DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY, 8(1), 111-123 (1982)



# INDUSTRIAL SUPPORT OF RESEARCH IN COLLEGES OF PHARMACY

Robert V. Smith
Drug Dynamics Institute
College of Pharmacy
University of Texas at Austin
Austin, TX 78712

".....our obligation remains clear: to pursue science at its frontiers and to join with our more applied colleagues in engaging society's harsher problems whenever genuinely constructive opportunity affords. Tommorrow, as yesterday, we shall be judged by our success in meeting both sets of challenges."

Philip Handler
1980[1]

Few colleges of pharmacy have sufficient financial resources to support high-quality research programs. Excellence must be sought extramurally by faculty. Funds are required for researchers' salaries and wages; for expendable supplies and equipment; for office supplies and computer time; for animals and their maintenance; occasionally to provide wages for office staff. Funds are solicited in what is

often referred to loosely as "grants"; however, there are a number of recognized vehicles for supporting academic research including: 1, grant-in-aid, 2, grant, 3, contract, 4, fellowship, and 5, scholarship. The nature of these instruments has been described carefully in a previous work[2] but some review of the characteristics of different grant-types will be provided subsequently. This paper describes methods for the procurement and execution of grants and contracts sponsored by the pharmaceutical industry. It is hoped that useful information may thus be provided for novice pharmacy faculty. For the experienced researcher, some new perspectives may be gleaned. In the later sections of this paper, a description is given of the advantages and potential pitfalls of industrially sponsored research.

One might ask -- why industrially sponsored research? Rhetorically, it might be added -- we have recently been doing very nicely with grants from the NIH and NSF[3]! Given the current financial and political climate in the United States, however, it is safe to assume that federally sponsored research will become more difficult to obtain in the eighties. Recent funding trends support this notion[4]. Most recently, clear evidence has appeared indicating a stiffening of competition for federal health research dollars[5]. This situation is exacerbated by a significant growth throughout the seventies in the number of scientists who are now applying for federal grants[1,2]. It seems clear that greater stability will be achieved in research efforts in colleges of pharmacy through a diversification in sources of support. With good judgement, this broadening of scope may coincidently enrich programs.

## SECURING INDUSTRIAL SUPPORT

The procurement of industrial support for research is somewhat shrouded in myth. In general, there are no clear-cut guides to the

process. Furthermore, private industry is not compelled to provide feedback on funding solicitations; thus, mistakes can go uncorrected. A variety of approaches for tapping industrial support are offered below. These suggestions are distilled from the mixed experiences of the author and a number of his colleagues over the past ten years. Additional thoughts on this subject were also recently provided by Simonelli[6] and Amann[7]. Before considering appraoches, however, a listing of some of the reasons why industry sponsors academically-based research is instructive. First, a firm may lack adequate expertise for a given task. Second, the current in-house manpower supply may be insufficient to tackle a particular project. Third, a faculty member may have synthesized or isolated a new and promising drug candidate that the company would like to develop. Alternatively, a new device or process may have been devised. Lastly, budget or funding situations may arise where a firm is in a good position to support academic activities. The recently expanded philanthropic ventures of the Smith-Kline Corporation provide an example; one that was probably instigated in part by the therapeutic success of the company's brand of cimetidine.

## Approaches to Industry

There are no foolproof methods for approaching industrial firms for research support. A variety of strategies are available and one or more may be useful in a given instance. The most "primative" situation occurs when the researcher has a good idea for a project but knows no one in the pharmaceutical industry who may guide him/her to a potential source of funding. The individual is in the position of having to devise unsolicited (with respect to the industrial firm) inquiries. These are initially developed in the form of a letter which should contain the following elements:[2,7]

1. A brief description of what and why something is to be done. This should address some problem that currently exists (e.g.

extend claims of a presently marketed drug product; provide a new source or route to a valuable drug synthon).

2. Who will do the work and why this person(s) is unusually qualified to perform the needed research. (A curriculum vitae should also be included in the mailing).
3. An estimate of how much time will be required for the project and how much it will cost.
4. Facilities and equipment needed to perform the study and if these are available to the investigator.
5. A best assessment of the profit potential of the study.
6. The question should be posed -- Can a full proposal be submitted?

Potential sources of support should be based on the apparent interests (product lines) of firms. A suitably prepared inquiry should be directed to a scientist or administrator who is in charge of an appropriate division within a company. Names of logical individuals may be gleaned from senior authors of papers of related interest or through one or two judiciously placed phone calls. A response by the industrial firm may request a full proposal. Clear evidence of a lack of interest at this stage or following evaluation of the proposal is usually final and additional follow-ups are futile.

Seeking grant and contract support is similar to a business venture. Consequently, there is no substitute for personal contacts with individuals who might subsequently guide or expedite the review of a proposal. Personal interactions can be made at scientific or professional meetings, or through former students who may be employed in a given firm. Simonelli[6] suggests that preliminary contacts be capped by an offer to present a seminar at a company which may have potential interest in a given individual's field of study. Colleagues or friends employed by a particular company are often knowledgeable about individuals who are

decision makers on outside funding. Leads of this type are invaluable. The best entry into a firm, of course, is through former consulting arrangements. A consultant often develops a highly regarded relationship with a given firm and the consultant will frequently be a first choice for outside contract work.

Approaches to industrially-sponsored research can be facilitated through a research center or institute. Such a unit will be mission-oriented and work through cross-disciplinary strategies. It may be as formally organized as our Drug Dynamics Institute at the University of Texas at Austin or informally constituted such as the Bioavailability Group Studies unit at the University of Georgia. What is important is a management structure that can formulate teams of individuals from different disciplines who are willing to work on mutually agreeable objectives.

Occasionally, a firm may take the initiative to contact an individual or institute regarding the possibility of contract work. These encounters may lead to fruitful results, however, the reader should be aware of one caveat. Industrial firms may be merely seeking quotes for a particular job. Worse, a request to develop a proposal may provide ideas for others who may ultimately complete the job. Good judgement is necessary to discern sincere intent. In this regard, the investigator should be particularly wary of requests made by third-party groups who are ostensibly soliciting information for an unnamed industrial firm.

## Formulating Industrial-Academic Agreements

There are several types of grant and contract arrangements that can be formulated between the academic institution and industrial firm. A free gift[2] or grant-in-aid[6] provides discretionary monies and implies no strict accountability. Universities generally designate a free gift

as a sum of money for which no specific objective and formal reports to the donor are required. Free gifts represent the hardest money to raise and will rarely provide the kind of funding to completely undergird a program or department.

Grants can be defined as more or less flexible instruments that a sponsor uses to stimulate or fund an area of research. The "scope" of the research is generally defined by the researcher and is most often for more fundamental-type research efforts. In contrast, a research contract is an agreement to perform a relatively carefully defined task. A contract, particularly for clinically-based research, will often be based on a relatively rigid protocol developed by or with the sponsoring firm. Furthermore, it will generally involve more "applied-types" of research efforts. Special contract work for specific measurements (e.g. dissolution profiles of solid dosage forms) or testing (e.g. validation of analytical methodology) are service-intensive activities that may or may not compliment a college's program objectives (vide infra).

Industrially sponsored fellowships can provide support for graduate students or postdoctoral fellows. These are most beneficial if they are established on a free-gift basis. The value of these awards is maximized because graduate students can be supported on a tax free basis; postdoctoral researchers with no formal employer-employee relationships are able to deduct $300 per month from federal income tax liability[8]. Predoctoral fellowship programs can also be arranged to provide for summer industrial internship experiences which include work in several different areas of a company. These are enriching experiences that are well received by students.

A major consideration in formulating funding agreements with companies are publication rights. This issue is of varying importance to the industrial firm. On the other hand, it is of crucial importance

to the investigator and his or her university. Most importantly, the investigator should be wary of secrecy clauses in confidentiality agreements or other contracts. Furthermore, the company should not have veto power over publication. Alternatively, prior review of manuscripts by the industrial sponsor is usually an acceptable practice.

In certain instances, an industrial scientist connected with a grant or contract may make meaningful contributions during the course of the work. Co-authorship of manuscripts may be quite appropriate and researchers should be sensitized to this possibility. Of course, it is important to properly acknowledge a sponsor's support in publications resulting from funded work.

Research projects that could lead to a patentable drug, device, or process will require a formal agreement between the sponsoring firm and the University. Written documentation must be developed that outlines exclusive license options by the industrial partner. These agreements may include provision for payment to the university and investigator and must be approved by the university's legal staff. Most academic institutions have patent committees, the chairmen of which are good sources of information in these matters.

Certain sponsored projects may yield results that may ultimately become part of a manufacturer's New Drug Application (NDA). In these instances, strict adherence to federal regulations will be required. For example, animal toxicity studies require compliance with Good Laboratory Practices (GLP's)[9]; manufacture of clinical supplies necessitate use of current Good Manufacturing Practices (cGMP's)[10,11]; clinical studies may call for attention to Clinical Study Guidelines[12]. The stipulations in the GLP's and GMP's may affect the feasibility of carrying out certain types of industrially-sponsored projects and the researcher should investigate the impact of these potentially prohibitive conditions prior to formulating any agreements.

Proposal Preparation

There is no set make-up for proposals submitted to industrial firms. Researchers who are comfortable with the NIH-398 format may wish to utilize it. For convenience, the elements of such a proposal are listed below.

1. Cover page
2. Abstract or Summary (key words can be underlined)
3. Budget
4. Short biographical sketches of investigator
5. Research plan
   A) Objectives
   B) Significance and background
   C) Progress report or preliminary studies
   D) Methods of procedure
   E) Collaborative arrangements where appropriate
   F) Facilities available and necessary for project

Strategies for preparing the various sections of a proposal have been well discussed elsewhere[2,13] however, some points merit reiterating. First, the abstract or summary is possibly the most important part of the proposal because it may be the only section read by some individuals who can influence the decision to fund a project. Consequently, the summary should be prepared with great care and only after the remainder of the proposal has been written so that all elements can be represented. Second, the proposal should be succinct; there is no place for excessive wordiness. Third, the significance portion should clearly indicate the monetary (profit) value of the proposed research. Finally, the budget should reflect a fair appraisal of the cost of a given project. At the same time, a supplemental grant-in-aid package might be negotiated to compliment the award for strict project-related costs. The level of grant-in-aid can be made inversely proportional to the research potential

of the planned study. The more service work necessary, the more the grant-in-aid. In this way, grant-in-aid is viewed as a type of "profit" -- a concept that should hardly be foreign to colleagues in industry!!

## IMPLEMENTING INDUSTRIAL GRANTS AND CONTRACTS

Whether one works on industrially-sponsored grants or contracts, there is usually a need for expediousness. Indeed, the researcher will often be confronted with a prospective contractor who wishes that a given project was done yesterday!! The obvious absurdity of this notion underlines the need for quick response by the researcher who accepts the industrial grant or contract. In contrast, universities and colleges tend to be places where there are erratic bursts of activity. That is, student schedules tend to cause a roller-coaster effect in research productivity. At examination or report times, output decreases; during less pressured intervals, productivity increases. These facts emphasize the need for a small cadre of staff and/or postdoctoral research associates who can be both flexible and continually available to respond to altered needs. It also takes a good manager-researcher who can balance the fluctuating needs of a dynamic research program[2].

During the execution of industrially-sponsored research, particular emphasis must be placed on data collection and record keeping. As noted earlier, results may be obtained that will wind up in an NDA application. The veracity of the results, properly dated and witnessed, may be double-checked at some future time. Careful organization and attention to archival needs will save embarrassment later.

The investigator performing industrially-supported work should not be surprised by requests by the sponsor to monitor certain aspects of a study. This is especially true of clinical projects where monitors

will wish to validate the implementation of safeguards for human subjects. Veterinary toxicological studies may prompt inspection of animal holding facilities and pathological evaluations. Even simple laboratory studies may stimulate a visit by industrial project officers to verify the availability of necessary instrumentation. The academic researcher should not be insulted by these activities. He/she should remember that the sponsor is merely protecting his business interests.

Reporting mechanisms will vary with the company supporter. However, all firms will require final progress reports. Projects lasting a year or more may require quarterly, biannual or yearly reports. A clear understanding of the reporting expectations should be understood during project negotiations.

Reports are best prepared in the style of papers prepared for publication. Again, the abstract will be most important! Standardized forms may be proposed for the reporting of certain types of data (e.g. blood level data - pharmacokinetic studies). The investigator should be sure to check on the company's need so that forms can be adopted early in a study thus avoiding transcription activities. Also, actions of the university's investigational review board (IRB; protection of human subjects in research) will have to be documented before studies are commenced. Timely and effective research reports are very important for continuity in funding since transmittal of portions of an award are often tied to the reporting cycle. A "business-like" approach is desirable in reporting and funding activities associated with industrially-supported projects.

## IMPORTANT CHARACTERISTICS OF INDUSTRIALLY SPONSORED RESEARCH

There are some important advantages to industrially-sponsored research. These have been alluded to earlier and are primarily: 1, less

paperwork, 2, the availability of (discretionary) grant-in-aid funds, and 3, unusually beneficial fellowship support for graduate and post-doctoral students. Additionally, recipients of industrial grants are often permitted to tap corporate resources. Included here are specialized equipment, pharmacological testing and/or screening procedures, unusual physical facilities (e.g. field stations, large animal laboratories), and counsel from "in-house" scientists. Furthermore "real-world" problems are confronted (see quote before introductory paragraph) that are a source of inspiration to faculty and students. For students, a sense of professionalism is experienced; a chance to practice some of the unusual facets of the profession of pharmacy is realized. Concurrently, students are provided relevant training situations. In this regard, it is important to reemphasize the service component of many industrially-sponsored grants and contracts. Service per se is not bad considering its utility in training activities, however, the professorial researcher must continually guard against becoming bogged down in service obligations. The author has previously discussed this with respect to the scholarly development of clinical faculty[14].

An additional point should be made about exclusive service activities. A researcher and indeed a laboratory or institute can gain a reputation for doing principally service-type work. This, in turn, can become a self-fulfilling prophesy as more and more contractors approach the unit or individual with enticing offers. The lure of "bankrolling resources" can be so strong as to compromise a commitment to fundamental research. Moderation is the key; a constant striving for a mix of support is paramount. By blending federal, industrial, and other private sources of support[1,5] one can strengthen the foundation of most college of pharmacy research programs.

## SUMMARY AND CONCLUSIONS

The procurement and execution of grants and contracts from the pharmaceutical industry have been discussed. Attention is focused on approaches to industrial sponsors, formulating agreements, proposal preparation, and efficiency measures as well as caveats during implementation of projects. Advantages and potential pitfalls of industrially-sponsored research are described. A judicious balance of federal, industrial and other privately-sponsored research is recommended for enrichment of research programs in colleges of pharmacy.

## ACKNOWLEDGEMENTS

The author is grateful to Dean James T. Doluisio and Professor James W. McGinity for their thoughtful critiques of this manuscript.

## REFERENCES

1. P. Handler, Can. J. Biochem., 58, 155 (1980).
2. R. V. Smith, Development and Management of Research Groups - A Guide for University Researchers, University of Texas Press, Austin, TX, 1980.
3. National Institutes of Health; National Science Foundation.
4. Chem. Eng. News, 57 (30), 43 (1979).
5. NIH Weekly, 1 (9), 1 (1981).
6. A. P. Simonelli, Symposium - Funding for University Research from the Pharmaceutical Industry, 29th National Meeting of the APhA Academy of Pharmaceutical Sciences, San Antonio, TX, November, 1980.
7. A. Amann, ibid.
8. Tax Information on Scholarships and Fellowship Grants, Publication 507 (10-70), U.S. Printing Office, Washington, DC.
9. Code of Federal Regulations-21, U.S. Printing Office, Washington, DC, 1980, Part 58, pp. 189-202.

10. Fed. Register, 43 (190), 45,014 (1978).

11. A. S. Arambulo, in Quality Control in the Pharmaceutical Industry, Vol. 3, M.S. Cooper, Ed., Academic Press, New York, 1979, pp. 1-103.

12. Clinical Study Guidelines consist of more than a dozen documents providing recommendations for the conduct of clinical investigations. The Guidelines, for the most part, are individually developed for different therapeutic classes of drugs and/or patient populations (e.g. Analgesics, Antirheumatic Drugs, Anticonvulsants in Children). All of these, including the initial set, General Considerations for the Clinical Evaluation of Drugs, 77-3040, are available from the Superintendent of Documents, U.S. Printing Office, Washington, DC along with a list of available Guidelines.

13. V. P. White, Grants: How to Find Out About Them and What to Do Next, Plenum Press, New York, 1975.

14. R.V. Smith, Amer. J. Pharm. Educ., 44, 74 (1980).

15. The federal government as well as industrial firms are sensitive to double funding of investigations. In cases of dual support of a large project, investigators must take care to delineate which portions are being funded by each sponsor.