Herbal Remedies: The Design of a New Course in Pharmacy

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Herbal Remedies is a new pharmacy course developed at Northeast Louisiana University School of Pharmacy to train pharmacy students in the area of herbs as self-selected over-the-counter products. Emphases are placed on the use of herbal preparations by the general public as alternative therapies, the safety and efficacy of herbs and other phytomedicinals and on the role of pharmacists in counseling consumers on the sensible way to use herbs.

INTRODUCTION

Millions of Americans today are convinced that herbs and other phytomedicinals, which are available as over-the-counter (OTC) products in health food and drug stores, are useful alternative therapies for treating a wide variety of diseases and syndromes. Because herbal preparations and other phytomedicinals are being marketed and sold in the U.S. as foods and/or nutritional supplements, these preparations are not regulated by the Food and Drug Administration (FDA) as drugs. As a result, consumers rely heavily on advocacy literature instead of scientific and authoritative literature regarding the safety and efficacy of herbal products(1,2). Clearly, consumers need, more than ever before, the pharmacist’s expertise and counseling on how to self-
select a safe and effective herbal product and the sensible way to use herbs as alternative therapies. However, with the disappearance of Pharmacognosy courses from pharmacy curricula in the U.S., pharmacy graduates do not have the knowledge nor the training to be able to advise consumers on phytomedicinals.

Another important dimension to the involvement of pharmacists in the herbal market is an economic one. Sales of herbs in pharmacies represent only about 5 percent of the total U.S. market which is estimated to be around $1.5 billion(1). The big winners in the herbal market are health food stores which have become “Pharmacies” without Pharmacists. Pharmacists are losing a big share of the herbal market and they need to know more about herbs to effectively sell them and share more profit with health food stores. Finally, there is a great need for the pharmacist’s expertise in promoting public health and educating consumers about the risks of herbal preparations and the toxicity of some of them, a public safety issue that is not being adequately addressed by the unregulated herb industry(2-4).

COURSE OBJECTIVES

At Northeast Louisiana University (NLU) School of Pharmacy, we have been involved in designing an elective course on herbs to fill the existing gap in our curriculum regarding the Use of herbs as alternative therapies. Like many other pharmacy curricula in the U.S., our curriculum covers natural products only as purified therapeutic agents, such as the antibiotics and the anticancer natural products, and not as crude drugs such as herbal preparations and phytomedicinals (teas, tinctures, and extracts). The three-hour course, entitled “Herbal Remedies”, is an elective course that will be offered to our pharmacy students in their second year of the professional pharmacy program beginning in the 1997-1998 academic year. The introduction of this new course to our curriculum was overwhelmingly supported by the faculty and members of the curriculum committee at NLU School of Pharmacy. Faculty in both basic sciences and clinical pharmacy practice were in total agreement on not only the need for training our students in the area of herbal remedies but also the positive impact that this training will have on pharmaceutical care practice well into the 21st century. The idea for designing this new course originated following a continuing education program, entitled “The Risks of Herbal Preparations”, which was presented by this author in 1995 to the practicing pharmacists in the State of Louisiana. The feedback that we received from those who attended the program indicated a tremendous demand for authoritative herbal information due to the increasing number of consumers who are seeking advice from their pharmacists on how to select safe and effective herbal products. In addition, it was very clear from reading the medical literature(5-7) that alternative therapies, including phytomedicine, are becoming an integral part of our society and the growing self-medicating trend among consumers. However, we quickly realized that our pharmacy graduates are not prepared to deal with the changes that have taken place in the behavior of a large number of consumers. Like other graduates from most schools of pharmacy in the U.S., our graduates have no experience in counseling patients on a whole new class of OTC products. We believe that the new course on herbs and phytomedicinals will provide our students with the background that they need to advise patrons on the sensible way to use herbs and to promote public health and safety.

Prerequisites for the new course include credit in Medicinal Chemistry-II and Biopharmaceutics, and credit or registration in Pharmacology-IV. Our Medicinal Chemistry-II course is a study of organic compounds of pharmaceutical and medicinal importance with emphasis on chemical structure, relationship of chemical structure to drug action, metabolism, Usage, incompatibilities, and synthesis. It is the second course in the medicinal chemistry sequence for professional pharmacy students which consists of five courses. The biopharmaceutics course is a study of the interrelationship between formulation factors and pharmacokinetic aspects of drug absorption, distribution, metabolism, and excretion. The third prerequisite that we selected for the new course is our Pharmacology-IV course which is the last course in the pharmacology sequence with emphasis on the gastrointestinal system, endocrine system, reproductive system, and chemotherapeutic agents. At NLU School of Pharmacy, a student must obtain a “C” grade or better in order to receive credit for a course in the pharmacy curriculum.

The new course “Herbal Remedies” is a study of herbal preparations and other phytomedicinals which are widely used by the general public as self-selected OTC products for therapeutic or preventative purposes. Emphasis will be placed on the need for phytomedicinals as alternative therapies, the safety and efficacy of herbal preparations, and the role of pharmacists in helping consumers select useful and safe herbal products. The regulatory and legislative aspects of marketing and selling phytomedicinals in the U.S. will also be discussed. The main objective of this course is to give our students the opportunity to learn about the following:

1. The use of herbal preparations as alternative therapies.
2. The regulatory dilemma of herbs and how phytomedicinals are being marketed and sold in the U.S.
3. The risks of herbal preparations.
4. How to differentiate between useful herbs and harmful ones.
5. How to counsel patients on the sensible way to use herbs.
6. The impact of herbs and other phytomedicinals on the practice of pharmaceutical care.

The required texts for this new course are the two books on herbal remedies, *The Honest Herbal—A Sensible Guide to the Use of Herbs and Related Remedies and Herbs of Choice—The Therapeutic Use of Phytomedicinals*(2,3), by Tyler. Students will also be required to consult other recommended texts, review articles, and herbal poisoning reports as well as computerized databases available at the Louisiana Drug and Poison Information Center.

COURSE OUTLINE

In developing the outline for this new course, we have accessed books and numerous research and review articles(1 - 36) from the pharmaceutical, medical, and natural products chemistry literature on the therapeutic use of herbs and phytomedicinals and the risks of herbal preparations. These references provided the background information we needed to develop and design the contents of our course. In addition, we have tried to incorporate as many case study sessions as possible into our course outline in order to address one of the most important objectives of this course which is to train students in counseling herbal users. We have also
Table I. Outline for the new course “Herbal Remedies”

Basic Principles
1. Terminology and definitions
2. Historical background
3. Differences between herbs and other drugs
4. Herbal quality
5. Herbal dosage forms
6. Rational herbalism
7. Herbal medicine and homeopathy
8. Naturopathy and aromatherapy

Herbs and the FDA
1. Drug regulation
2. FDA’s herbal regulatory initiative
3. The european experience
4. Proposals for reform

The Harmful Potential of Herbs and other Phytomedicinals
1. Causes of herbal poisoning
2. Factors contributing to potential problems with herbs
3. High risk groups of herbal users
4. Known toxic herbs and mechanisms of toxicity
5. The role of pharmacists

The Therapeutic Use of Phytomedicinals
1. Digestive system problems
2. Kidney, urinary tract, and prostate problems
3. Respiratory tract problems
4. Cardiovascular problems
5. Nervous system disorders
6. Metabolic and endocrine problems
7. Arthritis and musculoskeletal disorders
8. Skin, mucous membranes, and gingiva problems
9. Cancer and immune deficiencies
10. Endurance enhancers
11. Communicable diseases

Role of Pharmacist
1. Patient counseling
2. Authoritative vs. advocacy literature
3. Public education

added three field trips to this course to visit a local drug store, a health food store, and a green house or herb garden in order to give our students the opportunity to experience how herbs are grown (although many of the herbs sold in the U.S. are collected in the wild), processed, and sold. A brief version of the outline of “Herbal Remedies” is shown in Table I.

The course was divided into five main segments (Table I). The first segment highlights the history of herbal medicine and its relationship to conventional medicine as well as the physicochemical differences between herbal preparations and the purified therapeutic agents that the pharmacists are most familiar with. In addition, the discussion will address important issues including the quality of herbal products in the U.S. market, the absence of legal standards of identity and quality of herbal preparations sold in the U.S., the various herbal dosage forms in which herbs and phytomedicinals are consumed by the general public, and the relationship between rational herbal medicine and homeopathy. The second segment of this course is aimed at explaining the regulatory policy of the FDA which governs the marketing and sale of herbs and phytomedicinals in the U.S. In addition, topics concerning the proposed strategies to effectively regulate the herb industry in the U.S. and the reactions of the herb industry and the herbal users of the general public to the proposed regulatory changes will be discussed. Furthermore, students will learn about the regulatory changes that have already been implemented in Ger-

many and Canada regarding herbal products.

The third segment of our course addresses one of the most important aspects of the herbal market, public safety. When it comes to self-medication with herbs and phytomedicinals, the safety of the product is more important than identifying which conditions to treat and which ones deserve professional medical attention. The fact that some herbs have been used for centuries is not a guarantee of their safety, especially when chronic toxicity is in question. The medical literature on intoxications from the consumption of herbs, food additives, and other dietary supplements derived from plants is increasing(4,12-34) and we strongly believe that the pharmacist can play a crucial role in saving lives and minimizing the number of herbal poisoning cases reported every year. This segment of our course will report on the causes of herbal poisoning and the factors contributing to potential problems with herbs and phytomedicinals. In addition, students will learn about high risk groups of herbal users which include members of certain cultural groups, chronic users, consumers of large amounts or a great variety of herbs, children, newborn infants, fetuses, the elderly, the sick, the malnourished or undernourished, and those on long term medication. Furthermore, this segment will cover the known toxic herbs and their mechanisms of toxicity, the identity of the toxic ingredient(s), and any known drug-herb or food-herb interactions.

The fourth segment of this course tackles the therapeutic use of herbs and phytomedicinals. In this segment, most
The rest of the sessions (21 sessions) will be devoted to students about 10 percent of the total number of class periods. Of these, four sessions will be dedicated to field trips, which represent 40 percent of the number of class periods (17 sessions) devoted to field trips. The course will have a strong focus on the importance of patient counseling, and the need for training pharmacists in promoting public health and safety, the market. The last segment in this course emphasizes the role of pharmacists in promoting public health and safety, the importance of patient counseling, and the need for training future pharmacists in not only how to convey scientific and authoritative information on herbs to the consumer but also in how and where to find this information. Furthermore, we strongly feel that herbs and other plant-derived alternative therapies are having and will continue to have a profound effect on the cost of medicine and the behavior of consumers toward self-selected medications well into the 21st century, particularly in the case of patients with chronic diseases. As a result, we feel that it is necessary in our new course to address the impact of herbs and phytomedicinals on the practice of pharmaceutical care.

### Course Format

Based on preliminary information provided by our Office of Student and Professional Affairs, we are anticipating an enrollment of about 15 to 20 students in “Herbal Remedies” in the Spring semester of 1998. The small size of this class will allow us to emphasize cooperative learning and group discussion as the dominant features of our course. Approximately 40 percent of the number of class periods (17 sessions) will be devoted to patient counseling presentations by students, case study sessions, and group discussions. A total of four sessions will be dedicated to field trips, which represent about 10 percent of the total number of class periods. The rest of the sessions (21 sessions) will be devoted to lecture presentations by the instructor. Multimedia products and modules on herbal preparations and phytomedicine, developed by the American Botanical Council, will also be utilized throughout this course.

An important aspect of designing any new course is to identify the appropriate background and expertise that the instructor(s) should have in order to effectively teach the course. In our experience, we recognized early on that the instructor(s) of “Herbal Remedies” should have an advanced degree and/or research expertise in natural products chemistry, phytochemistry, phytotherapeutics, pharmacology of phytomedicinals, or chemical toxicology of natural products. Preferably, the instructor(s) should also have a background in pharmacy or medicine which will provide the expertise in the areas of patient counseling and therapeutics. Our new course will be taught by this author who is a Pharmacist and a natural products chemist.

### Student Assessment

Students in this course will be evaluated based on written exams, oral presentations, and field trips. Students will be required to take two written exams during the semester and one final exam at the end of the semester. The format of the written exams will be a combination of essay-type, short-answer, and multiple choice questions. In addition, students will be evaluated on their oral presentations during patient counseling and case study sessions. The written exams will represent 40 percent of a student’s final grade, whereas the oral presentations will amount to 40 percent of the final grade. Participation in field trips and the group discussions that will be held during and after the trips will represent 10 percent of the final grade.

### Learning Objectives

It is not surprising that, in a new course of this nature, we do have hundreds of individual learning or performance objectives for our students which specify in rigorous detail the skills that the student will be able to perform after completing this course. These objectives specify the task to be

| 1. | Determine the age and sex of the actual user of the herbal product. |
| 2. | Determine whether or not a female user is pregnant or attempting to become pregnant. |
| 3. | Determine whether or not a female user is nursing a newborn infant. |
| 4. | Determine whether or not the condition to be treated requires professional medical care. |
| 5. | Determine whether or not the user is suffering from other disorders. |
| 6. | Determine whether or not the herbal user is taking other types of medications to avoid any possible drug-herb interactions. |
| 7. | Determine whether or not the herbal product in question is safe when consumed internally. |
| 8. | Assess whether or not the selected herbal product is the most suitable product for the condition in question at the recommended dose. |
| 9. | Do not recommend or sell preparations that contain a known toxic ingredient(s). |
| 10. | Advise patients to stop taking an herbal product if adverse effects occur. |
| 11. | Do not recommend any preparation to be administered on a daily basis. |
| 12. | Do not recommend the administration of large quantities of any one herbal preparation for long periods of time. |
| 13. | Advise against administering herbal preparations to infants, children, nursing mothers, and pregnant women. |
| 14. | Recommend or sell only preparations from reputable sources with all the plants (in case of a mixture or an herbal tea) listed on the packet. |
| 15. | Recommend or sell standardized preparations as much as possible. |
| 16. | Recommend or sell only preparations that have labels showing the scientific name of the herb, the name and address of the manufacturer, a lot number, the date of manufacture, and the expiration date. |
| 17. | Advise against the administration of several herbal preparations simultaneously. |
| 18. | Do not recommend the administration of large quantities of any one herbal preparation for long periods of time. |
| 19. | Advise patients to stop taking an herbal product if adverse effects occur. |
| 20. | Do not recommend or sell preparations that contain a known toxic ingredient(s). |
| 21. | Advise against the administration of herbal preparations along with prescription or other OTC drugs. |
| 22. | Keep in mind that consumers may be seriously misinformed about the value of certain herbs as a result of the unsubstantiated claims they read in advocacy literature. |
performed, the conditions under which the task will occur, and the acceptable standards of performance. The learning objectives of this course also identify the knowledge that students have to master as a result of their individual learning efforts in the course. A list of these performance objectives will be provided to students at the beginning of the semester to let them know what the instructor considers to be important information in this class. A representative sample of our learning objectives are listed in Appendix A.

PATIENT COUNSELING
A great number of sessions in our new course will be dedicated to case study and patient counseling. Selected herbal poisoning cases from the literature will be presented to students ahead of time. Students will be asked to be prepared to discuss each case in detail and provide a specific counseling strategy which should prevent such poisoning incidents from happening. In addition, students will be trained in how and when to recommend or not recommend an herb or a phytomedicinal to a patron in different practice settings. A general strategy will be followed which consists of general commonsense guidelines that the pharmacist should apply whenever he or she is asked for advice on herbal products (Table III). Furthermore, students will have full access to computerized information that we have available at the Louisiana Drug and Poison Information Center at NLU School of Pharmacy. Students will be trained to be able to retrieve herbal information from computerized databases regarding efficacy and safety studies as well as herbal poisoning cases.

HERB-DRUG INTERACTIONS
The use of herbs by individuals receiving long-term or short-term medications or other OTC products poses the risk of herb-drug interactions, and exposes the individual to serious undesirable side effects which can be, in some cases, life-threatening. The issue of herb-drug interactions is complex and represents an area of phytomedicine for which reliable and authoritative information is scarce. The complexity of this issue is attributed to the following:

1. Always keep in mind that, in case of herbal preparations, we are dealing with mixtures of several ingredients and not with pure chemical entities.
2. The labels on these phytomedicinals may or may not list all of the ingredients or components of the mixture. In addition, the majority of the preparations on the market are not standardized.
3. The herb industry in the U.S. is not required by the FDA to conduct research on preclinical and clinical development of its products.
4. The only information available on herb-drug interactions has been documented following herbal poisoning cases.
5. The potential of many herbs and phytomedicinals to interact with other drugs and cause undesirable side effects is still unknown.
6. Herbal products can be adulterated, intentionally or otherwise, with a variety of other ingredients including prescription drugs.

The most widely documented herb-drug interactions were the result of induction of hepatic enzymes responsible for drug metabolism (4,12-14,18-20). Ingredients of many herbs, such as the pyrrolizidine alkaloids and the furanoneoclerodane diterpenes, are metabolized in the liver by cytochromes P450 to highly toxic, reactive intermediates which cause cell injury and tissue necrosis. Drugs that can induce P450 enzymes in the liver, such as phenobarbital, will enhance the metabolic activation of these herbal ingredients leading to liver damage and death. One important factor that is contributing a great deal to the occurrence of these unfavorable interactions is the fact that many of today’s herbal users are taking high doses of phytomedicinals for long periods of time (several months). Another important factor to take into consideration is that many herbal users are suffering from chronic diseases. As a result, these individuals are consuming several herbal preparations and phytomedicinals simultaneously with prescription medications and other OTC products. The increased intake of prescription and OTC drugs, including herbs, will undoubtedly increase the risk of unfavorable interactions.

In our new course on herbal remedies, we will approach the issue of herb-drug interactions as follows:

1. Students will learn all about the well-documented herb-drug interactions and their mechanisms.
2. In situations where the potential for interactions is unknown, students will learn to apply several of the guidelines for counseling herbal users which are listed in Table III. The most useful of these guidelines in preventing or minimizing unfavorable herb-drug interactions are:
   a. The pharmacist should determine whether or not the user is receiving other types of medications.
   b. The pharmacist must advise the patient to discontinue a phytomedicinal if adverse effects occur, which could be the result of a drug-herb interaction.
   c. The pharmacist should advise against the administration of large quantities of any one herb for long periods of time.
   d. The pharmacist should advise against the administration of several herbal preparations simultaneously or the administration of herbs along with prescription or OTC drugs.
3. Students will learn how to keep up-to-date on newly documented herbal poisoning reports and herb-drug interactions by consulting recommended authoritative sources of herbal information.

Considering the limited sources of reliable information, the lack of research, and the complicated issues that need to be taken into account when dealing with herb-drug interactions, we strongly believe that the aforementioned approach will prove to be practical and effective toward minimizing the risk of undesirable interactions.

CONCLUSION
Herbal remedies are rapidly gaining popularity in the U.S. for various medical conditions. Estimates of the percentage of patients using herbs and phytomedicinals as alternative therapies range from 4 to 50 percent (6). In 1990, Americans made $425 million visits to providers of unconventional therapies, which exceeded the number of visits to all primary care physicians, and they spent $13.7 billion, which exceeded the cost of all hospitalizations in the U.S. (7). It is believed that, regardless of how the scientific community
feels about it, the American public is actively seeking and will continue to seek alternative therapies including herbs and phytomedicinals. It is our responsibility, however, as health care professionals and drug experts to counsel consumers and educate them not only about the good things herbs can do but also about the harmful potential of some of these preparations. We feel that our new course on herbal remedies will prepare our students to face the challenges of the herbal market and promote confidence between the cost-conscious herbal enthusiasts and health care professionals.

We would like to invite other schools of pharmacy in the country to consider offering a course on herbs as alternative therapies like ours and we hope that our experience in developing such a course would prove to be useful to others. In addition, we intend to share with other schools of pharmacy the outcomes of teaching this new course for the first time as well as student evaluations in the near future. Furthermore, it is important to point out that we will continue to offer accredited continuing education programs on herbal products and phytomedicine to benefit those who are currently practicing pharmacy in drug stores and hospitals.

Acknowledgment. The author wishes to thank Dr. Gary A. Holt for helpful discussions. This article is dedicated to Professor James D. McChesney on the occasion of his fiftieth birthday.

Am. J. Pharm. Educ., 60, 358-364(1996); received 7/10/96, accepted 10/15/96.

References

APPENDIX A. A SAMPLE OF THE LEARNING OBJECTIVES OF HERBAL REMEDIES COURSE
1. Define the terms “herbs” and “phytomedicinals”.
2. Recognize how and why herbs and phytomedicinals are being utilized by the general public in the U.S. and other countries.
3. Indicate why herbs and phytomedicinals should be considered as drugs when used in the treatment of disease or improvement of health.
4. Indicate the differences between herbs and purified therapeutic agents.
5. Recognize the lack of legal standards of identity and quality for herbal preparations in the U.S.
6. Explain why the concentration of active constituents in different lots of supposedly identical plant material is highly variable.
7. Indicate which herbal dosage forms are most susceptible to fraud by adulteration or substitution.
8. Explain why it is very difficult to establish a specific dose of an...
herbal product in the U.S. market.
9. Indicate why herbs are more useful for the long-term treatment of mild or chronic ailments than for the treatment of acute illnesses.
10. Define the term “organic”.
11. Explain why there is no difference between natural and synthetic fertilizers.
12. Recognize the difference between “herbalism” and “paraherbalism”.
13. Explain why the use of herbs by humans for centuries is not a guarantee of their safety.
14. Explain why rational herbal medicine is conventional medicine.
15. Compare and contrast herbal medicine, homeopathy, naturopathy, and aromatherapy.
16. Describe the various dosage forms of herbs and phytomedicinals.
17. Indicate how herbs must be stored when purchased as dried herbs rather than processed dosage forms.
18. Explain the FDA’s herbal regulatory initiative.
19. Describe why the current herbal regulatory policy in the U.S. is unsatisfactory.
20. Discuss and debate the proposals for reforming the current herbal regulatory policy.
21. Review the factors that contribute to potential problems with herbs.
22. Explain how misidentification of plant species can occur in commercially sold and self-selected herbs.
23. Discuss the consequences of adulteration of herbal products.
24. Identify the groups of herbal users that are at higher risk of toxicity and explain why.
25. Explain why Comfrey is toxic when ingested internally.
26. Explain why Germander is hepatotoxic.
27. Explain why Chaparral is toxic.
28. Name the active anti-inflammatory and antispasmodic constituent(s) of Chamomile.
29. Name the active ingredient(s) responsible for the antiulcer activity of Licorice.
30. Discuss the anti-emetic mechanism of action of Ginger.
31. Explain why the use of the oil and seeds of Parsley must be avoided.
32. Name the active ingredient(s) responsible for the aquaretic effect of Parsley.
33. Explain how Thyme is extremely effective in treating bronchitis.
34. Discuss the “allacin yield” of a Garlic preparation and its effect on the therapeutic activities of Garlic.
35. Explain why Ginkgo is an effective treatment for cerebrovascular disease.
36. Describe the mechanism of action of the flavone glycosides present in Ginkgo extracts.
37. Explain why valepotriates, the iridoid principles of Valerian, do not show any in vivo toxicity despite their alkylating activity in vitro.
38. Name the active constituent(s) in Feverfew responsible for reducing the frequency and severity of migraine headache and explain why standardization of Feverfew products is critical to their efficacy.
39. Name the toxic constituent(s) in the volatile oil of Sage.
40. Indicate what percentage(s) of the Sanguinaria extract(s) are acceptable in antiplaque dentifrices and mouthwashes.
41. Explain why Sassafras, a widely used herb as a tonic or performance enhancer, is both unsafe and ineffective.
42. Explain why Pau d’Arco cannot be recommended for the treatment of cancer or any other condition.
43. Discuss the importance of age and gender differences relative to the counseling of herbal users.
44. Recognize the various factors that may affect your herbal counseling efforts.
45. Recognize the differences between authoritative and advocacy literature on herbal products.
46. Discuss the phases of an herbal counseling encounter.
47. Discuss the limitations of counseling as it relates to your herbal counseling efforts.
48. Review the factors that contribute to potential problems with herbs.
49. Discuss the topics which are appropriate for discussion with herbal users.
50. Demonstrate the ability to interpret the label language on herbal preparations and phytomedicinals.
51. Demonstrate the ability to inspect the labels of your herbal products before counseling patients.
52. Explain why herbs and phytomedicinals should be stored in childproof containers.
53. Develop strategies to encourage your patients to come only to your drug store for all their herbal needs.
54. Explain why it is important for the pharmacist to get to know the patient.
55. Demonstrate an understanding of the various characteristics of herbal users.
56. Demonstrate an understanding of the impact that patient counseling has on patient outcomes.
57. Discuss the pros and cons of self-medicating with herbs and phytomedicinals.
58. Recognize the differences between authoritative and advocacy literature on herbal products.
59. Describe the attitudes and skills necessary for successful counseling.
60. Develop programs and seminars to educate your community about the benefits and risks of herbal products.