreement with Magee Women's Hospital for access to all morbidity reports sent to Allegheny County Health Department of positive female gonorrhoea cases from their Medical Care Center to increase the number of Pro-Con patient acquisition; (c) Arrangements for identification of possible participants with Black Action, Inc., Mercy Hospital, Manchester Health Center and West Penn Hospital; (d) Budget and proposal submitted for extension of project to complete Pittsburgh field trial; (e) Bill submitted to Pennsylvania legislature proposing that it be legal for minors to give effective consent for participation in human experimentation; (f) Completion of administrative and laboratory work projected in annual progress report 1972.
- 2. Principal accomplishments prior to this reporting period include:
  - (a) Collection of baseline data; (b) Laboratory assay of products to identify most active products to field test; (c) Development of statistical models for selecting best products to test and determining degree of effectiveness for significant impact on rising venereal disease rates; (d) Development and approval of experimental design, field protocol, and all data forms by A.I.D., Committee on Research Involving Human Volunteers, Graduate School of Public Health, and Allegheny County Health Department; (e) Approval of I.N.D. for Conceptrol and Cooper Creme by F.D.A.; (f) Field trial with first product, Conceptrol, begun July 1, 1972; (g) Submission of a proposal for extension of time and funding to complete the investigation.

A. General Background

Various factors such as penicillin, a high degree of public interest, the condom, and public health programs helped decrease venereal disease rates after World War II. As the venereal disease rates declined, however, there ensued a serious decline in medical and public interest, as well as in government funding for research. As a result of this declining interest, we are again faced with rapidly rising rates of venereal disease throughout the world. The increase in venereal disease rates combined with steadily rising numbers of unwanted pregnancies presents one of the major world-wide public health problems today.

In view of the fact that both unwanted pregnancy and venereal disease are often the result of unprotected or casual contact, it is felt that an intravaginal precoital preparation offering protection to the female from venereal disease and pregnancy, as well as to the male from venereal disease, would significantly complement existing contraceptive and venereal disease control techniques. Such a preparation, which could be used alone or in conjunction with other types of contraceptive agents, which would not require medical prescription or intervention, and which would be readily available regardless of age, would appeal to a large number of the sexually active and promiscuous population whose major concern is self-protection. This preparation could be promoted effectively for wide distribution and could be incorporated into existing VD and family planning programs as well as other public health programs, with a high probability of utilization.

Although prophylactic treatment is accepted in many parts of the world, little systematic evaluation of mechanical, chemical or antibiotic agents as a means of preventing venereal disease has been made in recent years. It is hypothesized that a dual-purpose intravaginal agent can be developed through research by identifying existing contraceptive products that have a dual action, and also by combining substances which are effective as local prophylactics against syphilis and gonorrhoea with substances that are effective as intravaginal contraceptives.

B. Statement of Project Objectives as Stated in the Contract

This progress report, the sixth such report since the contract was awarded on July 1, 1970, covers the period from January 1, 1973 through June 30, 1973.

The objective of this project is to identify or develop a preparation for intra-vaginal pre-coital use which will offer protection to the female from both pregnancy and venereal disease and to the male from venereal disease. Under the terms of this contract, the project proposes to accomplish its objectives by means of: (1) Laboratory screening to assess in vitro, the effectiveness of vaginal contraceptive preparations against T. pallidum, N. gonorrhoeae, C. albicans, and T. vaginalis; (2) Clinical field trials on the high-risk population to assess the use effectiveness of selected preparations based on the laboratory results; (3) Widespread field trials to involve personnel and institutions of other countries, as well as of the United States, to assess the application of the products in the general population.

### C. Continued Relevance of Objectives

Data from both the United States and World Health Organization continue to show a world-wide rise in venereal disease. "Today's VD Control Problem 1973" published by the American Social Health Association states that gonorrhea, the most frequently reported communicable disease, continued to increase in FY 1972 and reached a total of reported cases nearly double that of five years ago. (At the same time, in no country has there been an abrupt decline in birth rates related to family planning or population programs).

In the recent report of the National Commission on Venereal Disease to the Secretary of the Department of Health, Education, and Welfare, particular attention has been paid to the importance of cooperation between venereal disease and family planning programs with respect to prevention. Both the condom and possible chemical prophylactic-contraceptive preparations have been singled out in this regard.

House Resolution 14455-Communicable Disease Control Program was passed by both Houses of Congress amending the Public Health Service Act. The resolution authorizes the Secretary of HEW to make grants for control programs relating to venereal diseases from the \$35-40 million appropriated for that purpose in 1973.

Bills have been introduced to the Pennsylvania legislature which would amend the Public School Code to require a course of study in venereal diseases in public junior and senior high-schools.

Thus it would appear that the concept accepted by A.I.D. in funding this study has been fully recognized by experts and workers in the venereal disease field, as well as by the federal government. With official increased interest and acceptance of this concept by the United States, the prospect of international acceptance of a combined prophylactic-contraceptive product as another tool for venereal disease programs appears to be enhanced should clinical studies validate the hypothesis.

D. Accomplishments to Date

1. Findings

Administrative - (1) Agreement with Black Action Inc., Mercy Hospital, Manchester Health Center, West Penn Hospital, and Miner's Clinics for identification of possible participants; (2) Revision of agreement with Magee Women's Hospital for access to State Morbidity Reports for more accurate identification of possible participants; (3) Drafting of a proposed bill with University Council for access to 18-20 year-old females for medical investigations to be submitted in Harrisburg; (4) Acceptance of proposal for an extension of original contract to complete local field trial with one product; (5) Reduction of Pro-Con Staff in accordance with terms of approved contract extension; (6) Continued negotiations with pharmaceutical companies - Ortho, U.S. Vitamin, Micro-Therapeutics, Whittaker and Pfizer, for possible funding to conduct overseas field trials that had been previously arranged.

Laboratory - (1) Completion of experimental work in vitro tests under original contract; (2) Improvement of technique for the making of, delivery of, and pickup of culture plates from various sites where participants are being re-examined; (3) Completion of in vivo rabbit experiments initiated under original contract; (4) Continuing of contacts with laboratories in various sites where participants are being identified for estimates of future possible participants from positive diagnosed cases; (5) Provision of diagnostic services and laboratory support for the field trial for participants who are regularly screened for genital infections with microorganisms such as Neisseria, Candida and Trichomonas as well as Syphilis Serology according to the field protocols.

Field - (1) Development of an instruction manual for personnel in other field trial sites; (2) Submission of first report to F.D.A. on progress of the local field trial (Appendix A); (3) Continuing revisions in patient tracking and identification to increase the number of possible participants; (4) Made revisions in data forms to obtain more meaningful information. (Appendix B); (5) Initiated reexaminations in Manchester Health Center to accommodate women not having access to the Allegheny County Health Department clinic; (6) Initiated reexamination procedure in Pro-Con physician's private

office to accommodate women not having access to Manchester or Allegheny County Health Department clinics; (7) Began to contact by telephone positive patients who do not return to clinics for smear and cultures to confirm success of treatment; (8) Began talking to all girls with second possible infections at Allegheny County Health Department prior to diagnosis in order to increase the number of girls who return for results, repeat smears or cultures; (9) Negotiated with several area hospitals (West Penn, Mercy and Allegheny General) to obtain participants from their clinics; (10) Found it feasible to hold field trial clinics with partial assistance from project physician ~~when he is busy with emergencies;~~ (11) Talked with girls who will be 21 within the next six months who are otherwise eligible for project so that they might return when they are 21 and join the project.

## D. 2. Interpretation of Data and Supporting Evidence

Clinical attendance at the Allegheny County Health Department Venereal Disease Clinic for this reporting period totaled 3343 female visits. Of these visits, 971 were for reasons not related to venereal infection i.e. pre-marital blood tests, etc., 1096 were second or third visits by the same women for repeat smears and cultures for confirmation of treatment or for results, and 1275 were actual first visits for a new possible venereal infection.

Of the total first visits for a new possible venereal infection, 692 or 54.27% were over 21 years of age, 333 or 26.11%, 18-20 years of age, and 250 or 19.60% were under 18 years of age. Of this group of women, 191 or 27.60% of the women over 21, 72 or 21.62% of the 18-20 year olds, and 47 or 18.80% of the under 18 year-olds had a history of at least one past infection. Of the total past infections, 99 or 51.83% of the over 21 year old women, 38 or 52.77% of the 18-20 year olds, and 27 or 57.44% of the under 18 year olds experienced their infection in the prior twelve months. Five of the six girls who were interviewed and refused to participate did so because they were not able to keep the required regular appointments; and one refused because she did not want to enter the study. (Appendix C).

During this reporting period, four participants dropped out of the study: two of the drop-outs were due to re-infection and were re-entered after successful completion of antibiotic therapy, and two never returned for reexamination and could not be contacted.

As of June 29, there are 29 cases in the study on whom data is being collected.

### D. 3. Research Design

Possible modifications of the research design are:

- (1) Inclusion of patients under 21 years of age in the field trials when laws governing legal age to give effective consent are revised;
- (2) The possibility of variations in procedure based on local conditions at field trial sites;
- (3) The possibility of changes in regard to the requirements for use of the oral contraceptive and IUD method of preventing unwanted pregnancies;
- (4) Interviewing of clinic patients with first confirmed infection to determine their attitude toward the study and possible future participation, with the hope of encouraging them to return to the clinic the next time they suspect an infection;
- (5) Multi-site field trials to use aggregate data collected as support of claim to F.D.A. for approval of the new indication of V.D. prophylaxis;
- (6) The use of proven high-risk sexually active females as participants (i.e., prostitutes).

E. 1. Dissemination and Utilization of Research Results

Every effort has been made by the Pro-Con Group to disseminate the results of the research findings. These findings have been presented to:

- (1) American Public Health Association 1971 and 1972
- (2) National Commission on Venereal Disease 1972
- (3) International Union Against the Venereal Diseases and the Treponematoses (Venice) 1972
- (4) First and Second International Venereal Disease Symposiums (St. Louis) 1971, 1972
- (5) Population Club (Hawaii) 1972
- (6) American Society of Microbiology (Philadelphia) 1972
- (7) W.H.O. Regional Office (Copenhagen) 1971
- (8) Pittsburgh Public School System and Parochial School System, 1973 - Seminars as part of instructional programs (Allegheny County Health Department)
- (9) Lectures of American and Foreign students of Graduate School of Public Health, University of Pittsburgh and surrounding colleges
- (10) Professional staff of local hospitals, health centers and free clinics
- (11) Exchange of Pro-Con scientific information via Neisseria Treponema Scientific Memoranda NIAID (NIH) - 2 contributions, 1973

In addition, results of laboratory testing have been supplied to all cooperating pharmaceutical companies concerning the antimicrobial activity of their product.

- (12) American Association of Planned Parenthood Physicians (Houston) 1973
- (13) American Social Health Association (New Orleans) 1973
- (14) Indiana State Physicians Association (Indianapolis) 1973

E. 2. Findings of the research project to date, in vitro results, cannot be directly applied to human response, and the preliminary results from the initial field trial do not allow for any conclusions at this time. Therefore, evidence to date has not been directly applied to the problem in the U.S.A. or L.D.C.'s. However, there has been recent interest stimulated by our research project in the application of Pro-Con findings in various areas: (a) The Commander of the U.S. Army 43rd Surgical Hospital near Uijcongbu, Korea has expressed an interest in the possibility of a study among the military forces and local population near the base; (b) Dr. Ferdinand Pauls, Kinshasa, Zaire, has indicated a need to reduce the incidence of gonorrhoea among patients attending the Mama Yemo Hospital Child Health Service; (c) Pharmaceutical companies have been in contact with the Pro-Con Project discussing field and laboratory testing of various products (Emko, U.S. Vitamin, Purdue-Frederick, Ortho, Gynechemic, Whittaker, Searle, and Dow); (d) Jamaica and Guatemala show continued interest in initiating field trials in their areas to attempt to control the V.D. problem. (Appendix D).

E. 3. Experience of the past years points out the need for educational and motivational material on V.D. prophylaxis for those sexually active individuals at risk. Plans for the field trial call for the development of appropriate educational and motivational material including information on prophylaxis as well as recognition of symptoms, and how and where to obtain treatment. This material will be directed toward the various population segments at risk.

Preliminary work in this area has begun and can be carried out under current provisions of the contract. It is expected that the Allegheny County Preventive Medicine Clinic and the American Social Health Association will be helpful in this endeavor, as well as in assisting with incorporation of the developed programs into existing school programs and existing venereal disease educational and motivational materials.

Little is known concerning attitudes and preferences toward creams, jellies, foams, suppositories and foaming tablets as intravaginal contraceptives. The Allegheny County Health Department field trials could be utilized to test different dosage forms to evaluate the acceptance factors of different delivery systems.

Our experience in the clinic, while limited to females, has brought to light the problem presented by the asymptomatic male. The research project could be expanded to define the scope of the asymptomatic male contribution to the V.D. epidemic.

E. 4. Under the original contract plans were to involve LDC personnel and institutions in at least two sites - Jamaica and Guatemala. Due to delays encountered in initiating the first local field trial, and slower than projected acquisition of participants, it became necessary to request an extension of funding to initiate and complete overseas field trials.

The proposed extension was reviewed by the R.A.C. review committee in March, 1973, and approval was granted to complete only the local field trial using one product. Since funding was not granted for additional overseas field trial sites, present plans do not include involvement of LDC's.

#### F. Statement of Expenditures and Obligations and Contract Resources

The most significant problem related to the Pittsburgh field trial continues to be slower-than-projected acquisition of patients. At present, possible participants for the trial must be 21 years of age or older to give effective consent for participation. However, a bill is pending in the state of Pennsylvania which might possibly lower the age to 18, which would increase the size of the sample for this project. In addition to this age restriction, a number of the women attending the various clinics used for participant identification do not give their correct name, address and phone number, which makes it impossible to contact them about the project after they have been identified. In an effort to counteract this problem, assistance from additional clinics has been obtained to increase the overall number of possible participants.

The clinic staff of the project is making further efforts to work out new methods of patient relationship and motivation which may provide interest in entering the project and then maintain cooperation for the entire study period.

Expenditures for the next reporting period reflect the revisions made in the contract extension. Specifically, budgeting for foreign field trials has been eliminated, and personnel costs lowered due to reductions in the core staff needed to complete the Pittsburgh field trial.

Expenditures and Obligations to Date

June 30, 1970 - June 30, 1973

Salaries		\$ 180,540
Fringe (13.1)		23,651
Local Hire of Foreign Nationals		---
Consultants		1,238
Travel & Transportation		6,570
Other Direct Costs		2,674
Telephone	\$1,056	
Postage	93	
Participants	1,106	
Publication	419	
Subcontract		---
Equipment, Material & Supplies <sup>1/</sup>		42,201
Expendable	\$30,192	
Non-expendable	12,009	
Total Direct		256,874
Indirect		128,482
GRAND TOTAL		\$ <u>385,356</u>

<sup>1/</sup>Includes maintenance

### G: Work Plan and Budget Forecast for Coming Six Months

Under provisions of the approved amendment to the original contract, the work plan for the coming six months is to maintain the cooperation of the participants presently in the trial and to further increase the rate of participant acquisition. To increase the rate of participant acquisition, contacts will be made with additional hospital clinics for cooperation, and with private physicians in an effort to gain their confidence and cooperation.

All laboratory back-up for the reexamination of the participants in the project will be continually performed. All measurable results from the field trial will be disseminated as widely as possible to the scientific community by means of articles in appropriate journals and by presentations at scientific meetings.

## Proposed Planned Expenditures

July 1, 1973 - December 31, 1973

Salaries and Wages		\$ 40,263
On Campus	\$25,363	
Off Campus	14,900	
Fringe (13.1)		5,275
Consultants		625
Travel and Transportation <sup>1/</sup>		475
Other Direct Costs		6,400
Telephone	\$ 250	
Postage	125	
Participants	5,875	
Publication	150	
Equipment and Supplies <sup>2/</sup>		5,568
Expendable	\$2,468	
Non-expendable	3,100	
Total Direct Costs		58,606
Indirect Costs		25,504
On Campus	\$ 17,830	
Off Campus	7,674	
GRAND TOTAL		\$ <u>84,110</u>

<sup>1/</sup>Includes local travel<sup>2/</sup>Includes maintenance & repairs

## APPENDIX A

Progress Report of Clinical Investigation  
I.N.D. 8788 - April 27, 1973

The clinical field trial to investigate the potential prophylactic value of Conceptrol Cream against venereal disease in the Allegheny County Health Department Venereal Disease Clinic was begun August 15, 1972, when the first patient agreed to participate in the project. The following four charts describe the participants in the project, drop-outs, side effects and infections encountered while on trial. Forty-seven women who met the criteria for participation have been interviewed. Of these women, twenty-nine agreed to participate and eighteen refused. At this time, ten test patients and ten control patients are on trial; their date of entry into the study and the length of stay with the project to date are given in Chart I. Nine women who agreed to participate have dropped out of the project for various reasons shown in Chart II. The majority of drop-outs have occurred within the first month on trial.

Side effects encountered during the trial in all cases were slight to moderate and were self-limiting after the first few weeks. However, each time the participants complained of itching and burning, it was found upon culture that a trichomonas and/or yeast infection was present. No side effects in the male partner have been reported by the participants; however, some of the males have complained of the cream being messy. This information is in Chart III.

The number of reinfections in both groups is shown in Chart IV. By chance, the results of a natural exposure to an infected male partner are part of the project data. Participant #156486, a test patient, and participant #053890, a control, both had intercourse with, and were named contacts by the same male. The test patient who used the cream prior to intercourse did not become infected while the control patient did become positive upon culture. In addition, participant #150368,

a test patient, became infected while in the trial. Prior to her positive culture, this patient reported during her routine interview that she suspected she had been exposed to an infected male. Upon interview after her culture was positive, this patient reported that she had not used the cream for each sex act, had intercourse longer than one hour after application of the cream, and in general had not used the cream as directed with this partner. It is felt that this infection most probably represents a patient failure (incorrect use of the product) rather than a product failure.

While the initial acquisition of patients was slow, improvement of interviewing technique, handling of patients, and identifying possible participants has increased the rate of acquisition and the trial is progressing satisfactorily. To date 108 aggregate women-weeks of exposure have been completed for the test group and 98 aggregate women-weeks of exposure for the control group.

Unless information is requested sooner, it is planned to submit the next progress report in September, 1973 in order to reflect one year's experience with the project.

Chart I  
Women on Trial

Test Group			Control Group		
Participant ID#	Entry Date	Weeks on Trial	Participant ID#	Entry Date	Weeks on Tri
150368	8/23/72	36	053785	10/10/72	28
153258	10/3/72	29	052434	10/11/72	27
156486	2/6/73	12	053890	2/6/73	12
149596 <sup>1</sup>	2/9/73	10	051408	2/14/73	10
146723	2/14/73	10	051489	2/26/73	8
157526	2/26/73	8	029207	3/20/73	5
155449	4/6/73	2	048331	4/5/73	3
116511	4/18/73	1	054740	4/6/73	3
151543 <sup>2</sup>	0 <sup>3</sup>	0	058323	4/12/73	2
128831 <sup>2</sup>	0	0	041855	0	0
		<u>108</u>			<u>98</u>

- <sup>1</sup>Has not kept regular appointments  
<sup>2</sup>Negative culture results not in  
<sup>3</sup>Awaiting culture result

Chart II  
Drop-Outs

Test Group

Participant ID#	Entry Date	Drop-Out Date	Weeks on Trial	Reasons
152993	8/15/72	8/15/72	0	Didn't return for first reexamination
154324	10/10/72	10/30/72	2	Unstable work hours
153509	10/10/72	10/10/72	0	Didn't return for first reexamination
150412	1/9/73	1/9/73	$\frac{0}{2}$	" "

Control Group

Participant ID#	Entry Date	Drop-Out Date	Weeks on Trial	Reasons
045139	10/5/72	11/22/72	6	New job, unable to keep appointments
052077	10/11/72	11/3/72	2	Refused to keep appointments
043853	11/10/72	11/10/72	0	Wrong address and phone no.
049012	11/16/72	11/16/72	0	Didn't return for first reexamination
052568	12/19/72	1/12/73	$\frac{4}{12}$	Unable to keep frequent appointments

## Chart III

## Test-Patient Side Effects &amp; Subjective Complaints

Participant ID#	Side Effect	Subjective Complaint	Weeks on Trial
150368 - 8/23/72	itching/burning <sup>1</sup>	Messy	36
152358 - 10/3/72	itching/burning (three times)	None	29
156486 - 2/6/73	None	Interfered with sex pleasure	12
149596 - 2/9/73	None	None	10
146723 - 2/14/73	itching/burning (first week)	Messy oral sex	10
157526 - 2/26/73	None	Messy	8

<sup>1</sup>#150368 reported using Tide detergent when bathing. Project physician recommended discontinuing this practice. Itching and burning disappeared by next examination.

The remaining participants reported no side effects or subjective complaints.

Pre-Trial History Form I

1. Date of Birth \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ Code No. \_\_\_\_\_  
Month Day Year

2. Age \_\_\_\_\_

3. Marital Status: Single \_\_\_\_\_ Married \_\_\_\_\_ Divorced \_\_\_\_\_ Separated \_\_\_\_\_  
Other \_\_\_\_\_

4. Contraceptive practice(s) before participation in study:  
None \_\_\_\_\_ IUD \_\_\_\_\_ Oral Pill \_\_\_\_\_ Surgical Sterilization \_\_\_\_\_ Other \_\_\_\_\_

5. Race: White \_\_\_\_\_ Black \_\_\_\_\_ Other \_\_\_\_\_

6. Educational level completed :  
7th grade or under \_\_\_\_\_ 8th to 9th grade \_\_\_\_\_ 10th to 12th grade \_\_\_\_\_  
College freshman to sophomore \_\_\_\_\_ College junior to senior \_\_\_\_\_  
Graduate school \_\_\_\_\_

7. Number of different sexual partners in past 12 months:  
One \_\_\_\_\_ Two \_\_\_\_\_ Three \_\_\_\_\_ 4-9 \_\_\_\_\_ More than 10 \_\_\_\_\_

8. Sex of partners: Male \_\_\_\_\_ Female \_\_\_\_\_ Both \_\_\_\_\_

9. Average number of times of sexual intercourse in a week: 1-2 \_\_\_\_\_ 3-4 \_\_\_\_\_  
5-6 \_\_\_\_\_ 7-8 \_\_\_\_\_ 9-10 \_\_\_\_\_ 11-14 \_\_\_\_\_ More than 14 \_\_\_\_\_

10. Have you ever used anything to prevent yourself from getting syphilis or gonorrhoea?  
Yes \_\_\_\_\_ No \_\_\_\_\_

A. If yes, which of the following do you use and how often?

	Always	Most of the time	Sometimes
Douche	_____	_____	_____
Wash	_____	_____	_____
Other	_____	_____	_____
(Specify other _____)			

B. If no, do you use any of the following in connection with intercourse and how often?

	Always	Most of the time	Sometimes
Douche	_____	_____	_____
Wash	_____	_____	_____
Other	_____	_____	_____
(Specify other _____)			

11. Do(es) your partner(s) ever use a condom? Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, how often? Always \_\_\_\_\_ Most of the time \_\_\_\_\_ Sometimes \_\_\_\_\_



PRODUCT INFORMATION SHEET

Please complete the following questions; if any questions are not clear, ask the Health Educator to explain them.

Date / /  
Month Day Year

Code No. / / / / / / / /

1. Any side effect(s) of product:

None \_\_\_\_\_ Itching \_\_\_\_\_ Burning \_\_\_\_\_  
Itching & Burning \_\_\_\_\_ Other \_\_\_\_\_

2. Do you feel that:

- a. The applicator is easy to use? Yes \_\_\_\_\_ No \_\_\_\_\_
- b. The applicator is comfortable to use? Yes \_\_\_\_\_ No \_\_\_\_\_
- c. The product is convenient to use? Yes \_\_\_\_\_ No \_\_\_\_\_
- d. The odor of the product is pleasant? Yes \_\_\_\_\_ No \_\_\_\_\_
- e. The taste of the product is offensive? Yes \_\_\_\_\_ No \_\_\_\_\_
- f. Using the product interferes with sex pleasure? Yes \_\_\_\_\_ No \_\_\_\_\_
- g. The product is easy to carry with you? Yes \_\_\_\_\_ No \_\_\_\_\_
- h. The product is messy to use? Yes \_\_\_\_\_ No \_\_\_\_\_  
(If yes, explain \_\_\_\_\_)
- i. Comments \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

3. In the past month, have any of your partner(s):

- a. Objected to use of product? Yes \_\_\_\_\_ No \_\_\_\_\_
- b. Complained of the odor of the product? Yes \_\_\_\_\_ No \_\_\_\_\_
- c. Complained of the taste of product? Yes \_\_\_\_\_ No \_\_\_\_\_
- d. Complained that the product is messy? Yes \_\_\_\_\_ No \_\_\_\_\_
- e. Complained that the product interfered with sex pleasure? Yes \_\_\_\_\_ No \_\_\_\_\_
- f. Comments \_\_\_\_\_  
\_\_\_\_\_

## APPENDIX C

## CLINIC ACTIVITY

Jan. 1, 1973 - June 29, 1973

Total female visits	<u>3343</u>	Non GC	<u>971</u>	Non-Diagnostic	<u>1096</u>	GC visits	<u>1275</u>
GC visits				% of total GC visits			
21+	692			54.27			
18-20	333			26.11			
-18	<u>250</u>			19.60			
	1275						
Past Infection				% of GC visits			
21+	191			27.60			
18-20	72			21.62			
-18	<u>47</u>			18.80			
	310						
Prior 12 months				% of past infections			
21+	99			51.83			
18-20	38			52.77			
-18	<u>27</u>			57.44			
	164						
Total Positives-prior 12 months, 21+		41		% of prior 12 months		41.41%	
Total Never Returned		13				31.70%	
Total Interviewed		28		% of 21+ positives		68.29%	
Total Acceptors		22		% of Interviewed		78.57%	
Total Refused		6		% of Interviewed		21.42%	

E.1. (1) Papers and publications developed under this contract fall into the following categories: (1) the role of prophylaxis in the control of venereal disease; (2) description and results of laboratory studies on the development of a vaginal preparation to provide venereal disease and genital infection prophylaxis as well as contraception; (3) statistical models for predicting relative risk contracting gonorrhea versus syphilis; and potential impact of chemical prophylaxis on incidences of venereal diseases; (4) description of Pittsburgh clinical field trial design.

(1) Role of Prophylaxis - points discussed are: the history of prophylaxis, the success of venereal disease prophylaxis in both World Wars, discontinuance of interest in prophylaxis after World War II, importance of reconsidering prophylaxis once again in light of current epidemics, importance of providing protection against unwanted pregnancy as well as transmission of venereal disease with one product, the importance of research to evaluate effectiveness of available products, and studies involving individual motivation, practice, responsibility, and delivery of public health services.

(2) Description and Results of Laboratory Studies - describes procedures used for testing, discusses survival and recovery of N. gonorrhoeae under different environmental conditions, reports the antimicrobial effects of a number of commonly used intravaginal contraceptives and other preparations on N. gonorrhoeae, T. pallidum, G. albicans, and T. vaginalis, and indicates that results are encouraging and postulates that an agent simultaneously offering prophylaxis against venereal disease and contraception would be of great value to both existing family planning and venereal disease control programs.

(3) Statistical Models - describes the development of a theoretical model and uses the model to predict the possible dramatic change in the prevalence of gonorrhea if topical venereal disease prophylaxis is incorporated into existing venereal disease programs and is used by population at risk. Also based upon joint probability of transmissibility and prevalence, the relative risk of contracting gonorrhea versus syphilis is calculated and used in an equation to predict effectiveness of contraceptive products tested in vitro.

(4) Description of Pittsburgh Clinical Field Trial Design - outlines the detailed field trial protocol under which Pittsburgh field trial is being conducted.

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- "Study Suggests Vaginal Infections May Lead to Missed GC Diagnosis," VD Clinical News, 3:2:1, 1973.
- "Vaginal Contraceptives Declared Anti-VD," VD Clinical News, 2:1:1; 1972.
- "Vaginal Prophylactic Research Advances," Family Practice News, 3:6:41, 1973.
- "VD Prophylactic That Answers Contraception Seen Promising," Ob., Gyn. News, 7:22:26, 1972.

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E. 1. (2) During this reporting period, material from the project was utilized as follows:

- (a) Listing of Pro-Con bibliography in Indiana University Institute for Sex Research Directory of Researchers in the area of sexual behavior and related fields;
- (b) Interview of Dr. J. C. Cutler on WQED-TV, N.E.T. outlet in Pittsburgh, April 1973, on "Newsroom" program, discussing the problem of venereal disease and prophylaxis. This program was part of the "V.D. Blues" update which was originally shown in October, 1972.
- (c) Statement for the American Social Health Association in support of a New York State bill for inclusion of intravaginal preparations as prophylactics in a recent distribution bill;
- (d) Training session for Pittsburgh Public School physical education and health education teachers, conducted by Allegheny County Health Department;
- (e) Training session for parochial school teachers, conducted by the Allegheny County Health Department.



EACICS

DEPARTMENT OF THE ARMY  
HEADQUARTERS I CORPS (ROK/US) GROUP  
APO SAN FRANCISCO 96356

3 January 1973

Mr. Uri Carpenter, ~~M.D.~~ (Hyg)  
Principal Research Assistant  
Graduate School of Public Health  
Population Division  
University of Pittsburg  
Pittsburg, Pennsylvania 15213

Dear Dr. Carpenter:

This letter is sent to you in hope that you might be of some help in handling a problem plaguing the American troops in Korea. As you probably guessed, the subject is VD, and especially Gonorrhea.

Your name has been referred to me by Mr. R.S. Fox, Public Health Advisor, Division of Health, State of Nevada. He speaks very highly of your research work with Dr. John Cutler and mentioned that you might have some answers.

In the Uijeongbu area (the city outside Camp Red Cloud, located about 20 miles north of Seoul) there are about nine hundred "business girls"; mostly free-lance prostitutes. During a recent test at a US Field Hospital, it was discovered that about 20% of the girls tested (more than 700) were infected. The detection method was the culture test, which is more reliable than the smear test (used in the local Korean hospitals). Army doctors have evaluated the administration of smear tests in Korean hospitals and found it unsatisfactory, due to poor hygiene and faulty equipment. Since then, some US equipment has been supplied and a special assistance team has been working in the local clinics to demonstrate proper testing technique.

Through the local government, the US Army has been attempting to solve this problem by giving mass penicillin shots, free treatments, and by educating the girls on how to detect and prevent VD. An intensive campaign has been initiated to educate the soldier in the dangers of VD and its prevention. "Rubbers" are available, free, in orderly rooms, at post gates, in NCO, EM, and Officer clubs, and furnished gratis to off-post "night clubs" for distribution to girls and for display and availability at bars. Meetings are held monthly with the province

governor for coordination, and there is a close working relationship with the town officials. All this has made a dint in the VD statistics, but progress has been slow.

I believe that educating the girls in the protective value of a VD preventative gel, and getting them to use it, would add to the effectiveness of our efforts. When a young soldier, slightly stoned on booze or other drugs, faces temptation, he will probably not use a prophylactic device.

I am sure that you can visualize the advantages of a vaginal gel in such a situation. Undoubtedly, you can see that this would be an ideal test site for your products.

Please send me your latest results.

Sincerely,

A handwritten signature in cursive script that reads "Alex Spataru".

ALEX SPATARU  
1LT, Armor  
Aide-de-Camp

1/22/73



UNIVERSITY OF MINNESOTA  
TWIN CITIES

Program for Applied Research on Fertility Regulation  
Medical School  
Suite 226, University Park Plaza  
2829 University Avenue S.E.  
Minneapolis, Minnesota 55414

January 17, 1972

John C. Cutler, M.D.  
Chairman  
Department of Public Health Preventive Medicine  
School of Public Health  
University of Pittsburgh  
Pittsburgh, Pennsylvania 15213

Dear Dr. Cutler:

Prior to leaving on my trip around the world for the Program for Applied Research on Fertility Regulation, I spoke with you about the possibility of placing your Department's spermicidal and gonorrheal suppressive agent in certain lesser developed countries. One of the pleasures I experienced was a meeting with Dr. Ferdinand Pauls who is the Chairman of Obstetrics and Gynecology and the Head of the Maternal and Child Health Service in Kinshasa, Zaire. I have enclosed just some of the statistics provided to me by Dr. Pauls, denoting the great amount of obstetrics that this hospital has to contend with. As I explained during our telephone conversation, the incidence of gonorrhea in the obstetrical and gynecological population at the Mama Yemo Hospital is probably in excess of some 60%. It is a very serious public health concern and one in which Dr. Pauls could quickly evaluate the effectiveness of said agents.

The Belgians, who have been most supportive of health care measures in the new republic of Zaire, have provided the Mama Yemo Hospital with a computer and the data processing skills for keeping track of health care systems. I have been assured by Dr. Pauls that they could evaluate any number of contraceptive techniques, methods, and anti-venereal agents.

I am imposing upon you to ask that your Department communicate to ascertain if a study of mutual benefit can be established between the University of Pittsburgh and the Mama Yemo Hospital in Zaire. If Dr. Pauls and you can reach some agreement as to the possibility of testing such spermicidal foams and creams that would also provide protection against gonorrhea, the PARFR organization would be most interested in reviewing a joint proposal.

John C. Cutler, M.D.  
Page 2

I appreciate your very kind attention and look forward to hearing from you about this matter.

Sincerely,

*Julius C. Butler MD.*  
Julius C. Butler, Jr., M.D.  
Assistant Professor  
Obstetrics and Gynecology  
PARFR Project Coordinator

*rh signed  
in Dr. Butler  
absence*

JCB:njh

Enclosure

cc: Dr. Singh

Ferdinand Pauls, M.D.

J. Joseph Speidel, M.D.

Ms. DeVerille A. Huston