INTRODUCTION

The usual basic pharmacetics courses, taught in the first professional year, have traditionally been given in the lecture-examination format. This approach has been defended by the idea that there exists, for this subject, a body of information and data to be transmitted to the student and, after this has been presented (the lecture), the attainment of this information can then be tested (the examination). This method may not provide the best way of achieving what is actually desired for the student of any college course, i.e., understanding the concepts involved in the course and the ability to use these concepts. However, student-centered methods used in other fields, and in more clinical areas of the pharmacy curriculum(1), have traditionally not been considered suitable for the basic sciences.

The practical implementation of student-oriented, case study-based courses varies widely, but all these teaching approaches are generally labeled as Problem-Based Learning (PBL). The attempts that have been made to extend the teaching of the basic sciences in the case study direction usually retain lectures and exams, but perhaps add cases or essay questions to the testing aspect. Discussions, when included, are most often ‘demi-lectures’ as the students usually do not have their inquisitive-disputative ‘center’ sufficiently well developed to allow useful discussions. A number of examples of workable models for such courses in Medicinal Chemistry(2,3), Therapeutics(4), Pharmacokinetics(5) and Pharmaceutics(6, 7) have been described, but the comparative advantages of each are still unclear. Some evidence for an improved retention of knowledge obtained through the PBL approach, compared to more didactic approaches, has been presented(8,9), but there is still considerable disagreement over this issue.

In 1993, faculty in the Department of Pharmaceutical Sciences of the School of Pharmacy at the University of Southern California were challenged to change to a student-oriented, case-study approach to the teaching of Pharmaceutics to a class of 170 students. The design of the course, and the subsequent modifications that we have made, in response to this challenge, as well as the successes we have achieved and the difficulties we have faced, are described in this paper. An interesting and thoughtful analysis of PBL applied to Pharmaceutics has been presented by Duncan-Hewitt (10) and many similarities emerge between this and our own experiences. In particular, these revolve around the anxiety apparent amongst many students as they try to deal with the PBL approach for the first time, and the difficulty, for such a large class size, of establishing sufficient faculty-student contact to calm these anxieties. Addressing these problems has meant that the course structure has been and is still in some flux, but it has been concretized sufficiently to permit an intelligent presentation of the basic structure and philosophy. More detailed aspects of the course, such as the utilization of computer-based case studies, which is an integral part of the program, have previously been presented in other papers(11,12)
GOALS AND OBJECTIVES OF THE COURSE DESIGN

There were three fundamental objectives in our original course design. These were: (i) to promote student-led learning; (ii) to give students experience in group functioning; and (iii) to develop meaningful evaluation methods that are responsive to the nature of the course. Our current thoughts on the successes and failures in each of these areas are summarized below. In understanding these thoughts and the following discussion on the course structure, it is important that the reader recognizes that the class size is approximately 170 students, and, given the demands on faculty time, that this leads to a necessity for compromise between ideal and practical approaches. A fourth area, the development of leadership skills amongst the students and student mentors, has emerged as we have proceeded with the class. This is not dealt with in a specific manner, but should be apparent in the description of the activities of the students and the mentors in this and subsequent parts of the paper.

Student-Led Learning. To enhance retention of the fundamental concepts involved in pharmaceutics, the main objective was to develop self-motivated learning. While concepts should, and perhaps must, be presented by faculty members who have a clear understanding of the utility of, and reasoning behind, those concepts, it should be the student’s responsibility to seek sources of that information that were both understandable and meaningful for him/her. This approach is designed to develop familiarity with a wide spectrum of the pharmaceutical literature and begin the development of the ancillary, but no less essential, skill of evaluating that literature (e.g., ‘don’t believe everything you hear or are told,’ ‘I never understand what author X writes’, etc.).

Our approach to this has been an attempt to foster the idea that there are actually few ‘right answers’ to the application problems faced by the pharmacist, including those examples presented while in school and, to an even greater extent, those to be faced after graduating and beginning practice. There are, of course, ‘right answers’ to specific technical and scientific questions. The students are urged to consider ‘correct’ applications of their knowledge to be only those that they can logically defend with either literature citation or scientific reasoning. They are encouraged to use information from all current and previous classes for this defense. They are further encouraged to file this information in some retrievable manner for future use.

Group Functioning. Both the business and the scientific world function as group efforts, quite in contrast to the lecture/exam, academic world. Group efforts require quite different skills than individual work or study. Although the concepts can be taught in principle, they are best learned by practice. In order to foster group functioning, all recommended reading, homework, and case studies require time far in excess of that available to any one student in the course. Students can only get the work done through group efforts, and, in conjunction, must provide the results of that research effort in a meaningful written and verbal form to the other members of the group.

Working as part of a group (and depending, to some extent, on that group’s efforts for their grade) has been found to be difficult for many students, whose educational success to this point in their careers has been largely based on their being ‘individual’ workers and learners. However, students soon learn the benefits of good leadership and ‘doing their part’. Leaders develop and ‘appear’ quickly, as do those that can explain what they have read to the group. The group leader is appointed at the start of the academic year and then changed several times over the year, through an internal group decision. In contrast to other PBL approaches(10), we have largely resisted the temptation to interfere with the workings of each group. At the beginning of the year we provide some basic written instructions (see Appendix A) on the role of the group leader and on group functioning, and additional material on the student-mentor relationship, and on the case study method. This material is supplemented by faculty-led discussions on the same issues in the early part of the year.

Meaningful Evaluation. The most difficult goal to accomplish has been to develop meaningful methods of evaluation for the individual efforts of each student. The essential problem is that, while instructors want to encourage group working and cooperative effort for the benefit of all, the same instructors are still faced with the necessity of assigning grades on an individual basis. This leads to a contradiction which has been difficult to resolve.

The first efforts included no comprehensive, individual evaluations at all. All student grading was based on the group case study reports (one grade for all group members) modified for each student based on evaluations of their participation by their peers in the group. This proved to be more valuable in concept than in practice. Students were very reluctant to grade their group members; but were quick to complain about those that did not do their share. To address the issue of individual participation in the group effort in completing the case studies and other assigned work, we have since tried to incorporate some faculty evaluation of this part of the course. However, this was felt to be feasible only when done in small groups and, in a large class, insufficient contact with some students or groups made meaningful evaluations extremely difficult.

After trying several different approaches, the follow-
ing has been found to be an effective, if not ideal, compromise between stressing group effort over individual gain, while still recognizing outstanding students and providing sufficient incentive to contribute fully to the group effort. The breakdown of grading over the semester is summarized in Table I, and is explained as follows:

- There are two case studies assigned during each semester and about four weeks allowed for their completion; these are group efforts and are quite sophisticated. A number of these cases have been described previously (11) and a typical case study is shown in Appendix B. A final ‘mini-case’ is also required, to be done individually and in the final examination room, where conceptual understanding and ability to use these concepts is evaluated. Each case study is worth 30 percent of the course grade in each semester, and the examination is worth 40 percent.

- Each group is graded jointly on their case report and the same grade is received by all group members for this part of their grade, which represents about 53 percent of the case grade (and 16 percent of the final course grade) for each case.

- Each group member is graded by the faculty (who see the group several times during each case study in formal discussion sessions, with rotation of faculty amongst the groups), the group’s mentor (a Level II student, who also meets with the group at least once each week - see below), and by each of the other members of the group (the peer grade, with the grade for each student being determined as an average of all the grades from their group peers). The basis for these grades are attendance, participation, effort, contribution to group discussions and the ability to function within the group. The faculty, mentor and peer grades are, of themselves, only a small percentage of the overall grade (each is 10 percent of the case study grade), but collectively they provide a general, albeit limited and not always entirely accurate, picture of the efforts of each student. We stress that, while this approach is used as part of the determination of the final letter grade, it also provides us with a means of identifying students who may be having some problems in the course. This is particularly important, given that the course is offered to Level I students, and that the absence of the ‘traditional’ mid-term examination gives us no other means of assessing student progress.

- Group interviews by a faculty member are held immediately after the reports are completed. Evaluation of each student’s contribution to the case report and their understanding of the other parts of the group’s report has been found to be quite straightforward using this procedure. This grade accounts for about 17 percent of each case study grade.

COURSE STRUCTURE

The course is structured in the following manner. The traditional transfer of information through the lecture addressed to the whole class is largely replaced by concept presentations which are still in a lecture-format, although with a somewhat different purpose and by discussions with faculty and with mentors. Attendance is required at the presentations and discussions. Overlaying this structure is the assignment of case studies, which provide a basis for the full integration of the presented concepts. Two such cases are given in each semester. Because group operation is required, both for the case studies and in the discussion sections, the student groups also meet informally several times each week to distribute work assignments, collect results and discuss problems. The frequency, places and times for these are worked out by the students themselves and implementation is the responsibility of the student group leader (see below). Appendix C shows a typical schedule for the year. The development of the course structure is described in detail in the following sections.

Weekly Course Structure. We have experimented with two different course structures. Initially, we devoted each week to a different concept. On the first meeting day of the week, the concept was presented by a faculty member to the whole class. This presentation is, in actuality, a lecture, but its structure and purpose is quite different from the usual course lecture. The concept presentation is intended not so much to teach, develop, or derive the concept for the week, as it is to introduce that topic and define the scope the students are intended to cover in their readings. The reading assignments, key objectives and several illuminating questions for each concept are all in the student’s hands from the beginning of the semester. These reading assignments include papers, chapters and/or whole sections of texts. On the next meeting day the students meet with their mentor to discuss the questions and assign reading based on the suggested sources. The mentor serves to clarify and discuss the concepts introduced that week. On the third day the group meet with their faculty discussion leader for a further discussion of the concepts of the week. In these meetings it is assumed that the key questions are answered (a group answer for this is required) and that the reading has been done, so the discussion begins from that standpoint. The discussion is intended to develop understanding of the meaning and the use of each concept in pharmaceutical situations.

Although the above schedule worked reasonably well, and the components within it have largely been retained in the new schedule, it was also found that the concepts were learned and retained in a somewhat fragmentary manner. To address this issue, we have now moved to a schedule (see Appendix C) in which six concepts are presented in successive lectures over three weeks, and then six faculty-led discussion sessions are held over the next three weeks, in which a more broad-based discussion is possible, and in which the integration of a significant amount of material can occur. This sequence of three weeks of lectures and three weeks of discussions occurs twice through the semester, and four times over the entire year. A further advantage of this approach is that the three weeks of discussion coincide with the period devoted to performance of the case studies, and the due date for each case study is set for the end of the three week discussion period. This has allowed us to much more effectively discuss the case with the students, and to guide them in their problem-solving, thus addressing one of the concerns regarding student anxiety and problem-based learning. In this schedule the mentor sessions retain the same character as that described above, and are still used to explore more specific concepts on a weekly basis, and to discuss assigned weekly questions.
Case Studies. Case studies are assigned in approximately the third and eighth week of a 14 week semester, and each group (of six or seven students) is given about four weeks to complete their report. As exemplified in Appendix B, and also in related papers dealing with computer-based case studies in the course(11,12), the case studies are complex problems which require considerable sophistication and background reading in order to arrive at an appropriate answer. Much of the material required for answering the case study has not formally been covered in the lecture presentations, and this forms the basis of the faculty-led discussions during the case study period. This has been found to be particularly effective, because the students then have a reason to engage in these discussions (since they are having to address problems within their case study) and, when the system works most effectively, they are already formulating questions from the background case study reading which might be answered in the discussion periods. For example, the question might arise ‘How can I know the ionization state of my drug at my formulation pH when I cannot find its pKa anywhere in the literature?’, which might be effectively answered by a discussion of the empirical Hammett-Taft approach to pKa calculation(13).

Based on informal conversations with faculty in other pharmacy schools, this version of problem-based learning and of case-study implementation varies somewhat with that used elsewhere. Typically, relatively discrete case studies are given which can be answered in a formal scheduled class period, and cover a relatively specific concept each week. Rather than taking this approach, our case studies are complex, require several weeks of group effort to answer, and involve the understanding and integration of a number of different concepts. For the range of concepts covered over the year, see Appendix C. The complexity of the case studies increases as the year progresses, as each case incorporates material from earlier in the year. This approach has advantages with respect to integration of material, but also places considerable demands on both students and faculty. It probably also requires more extensive faculty-student contact, because the potential for students to go astray in answering the case is considerable.

ROLES OF INDIVIDUALS AND GROUPS IN THE COURSE

The course is based on the activities of a number of different groups and individuals, in addition to the faculty, as described above.

Student Groups. Case studies are performed by groups of six or seven students, giving a total of 26 groups (and hence the requirement for the writing of two sets of 26 similar, but substantively different, case studies each semester - see Appendix B for a typical approach). The groups do not change over the whole year, and only in certain circumstances are students allowed to transfer between groups. In insisting upon this, we wanted to stress that the professional environment may not be filled with colleagues whose views always coincide with your own, and that compromise and the development of working relationships is an essential element in any successful professional enterprise. This insistence can lead to conflicts, but we believe that, for certain individuals, it can provide invaluable insights into their personalities which will serve them well in their professional lives.

Student Group Discussion Leaders. Each group is requested to select a leader to serve as the guide for research assignments, resulting reports, case work, and meetings. At the beginning of the first semester (as the students are unfamiliar with their cohorts) the leader is selected by the faculty. A different leader is selected after each case is completed; giving four students experience of leadership for each group of six or seven students over the two semesters. Some minimal guidance is provided to these leaders (Appendix A) and their skills improve visiibly with each case study.

Mentors. As problem-based learning is foreign to nearly all of our entering students and as few grades are provided to inform them on their course progress, ‘engineered’ contacts with members of the previous year’s class (referred to as mentors) help to increase student comfort and performance level. These mentors are selected by the course faculty based on their performance in the class, their communications skills and their willingness to act in the mentor capacity. They are paid a small stipend and are described in their transcripts as having received a ‘Leadership Fellowship’. The function of the mentors is not to lecture, not to answer key questions and not to help directly in the preparation of the case reports. Their role is to provide advice as ‘big brothers or sisters’, and they have proved to be particularly influential and are an essential element in the course.

Teaching Assistants. Since at the University of Southern California there is an active PhD program. Graduate students (TA’s) are used to supplement the faculty activity in discussion sections. Our current feeling is, however, that the level of discussion and interaction preferably requires the participation of more senior graduate students. Even then, this is still a difficult task for TA’s who, themselves, have not usually been involved in this type of teaching, and perhaps do not have the requisite pharmaceutical experience. The discussions demand considerable skill and experience, skill both in leading discussions (a very different skill than that required for lecturing or for performing research), as well as in finding suitable applications of the concepts being considered. Nonetheless, many of the TA’s that have been involved in the course have responded very well to the challenge, and have enhanced considerably their own teaching abilities.

FACULTY PERSPECTIVE: COMMENTS AND CONCLUSIONS

The major problem remains the evaluation of individual performance and contribution. While still difficult, we believe this can be done effectively using the approaches described above. These provide sufficient contacts with each student to allow individual evaluation. While evaluation on the basis of individual interviews (without ‘grades’) would appear to be ideal, in classes of any size this is not feasible, and numerical grades are still used. Group operations remain difficult for students. Problems, while infrequent, are sometimes rancorous and group leaders must be reminded frequently to bring these to faculty attention, not so much for grading purposes, but for
working through those personal difficulties which stand in the way of the student’s understanding of the material.

From a faculty perspective, the course provides two major demands which are perhaps beyond those typically encountered in the lecture/examination format. First, because students are openly encouraged to ask questions throughout the semester, because there is an open-door policy regarding student-faculty interaction. With 170 students in the class, the effects on faculty time are obvious. Second, students are provided with a case study that has 26 variations and a number of inter-related sections, and that can be answered in a large number of ways, the course demands the faculty to constantly react to and advise on student theories and ideas (some of which are extremely imaginative and interesting). This type of interaction is at the very heart of the course, because it is challenging the students to think for themselves, rather than simply digesting the ‘accepted wisdom’, but it is also demanding of the faculty, and requires a breadth and depth of understanding of many, diverse subjects. This is further emphasized by the material covered in the year, which ranges from basic physical chemistry to cell biology to pharmaceutical formulation and delivery.

After five years of experience, it is our belief that this approach, while demanding to administer, is effective in meeting the objectives outlined above. We are unable to provide quantitative information to support this, because of the relatively short time since the course was first designed, and so we base this belief mainly on the reactions of students to the course. Given the considerable change in the approaches taken, compared to those most students are familiar with, we believe that the generally positive comments we have received are encouraging. The following section of the manuscripts reflects these opinions, and was independently written by several students who have been closely involved in the course over a two year period, first as students and then as mentors.

A STUDENT PERSPECTIVE

The Pharmaceutics course at the University of Southern California School of Pharmacy has been taught using a student-oriented, case study approach for the last five years. The course from a faculty perspective has been described above. As former students and then mentors of this course, we draw on our experiences to evaluate the case study method and discuss, from the students’ perspective, characteristics which are imperative for success of the course. Much of what is written reflects the authors’ experience in discussing issues with other students over a two-year period as students, and then as mentors, and is not necessarily the opinion of the authors specifically.

To the student, a class has been successful if two things are accomplished. First, at this level of education, the student is interested in obtaining the largest knowledge base possible within the constraints of a semester. And secondly, the student strives to retain as much of this newfound knowledge as possible. All too often, students struggle through courses spending endless hours studying and memorizing only to forget almost everything merely weeks, if not days, after the exams. Such courses are not classified as ‘successful’ to the student. On the other hand, the Pharmaceutics course, which is organized in an unconventional manner, leaves the student not only with the very broad knowledge base, but more importantly with the ability to draw from this knowledge long after the course ends. Initially, the course seems radically different from any other basic science course. The conventional series of lectures interspersed with two or three exams is replaced by fewer lectures and many more discussions, group interactions, research and brainstorming for logical conclusions to posed pharmaceutical questions. Needless to say, confusion and frustration are initially widespread. However, as the routine becomes more familiar, frustration is replaced by acceptance and eventually appreciation. Looking back at the experiences of completing the course as students and then helping to lead the course as mentors, there are many areas of the course which are integral to the learning experience that can be discussed. The following is a discussion of these areas with suggestions to maximize the learning experience for the students.

Group Dynamics. One of the most fundamental aspects of this course is the experience gained in group dynamics. As future members of health care delivery teams, our ability to function in groups will be essential. Unfortunately, group friction is bound to arise in any situation where individuals must work long hours together to obtain a goal. In the context of the course, problems usually develop due to lack of experience in working with others and adjusting to the idea of depending on other students. For instance, students depend on each other to share the workload of acquiring the information necessary to answer the case study questions. This ultimately leads to the same case study grade for all members in the group. At the time, students find this to be frustrating, because it requires group meetings (time spent outside of scheduled classes) and a dependence on other students to learn the material. Later, however, students look back to appreciate the experience as it simulates a ‘real world’ work environment where depending on others and working together is necessary to achieve a final goal. To minimize group friction and help nurture smooth group functioning, group leaders need to utilize the guidelines provided in the course syllabus and actively take on the duties of the leader. Group members, on the other hand, must learn to follow the direction of the leader. Students quickly learn that group cooperation is essential for individual success, and most agree that it is best if faculty intervention is discouraged in order to train students to work together in often stressful situations. With time, students learn how to work out internal disputes and carry on with group business. To facilitate progress in this respect, complete guidelines describing group leader and member responsibilities that students can refer to might be provided. This is analogous to a job description used in the real work environment. However, it should be emphasized that faculty intervention in group disputes is strongly discouraged.

Faculty - Student Interaction. This course is often student-led in the sense that much of the learning occurs during group discussions and individual research rather than in lecture. The obvious advantage to this technique is that students retain more information longer and learn how to obtain information from the most current resources. However this method also demands faculty support. On several occasions during the course, the students are...
required to develop an understanding of a concept which has not yet been introduced in lectures. It is imperative that the faculty be available to clarify confusing concepts and direct students on the right track, and an open door policy is essential. However, to a certain extent, the faculty should also encourage students to be as self-reliant as possible. It is beneficial for students to get some direction when they hit an obstacle that they cannot overcome on their own. However, students should not need to check in with a faculty member at every step of the process, and a compromise between guidance and ‘spoon-feeding’ should be sought.

**Mentors.** Mentors provide a perspective that can only come from one who has recently completed the course. As time goes on, the mentor evolves from acting as a ‘big brother’ or ‘big sister’ to a source of information and guidance. The mentors are called on to draw from their own experiences as students to help the students in their groups. It is easier, being students themselves, for mentors to see the students’ perspective and to work at the students’ level to help guide them. We believe that, for a successful mentoring program, consistency between mentors is important. Such consistency would best be obtained by providing mentors with a mandatory training session in being facilitators. The mentors should also be provided with complete responses to the weekly lecture questions so that they may better maintain consistency and accuracy.

**Critical Thinking.** Critical thinking is an essential skill for any health care professional. Pharmacists are called on daily to draw on their knowledge and experience to make professional decisions. The skill of critical thinking has not been previously developed in most students. Since this course revolves around critical thinking, this presents a challenge to most students. In this course, students are required to look at current pharmaceutical theories, which don’t always necessarily agree, and then analyze them and try to put them to use. Since most students don’t have too much first-hand experience with the pharmaceutical theories, considerable research, reading and discussions with fellow students, mentors and the faculty are necessary. After this ‘gathering’ of essential information and opinions, the student must then put all this together and finally come to a conclusion. The faculty emphasis of the importance of supporting ones position rather than searching for a single correct answer is essential, because it encourages critical thinking rather than random search for what one source may support as a probable solution.

**Resources.** The case study method requires that students with different educational and skill levels work closely together. The class is made up of a diverse student pool ranging from students with only two years of undergraduate experience to students with many years of pharmacy experience. Such a variety of skills is desirable as each group is bound to have members with different strengths to provide the group. However, it also means that students are starting at different levels and must be provided with some basic resources that they can be functional in areas which are less familiar to them. A good example is computer technology. While some students can develop programs of their own, others cannot even log on to a computer. To avoid unnecessary confusion and frustration, students should be provided with a primer at the onset of the course. This primer should have detailed information on how to access and utilize basic programs on the computer, and introduce the student to on-line and library resources. Such a primer would prevent confusion dealing with basic logistics and direct students to focused research, study and analysis. Another component of the course, the compounding laboratory, is felt to be very important by most students, because it allows the student hands-on experience with all the basic pharmaceutical techniques, and reinforces concepts discussed in the abstract during discussion sessions (note, the compounding laboratory is now no longer a formal part of the course described in this manuscript). For such laboratories to be successful, it is important that student have access to a comprehensive laboratory manual and adequate laboratory equipment, and that the laboratories are performed by small groups of students.

**Relevance of Coursework.** As a final evaluative measure, a discussion of the outcome of this course is necessary. The authors believe that the case study method helps put physical chemistry into a clinical context. By doing research and searching for solutions to pharmaceutical cases, students are placed in a unique position to determine the relevance of physical chemistry to the pharmacist. While the course is considered difficult by many students, most generally agree that the challenge is worthwhile as it develops a knowledge base that is important for any pharmacist to have. As a discipline, Pharmacetics is a demanding course introducing concepts which are new to most students. As a class, group and student-oriented teaching are also foreign to most students. Thus, as may be expected, confusion and frustration are initially widespread. The suggestions previously made should minimize confusion and help direct students. The outcome is that the student obtains, for himself or herself, a knowledge base which can be accessed again and again for years to come.

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**References**

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APPENDIX A: MATERIAL PROVIDED TO STUDENTS ON THE ROLE OF THE GROUP LEADER AND ON GROUP FUNCTIONING

The following material (presented here in an abbreviated form) is given to the students at the beginning of the year, and provides some background information on key issues in the course. The material is reinforced further by class discussions of these issues.

What is a Group Leader and What Does He/She Do?
The efficient functioning of a group demands that someone be 'in-charge' of that group, to set goals (with the assistance of the group) and to 'run' the meetings. In order for your group to 'get started', the faculty has selected one member of your group to act in that capacity at the beginning of the Fall semester. After each case study has been completed, you will be expected to select your next leader. A new group leader must be selected for each new case study. Thus four of you will have the opportunity to be a group leader over the year. Please realize that this task is neither easy nor always pleasant. Someone with the skill to work with people and the willingness to make often unpleasant decisions is required, and the results of your case studies will depend somewhat on the effective functioning of the leader you select.

A few guidelines for Group Leader functions may help. These are not all of the activities the leader will find him/herself doing, but should serve as an adequate starting point. The leader will: (i) call and conduct team meetings; (ii) make assignments to each team member either in preparation for class discussions or case study work; (iii) coordinate all aspects of the completion of case studies, including the writing, final editing, and submission of the group report; (iv) continuously evaluate the performance and contribution of each team member to the case study, counseling those members whose performance is detracting from the performance of the team, and directing those students to the mentor or a faculty member for assistance; (v) work to develop one or two group members to be future leaders; and (vi) fairly assign each group member a share of the responsibility for reading background material for case studies and class discussions and for briefing the rest of the group on the important points in the background material.

Group Functioning in Pharmaceutics I and II
Each of you have been assigned to a group of six or seven people. You will remain in this group for the duration of Pharmaceutics I and II, and only under extreme circumstances will changes in the group be considered. You will be expected to do your work as part of this group for both in-class discussions and the out-of-class projects (case studies) assigned to you. After concepts have been presented in the lecture blocks, your group have discussion meetings with the TAs and faculty members. These discussions are important, they are graded, and they are part of the class. Information will be discussed regarding the current case study, and the answers to the weekly key questions will be discussed and collected. You will be judged on your ability to contribute to the discussion, and so you must act as a contributing member of the group at all times. You must make every effort to be present or to be adequately excused.

One member of your group has been assigned to be the initial leader of the group, and he/she will be responsible for seeing that the group's first case study is completed as assigned, that all people in the group have a part to play and, of even more importance, that all do their share of the work on the first case study. You will each be required to maintain a record of your impressions of the contributions of each member of your group, and provide a grade for each member following completion of the case study. This record and grade will be collected anonymously when the case reports are handed in. The leader is critical to the functioning of the group (please see the attached document for details of the role of the leader).

We do understand that group-based working is not your usual method of study or learning, and that it is a skill that must be learned and practiced. Our purpose is to provide this practice and, in operation, to identify any group function problems you may have. There may be some problems in your group, e.g., perceptions of inequity in work assignments or work quality, disagreements, or personality conflicts. This is not abnormal, and it is the responsibility of the leader and other members of the group to solve these problems. These may also be problems similar to those that you will face in your future professional life. We expect that you will try to deal with them using persuasion, diplomacy, and appeals to effort for the good of the group. We would much prefer that you only report problems to the faculty as a last resort.

Two case studies will be assigned during each semester. These are very complex assignments and will require you to work with your group outside of class, either in the library or at some other place of your group's choosing. The case study report will be due about four weeks after assignment. Following submission of the report, the group members will meet with a faculty member (the interview) and be asked about the report. You will be expected to be able to discuss what you did and to describe how your work fits into the overall report. The report and the interview will be graded on content, scientific logic, imagination and creativity, and each member will receive the same grade for the report made. Each member may receive different grades from the interview. A full breakdown of grading for the course will be provided in the detailed syllabus.

APPENDIX B: SAMPLE CASE STUDY

This case study is representative of that given as the third of the year. Case studies given at an earlier stage of the course would focus more explicitly on specific physical chemistry concepts, such as pKa, the use of buffer solutions, isotonicity, solubility, or chemical kinetics. In the following case study these concepts are included in a less explicit manner, and the students are expected to integrate them into the formulation problem. For concepts covered in the course, see Appendix C.

The ear, nose, and throat department of your hospital has been doing research into new and sometimes previously unused combinations of older drugs, for use as nasal sprays to relieve severe nasal inflammation and congestion. These products will be used in their research projects on youth and young adults (ages 12 - 21 years, anticipated body weights are 100 to 175 pounds).

Your group has been given the task of proposing an initial formulation for a batch of five liters of one of these products. This batch is expected to last for about three months. The customary application (dose) is to be ‘two sprays’ into each nostril. Your spray containers have been calibrated to produce 0.125 cc/spray and the medication will be applied four times per day. Your formulation (four sprays) is to contain X mg of Insoluble Drug A and Y mg of Soluble Drug B.

Please propose a suitable and defensible formulation for the
ENT request and discuss your reasoning for proposing this formulation. If you feel that quantitative data are required for adequate responses, seek that data, and, if it is unavailable, make educated estimates of the needed values. Please limit your discussion to 10 pages and to the following concepts:

(i) The ‘comfort’ and acceptability, as well as the appearance, of the final product.
(ii) The stability of the drugs in the solution; do you anticipate the stability to be sufficient to allow the use of the 5 liters for the desired three months?
(iii) The effects caused by the increased nasal mucous one might expect in conditions such as this.

(iv) The particle size most suitable for such insoluble drugs as might be present and how as well as why this might be expected to affect the availability and the efficacy of the drugs.
(v) Molecular interactions between the drugs, and if undesirable, how these may be overcome.

The case study was given to all the groups, but the specific drugs and/or doses chosen were different for each group. These were chosen from the following table, with one soluble drug and one insoluble drug for each group, thus creating different problems for each formulation.

<table>
<thead>
<tr>
<th>Insoluble drug A</th>
<th>Dose (4 sprays)</th>
<th>Soluble drug B</th>
<th>Dose (4 sprays)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone</td>
<td>2mg or 3mg</td>
<td>Ephedrine Sulfate</td>
<td>100mg</td>
</tr>
<tr>
<td>Prednisone</td>
<td>2mg or 3mg</td>
<td>Terbutaline Sulfate</td>
<td>0.5mg</td>
</tr>
<tr>
<td>Triamcinolone</td>
<td>2mg or 2.5mg</td>
<td>Theophylline Ethylenediamine</td>
<td>40mg</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>0.6mg or 4mg</td>
<td>Theophylline Hydrobromide</td>
<td>40mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oxyxometoline Hydrochloride</td>
<td>0.05 or 0.1 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Xylometoline Hydrochloride</td>
<td>0.1 or 0.2 mg</td>
</tr>
</tbody>
</table>

APPENDIX C. DETAILED COURSE SCHEDULE
A representation of the detailed schedule of lectures, case studies and discussion groups is shown below. The scheduled dates and topics are based essentially on those used for the 1997-98 academic year, but also incorporate some minor changes (regarding the order of concept presentation) that we project for the 1998-99 academic year. In addition to the scheduled lectures and meetings detailed below, each group meets with their men tor for two hours each week (every Friday - these meetings are occasionally replaced by case study interviews), and a computer laboratory is held every week in Pharmaceutics I. The case studies ‘build’ on each other and all concepts discussed in earlier cases are used in later ones. An indication of the general scope of each case study, and its position in the course, is given below.

Course Overview and Organization (two two-hour lectures)  
Aug. 28th : Introduction to the Course; Sept. 2nd : Case Study Method

Lecture Block 1 : Physical Organic Chemistry (six two-hour lectures)
- Sept. 4th: Functional Group Chemistry
- Sept. 9th: Chemical Energetics
- Sept. 11th: Chemical Equilibria
- Sept. 16th: Acids and Bases / pKa
- Sept. 18th: Buffer Solutions / Isotonicity
- Sept. 23rd: Kinetics and Drug Stability

Lecture Block 2 : Molecular Interactions (six two-hour lectures)
- Oct. 16th: Non-Covalent Interactions
- Oct. 21st: Protein Binding
- Oct. 23rd: Solubility and Rate of Solution
- Oct. 28th: Partitioning
- Nov. 4th: Solid Dosage Forms I
- Nov. 10th: Solid Dosage Forms II

Lecture Block 3 : Biphasic Systems (six two-hour lectures)
- Jan. 8th: Surface Chemistry : Liquid/Liquid
- Jan. 13th: Surface Chemistry : Liquid/Solid
- Jan. 15th: Solubilization and Micelles
- Jan. 20th: Emulsions
- Jan. 22nd: Suspensions and Rheology
- Jan. 27th: Preservatives / Sterility

Lecture Block 4 : Drug Delivery and Absorption (six two-hour lectures)
- Feb. 24th: Cellular/Membrane transport I
- Feb. 26th: Cellular/Membrane transport II
- Mar. 3rd: Oral Delivery
- Mar. 5th: Transdermal Drug Delivery I
- Mar. 17th: Transdermal Drug Delivery II
- Mar. 19th: Ophthalmic Drug Delivery

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