

## Pharmacy and the Future, Options and Opportunities

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It is a very great honor for me to have been asked to be the 2003 Kenneth L. Waters Lecturer. Dean Waters was a dynamic and visionary leader who was so very instrumental in stimulating the research, teaching, and service missions here at the University of Georgia College of Pharmacy. Dean Waters would be pleased with the progress the College has made, and the stature in which it is held in the state, region, nation, and beyond.

From an historical perspective, I feel it is useful to examine how pharmacy has changed in Georgia in the past 100 years. Dean Wilson in the text: *Drugs and pharmacy in the life of Georgia 1733-1959*, [1] noted numerous interesting facets of health and health care in the last century. A State Board of Health was created in 1875, ceased to function 2 years later due to a lack of funding, and 25 years later was resurrected with an annual appropriation. Finally, a century ago, one woman applied for pharmacy licensure in Georgia. No doubt some remarkable changes have ensued since then.

Today, I would like to examine three major issues affecting pharmacy:

1. medication issues
2. pharmacy education
3. public health concerns

In the context of opportunities, individuals have options. These options can include doing the same amount, less, or more. The need for involvement in medication related issues: compliance, counterfeit drugs, drug use in the elderly, drug errors, and impacting reimbursement has never been greater. Pharmacy education can impact all of what is being discussed today, but dealing with ethics, service learning, and the scope of pharmacy practice are immediate concerns. Finally, I would like to discuss public health, specifically bioterrorism, the enhanced use of epidemiology, preventive health, and tobacco use. Pharmacists can choose the option of partially impacting each of the above. I sincerely hope that pharmacists can choose the option of seizing these opportunities to advance the health and well-being of their patients.

### Medication Issues

Drug costs. Spending for prescription drugs in the US has skyrocketed in the recent past.[2] An increase of spending to the magnitude of 43% (in dollars) has stressed financing of the health care system. Americans pay the highest price for prescription drugs anywhere in the world.[3] US prices are 72% higher than those in Canada, and 102% higher than those in Mexico.[3] An increase of 25% in percentage expenditures for prescription drugs as a percentage of all health care costs has occurred over the past 5 years. The Kaiser Family Foundation suggests that the reasons for these large increases include an increased volume of prescription drug usage (47%), changes in the types of drugs used (27%), and manufacturer price increases (26%).[4]

Health insurance entities offering drug benefits, regardless of type (public or private) have seen costs increase. Pharmacy costs in the Kansas Medicaid program have reached 33% of costs incurred; this has followed a steady increase in drug costs over the past decade.

Georgia is not immune to these increases, recent reports indicate a \$172 million shortfall in the Georgia Medicaid program. Drugs are heavily used in the Georgia Medicaid program (\$760 million), but

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surprisingly, only 69% of eligible recipients used services in FY2002. [5] Researchers at Georgia State suggest 1% of Medicaid recipients account for 23% of expenditures.[5] Disease management has been suggested as a way to stem rising costs. The Georgia Board of Pharmacy recognizes four pharmacist disease management certifications (anticoagulation, asthma, diabetes, and dyslipidemia).

Marketing driven usage of prescription drugs has come under increasing scrutiny concerning the use of costly alternatives rather than less expensive therapies that might be equally advantageous.[6] More and more of these types of comparisons are appearing in the lay press (magazines and newspapers).[7] A good share of the success of the pharmaceutical industry is due to lobbying efforts, which have been substantive and effective. Unlikely advocates for cost containment have emerged. The US Food and Drug Administration (FDA), the agency charged with regulation of the drug approval process in the US, has recently been a proponent of generic drug usage.

In the book, *The Merck Druggernaut*,[8] written by Fran Hawthorne, Merck and Company, arguably the most successful of US pharmaceutical manufacturers, has fallen from champion to an often chastised company. The praise for discovering a treatment for river blindness in Africa (transmitted by black flies that breed in fast-flowing rivers) and then providing ivermectin free of charge was hailed as an example of outstanding public service. The long-standing criticism of the purchase of Medco (a major pharmacy benefit management (PBM) company) has made Merck one of the most criticized pharmaceutical industry companies. In hindsight, this was a major public relations and economic mistake. A judgment against Medco for \$42.5 million for inappropriate marketplace activities was recently awarded.[9]

Much attention has been focused on the price of drugs obtained from Canada as cross-border sales have reached almost \$1 billion per year. The number of sales representatives has tripled in the past decade. Some suggest that this is but one reason for drugs being so much more expensive in the US as opposed to elsewhere. The Canada drug connection has been troublesome for manufacturers, pharmacists, and the FDA. The Canada drug issue, has led some manufacturers to limit how their manufactured drugs can be purchased.[10] Some cities have promoted drugs from Canada in order to save costs on municipal sponsored benefit programs. Springfield, MA has sponsored programs to have employees receive drugs from Canada.[11]

Pharmacists can play a major role in cost containment activities, but without some effort to control costs at a global level, the extent to which costs can decrease is not what it could conceivably be. The United States is the remaining industrialized country without some type of price controls on drugs.

Compliance issues. Patient noncompliance with prescription regimens is one of the most understated problems in the health care system. The effects of noncompliance have enormous ramifications for patients, caregivers, and health professionals. Compliance with medications is a worldwide problem, and impacts in one country may not have applicability elsewhere.

In the recently released book on worldwide compliance issues (*Adherence to Long-term Therapies, Evidence for Action*), [12] published by the World Health Organization (WHO), researchers indicate the problem of noncompliance is worse in countries in the developing world when compared with the countries comprising the industrialized world. Many parts of the US have similar morbidity and mortality profiles as do countries in the third world. Specific disease states may have significant additional, noncompliance ramifications due to the development of drug resistant strains of bacteria.[13] Many times what is necessary is referral to specific caregivers for individualized treatment and monitoring to enhance compliance.

Counterfeit drugs. The unsavory topic of drug counterfeiting is a topic unanticipated in the past. The FDA has seen the number of counterfeit drug cases increase in the past 6 years [14]. The concern is pressing and unprecedented. It has reached the point where the integrity of the nation's drug supply is suspect. Counterfeit drugs have been suggested to account for 10% of the supply of drugs worldwide.[14] Continuing problems in the future may require drug validation and control by pharmacists as yet unseen. These validations may include the use of color changing inks, or invisible bar coding.

Coupled with this important issue of counterfeiting is the unsavory consideration of unscrupulous and unethical pharmacists.

Numerous reasons exist for why counterfeiting has increased in the US. The upsurge in the number of secondary wholesalers has made it easier for counterfeited drugs to enter the channel of distribution for pharmaceuticals. Secondary, wholesales are ostensibly set up to provide legitimate drugs for sale at reduced prices. In fact, secondary wholesalers make an easy entry point for substandard drugs. Increasingly, the type of drugs counterfeited has moved from obscure, expensive drugs to more commonly used drugs at lower price echelons (e.g., Lipitor<sup>®</sup>). Fakes are becoming more sophisticated (Serostim<sup>®</sup>) in package design and presentation. And unfortunately, to carry this issue one step further, the presence of organized crime and/or terrorist groups playing a role has been suggested.[15] The willful sale of substandard products with adulterated content, and the intent to harm can now more easily occur in the US with imported drugs. The near and far term future will see substandard drugs flooding the US market from India and China.[14]

Drug use in the elderly. Various components of drug usage in the elderly are worth noting. Problems with health literacy are more common with the elderly.[16] The burgeoning population of the elderly coupled with health literacy problems is an indication that this issue will increase in intensity in the future.[16] A vast majority of seniors have one chronic condition, and 50% have two.[17] Seniors on average consume 23.5 prescriptions per year while seeing on average 8 different physicians for health care needs.[17] The average rate of prescription drug utilization increased by about two prescriptions per patient per year for the four year period between 1997-2000.

Drug noncompliance is increasing in the elderly, not because of age per se, but because of age related factors that may include:

- a. social isolation
- b. aforementioned occurrence of chronic disease
- c. multiple and complex drug regimens
- d. the degree of morbidity associated with chronic diseases[18]

Over the next decade, seniors will spend \$1.8 trillion on prescription medications. Medicare proposals to provide a drug benefit for seniors have been suggested to cost \$400 billion over a 10-year period. Thus the most elaborate of the current drug programs will pay only 22% of seniors' drug costs.

The structure of any drug benefit program at this point is not well defined. Prescription drug cards have been promoted as a stopgap measure between 2004 and 2006 when the Medicare benefit will be in place. There are stipulations that some, but not all, savings attributable to card programs should be passed on to consumers, along with modest requirements pertaining to the rate of occurrence of price increase. The implementation of a Medicare drug benefit in 2006 would require an annual premium, and an annual drug cost of \$3,160 for seniors would reduce the amount spent to slightly over \$1,760 per year.[19]

A Medicare drug benefit can have the potential to enhance the delivery of health care to seniors. The federal government through market clout and sheer market share should theoretically be positioned to obtain the best price on drugs, obtain discounts currently provided to others, and optimally allow all pharmacies to compete on an equal footing. Finally, reining the variance in operating procedures of PBMs could benefit patient and provider alike.

Embedded requirements in current Medicare proposals provide a significant opportunity for pharmacists to provide non-distributive, cognitive services for patients. A medication therapy management program will be established through the drug discount card program beginning in 2004. Pharmacists and other health professionals will be eligible to participate, and can be compensated for such services. The goal of this program will be to provide cost and drug utilization management, quality assurance, and a reduction in medication errors and adverse drug reactions. Collaborative efforts are included to reach various health professions. An e-prescribing program is to be in place by 2007.[19] It is certain that e-prescribing will become more prominent in the future. Pilot studies have implemented this technological enhancement for physician order entry (via personal data assistant (PDA) or through web access to

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pharmacies) in order to reduce drug errors. Findings have indicated that there are decreases in calls for clarification of physician orders, and data indicates a time saving of an average of one hour per pharmacist per day.[19] The savings in time are due to a lessening need to follow up on questions pertaining to drug orders.

The bottom line is that the quality of care in the US needs improvement, seniors do not receive preventive inoculations (pharmacists can immunize in Georgia); and myocardial infarction patients do not receive necessary, standard therapies.[20] About 30% of persons with diabetes are not assessed for blood sugar levels.[20] And surprisingly, only 50% of recommended medical care procedures are received.[20]

Medication errors. Brass,[21] commenting on prescription to over-the-counter switching of medications, notes problems with polypharmacy, and specific problem drugs which will not surprise anyone today. These problem drugs include: analgesics, sleep preparations, pseudoephedrine, caffeine, cough and cold preparations, and laxatives. These problem drugs have been also noted in studies elsewhere.[22] Inaccurate self-diagnosis leads to suboptimal therapy, high patient cost, and more adverse effects and/or drug interactions.[21]

Barker and colleagues,[23] have found an error rate of 19% in a multi-institutional study of long-term care and hospital facilities. Also found was a 4% rate of unauthorized (unordered) drug use, and a rate of harmful error occurrence of 7%, amounting to forty harmful errors occurring daily in a typical 300 bed facility. In a study examining Cox-2 use and occurrence of gastropathy, it was determined that an increase in gastropathy occurred with Cox-2 usage.[24] Surprisingly, concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) and Cox-2s was found.[24] Elsewhere, it was found that the occurrence of errors by physicians and others is often not reported to patients, and surprisingly, 23% of physicians and 11% of patients in one study did not feel that physicians should report such occurrences of errors to patients.[25]

Pharmacists are at a crucial juncture as we face an uncertain, yet promising future. We need to pursue non-dispensing activities and move toward delivery of pharmaceutical care in all practice settings, not just in institutional settings. Expanding the types of services provided, seeking reimbursement for such, and continuing to document economic and clinical benefits will be even more important in the future than they are at present.

### **Pharmacy Education**

Pharmacy education has been and is being called upon to impact problems identified today. Increased demand for services, diminished resources, and the need for applied research in order to examine outcomes have come together at this juncture for our profession. A half century ago, Dean Wilson captured the essence of needs pertaining to pharmacy education and the future with 3 objectives dealing with education, pharmacy practice, and research.[1]

Ethics. Both Deans Waters[26] and Wilson[27] noted the need for professionalism and high ethical standards in the pharmacy profession. Not surprisingly, these needs exist today to an even greater extent. The pharmacy profession was rocked in 2002 by the revelation of greedy, egregious, and illegal actions, including drug dilution schemes, of a pharmacist, Robert Courtney, in Kansas City, MO. Whether this incident is an isolated one, or just one of several, immediate and sustained efforts are needed to avert this and similarly devastating activities from happening ever again.

Service learning. The strategic plan crafted here at the University of Georgia College of Pharmacy provides a template to implement service-learning programs for students through complementary educational opportunities.[28] Dr. Nichols-English and colleagues have written of the bridging of community based pharmacy outreach with service learning principles.[29] These activities are very important for exposure to students in training. Students come from communities, they study at our universities, and then they return to a community. These activities that benefit individuals, institutions, and society also benefit the provider. Providing these options for pharmacists in training is vitally important for them and for the greater profession.

Scope of pharmacy practice. As the scope of pharmacy practice has changed, pharmacy education must change to meet even more dramatic educational and practice needs for the future. Current and future pharmacists need to have the ability to: make tough decisions; communicate effectively with patients, other providers, and administrators; serve an ever aging population; help to ensure appropriate drug utilization; help to manage drug therapies; and work to harness technology to meet patient and practitioner needs.

A continuing focus on the outcomes of drug use will be even more important in the future. Demands for appropriate clinical, economic, and humanistic outcomes of health care delivery will rely heavily on practitioners able to evaluate therapies from these multiple standpoints. Pharmaceutical care must be applicable and useful for patients and their well-being. If the implementation of pharmaceutical care can pass these hurdles, it will become useful in all patient care settings. Pharmaceutical care will need to be implemented in rural and urban parts of Georgia. The process can be enabled through residencies and fellowships in varying practice settings: community, health-system, and managed care milieus.

Pharmacists will increasingly be called upon to monitor the positive and negative effects of drug therapy. Monitoring for patient compliance will expand as drug coverage expands to meet more patient needs. Post-dispensing review of therapies and their effects upon the quality of life of patients will be not only suggested, but in many cases required. An increasing number of pharmacists will have staff positions in outpatient facilities and medical practices in an evaluative role with no dispensing responsibilities.

Patients with chronic conditions, such as dyslipidemia, have been shown to experience improved outcomes with pharmacist interventions and monitoring. The Stanford Coronary Risk Intervention Project (SCRIP) study indicated better cholesterol management in high risk patients with pharmacist involvement.[30] Disease state management certification in dyslipidemia is a recognized certification by the Georgia Board of Pharmacy. One of the benefits of pharmacy education is applicable to practitioners through assistance in collecting and collating results of interventions. This is occurring through the clinical outcomes research group (CORG), and the community pharmacist research network (CPR-Net) facilitated by several of your faculty at present throughout Georgia.

Pharmacy colleges are being called upon more and more to be responsive to pharmacy practice clinical, political, and economic needs. One of the best ways to ensure that these needs are met is to structure curricula that have pertinence to future practitioners, as well as current pharmacy practitioners.

### **Public Health**

Historically, pharmacy has participated in public health activities in a sporadic fashion. This is an area where passive participation will no longer be an option for any health profession, including pharmacy. Past and current opportunities will evolve into options that pharmacists must grasp, and pharmacy education can play a role in empowering pharmacists to play more active roles.

Bioterrorism. The unfortunate specter of bioterrorism points to several needs that pharmacists can readily meet.[31] The anthrax crisis highlighted the lack of preparedness in many sectors of the health care system. Data management and epidemiological foci on outbreaks and intensity can allow for other disease conditions to be tracked as well in a similar fashion, i.e., cluster analysis to analyze cancer and locations of intense occurrence.[31] Information and referral needs highlight communication processes that need enhancement.[31] Pharmacist directed drug information centers with a compelling history of success will no doubt be called upon to answer yet unanticipated needs related to disease outbreaks, natural or contrived. Vaccination requirements will allow pharmacists to fill much-needed gaps in current processes for immunization and prevention of certain diseases.

Biochemical terrorism is not something that has been addressed in the past in curricula. This has changed recently, Ali and Warren[32] suggest sound concepts for pharmacists to employ to meet such disasters: planning, science based plans, using pharmacy resources, working with local networks of providers, and identifying local resources for assistance.[32] Schulz and colleagues[33] note that few hospitals are prepared to manage sequelae of biochemical terrorism, fewer still are capable of meeting

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patient, logistic, and educational needs. The unfortunate anthrax crisis serves as an example of how pharmacists can serve in the midst of uncertainty as resource persons and active clinicians involved in education and prescribing in institutional settings[34].

Epidemiology and preventive health. The University of Georgia College of Pharmacy strategic plan approved in May 2002[28] outlines the need for strong community programs in disease management, and wellness activities through prevention and screening. Using epidemiologic tools to assess where diseases are occurring, and then structuring an organized effort to impact morbidity can help patients and pharmacy providers. Expanding the recognized disease management options for pharmacists can utilize cluster analysis and other techniques to identify underserved areas, and thus allow for planning to implement structured means to address unmet needs. Preventive health activities and educational programming [28] can tie in nicely with health plan employer data and information sets (HEDIS) guidelines that point to 5 areas where pharmacists can actively participate in either preventive or active treatment programs.

Active participation in health screening activities allows pharmacists to impact hypertension, dyslipidemia, diabetes, and osteoporosis, as well as other potential conditions. Future use of epidemiologic techniques can allow pharmacists and schools of pharmacy to target how resources can be applied to meet both educational and practice based outreach activities.

Using several disease states as examples helps to clarify the need. The prevalence of diagnosed diabetes in the US in general, and in Georgia in particular, is steadily increasing.[35] Obesity in the US population has increased significantly in the recent past.[36] Data indicates that Georgia has experienced the highest increase in rates of obesity in the US between 1991 (9.2%) and 1998 (18.7%).[36] This 102% increase is an indicator of the need for pharmacist involvement. Coupling diabetes and obesity influences many organ systems, conditions, and outcomes. In fact, according the WHO, chronic disease has more of an impact now than does infectious disease throughout the world, and obesity is the causative factor.

#### Other public health issues

Health literacy, indigent care. The negative influence of health illiteracy has tangible outcomes in higher rates of hospitalization with lower rates of health literacy.[37] Dr. Chisholm and colleagues have identified a role for pharmacists to play in indigent care through advocacy, intervention, and serving in a liaison role between interested parties.[38] Mapping occurrence and demographics at a macro level can allow for local interventions and subsequent successes. The impact of much of the elaborate technology in the US health care system is not available for the uninsured. It is projected that \$1.1 billion per year in additional expenditures is needed to deal with under treatment of myocardial infarction, cataracts, and depression.[39]

Immunization. Much work remains to accomplish the full immunization of young children everywhere, including Georgia.[40] In Georgia, slightly over 70% of immunizations for diphtheria, polio, chickenpox, measles, and hepatitis B is provided through private providers. The rate of success in immunizing children 2 years of age is slightly less than 80% in Georgia.[40] Pharmacists can help close this coverage gap and help to provide tangible success immediately.

Human immunodeficiency virus, acquired immunodeficiency syndrome (HIV/AIDS). The number of cases in the rural south is increasing, and is disproportionately occurring among people of color and the rural poor.[41,42] Georgia ranks among the top 10 states in prevalence of HIV/AIDS. Pharmacists could have such a major impact from educational and preventive perspectives with HIV/AIDS.

Tobacco use. In 1998, almost 35% of children in grades 9-12 reported smoking within the past 30 days. Some 6,000 adolescents try a cigarette every day; and 3,000 become regular smokers. Over 500,000 Americans die each year from tobacco related morbidity; over 50,000 die from passive smoking related health problems. For example, there is an increased rate of meningococcal disease in young children with mothers who smoke.[43] In Georgia, 23.5% of the population smokes, this is a percentage point

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greater than the national average. There is much room for many health professionals, including pharmacists to play a much more proactive role in smoking cessation activities.

Rural health care. Spending for drugs in Medicaid programs varies from rural to urban areas, with spending being greater for drugs in rural states.[44] Pharmacists can play an active role in enhancing health care in rural areas of the US, many rural communities struggle to maintain economic and social viability. Often, rural communities retain a community pharmacy as the only health care entry point for care. Working with such pharmacies to document outcomes, encourage preventive activities, and encourage drug therapy management activities is a vital role for colleges in which to become engaged.

Maintenance of health benefits. A major concern of many health insurance enrollees is the ability to maintain health insurance coverage. This so called “security of benefits” is important to many who have coverage, or who have limited coverage for intermittent periods.[45] It is a significant concern to 34% of consumers who indicate that they are worried about continuation of benefits.

### Summary

The ability to impact students in training, conduct state of the art, cutting edge research, and impact the lives of a majority of members of society was eloquently noted by Dean Wilson in the past. The promotion of pharmacy through the College’s Strategic Plan as the primary drug therapy resource for other professions and for society in general would no doubt please him.

The University of Georgia College of Pharmacy has a distinguished record for both basic and applied research. What I have spoken about today concerns health policy and clinical research. They are important research components that will allow pharmacists to choose to exercise proactive options for opportunities that will arise in the future. Patients and practitioners view the College of Pharmacy as located not in one locale, but across the entire state. Through response to their known and unknown future health needs, the College can meet the important missions outlined by Deans Wilson and Waters and supported so strongly and vigorously by succeeding deans.

When faced with future opportunities, I hope pharmacists choose the option of proactive involvement in the health and health care needs of people in Georgia and elsewhere.

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