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Factors Affecting the Innovation Process for Contraceptive Products

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FACTORS AFFECTING THE INNOVATION PROCESS FOR CONTRACEPTIVE PRODUCTS

The Technology Management Group

Pugh-Roberts Associates, Inc.

April 1982

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PREFACE

This report presents the results of an 18-month study that had two primary objectives:

- To identify the principal management factors affecting contraceptive innovation and development; and
- To suggest, at least tentatively, means to help improve the effectiveness and efficiency of contraceptive development and, thereby, to improve the prospects for increased donor commitment.

This report is based on a series of interviews with representatives of contraceptive development organizations and other knowledgeable individuals, as well as on the general experience of the Technology Management Group of Pugh-Roberts Associates, Inc. dealing with technology-based innovations in industrial settings. Reinterviews with some respondents and additional interviews suggested by the initial series have confirmed the investigators' preliminary conclusions and helped refine the analysis.

The analysis (p. 25) focuses on a process that involves a variety of government, multinational, and private philanthropic donors, as well as numerous public and private agencies and institutions engaged in the various aspects of contraceptive development. The governments, organizations, and institutions

involved have different perceived needs and priorities; each has limited but often overlapping roles; and communications and links between them range from fairly strong to nonexistent. The unique characteristics of this multiorganizational "system" for contraceptive innovation give rise to the special problems and needs analyzed in this report.

It is important to bear in mind that it is the contraceptive development system itself with which this report is concerned. It is not intended to reflect on the quality of work of any organization. Clearly, contraceptive development is pursued by scientists and technicians of outstanding professional competence and dedication working in institutional settings that are often individually exemplary. The donors, too, are virtually all motivated by a sincere concern about health, welfare, and population problems. But all are often frustrated by problems such as difficulties in formulating strategy or in moving prototype products to mass manufacture and distribution. The challenge lies in how best to improve the system by making the optimum use of the resources available.

Costs of the study were underwritten by the Ford Foundation and the International Development Research Centre of Canada. These donor agencies felt it would be useful for a management consulting firm with relevant experience in working with industry, but without ties to the contraceptive development process, to undertake an objective, critical examination of this process.

SUMMARY

Prior to the mid-1960s, reproductive and contraceptive research had been supported primarily by private philanthropists and the pharmaceutical industry. The introduction of the pill and the modified IUD, revolutionary new methods, coupled with increased governmental concern about rapid world population growth, led to a surge in public sector and private foundation funding to help develop new birth control methods and the establishment of several public sector and nonprofit research and development (R&D) organizations. A number of important new approaches, including simplified abortion and sterilization procedures, metal- and drug-carrying IUDs, long-acting injectable hormones, and low-dose oral contraceptives were developed, and others, such as hormonal implants and vaginal rings are close to the marketing stage. However, expected radically new methods like vaccines, a pill for men, and a menses inducer proved to be much more elusive than some scientists and donors had projected.

Disappointment over perceived slow progress is believed to be one reason that public sector and foundation support for contraceptive research has been declining since the mid-1970s. The participation of the pharmaceutical industry started to decline in the late 1960s, largely because many of the new methods under consideration did not promise as great a profit for them as had the pill.

Innovation in contraceptive development, like that in other fields, moves through stages from idea generation through fundamental and mission-oriented research to the final manufacturing and marketing of a product. What is unique about the contraceptive innovation "system" is the number of separate groups involved, with no unifying structure to facilitate strategy formulation or bring a project efficiently through the system. There has been a tendency for R&D organizations to stay with a project even after testing of a prototype has been completed. This means that these organizations have fewer resources to devote to new projects and that development is slower than it would normally be.

Although each organization in the system has special strengths, there are few mechanisms to facilitate the integration of data or to build on these strengths. Lack of information sharing and coordination among the organizations results in redundant effort as well as gaps. Because the products are largely subsidized by government and do not have to compete in a free-market system, those that are produced inefficiently continue to exist. The links between research, development, and production need to be strengthened, especially feedback from manufacturers and the marketing personnel before major investments are made in the testing of prototypes.

Although the scientists and technicians currently involved in contraceptive development tend to be of high caliber and great dedication, the innovation process might benefit from greater diversity in the disciplines of project staff. Organizational and donor goals and the strategies to meet them need to be better defined, and collaboration between the public and private sectors needs to be improved. Finally, there needs to be a better balance between investment in fundamental and in applied research. Funding for the latter needs to be increased, although first, it may be necessary to make the system demonstrably more efficient and effective.

Several mechanisms to effect needed changes are suggested; these include: the establishment of an information office for donors and developers, which might have attached to it special expert advisory committees representing both the technical and the marketing sides of contraceptive innovation; the acceptance by donors and developers of criteria against which to examine projects and technical goals toward which they can pool funds and focus efforts; and the establishment of an international contraceptive research and development association with the aim of improving information sharing and identifying the numerous disciplines involved with the contraceptive development field. Thus, in the long run, the association might increase funding commitments to the field.

HISTORICAL PERSPECTIVE

The introduction of oral contraceptives and improved IUDs in the 1960s was widely believed to herald a contraceptive revolution that would soon bring many other new approaches to contraception in its wake.[1]

Encouraged by these breakthroughs, and prompted by growing concern about the social, economic, and health consequences of rapid population growth, national and international public agencies began in the late 1960s and early 1970s to initiate or increase funding for research in reproduction and contraception. As a result, financing of all aspects of reproductive and contraceptive research (which prior to the mid-1960s had been supported primarily by private foundations, a few individual philanthropists, and the pharmaceutical industry) rose from an estimated U.S.$31 million in 1965 to $117 million in 1973.[2]

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[1]C. Djerassi, The Politics of Contraception, W. W. Norton & Co. New York, 1980, 76.

[2]For a detailed description of funding for reproductive and contraceptive research, see L. Atkinson et al., "Prospects for Improved Contraception," International Family Planning Perspectives, June 1980, 45-38.

During this surge in funding, several foreign assistance agencies of industrial nations, two private foundations, an intergovernmental agency, and the U.S. government established public sector and nonprofit programs to help develop new birth control methods. These programs, all of which are currently operating today, are: the Special Programme of Research, Development and Research Training in Human Reproduction of the World Health Organization (HRP); the Population Council's International Committee for Contraceptive Research (ICCR); the International Fertility Research Program (IFRP); the Program for Applied Research on Fertility Regulation (PARFR); the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT); and the Contraceptive Development Branch (CDB) of the Center for Population Research, U.S. National Institute for Child Health and Human Development (p. 18-19).

With the exception of the CDB, which focuses on domestic needs, each of these programs was established to address the special needs of developing countries. The principal donors to the international programs recognized that technologically feasible improvements in birth control methods could be made, but improvements were unlikely to be undertaken by existing organizations. Private industry, which had traditionally been depended upon to develop new drugs and devices, was by the late 1960s decreasing its investments in new contraceptive development. It had little incentive to develop methods for

developing countries, a market that was perceived to offer poor profit potential, while the costs of research to meet regulatory requirements and the risk of product liability were increasing. National medical research councils in industrial countries directed their funding primarily toward fundamental research. Among the developing countries, only India's medical research council assumed a leading role in support of reproductive or contraceptive research.

Since public sector agencies increased their involvement in contraceptive development, important technological improvements have been made in birth control methods. These include a new generation of metal- and drug-carrying IUDs, simplified and safer sterilization and abortion procedures (primarily developed by public sector organizations), long-acting injectable steroids, and lower dose yet highly effective oral contraceptives (developed by the pharmaceutical industry). Several other developments, such as vaginal rings, new implantable or injectable preparations, prostaglandins to induce early abortions, and IUDs causing less bleeding and pain are approaching the completion of development and may be widely available within 5 years.

These developments represent impressive achievements. However, they have fallen short of the expectations bred by overenthusiastic forecasts that radically new methods such as a contraceptive pill for men, a menses inducer, and a contraceptive vaccine would soon follow the pill and the IUD. These methods continue to be in early stages of development, and considerable research over a long time will be needed before they become generally available. These kinds of advances have proved to be more elusive than some scientists and donors once believed. In part, perhaps, because of disappointment over the perceived slow pace of progress, in part because funding for research generally leveled in the 1970s, and in part because of mistaken complacency bred by recent declines in population growth rates, worldwide expenditures for reproductive and contraceptive research are declining. Expenditures, expressed in constant dollars, peaked in 1973 and are now below 1970 levels.[3] Not only public sector agencies, but pharmaceutical companies and philanthropic foundations, have decreased their involvement in the field. The result of the decline in funds for contraceptive research and development is that the public sector contraceptive development organizations must now compete for even smaller shares of a declining worldwide budget.

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[3] L.Atkinson et al., 1980, op. cit.

The task now is to use available resources as productively as possible. By increasing the effectiveness and efficiency of the process leading to new contraceptive products, agencies may be able to shorten the time for development, improve the quality of products pursued, and, thus, over the long term attract new funding and increased donor commitment to the innovation process.

THE INNOVATION PROCESS AND ORGANIZATION

The development of a new contraceptive, like the development of any new product, is a process that starts with an idea and goes through a number of stages before it can be marketed. Innovation encompasses both invention and exploitation. What is commonly referred to as research and development only provides the prototype product; exploitation depends on such functions as product development, manufacturing, and marketing to convert the prototype--if it meets a significant social need--into a widely distributed and used product.[4]

The kinds of activities and amount of time involved in the innovation process vary for different kinds of contraceptive drugs and devices; both depend on the existing knowledge base. An incremental change or modification of an existing product usually involves less effort than developing a new technology from a basic research lead. Long-term development, such as is needed for synthesizing, screening, and testing a new contraceptive drug, can take 10-20 years. Short-term

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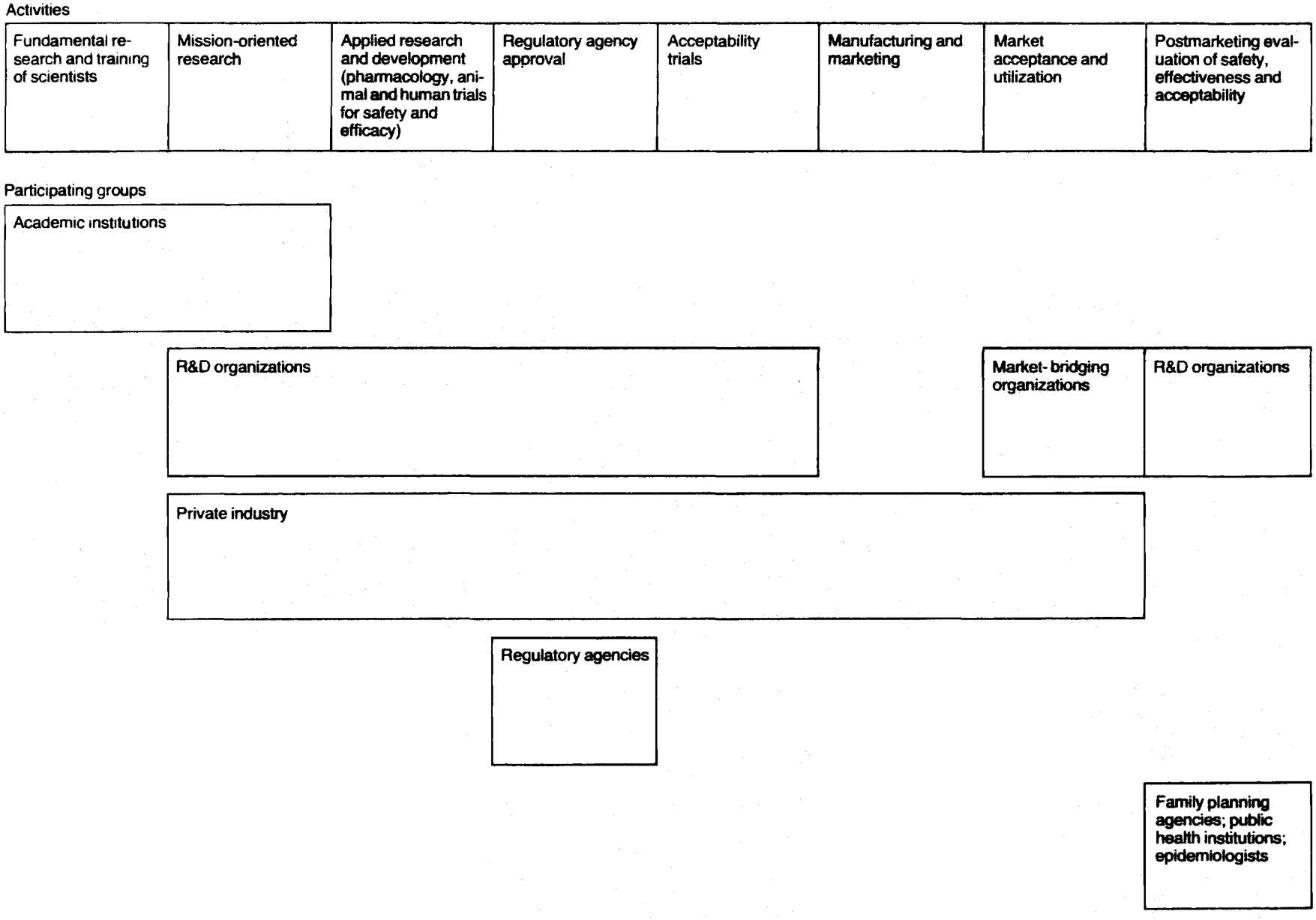
[4]For a more detailed description of the innovation process, see E.B. Roberts and A. L. Frohman, "Strategies for Improving Research Utilization," Innovation-Technology Review, 35-41.

development, as, for example, for a modified IUD, can take 5-10 years. Activities involved in product introduction also vary, depending on whether the products are distributed directly through the private sector to the ultimate consumer, such as condoms, or are distributed through public sector channels, which usually involve third-party purchasing for developing country programs.

The contraceptive innovation process (Figure 1) generally involves five basic stages:

- The generation of ideas comes from basic research in a wide range of scientific disciplines (without any specific application in mind) and from mission-oriented research, which harnesses basic scientific knowledge and techniques to meet a perceived contraceptive need (e.g., a male method, a vaccine, or a postcoital method).

Figure 1. The contraceptive innovation process, and involvement of the various participating groups.



- Research and development involves the use of scientific research procedures in conjunction with engineering and manufacturing capabilities to design, test, and refine new prototypes. This phase usually comprises a series of pharmacological and laboratory studies in animals and clinical trials with humans to establish the efficacy and safety of a prototype product. When these studies have been completed successfully, government regulatory-agency approval (e.g., of the Food and Drug Administration in the United States) may be obtained for the manufacture and distribution of the product. Once the initial research studies have shown an idea is biologically feasible, product development activities tend to constitute a larger and larger proportion of the activities in this phase. These are aimed at developing and refining prototypes for testing in the successive clinical trials; designing and developing the manufacturing process by which the product will eventually be produced on a large scale; and developing packaging, labeling, informational materials, and quality control procedures. In addition, the potential market and estimated costs should be determined and proprietary interests, licencing arrangements, and regulatory review considered.

- Manufacturing and marketing of the product through marketing channels follows the completion of research and development.

- Market acceptance and utilization begins once regulatory-agency approval has been obtained and a commercial production capability has been identified. The product and its support materials are often adapted to the local cultural and social characteristics of each population that will use it. Studies may also be undertaken to assess local acceptability and side effects and to develop and evaluate packaging and support materials. At this stage the product is clearly defined and business and marketing strategies can be developed.

- Post-marketing surveillance of safety, effectiveness, and acceptability may continue for many years after the product is introduced. Such types of evaluation are especially necessary to determine rarely occurring or long-term complications (such as cardiovascular complications with the pill) that cannot be seen in the initial trials. This follow-up is often required as a condition of the regulatory-agency approval to manufacture and distribute the product.

This simplified model does not capture the feedback and links that occur between the various stages of innovation. For example, pharmacological studies showing that a substance that successfully interferes with sperm maturation has unacceptably

toxic properties may result in the R&D organizations' working to produce new analogues or the academic researchers' attempting to develop better basic knowledge about the functioning of this phase of the male physiology. Often basic and applied efforts are pursued simultaneously. Research to determine user acceptability (for instance, of a method that interferes with normal patterns of menstruation) may be undertaken simultaneously with the development of a prototype and may lead to modification of the prototype before large-scale manufacturing begins. For example, acceptability studies may highlight odour or colour problems with the product or storage problems under particular climatic conditions. The development of the prototype itself may be modified according to advice from potential manufacturers about the practicability of particular manufacturing techniques.

Contraceptive innovation is carried out through individual public and private organizations and institutions, each of which has a limited role in the innovation process (Figure 1).

Basic research and some mission-oriented research are performed primarily in academic institutions, largely with public sector funding. The public sector now also supports much of the mission-oriented research and most research and development efforts through six development programs.

The Special Programme of Research, Development and Research Training in Human Reproduction of the World Health Organization (HRP) has a research and development component that operates through task forces that plan and organize research on specified leads to new methods of fertility control. Approximately 30 percent of the Programme's annual budget of about $16 million is devoted to this effort, while the remainder is devoted to strengthening scientific institutions and personnel in developing countries, setting scientific and technical standards, and establishing information about the performance of existing methods of birth planning.

The Population Council's International Committee for Contraceptive Research (ICCR) focuses primarily on research and development, mostly for leads that are at or near the human trial stage. It has a role analogous to that traditionally played by pharmaceutical company R&D divisions and operates with an annual budget of approximately $3 million.

The Contraceptive Development Branch of the Center for Population Research of the U.S. National Institute for Child Health and Human Development (CDB) operates a centrally designed and coordinated program through the use of government contracts with universities, nonprofit institutes, and industry. With an annual budget of about $8 million, it is the largest source of funds for contraceptive development. Although none of the international programs receive CDB support, they maintain close working ties and benefit from both the Branch's work in mission-oriented research and R&D and NIH-supported work in basic research.

The International Fertility Research Program (IFRP) concentrates on large-scale clinical trials of contraceptive technologies that are near the completion of development. Trials, carried out through national networks in developing countries, are aimed at evaluating the performance of contraceptives and promoting their local introduction and use. The program also carries out studies to evaluate long-term risks and benefits of methods in use. Its annual budget is about $5 million.

The Program for Applied Research on Fertility Regulation (PARFR) was established to provide funds for mission-oriented research on promising ideas for potential new methods that were not being funded by HRP or ICCR. It is now operating a more directed grants program and is establishing its own clinical testing network. Its annual budget is nearly $2 million.

The Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) was founded in 1976, to close the gap between contraceptive research and development efforts and product introduction. It generally concentrates on market-bridging activities such as packaging, manufacturing, informational materials, product servicing and repair capacities, and product distribution needs. Its annual budget is about $4 million.

The public sector research and development organizations maintain ties with the private sector pharmaceutical industry to gain access to proprietary information on compounds that may have been developed by industry but are not being pursued for contraceptive application, as well as to arrange for industry to manufacture and distribute new prototype products it has developed. Although private sector pharmaceutical firms have in general decreased their activity in contraceptive innovation, there are still several that maintain programs to develop, manufacture, and market contraceptive products.

Other organizations have a less-direct role in contraceptive research and development but are important in the overall innovation process. These include the various national family planning programs and the voluntary programs operated under such auspices as the International Planned Parenthood Federation. They are the main channels for delivering products and services to users. They are often--particularly in developing countries--the purchasers of the contraceptive products and, often in conjunction with R&D and public health organizations, help to monitor the long-term usage, acceptability, safety, and effectiveness of the product. As such, these family planning organizations are an important constituent of the marketing and evaluation stage of contraceptive innovation and the main source of information in developing countries about the impact of the product on the individual consumer.

FRAMEWORK FOR ANALYSIS

Because innovation requires both invention and exploitation, any analysis of the effectiveness of the contraceptive innovation process must encompass the various steps that support innovation, including the evaluation of technological potential, focusing of development efforts toward particular technical targets, transfer of research results, and broad-based utilization and diffusion. To diagnose the effectiveness of the contraceptive innovation system in each of these activities, it is useful to examine the factors that are known to influence innovation in other settings. These can be divided into strategy, structure, and staffing.[5]

Strategy includes such considerations as organizational roles, priorities, and resources. How large should the development effort be, how should its resources be allocated and over what different objectives? In the contraceptive innovation process, for example, should greater priority be given to learning about the male or female reproductive

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[5] For a more detailed description of factors influencing innovation, see E.B. Roberts, "Influences in Innovation: Extrapolation to Biomedical Technology," in Roberts et al., Biomedical Innovation, MIT Press, Cambridge, 1981, 50-54.

physiology than to applying basic scientific knowledge to the development of prototype drugs or devices? Or should equal priority be given both? Strategy provides the framework for planning the appropriate mix and addresses such issues as the types of projects to be undertaken, the amount of resources to be devoted to each, and the technological skills and staffing mix needed to carry the projects through to completion. Strategy, in short, provides the focus for development efforts.

Structure involves the formal and informal relationships between the organizations involved in the process and between the component parts of each organization. The way in which development efforts are structured or sited can affect the flow of a developing technology through the various stages of the innovation process. Links are needed between the sources of ideas for innovation (e.g., academic institutions or market-need analysis), the sources of effective technical solutions (e.g., the R&D organizations or pharmaceutical companies), and the channels for exploiting new developments (e.g., the manufacturers, family planning organizations, and bridging organizations like PIACT). The establishment of links is especially important when the process of innovation depends on the coordination of a number of individual efforts of separate organizations, as is the case with contraceptive development. Innovation, involving many different independent groups, requires an extraordinary degree of coordination and information sharing.

Staffing includes consideration of the disciplines of the individuals as well as the characteristics each individual brings to the innovation process. There needs to be an appropriate diversity of disciplines with different types of experience represented for maximum creativity among project teams. Stability, up to a certain point, provides for needed continuity of effort, but keeping the same groups of specialists together for too long can lead to stagnation and decline in creativity.

Five different types of staff serve critical functions in the innovation process. They include:

- Idea generators, the creative contributors often associated with research and development;
- Entrepreneurs, the product champions, who exploit ideas by getting them developed and adopted;
- Project managers, who handle the supportive functions of planning, scheduling, business, and financing relating to development activities;
- Gatekeepers, or special communicators, who bring in information from outside sources, usually in technical, marketing, or manufacturing areas; and
- The sponsor or coach, the senior person who supports, directs, and recruits those involved in the innovation process.[6]

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[6]For a more detailed description of critical functions, see E.B. Roberts and A.R. Fusfeld, "Staffing the Innovative Technology-Based Organization," Sloan Management Review, Spring 1981, 19-34.

The criteria that donors use to fund projects can also affect significantly the efficiency of the contraceptive innovation process. The donors can encourage information sharing and coordination among development organizations or, in effect, help entrench inefficiencies and redundancies that tend to be endemic to a multiorganizational innovative process left to its own devices.

In multiorganizational innovations, such as contraceptive development, the progress and direction achieved by the system as a whole depend on the decisions made by each individual organization. In the field of contraceptive development, this process is particularly complex because of the number of organizations involved. It can, nevertheless, be evaluated according to how efficiently and effectively it brings an innovation through the various stages.

Thus, the Technology Management Group of Pugh-Roberts Associates, Inc. has examined the decision-making criteria of each organization for clarity and consensus of goals and the control and stability mechanisms for mismatch of goals; it has also examined the links between organizations and the individual organizations' characteristics that lead to the aggregate of decisions to assess their effectiveness in meeting consumer needs and in linking up with channels for exploiting ideas and prototypes. Finally, it has examined the possibility that there are fundamental biases in the system in terms of staffing and funding patterns.

Data were collected for each innovation stage -- from idea generation through postmarketing evaluation -- by means of a series of interviews with the principal actors in the system. The agencies, groups, and individuals interviewed are listed in the appendix. Initial interviews were carried out during the first half of 1981. These involved inquiries about the objectives and functions of each organization, the basis for allocating funds, and the criteria for measuring effective performance and success in achieving goals. The opinions of respondents were solicited concerning the perceived and optimum role of the private sector in contraceptive development, and they were asked to suggest strategic and tactical initiatives to improve the effectiveness and efficiency of the system. Special emphasis in this analysis has been placed on the strategies, structure, and staffing employed in the current contraceptive development system as these are found to be consistent or inconsistent with those characterizing overall efficiency of innovation in other settings.

Interviews conducted with a subset of the original respondents in late 1981 and early 1982 elicited comments on the preliminary findings and contributed to refining the analysis.

ANALYSIS OF MAJOR ISSUES

The main organizations involved in the contraceptive innovation process are:

- Academic institutions;
- Public sector and nonprofit contraceptive development organizations such as the HRP, CDB, ICCR, IFRP, and PARFR;
- Private-sector pharmaceutical product organizations (Syntex, Searle, Ortho, Schering, Organon, etc.);
- Public sector market-bridging organizations that support the introduction of products (the main one is PIACT);
- National and voluntary family planning associations;
- Public health institutions and epidemiologists from universities;
- National governmental and intergovernmental donors such as the United Nations Fund for Population Activities (UNFPA), the U.S. National Institutes of Health (NIH), and Agency for International Development (AID), the Swedish Agency for Research and Economic Cooperation (SAREC), the International Development Research Centre (IDRC) of Canada, and medical research councils and overseas assistance agencies of a number of nations; and
- Private philanthropic donors such as the Ford, Rockefeller, and Mellon foundations.

Each type of organization has a limited role in the innovation process (Figure 1). As there is no unifying organizational structure, formulating a coherent strategy for the entire innovation process is difficult. When no single organization has full responsibility for pulling a project through the system, there is likely to be a lack of strategy, an inability to assess resources and apply them efficiently and effectively, and a failure to coordinate and review activities or share information. In other words, lack of consensus on the part of the donors and organizations on collective goals, along with inadequate information sharing and coordination of activities, is likely to result in redundancies and gaps in development efforts with no guarantee that the redundancies are concentrated in the most important activities and the gaps in the least important. For most products in a free-market system, redundancies resulting from a multiorganizational system are corrected in the marketplace. Inefficiencies of production are reflected in a product's quality or its cost, and consumers force it off the market by choosing a competitive product that is cheaper or better. In the case of contraception, however, inefficient production may, in effect, be subsidized by governments or private philanthropic groups.

It is not being suggested here that a unifying structure for contraceptive innovation can or should be realized by the placing of all phases of the process under one group's direction. What can be done is to develop means whereby information can be shared and intelligent decisions made, while the independence of action of each of the organizations involved is maintained.

There are numerous ways to integrate elements in the system to accelerate the innovation process. The areas in which integration is needed are strategy; links to information on market needs and manufacturing and marketing functions; external factors; staffing mix; and research mix.

Strategy. The organizational goals of the various public sector and nonprofit development groups are broadly stated. They provide little explicit strategy to focus development on particular technical targets. For the most part, donors do not provide a strategic focus either. As a consequence, the contraceptive development groups tend to develop their work programs primarily on the basis of the risks, costs, and time involved in pursuing various projects; the resources available; and the criteria and characteristics of the donors involved.

Development of a new contraceptive drug in the United States is estimated to require from $15 million to $46 million over 10 - 17 years.[7] Total costs and time could be less in other countries and is less even in the United States for contraceptive devices or for products using already approved drugs. Development nevertheless requires substantial annual investments. It is estimated, for example, that development efforts for a postpartum IUD require annual investments of $1.5 million if the device is to be developed in 5-7 years.[8] Current annual budgets for public sector contraceptive development organizations range from $2 million to $8 million.

With limited resources, each organization is restricted as to the number of specific projects and options with which it can become involved. It can make a conscious choice to let go of projects once they reach a certain point in development, or it can follow those projects all the way through to product introduction. Most of the organizations are not large or complex enough to do everything. If the organization follows projects, it has fewer resources to evaluate potential projects. As a result, there will begin to be gaps in the innovation process. This problem is compounded when a number of organizations begin following projects all the way through to product introduction. Overall, the development process is slowed, because new ideas are not being brought further along.

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[7] C. Djerassi, 1980, op.cit., 77.

[8] L. Atkinson, et al., 1980, op.cit., 56.

In the past, this gap in the innovation process led to the establishment of new developing organizations, but, because of reduced level of overall funding, this is unlikely today.

Because most funding is short-term, development organizations tend to adopt a short-term perspective in order to show results to the donors. As there are a limited number of leads that can be developed in a short time, several groups tend to work on different approaches to the same lead and tend to produce similar products. For example, three groups have developed approaches to hormonal implants. Since each has been developed by a different organization, and with different funders, all three will probably proceed to manufacturing. A similar situation exists with regard to development of a vaginal ring. Although all approaches should be investigated so that the best technical solution or solutions are found, it would be more cost-effective if there were a screening mechanism to determine, based on desired product criteria, which, if any, of the approaches should proceed to manufacturing. In this way, resources freed from pursuing further development on one approach might be directed toward bringing another method to the same stage.

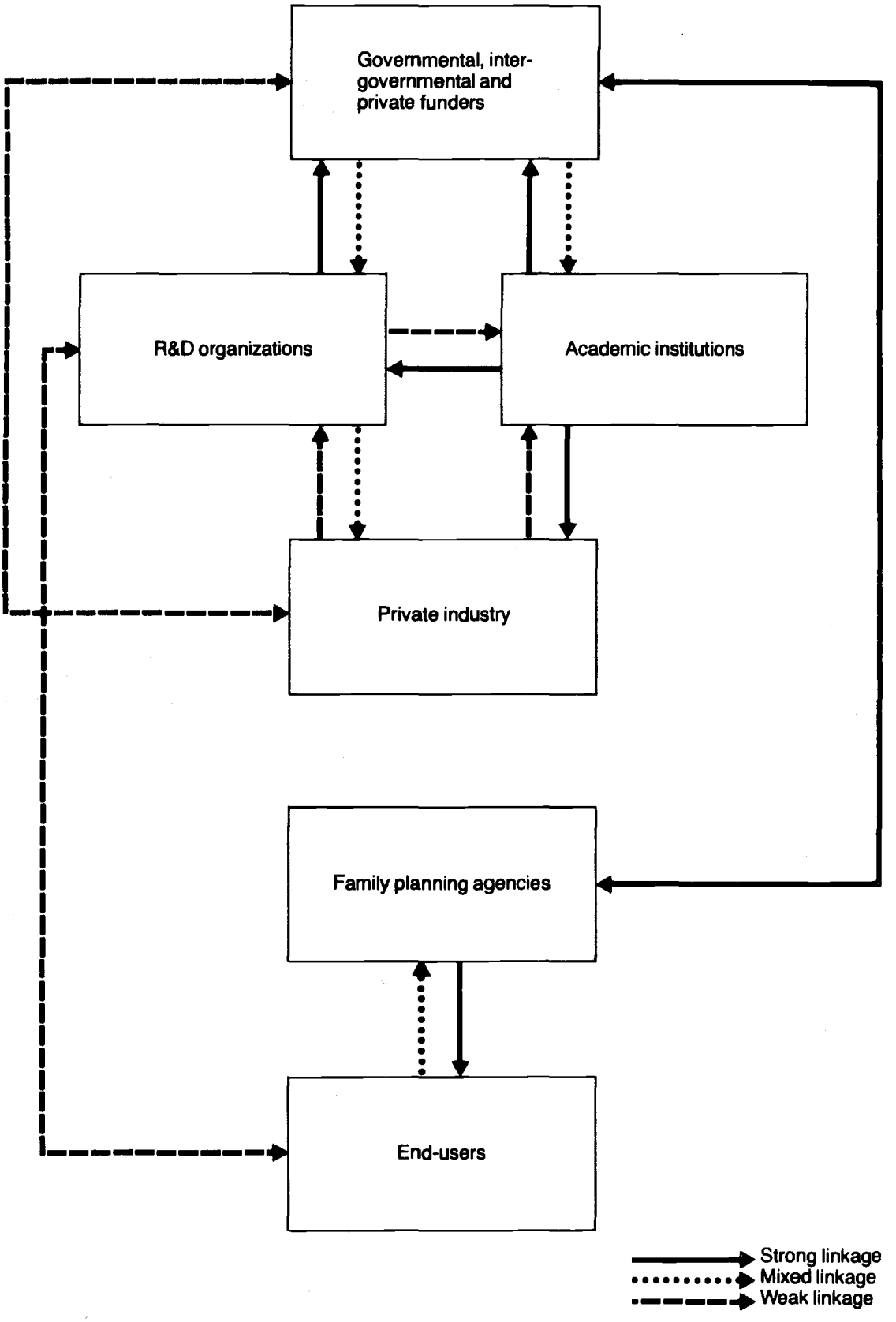
While each organization has developed strengths in different aspects of R&D, there are at present few mechanisms to facilitate the integration of data or to build on the strengths of each. Nor are there mechanisms for rewarding organizations for handing on projects at some stage to another more appropriate group and going back to bring a new idea to the same stage.

To change these patterns, more of the participants in the innovation process will have to be involved in creating an explicit, conscious strategy. Of particular importance is the need to establish a focus that will take an idea from fundamental research and pull it through the system to achieve a product available for widespread use. Funders will also need to understand how the activities they fund fit into the innovation process as a whole. If, for example, a group of donors and developers could agree on a unified set of criteria against which to examine individual projects, they could focus efforts toward particular technical goals. This could substantially increase the effectiveness of the innovation process.

Links. There is no one public sector or nonprofit organization that effectively encompasses needs assessment, the various stages of R&D, along with manufacturing and marketing. Although the organizations were not established to encompass all of these functions, there are ways to facilitate communication among organizations to ensure that each of these functions is appropriately implemented.

The way in which the system works at present, along with potential areas for stengthening links, is illustrated in Figure 2. Direction and priorities for research and development tend to be controlled by reproductive scientists in university departments and in contraceptive development organizations such as the HRP, ICCR, and IFRP. They, in turn, influence the funding agencies, most of which cannot afford to maintain a full range of expert staff to judge independently the potential for contraceptive application of discoveries in diverse technical fields. The information provided to funders by population research and policy organizations is primarily based in the social sciences and demography and offers no explicit technology goals or project selection criteria. Once the development agencies are funded, they tend to work on their ideas through advanced clinical trials and begin to transfer product information to manufacturers, only after substantial expenditures of time and money have been made in clinical testing. Feedback from the manufacturing process at that point is too late for optimum use in production development. Studies to assess acceptability to users, if carried out at all, tend to begin only at this time. Following manufacture, contraceptive products are sold and shipped by the private sector, with most sales to developing countries mediated by third-party purchasers such as AID, IPPF, and UNFPA. The end users, thus, have little direct influence on the research priorities in the development process.

Figure 2. Opportunities for strengthening linkages for contraceptive innovation.



While it is appropriate that industry continue to provide manufacturing and marketing functions, the public sector development groups could benefit from early access to expertise in these areas. This would allow integration of such manufacturing and marketing concerns as potential market, eventual product costs, quality control, and problems in moving to full-scale production earlier in the R&D effort.

Private industry has developed mechanisms to overcome the difficulties involved in communication and coordination among the diverse groups involved in making the innovation process work. These either ensure that all the relevant groups operate with the same strategy and the same specific goals or reinforce links between groups through the use of human bridges such as joint working teams, meetings, or conferences, or procedural bridges such as joint planning, joint funding, or joint appraisals of projects.

Improvement in the links among groups involved in contraceptive innovation could be aided by similar human and procedural bridges to provide the contact and communication necessary to smooth the flow of the process. For example, individuals from a number of different development organizations might work together on interorganizational project teams. The staff disciplinary mix could be widened by the inclusion, on a part-time basis, of engineers, biogeneticists, biophysicists, market researchers, and

manufacturers. Individuals could participate in interorganizational exchange programs -- for example, for the exchange of personnel between public sector or nonprofit contraceptive development groups and family planning programs or consumer product research organizations. Special teams could ensure involvement of manufacturing considerations at a stage early enough for the feedback to influence the prototype development. Or a team might be responsible for acceptability research[9] when a prototype is introduced into the first phase of clinical trials.

External factors. The environment in which the innovation process operates contributes to the costs and uncertainties of planning by the individual organizations. Strategies need to be adjusted so that these external factors are taken into account. Environmental factors are of two major types, legal and social. The former include regulatory-agency procedures, patent protection, product liability, customs regulations, and taxation policies as well as uncertainty about future governmental science and regulatory policies. All these have been widely and forcefully cited as discouraging pharmaceutical firms from continuing to participate in the development process. Carl Djerassi, for example, has maintained that

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[9]That is, the team could develop an "acceptability profile" on whether a proposed method is attractive and easy to use and whether it conforms with prevailing legal, cultural, and moral norms.

companies need to be granted longer patent protection; that regulations, such as the FDA's, have to be made less onerous; that companies need to be protected by the government against consumer litigation and be given government subsidies for long-term toxicology and other studies if they are to become major actors again in the contraceptive development system.[10] The industry representatives interviewed by the Technology Management Group agreed that insofar as legal restrictions affect profitability, they tend to discourage industry participation. However, it does not appear to be generally felt that the length of patent protection is important for products that depend on complex hormonal processes, although it may be so for simple products and devices. FDA and other regulatory-agency procedures are not felt by most to be a major inhibiting factor but do enter the profitability equation. One industry respondent cited a recent innovation by the U.K. drug regulatory agency that permits pharmaceutical firms to undertake carefully monitored Phase I and Phase II clinical studies with minimal toxicology studies and without applying for investigative new drug clearance. This approach permits a rapid answer with respect to failures, greatly reducing development time and cost. Product liability is conceded to be a major deterrent to new product research, as suits against drug companies become more prevalent all over the world. A program of government insurance would probably be attractive to industry.

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[10] C. Djerassi, 1980, op.cit., passim.

Legal restrictions not only are discouraging to industry but also affect nonprofit organizations. The costs involved in complex regulatory processes, and fears about product liability, may inhibit some organizations contemplating massive field trials of new prototypes. Laws against providing or facilitating abortions can make it difficult to do research on or test any kind of postcoital contraceptive, or a method that acts after fertilization.

Numerous social and cultural factors also may pose problems for contraceptive innovation. These include political attitudes, religious influences, consumer distrust, or male "machismo." For example, the slight stigma attached to contraceptive manufacture is becoming more of a problem for U.S. companies with the rise in influence of such groups as the Moral Majority. (Note the threats of boycott against a pharmaceutical firm because of its role in developing prostaglandins, used commonly as a second-trimester abortifacient.) Consumer attitudes can have the same effect (as in the attack mounted by feminist and consumer organizations against the same company for its role in developing the injectable Depo-Provera.)

Staffing mix. Although the public sector and nonprofit contraceptive development system has attracted outstanding scientists and administrators, the mix of disciplines represented may be too limited. At present, the fundamental research base that has been relied upon is reproductive endocrinology, and research and development are carried out primarily by reproductive biologists and obstetrician/gynecologists. Contraceptive innovation would probably benefit from systematic scanning for potential leads from molecular biologists and immunologists (for vaccines, for example) or from polymer chemists and technicians from the consumer-goods industries (for improved nonsystemic barrier methods, for example).

Staffing needs for the innovation process vary through a project's life cycle and according to an organization's role in the process. As noted earlier, during preliminary stages of project conceptualization, idea generators are most needed, whereas project managers and marketing experts and communicators are more important later. In the same way, organizations involved in basic or even mission-oriented research need to be richly staffed by idea generators, while entrepreneurs or project managers are more important in organizations with major roles in product development, manufacturing, and marketing.

At present, the critical functions in the contraceptive development system are not balanced. In particular, the system would benefit from more entrepreneurs capable of linking leads to products and stimulating access to needed funds and technical expertise.

Three types of well-informed experts are needed to facilitate links in the innovation process -- technical, marketing, and manufacturing. Technical experts in contraceptive development are most commonly found in the university community and industry. Marketing experts familiar with the needs of the user and distributor are scarce. (In industrial countries, organized consumer groups often oppose new contraceptive developments, and, in developing countries, the consumers' voice is usually unheard.) There has not been enough explicit recognition of the need for this type of expert by many of the development organizations. PIACT was established in 1976 in explicit recognition of this need. There has been relatively little use by development agencies of the extensive marketing information now contained in social surveys (such as the World Fertility or Contraceptive Prevalence Surveys) or attempts to include questions in these surveys of more direct interest to contraceptive development groups. This is another area where greater coordination between disciplines could have considerable payoff. Manufacturing experts are found in private sector organizations such as pharmaceutical manufacturers and consumer product companies. These are not being sufficiently employed by the public-sector contraceptive development system.

Collaboration between the public and private sector has been most successful when negotiated by "neutral" professional individuals or groups that understand the requirements of each. (One example cited was the collaboration of the Allied Chemical Company and the World Health Organization with the time-temperature marker for measles vaccine, brought about by a third party who understood the requirements of each agency.) In general, pharmaceutical manufacturers are more likely to be willing to engage in collaborative efforts with the public sector on leads that have applications in addition to fertility regulation (such as LH-RH agonists and antagonists), and on projects that have some prospect of profitability. (For example, a 6-month injectable dose sold for U.S.$1 might stand a reasonable chance of turning a profit but not a 15-year hormonal implant sold for the same price.) It is sometimes asserted that pharmaceutical companies are not going to be willing to devote substantial funds to develop new contraceptives that will compete with products that are already being marketed. Our interviews suggest the contrary: that manufacturers would prefer to have a line of varied contraceptives than to depend on a single product.

Research mix. The balance of research within any industry is responsive to the stage of maturity of the technology. If the technology is newly emerging, the typical pattern of expenditure is heavily directed to fundamental research, with a much smaller percentage devoted to applied long-term or short-term development. As a technology matures, the balance shifts. The overall dollars continue to increase, but the proportion of resources devoted to the fundamental effort starts to decrease in comparison with those devoted to R&D. Increased expenditures for the latter typically increase expectations that a useful product is near production.

At present, only about $0.23 of every reproductive and contraceptive research dollar is going into contraceptive research, compared with $0.70 for fundamental research and training,[11] and $0.07 for safety studies. The small proportion of funds devoted to R&D is bound to disappoint those donors who are eager to see new products emerge quickly from the contraceptive development system. It would be incorrect to presume, however, that too much is being expended on fundamental research. There is still insufficient knowledge of reproductive mechanisms to make the kinds of advances needed to develop certain new products such as a vaccine, male method, or

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[11]Fundamental research in reproductive science may, of course, have a wide range of applications, of which improved methods of contraception are only one segment.

menses inducer. Clearly, however, the applied R&D activities are badly underfunded. Additional funds can only come from increased public sector donor commitment, increased private sector participation, or more efficient and more effective management of the innovation process. The last item may be a condition for attaining either of the other two.

SUGGESTED MEANS TO IMPROVE THE SYSTEM

This analysis suggests that improvements in the system are not likely to occur unless there are changes in the practices of the individual participating organizations to reflect greater consensus on goals and strategy. Shifts by donors in criteria for funding and in the amounts and proportional distribution of financial resources could have broad system effects. So could the establishment of stronger links between development organizations to reduce problems of market evaluation and transfer to the product manufacture stage.

Several other types of adjustment could magnify the effects of these primary changes. Examples include: broadening the discipline mix within organizations and within projects; developing joint projects between existing development groups; and consolidating existing funding streams to strengthen support for priority projects.

In addition, the system could be improved through: greater information sharing among the various development organizations and donors about ongoing projects and scientific development; better coordination among donors regarding funding prospects and project selection techniques; encouragement of creativity through the use of incentives or awards; and the dissemination of relevant technical, marketing, and manufacturing information.

In this context, the following suggestions are offered as possible mechanisms to effect such changes. They should be considered as tentative and are offered as a basis for discussion.

- Establish an information office for donors and developers in the private and public sectors. It could compile information on new scientific developments, projects proposed and funded, products introduced, the results of marketing surveys that might provide insights into unsatisfied consumer demand and of field trials that might offer information on the likely utilization of products under development. It could also report on the current mix of research and types of projects within the system and provide information on techniques for assessing project feasibility. Information could be relayed through a regular newsletter as well as occasional papers and responses to individual requests from donors and development organizations. Expenses of the proposed information office might be provided by a consortium of interested donors to reduce the drain of funds available to each donor agency for support of research.

- Allow the information office sufficient latitude to appoint expert advisory committees to which it could turn for special help. One such committee might bring together experts concerned with science and technology for consultation on specific problems; another might be composed of developing country representatives familiar with family planning programs and market conditions to consult on questions involving unsatisfied consumer demand.

- Agreement by donors and developers on unified criteria against which to examine individual projects and on technical goals toward which they could pool funds and focus efforts. This could substantially increase the effectiveness of the innovation process.

- Establish or add to an existing organization professional capacity to encourage collaboration between the public and private sectors on specific projects.

- Provide seed money for the establishment of an international contraceptive research and development association. Such an association could, over the long term, help develop a constituency and identify a field that is now split between numerous disciplines and types of organizations with little coordination between them. The members of the association might include academic researchers from appropriate scientific disciplines, scientists, and technicians from public sector, nonprofit, and private sector organizations, family planning program planners, social science researchers, physicians, and donors. Activities of such an association could include publications, sponsorship of study groups, advocacy for (and developing justification for) increased funding commitments; and acting as a basis for exchange of ideas between resource groups, for assessments of technology, and for information coordination of programs.

APPENDIX

CONTRACEPTIVE INNOVATION ASSESSMENT

INTERVIEWS CONDUCTED TO DATE

Agency for International Development (AID)	Joseph J. Speidel James Shelton
Alan Guttmacher Institute	Jeannie I. Rosoff Richard Lincoln
Canadian International Development Agency	Charles Nobbé
Collagen	Bruce Pharris
Columbia University	Allan Rosenfield Georgiana Jagielo
Ford Foundation	Oscar Harkavy Linda Atkinson Lowell Hardin
Harvard University	David E. Bell Kenneth J. Ryan
International Development Research Centre (IDRC)	John Gill Lourdes Flor
International Fertility Research Program	Malcolm Potts
International Planned Parenthood Federation (IPPF)	Carl Wahren P. Senanayake
Massachusetts Institute of Technology	Stanley Finkelstein Dorothy Leonard-Barton Glen Urban
Mellon Foundation	J. Kellum Smith
National Institute of Child Health and Human Development (NICHD) Center for Population Research (CPR) Contraceptive Development Branch (CDB)	Philip Corfman Gabriel Bialy Henry Gablenick
National Institutes of Health (NIH) Heart, Lung, and Blood Institute	Edward Sondick
Office of Technology Assessment	Louise Williams Mick Riddiough

Office of Population Affairs, U.S. State Department	Amb. Richard Benedick
Organon	Evert DeJager M. Neves-eCastro
Planned Parenthood of N.Y.C.	Alfred Moran
Population Council	George Zeidenstein George Brown Bruce Schearer C. Wayne Bardin Harold Nash
Population Resource Center	Robert Batscha Ann Harrison-Clarke
Program for the Introduction and Adaptation of Contraceptive Technology (PIACT)	Gordon Perkin
Rockefeller Foundation	Sheldon J. Segal
Swedish International Development Authority (SIDA)	Bo Stenson
Stanford University	Carl Djerassi
Syntex	Richard Edgren
United Nations Fund for Population Activities (UNFPA)	Nafis Sadik Paul Micou Stephen Viederman Auden Gythfeldt M. Sacklowski
Upjohn Company	Gordan Duncan John Stucki
World Bank	K. Kanagaratnam
World Health Organization	Alexander Kessler