Introduction:

Society does not usually look to the pharmacist as a supreme source of information on diet, exercise, and nutrition. Nevertheless, the pharmacist’s role in healthcare places them in a position where they play an integral part and can make difference in this area of patient’s lives. Patients purchase a variety of health and nutrition products at the pharmacy counter, and while they are there the pharmacist has the ability to counsel them about these products as well as their physical health. Many ethical situations arise in the pharmacist’s daily practice, and some of these involve the aforementioned products as well as individual’s personal diet, exercise and nutrition choices. Pharmacists have duties with respect to health, nutrition and fitness due to normative ethical principles they must adhere to according to the code of ethics that guides their behavior.

With so many diets, nutritional products, and exercise options, patients need to be educated about the choices they make to have the most positive impact on their health. According to the FDA’s website, as of 2004 Americans spend over $15 billion a year on dietary supplements which include vitamins, minerals, herbs, and other plant-derived substances. These dietary supplements have the potential of causing harm to the patient if misused, and they can also interact with medications the patient takes. If the patient fails to inform their healthcare provider about their use of supplements, the consequences can be severe. If on the other hand patients are well informed about these products they may be able to not only save their money, but also improve their health.

Dietary supplements are not the only issue that requires action by pharmacists. Obesity plagues our nation, with over ½ of the adult population suffering from being either overweight or obese. Not only does this impact people’s health, but the direct and indirect costs associated with it in 2005 were over $115 billion. Obesity causes an increased risk for a host of disease states, including coronary heart disease, type 2 diabetes, cancers (endometrial, breast, and colon), hypertension, dyslipidemia, stroke liver and gallbladder disease, sleep apnea and respiratory problems, osteoarthritis, and gynecological problems (abnormal menses, infertility). Pharmacists can have an impact on these problems by making patients aware of some of the complications and costs associated with obesity, as well as giving them advice on how to manage their health.

Diet, Nutrition, and Exercise Basics:

The U.S. Department of agriculture currently recommends following a food pyramid specifically tailored to your age, height, weight, gender, and exercise level. The formation of this pyramid is based around food groups, and a specific number of calories needed from each of these groups.
If patients follow this pyramid, they will receive all the nutrients they need and they can adjust their caloric intake as needed for weight gain or loss. Pharmacists can instruct their patients to look at www.mypyramid.gov to find out what their food pyramid looks like and how much of each food group they should eat.

There are a wide variety of other diet plans available to patients to help them lose weight, and pharmacists should be prepared to help patients evaluate these plans to ensure that they are receiving the nutrients they need and will achieve their health goals. Because patients spend so much money on dietary supplements and they can have such a great impact on their health, pharmacists have a great opportunity, perhaps even a duty to counsel these patients on what they are purchasing.

Exercise is also a key component of a healthy lifestyle. Overweight or obese patients can lose weight not only by adjusting their diet, but also by exercising. The benefits of exercise are enormous. With just 30 minutes a day, studies have shown improvements in self-esteem, muscle and bone development and strength, flexibility, weight management, blood pressure control, feelings of depression/anxiety, risk of heart disease, colon cancer, and type 2 diabetes. With all of these benefits, pharmacists should recommend that every patient exercise at least 30 minutes a day for overall good health. Patients who choose to do aerobic activities will improve their heart and lung health, whereas patients who do strength and resistance training will improve muscle and bone. Some examples of aerobic activities include jogging, swimming or walking, while strength training would include weight lifting.

**Dietary Supplements:**

Because dietary supplements have such an enormous economic impact, pharmacists need to be aware of these products and how best to counsel their patients about them. Before 1994, the FDA would monitor dietary supplements the same as food based on the Food Drug and Cosmetic act (FD&C) of 1958. In 1994, President Bill Clinton signed into law the Dietary Supplement Health and Education Act of 1994 (DSHEA) which amended the FD&C act. This new act defined a large category of items as dietary supplements and made them a separate regulatory category. This allowed suppliers to provide third-party information they choose to about these products, weakening the FDA’s jurisdiction over these types of products. Under DSHEA, the labeling of the dietary supplement must not claim to diagnose, prevent, mitigate, treat, or cure a specific disease. The labeling may indicate benefits to structure and function associated with the supplement.

The American Society of Health System Pharmacists (ASHP) put out a statement that indicates that current regulations of dietary supplements are inadequate at addressing risks to public health. ASHP pushes for a revision of these laws, mainly for amending the Dietary Supplement Health and Education Act of 1994 which states that once a dietary supplement is marketed, the FDA must prove that it causes harm before it can be removed. One example of this was with ephedra, which is now banned from the market after years of testing by the FDA. ASHP states that congress should amend DSHEA so that practitioners and consumers will have access to information they need to use dietary supplements safely. ASHP also concluded that pharmacists have opportunity and responsibility for reducing the risks presented by dietary supplements.
The ASHP statement brought up several points for why dietary supplements require further regulation. They stated that the widespread use of dietary supplements presents risk to public health in five categories: 1. Some dietary supplements are harmful when ingested (i.e. ephedra) 2. Poor regulation of manufacturing of dietary supplements risks contaminated products, and potentially dangerous variability in active ingredient concentrations 3. The use of supplements may delay use of proven efficacious therapies 4. Special populations may be at increased risk with use of dietary supplements (i.e. pregnant women, children) 5. Spending indicates enormous expense on unsubstantiated products/values.\textsuperscript{7}

ASHP also recommended ways in which congress could amend DSHEA to improve public health and consumer knowledge. In order to reduce the risks associated with the current regulatory framework, ASHP proposes five changes, which include: 1. Dietary Supplements must undergo FDA approval for safety and efficacy 2. Mandate FDA approved labeling for all dietary products with information about appropriate use and potential for interactions or harm in special populations 3. The FDA should make and enforce good manufacturing practices for dietary supplements 4. All dietary supplements must meet FDA standards for quality, purity, strength, and identity 5. The FDA should be given the ability to create an event reporting system for dietary supplements, and require supplement manufacturers to report adverse events.\textsuperscript{7}

Pharmacists have an ethical duty to be aware of these products and the quantity consumed by the population. Current regulations do not meet standards that are adequate for protecting patients, so pharmacists should be proactive about their patients’ use of these products. In the future, the government may alter these regulatory laws to protect the public more effectively as ASHP has requested.

\textbf{Cultural Issues:}

Obesity puts patients at an increased risk for several disease states as noted previously. Diabetes is one of these diseases, and patient’s ethnic backgrounds seem to play a role in the likelihood of contracting this condition. Below is a chart displaying the percent of the population nationally against New York in various cultural patient populations with diabetes.\textsuperscript{8}
Clearly, minority groups seem to suffer from this condition greater than white Americans do. What does this mean for the pharmacist and what ethical implications are associated with it? If patients cannot understand English, is it the pharmacist’s duty to find a way to communicate the information to them in order to provide proper care?

New York’s 11 public hospitals have tried to tailor care to specific ethnic groups with a variety of methods. These hospitals used ideas such as multilingual handouts, electronic data-sharing and on-site cooking lessons to care for their patients and try to help these ethnic diabetic populations. "It's imperative that you get this information across to patients and help them treat these ailments, because they result in increased mortality," said Dr. South-Paul, of the University of Pittsburg school of Medicine. The system New York has put in place to help reach ethnic populations is showing results. Reductions in the number of patients with poor blood sugar control are one example of these results.

Further evidence of this minority disparity is seen in the center for disease control statistics. According to their data, two out of every five African Americans and Hispanics born in the year 2000 will contract the disease within their lifetime, compared to only one out of three in the general population as a whole. Their data shows that African Americans, Hispanics, American Indians, and Alaskan natives are twice as likely to have type 2 diabetes as white Americans. The total direct and indirect cost of this disease in 2007 was $174 billion. According the CDC website, “Research suggests that the progression from pre-diabetes to type 2 diabetes can be prevented or delayed. In 2001, results from landmark clinical trials, including the Diabetes Prevention Program (DPP), showed that sustained lifestyle changes that included modest weight loss and physical activity substantially reduced progression to type 2 diabetes among adults who were at very high risk.” Since this disease has such a great expense, and the data that this disease is preventable and controllable exists, it is up to pharmacists and all health care workers to insure that these patients understand how they can prevent this illness.

Undoubtedly, culture plays a role in how pharmacists reach patients, and it is their responsibility to figure out techniques so that they can best reach their patient population. The great cost and the evidence for preventing disease give pharmacists many opportunities to have an impact in...
patients’ lives. Small reductions in weight can have a huge impact on patients’ outcomes, and in order to teach these patients, pharmacists must figure out a way to communicate with them.

**Counseling Methods:**

Certainly, obesity is not the only important issue for pharmacists to counsel their patients about. Smoking is another huge problem that puts patients at risk for many illnesses. The question then arises; how can pharmacists best reach their patients who are perhaps hurting themselves with destructive habits, without invading the patient’s autonomy or offending the patient? When, if ever, should the pharmacist intervene in a patient’s behavior to protect their health from themselves? Once they have determined that they should or should not, what is the best method for reaching these patients?

The answers to these questions are difficult. Changing lifestyle behaviors like smoking or overeating are not a single step. For most people, quitting a bad habit requires a process and often times multiple attempts. Dr. Candice Garwood of Wayne State University divides tobacco users into four stages of readiness to quit. Stage one patients are not ready to quit within the next month. Stage two patients are ready to quit within the next month. Stage three patients are recent quitters; they have quit within the past six months. Stage four patients are classified as former tobacco users and have quit greater than six months ago. Once pharmacists determine what stage a patient is in, they can best decide how to approach the patient about quitting tobacco. Using motivational techniques and providing support to patients who are not ready to quit are great ways to help them get the courage to want to quit on their own. Simply telling patients that you are there to help them when they are ready is a great way to motivate them.

Although Dr. Garwood does not address obesity, she offers some very good methods for counseling patients on how to quit smoking. Motivating patients is essential to get them to take action on their own. Only the patient can decide to quit smoking, or to reduce their caloric intake and exercise. Pharmacists cannot help an individual improve a bad health choice when he or she does not want help. Patients retain the ability to make their own decisions and pharmacists must respect this fact. It is the pharmacists duty to do everything they can to help the patient, but they cannot force them to do anything.

Using motivational techniques and providing support to patients are good methods to use not only for smokers but for obese patients as well. Making patients aware that they are at risk for diseases and offering to help is a noble endeavor, but pharmacists need to be careful not to offend their patients as well. This concept raises several important questions: when is it a pharmacist’s duty to intervene with a patient? Do pharmacists have an ethical responsibility to counsel patients who are putting themselves at risk for several disease states? Should pharmacists counsel every obese patient that comes to their counter about proper fitness, diet, and exercise? Should pharmacists target patients based upon what medications they are taking to decide when to counsel (i.e. should a pharmacist counsel a patient taking cholesterol or diabetes medication to lose weight)? When should pharmacists stand back and not counsel their patients about these matters?

**Pharmacist Code of Ethics:**
Before addressing these questions in further detail, one must understand what the pharmacist’s code of ethics states regarding them. The pharmacist’s code of ethics contains several statements that pharmacists must adhere to in their practice in order to be acceptable members of their profession. Two particular statements in the code of ethics apply to these questions: 1. “A pharmacist respects the autonomy and dignity of each patient,” and 2. “A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.” Pharmacists have a duty to respect their patients’ personal health wishes according to the code of ethics and encourage them to make their own personal health decisions (autonomy). They also have a duty to do what is best for the patient (beneficence) and these two values can conflict with one another. Pharmacists must do what is good for the patient without invading their privacy or autonomy.

**Intervening with Patients:**

Deciding when and how to intervene with patients is critical for a pharmacist who desires to make sound ethical judgments. With respect to dietary supplements, these interventions are often times necessary to protect patients from harming themselves unknowingly. In one study, a system for nutritional consulting was evaluated using a quick questionnaire for diet and unidentified complaints. The questionnaire evaluated what the patients generally ate, how much rest/exercise they were getting, how they feel on a daily basis with a multitude of symptoms ranging from always to never. The study used a system that allowed consumers to have comprehensive support for self-medicating with dietary supplements from a pharmacist who would check lab values as well as the questionnaire from one computer terminal. The patient would input data into another terminal and could review the results about his or her physical condition. Together with the pharmacist or dietician, they would make a decision about supplement use. The study found a degree of correlation between the results to the questionnaire and potential micronutrient (vitamin and mineral) deficiencies in the patients.

Although this study did find some correlation between micronutrient deficiencies and the patients overall physical condition, much more studying needs to be done before anything can really be determined from the results. It is good for pharmacists to work with their patients about the dietary supplements they consume. Deciding when to intervene with these patients is currently at the pharmacist’s discretion, although every patient must be counseled and dietary supplements should be addressed. Certainly if a patient is taking medications prone to interactions, it is wise for a pharmacist to counsel their patient about the potential interactions with dietary supplements. Similarly, if a patient is a part of a special population at risk for harm from these supplements, the pharmacist needs to be prepared to consult the patients about these risks.

Another situation where pharmacists need to evaluate if it is their duty to counsel patients is with respect to weight loss. If an obese patient steps into the pharmacy, is it the pharmacist’s duty to counsel this patient and attempt an intervention? Since being obese or overweight puts patients at numerous health risks, applying the code of ethics to this situation seems to indicate that the pharmacist must intervene to promote the good of the patient. However, if the patient refuses consultation, the pharmacist has still attempted to promote the good of the patient, while at the
same time respecting his or her autonomy, which is also required according to the code of ethics. Counseling overweight patients on how to lose weight can be difficult because frequently these patients have tried to lose weight and have not been successful. In an effort to help patients like these, the national weight control registry was created in 1993. It tracks 4,200 people who have lost at least 30 pounds and kept them off for at least one year. Dr. James O. Hill, one of the founders of this registry has uncovered four common characteristics among these people and sharing these ideas with patients may give them the hope and courage they need to lose weight and benefit their health. The four common traits of these patients were: 1. Eat a high carbohydrate, low fat diet. 2. Exercise every day. 3. Eat breakfast every day. 4. Keep track of your weight and eating. Of course there is more to it than this, but these four commonalities between the subjects of this registry seems to have helped them lose weight and keep it off. Sharing this type of information with patients is one way to intervene and it will inspire them to want to improve their own health.

Exercise, which was one of the four similarities between the patients in the study, is also very important not only for obese patients, but for everyone. Exercise has been shown to cure some forms of heart disease, reduce arthritis complications, prevent depression, and even help patients recover from cancer. Deciding what exercises to do and knowing how to do them can be overwhelming for some people. It is important for pharmacists to be aware that patients may not understand what qualifies as exercise, or how best to execute these exercises for their health. With so many choices from walking, running, weight lifting, dancing, biking, yard work, etc. it is no surprise that patients may not understand what constitutes exercise. For heart health, the American Heart Association recommends at least 30 minutes of moderate physical activity on most days of the week, such as walking. A good way for patients to monitor if they are getting moderate physical activity, is to check their pulse during exercise. The pulse should increase from 50-70% of their normal heart rate. It is important to make sure that patients are aware that even if they don’t do this much exercise, any exercise at all is better than none! Benefits are evident even from 5 or 10 minutes worth of activity.

Not only do these interventions lead to health benefits in patient populations, but it also improves their satisfaction with pharmacy services. One control trial was conducted in a group of 265 cancer patients, who frequently take natural health products. This trial showed increased patient satisfaction in a group of patients who received structured routine counseling on their natural health products vs. those who did not receive the counseling. The pharmacists made it clear in the structured counseling to the 123 patients that were selected to receive it, that there is usually not enough evidence behind the natural health products to show they are effective, though many are claimed to help cancer. The remaining 142 patients did not receive the structured counseling. They would then assess the efficacy and safety of the product with the patient, and make sure the patient understands the risks involved with taking the health product, as well as asses the amount of time, money, and hope the patient wants to invest in the product. The patient satisfaction in the study was assed via a questionnaire known as the Patient Satisfaction with Cancer Treatment Education (PS-CA TE) questionnaire, which had been validated previously in various other studies. These were completed after patients visited the pharmacy, and were anonymous to insure the most accurate and truthful responses. This extra counseling took about 9 minutes per patient, and cost the patients an average of $7.49 CDN more than had they not received the
Selectively targeting patients to intervene with is something pharmacists must do to be effective in benefiting the public health. One subset of patients pharmacists have a prime opportunity to intervene with is the group taking cholesterol-lowering medications. A study conducted comparing the effects of simvastatin vs. lifestyle modifications and red yeast rice plus fish oil ingestion showed results were similar in LDL lowering. Furthermore, the alternative group (those not taking simvastatin) also showed reductions in triglycerides and weight, much greater than the simvastatin group. If patients are unable or unwilling to take statins, this alternative was shown to be as effective. Making these patients aware of alternatives and the benefits of exercise and diet is important for patient satisfaction, adherence, and health outcomes. Counseling should always include non-pharmacological treatment methods and lifestyle modifications.

**Ethical Problems:**

Deciding when to intervene in a patient’s lifestyle choices can create an ethical dilemma. Should the pharmacist do what he believes is good and in the best interest of the patient by attempting to make an intervention, or does the patient’s autonomy override this principle? Since pharmacists are required to adhere to both principles, it is their obligation to make individual situations fit both normative principles— one does not override the other. The privacy and individuality of a patient is equally important as doing good and making the best decisions for a patient.

Another ethical problem associated with doing good for the patient and counseling them on fitness and good health, is the apparent conflict of interest. Certainly, it is in the pharmacist’s interest to make money and run a profitable business. Counseling patients on lifestyle modifications that may very well decrease their need for medications that the pharmacist provides is apparently counterproductive and creates a conflict of interest for the pharmacist. Members of the profession of pharmacy have a duty to avoid conflicts of interest whenever possible. However, this situation is inescapable. Pharmacists must do what is good for the patient by counseling them about their diet, health products, and physical fitness when necessary even though this may inhibit their ability to turn a profit.

One other potential issue is the pharmacists standing in society and possible duty to be a good example. If all pharmacists were obese smokers, certainly patients would see no reason from the profession to try to avoid these poor life-style choices. While the pharmacist’s code of ethics does not directly state that pharmacists must be a good example to their patients, it seems to be understood that pharmacists should practice what they preach when it comes to diet, exercise, and nutrition.

**Making Sound Ethical Decisions:**

Individual situations can arise where deciding what the correct course of action is may be difficult. Some examples of these situations include being busy in the pharmacy and not having time to counsel, choosing whether to counsel patients about non-pharmacologic treatment
options when a conflict of interest is present, and the dilemma of patient autonomy vs. beneficence. Applying five simple steps to these problematic situations can help pharmacists always make the right decisions. 1. Identify the nature of the problem. 2. Clarify the facts. 3. Clarify the concepts. 4. Determine and rank which ethical principles apply to the situation. 5. Determine the pharmacist’s duty. Striving to make sound ethical decisions is a requirement for pharmacists. If pharmacists use this five-step process for solving ethical dilemmas they will be able to better abide by the code of ethics their profession mandates, which they have a duty to follow.

**Conclusion:**

Pharmacists have several duties in the field of health, exercise, and nutrition. It is the duty of a pharmacist to counsel every patient by law, unless the patient refuses. It is the duty of pharmacists to abide by the code of ethics that the profession has determined appropriate. Part of this code of ethics includes doing what is best for every patient, and respecting the individual’s autonomy. It is the pharmacist’s duty to avoid conflicts of interest and when put in such a situation, act objectively and justly with the patient’s health needs as the top priority. Pharmacists also need to be aware of dietary supplements and the health benefits and risks that these products can cause. They need to make sure that their patients are not inadvertently hurting themselves with these products, be it physically or financially. Pharmacists have a duty to be aware of appropriate counseling techniques so that they can have the most positive impact on their patient’s health outcomes. They also need to know when to intervene with patients and how to do this most effectively without invading the individual’s personal health decisions. Pharmacists need to be aware of cultural issues that are present in society so that they can reach their patients most effectively.

Health, nutrition, and exercise play a key role in patient’s lives. If pharmacists take the initiative to abide by all of these duties, their patients will be healthier and happier. The code of ethics the profession of pharmacy has put in place is an appropriate starting point for pharmacists to look to when they are deciding how to behave ethically. Solving ethical dilemmas can be difficult, but it is vital to the practice of pharmacy and doing what is right for patients. Pharmacists must do everything in their power to abide by the code of ethics their profession has put in place for the benefit of society, and special attention is required in the area of health, exercise, and nutrition.
Sources:


