



The University of Georgia

University Council
Athens, Georgia 30602

December 6, 2004

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Dear Colleagues:

Attached is a request from the College of Pharmacy to establish a Center for Drug Discovery. This request will be an agenda item for the next Full University Curriculum Committee meeting.

Sincerely,

Jan M. Hathcote, Chair
University Curriculum Committee

cc: Dr. Arnett C. Mace, Jr.
Dr. Delmer D. Dunn

Proposal
For the Establishment of
The Center for Drug Discovery (CDD)
in the
College of Pharmacy at The University of Georgia
Athens, Georgia 30602

Submitted
By

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Research and Associate Provost

Svein Øie, Ph.D., Dean of the College of Pharmacy

This document and the concept of creating the Center for Drug Discovery have been approved by the Dean of the College of Pharmacy and unanimously by the College of Pharmacy Executive Committee and Council, and also by the faculty at its general meeting on May 10, 2004.

September 1, 2004

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Abstract

A proposal to establish a Center for Drug Discovery at the University of Georgia is outlined. Establishment of the Center is consistent with the Strategic Plans of the College of Pharmacy and the University of Georgia. The mission of the Center for Drug Discovery is to create a world-class center to promote interdisciplinary scientific research for the discovery of new chemical and biological entities targeted against infectious diseases and cancer and, through these discoveries, contribute to the research and teaching mission and increased national stature of the University of Georgia. Other therapeutic areas will also be considered for inclusion. Headquarters of the Center will be in the College of Pharmacy and funds for the initiation and operation of the Center for the first few years already exist. This seed money has been targeted specifically to create a Center for Drug Discovery. Initial membership of the Center will include extramurally-funded, research-active scientists with interests in drug discovery selected from faculty members at the University of Georgia, the Medical College of Georgia, Emory University, Georgia State University and Georgia Institute of Technology. Affiliation with selected scientists in drug discovery at other universities and with pharmaceutical companies is also planned. Eventual benefits of the Center for participants and the University of Georgia include, among other examples, a mechanism to better integrate research efforts in developing new chemical and biological entities to combat infectious diseases and cancer (and other therapeutic areas), an administrative core with a central data base for scientific expertise that can administer and coordinate interdisciplinary efforts in drug discovery, a program of seed grant support, a NIH-funded training grant in the area of drug discovery, enhancement of core facilities, and joint seminars and an annual conference on drug discovery. Establishment of the Center would also provide further national and international recognition in state-of-the-art, interdisciplinary research in drug discovery at the University of Georgia, enhance interactions with pharmaceutical companies, and contribute to the recruitment and retention of highly competent faculty, staff, postdoctoral associates and graduate students. Furthermore, it is anticipated that the Center will serve as an “economic engine” for the State of Georgia in the area of pharmaceuticals and related biotechnology.

The Center for Drug Discovery

*“...knowledge belongs to humanity and is the torch which illuminates the world.”
Louis Pasteur*

Introduction and Background

Therapeutic drugs have played a major role in increasing average life expectancy in the United States from about 47 years a century ago to more than 76 today. However, while many of the drugs in use in the last fifty years or more have been of synthetic or semi-synthetic origin, the pharmacopoeias for many years prior to the age of these pharmaceutical drugs were of natural origin.

The medicinal value of plants has been recognized by almost every society on this planet. In the nineteenth and earlier centuries, natural product extracts, particularly those derived from botanical species, provided the main source of most medicines. However, in the latter part of the nineteenth century, biologically-active organic molecules began to be isolated in relatively pure form for medicinal use. For example, salicylic acid, the precursor of aspirin, was isolated in 1874 from willow bark. Various more potent painkillers, such as morphine and codeine, were isolated from the opium poppy. The anti-malarial agent, quinine, was separated from cinchona (china bark). The leaves of the purple foxglove plant provided an excellent source of digitalis that was purified for use against heart disease. There are numerous other examples in folk medicine. Interestingly, the complete structure and stereochemistry of most of these organic molecules were elucidated many years later. While the beginning of the pharmaceutical century is attributed as being in the early 1900s, synthesis of one of the first synthetic pharmaceutical drugs, aspirin, occurred in the latter half of the nineteenth century. Interestingly, it was not until the early 1900s that the recognition of aspirin as a universal pain reliever was realized and this discovery spawned the era of therapeutic agents.

However, it was not until the beginning of the age of medical microbiology and the recognition that many infectious diseases were caused by microorganisms that the real impetus in the development of pharmaceuticals, both natural and non-natural, began to occur. Concurrent with discoveries in medical microbiology were major advances in synthetic organic chemistry and biochemistry that provided further momentum in the area of therapeutic pharmaceutical agents. Synthetic sulfa drugs, the natural antibiotic, penicillin, from *Penicillium notatum* (Alexander Fleming), the semi-synthetic antibiotic, tetracycline, produced from natural chlortetracycline elaborated by *Streptomyces aureofaciens* (Benjamin Duggar) and the anti-tubercular aminoglycoside, streptomycin, from *Streptomyces griseus* (Salman Waksman) were all major landmark discoveries of the 1930s and 1940s. The importance of vitamins and diseases caused by deficiencies in vitamins were also being uncovered during this period. Non-antibiotic discoveries of the 1940s included the anti-leukemic compound, 6-mercaptopurine (Gertrude Elion and George Hitchings), the anti-rheumatoid arthritis agent, cortisone (Edward Kendall, Thadeus Reichstein and Philip Hench) and the anti-coagulant, warfarin (Karl Link). Spectacular advances in structural techniques during the next several decades such as X-ray crystallography, magnetic resonance spectroscopy (NMR) and mass spectrometry and developments in other technologies such as electrophoresis, ultracentrifugation, gas chromatography, high performance liquid chromatography and other instrumentation-based advances contributed to the discovery of other chemical and biological entities with therapeutic activities and to the development of some vaccines. Selected examples include oral contraceptives (Margaret Sanger, Katherine McCormick, Russell Marker, Gregory Pinckus and Carl Djerassi), tranquilizers (e.g., valium) and poliomyelitis vaccines (Salk and Sabine).

The seeds for the concept of rational drug design were laid in the 1940s and 1950s by George Hitchings and Gertrude Elion in their work on DNA-based antimetabolite program which led to the discovery of modified purines with anticancer activity. However, the era of DNA and medicine was largely stimulated by the elucidation of the double-helical structure of DNA by Watson and Crick in 1953. This discovery spawned the field of molecular

biology and also contributed enormously to molecular genetics and microbiology. The field of virology was moving forward rapidly in the 1940s but the discovery of the nature of the structure of DNA in the 1950s and its subsequent ramifications in DNA replication, transcription and translation led to a much better understanding of viral replication. This laid the foundation for antiviral drug discovery in subsequent decades as molecular targets in the viral replication cycle began to be identified. The 1950s also saw the discovery of vancomycin, a glycopeptide which was developed much later for use against staphylococci infections. Some fundamental breakthroughs in protein chemistry, for example new information on DNA and RNA polymerases and their structure and function, occurred during the 1950s and 1960s after the structure of double-stranded DNA was elucidated. This was followed by the era of recombinant DNA technology and molecular cloning which began around the mid-1970s. Spectacular accomplishments in the area of synthesis of complex, biologically-active natural products also occurred during this period including the monumental synthesis of vitamin B₁₂ by Nobel Prizewinner, Robert Woodward, and his research team which included Dr. Nair. The natural product, taxol, isolated originally from *Taxus brevifolia* in 1971, represents an excellent example of the contribution of a combination of natural product isolation and organic synthesis in the development of an anticancer agent. Taxol finally progressed into clinical use in 1993.

Developments in molecular biology and virology had a major impact in the scientific understanding in the 1980s and early 1990s of the replication of the retrovirus, HIV. By the 1980s, it had already been established that T-cells provided the key to the human immune system. Understanding of the virus-host interaction was aided by the development of sensitive and reliable assays of viral load. The picture that emerged about HIV was that the virus attacks T-cells and ultimately incapacitates the human body's immune system. This makes the body highly susceptible to many bacterial and viral infections and neoplasms. Identification of the possible biochemical points of attack on the virus replication cycle gave drug discovery efforts around the world major impetus for the design and synthesis of nucleoside, non-nucleoside and peptide analogs as targeted anti-HIV agents. Successes in this area have been simply outstanding. The emergence of drug-resistant virus of both

natural and non-natural origin has complicated the therapeutic picture considerably and has necessitated the use of drug combination therapy. The polymerase chain reaction (PCR) of the 1980s brought about another major advance in biotechnology that has had significant ramifications in molecular biology, including sequencing, and in the human genome project. In the 1990s, combinatorial chemistry, molecular modeling and bioinformatics contributed to the discovery of newer generation drugs based on genomics and proteomics.

The beginning years of the new millennium will see further advances in drug discovery that will likely be based on state-of-the art chemistry and chemical genetics, new advances in biology, enzyme-based molecular syntheses, proteomics and genomics, recombinant biomolecules, high-throughput screening, and gene and cell therapy.

Mission and Goals of the Center for Drug Discovery

The mission of the Center for Drug Discovery is to create a world-class center to promote interdisciplinary scientific research and discoveries in the general area of therapeutic agents targeted against infectious diseases and cancer and, through these scientific discoveries, contribute to the research and teaching mission and increased national stature of the college and the university. Other therapeutic areas will also be considered for inclusion. Interdisciplinary research areas that are relevant to drug discovery include, but are not limited to, the following: state-of-the art chemistry, molecular modeling, chemical biology including signal transduction, bacteriology and virology, proteomics and genomics, biochemical pharmacology, drug delivery and nanotechnology, high-throughput screening and gene and cell therapeutics.

The University of Georgia policy on centers and the College of Pharmacy policy on centers are closely related. According to the collegiate policy on centers, a “center is defined as an organizational base for scholarship in a given academic area or closely related

areas. It provides a vehicle for interdisciplinary research in a given area for faculty and students. The Center structure may facilitate efforts of the College of Pharmacy to obtain extramural funding in specific areas. It serves as a formalized link between the academic community and the professional community in the area of focus. A Center is part of the traditional administrative structure of the College of Pharmacy. A Center is not involved in the independent offering of course credit or degree programs.”

The need for the discovery of new therapeutic agents for combating existing and emerging infectious diseases caused by viruses is extremely high. The College of Pharmacy has a current and past history in the area of discovery of antiviral agents. This includes major NIH (National Institute of Allergy and Infectious Diseases) funding for Dr. Nair for programs in the area of the discovery of antiviral agents against existing (e.g., retroviruses and DNA viruses) and emerging viruses (e.g., exotic RNA viruses).

The discovery of anticancer compounds is another target area for the Center. Cancer cells differ from normal cells in a variety of ways that include structural, functional and metabolic differences. These differences, which result in uncontrolled cell proliferation, may be caused by agents that damage DNA or that interfere with DNA replication or repair. Of particular significance to Dr. Nair’s research programs is the observation that some viruses can induce the formation of malignant tumors in their hosts. For example, certain retroviruses, such as the Rous sarcoma virus (RSV), carry oncogenes that maintain the infected cell in a proliferative state, presumably to enhance the viral replication rate. Malignancies such as retroviral-related lymphoma and Kaposi’s sarcoma are very well documented. Thus, their antiviral research work has also created spin-offs in the area of potential anti-cancer agents.

Newer chemotherapeutic agents against cancer include, among others, inhibitors of signal transduction (e.g., *ras* inhibitors, tyrosine kinase inhibitors, protein kinase C inhibitors, inhibitors of cyclin-dependent kinases), inhibitors of matrix metalloproteinases (MMPs), and those that are selectively targeted toward metabolic differences between

normal and cancerous cells. Many types of cancer cells appear to differentiate terminally into mature, non-proliferating cells following treatment with antimetabolites. One such area is being pursued in Dr. Nair's laboratory with the enzyme, inosine monophosphate dehydrogenase (IMPDH).

A third area of interest is that involved with the discovery of novel antimicrobial agents. The discovery and use of penicillin as an antibiotic also brought about the beginning of the era of antibiotic resistance. In response to the biological threat posed by antibiotics, bacteria evolve and generate defense mechanisms to elude the threat. Thus, the discovery of new antimicrobial agents is a much-needed and continuing scientific pursuit. A recent jolt for the need and importance of new antimicrobial agents arose in 1998 when vancomycin-resistant *S. aureus* was discovered in several different locations. Vancomycin is the most commonly used drug against staphylococci infections

It is relevant to note that as part of its strategic plan, the University of Georgia set out a few years ago to dramatically increase the emphasis on biomedical research and education on this campus, including cancer research and education. This part of the strategic plan was implemented through faculty and staff recruitment, through the acquisition of major research equipment, through renovation and new construction, and through increased funding from the National Institutes of Health for biomedical research including cancer research. Two other key elements of this development were the hiring of several distinguished scientists and scholars in this area and the establishment of the Biomedical and Health Sciences Institute. This institute promotes interdisciplinary research and instructional efforts at the UGA in the fields of biomedical and health sciences through its faculty leadership, institutional structure, funding, academic programs, and various resources. In addition, in 2002, faculty members and administrators at the University of Georgia proposed the establishment of a Cancer Center. Such a center would coordinate programs and research associated with cancer and would provide an interface with the Georgia Cancer Coalition and would interact with cancer programs throughout the state, including programs at the Medical College of Georgia. The Drug Discovery Center housed

in the College of Pharmacy would interact with and complement both the BHSI and the Cancer Center in research work. However, the focus of the research work in drug discovery ongoing in the College of Pharmacy and planned for the future in the interdisciplinary Center for Drug Discovery will have its own uniqueness in its research mission.

Finally, it should be stated that a significant component of the offer letter that Dr. Nair received from the University of Georgia pertained to the creation of a world-class Center for Drug Discovery. This center component of the offer letter strongly influenced his decision to move from the University of Iowa to the University of Georgia.

Benefits of the Center to Participants, the University of Georgia and the State of Georgia

The objectives of the CDD are expected to have the following eventual benefits for participants, the University of Georgia and the State of Georgia:

- (1) provide a mechanism to better integrate interdisciplinary research efforts in developing new chemical and biological entities to combat targeted diseases;
- (2) act as an administrative core with a central data base for scientific expertise and facilities and administer and coordinate joint efforts in drug discovery;
- (3) seek new research opportunities through identifying potential resources, through helping to link researchers to form strong interdisciplinary groups, through obtaining access to shared core resources, and through a program of seed grant support;
- (4) develop joint recruitment plans for graduate students interested in drug discovery from relevant disciplines and achieve success in obtaining a NIH-funded training grant for integrated, interdisciplinary research efforts in drug discovery;
- (5) contribute to enhancing core facilities;

- (6) organize joint seminars and an annual conference on drug discovery;
- (7) seek funds (e.g., through the GRA) to improve research facilities for drug discovery participants;
- (8) work with Schools and Colleges to strengthen education on drug discovery;
- (9) work to establish endowments that will support the CDD;
- (10) work to enhance scientific interactions with pharmaceutical companies;
- (11) contribute to the recruitment and retention of highly competent faculty, staff and postdoctoral associates in drug discovery and complementary sciences.
- (12) utilize the Center as an “economic engine” for the State of Georgia in the area of pharmaceuticals and related biotechnology.

Core Values of the Center

The core values of the Center summarized below are closely related to that outlined in the “Strategic Plan” of the College of Pharmacy and to the “Core Values for Planning” and “Institutional Values” of the University of Georgia.

Research and Scholarship

Aspiration to achieve the highest levels of research, scholarship and creative expression.
Furthering research and education through innovative discoveries.

Integrity

Dedication to the highest levels of integrity in scientific research.

Collaboration

Promoting partnership, teamwork and mutual respect.

Diversity

Promoting diversity among participating members and their coworkers.

Service and Outreach

Sustained scholarly activities of members and learning opportunities for students and staff.

Positive Work Environment

Promoting a supportive and positive work environment for students, staff and faculty.

Location of the Center for Drug Discovery at The University of Georgia

The selection of the University of Georgia as home to the Center for Drug Discovery is supported by many factors. The University of Georgia is a rising, top-twenty public institution with a strong commitment to enhance basic biomedical sciences. As such, University administration and faculty are dedicated to the recruitment of outstanding talent and the development of excellent facilities. A variety of initiatives currently directed toward this end include the University's involvement in the Cancer Coalition of Georgia and shared programs with the Medical College of Georgia. A number of strong centers contributing to these initiatives already are established or are being established at the University, including the Biomedical and Health Sciences Institute, the Complex Carbohydrate Research Center (CCRC), the Center for Tropical and Emerging Global Diseases (CTEGD) and the Cancer Center. Excellent research facilities exist including the Central Research Stores, Integrated Biotechnology Laboratories, the Southeast Collaboratory for Structural Genomics, various X-ray facilities including the Georgia X-ray Crystallographic Center, the Southeast Collaboratory for High-Field Biomolecular NMR, various mass spectrometry facilities, and the Chemical Analysis Laboratory. In addition, the College of Pharmacy has major instrumentation that will be available to the Center for

Drug Discovery including Varian multinuclear 500 MHz and 400 MHz high-field NMR spectrometers, an X-ray diffractometer - a Bruker Kappa CCD system mounted on a Nonius FR591 X-ray Generator and Accessories, Micromass Quattro II-Z and Micromass Quattro-LC Atmospheric Pressure Ionization Triple Quadrupole Mass Spectrometers, Micromass LCT TOF Mass Spectrometer, Agilent Technologies Model 6890/5973 Gas Chromatography Mass Spectrometer, Beckman Model P/ACE 5000 Capillary Electrophoresis System, Beckman 6500 and LS3801 Liquid Scintillation Counters, 16-Station Tablet Presses, Accusizer 780 and Nicomp 380 Particle Sizers, Differential Scanning Calorimeter, Vankel Dissolution Apparatus, Fisher Scientific 60 Sonic Dismembrator and Alpha Imager. Numerous other items of equipment such as UV-Visible Spectrometers, IR Spectrometers, DNA Synthesizers, HPLCs, Gas Chromatographs, Microscopes, Refrigerated Preparative Centrifuges, Microcentrifuges, Incubators, PCs, Molecular Modeling Equipment, etc., exist in the college in various laboratories. In short, the University of Georgia provides an outstanding research environment in which to build such a center.

Dr. Nair is a Georgia Research Alliance (GRA) Eminent Scholar in Drug Discovery. The Georgia Research Alliance has the following statement in its brochure/ website: “As an internationally-acclaimed model for bringing business, research universities and state government together, GRA’s goal is to create and sustain a vibrant, technology-driven economy for the state. The Alliance achieves its goals through strategic investments at the state’s leading research universities in eminent scholars, collaborative research laboratories, national centers for research and innovation and technology transfer programs. Since its founding in 1990, the Alliance has invested some \$350 million, which has helped to attract 40 Eminent Scholars, leverage an additional \$2 billion in federal and private funding, create nearly 3,000 new technology jobs, generate more than 80 technology companies and help established companies expand into new markets.”

One of the areas specifically targeted by the GRA, through overwhelming support from its Eminent Scholars, is the area of drug discovery. It is evident that support from the Georgia

Research Alliance is critical for translating innovative successes in the laboratory to commercially useful products such as drugs targeted against infectious diseases and cancer.

The Center for Drug Discovery, the Strategic Plan of the College of Pharmacy and the Strategic Planning of the University of Georgia

Creation of the Center for Drug Discovery within the College of Pharmacy is a stated goal of the College's Strategic Plan. For example, Goal 9 states: "Achieve recognition as a leader in state-of-the art research." Included in this goal are such specific directives as promoting research with global perspectives and enhancement of interactions with the pharmaceutical industry. The Collegiate Goal with the most direct reference to the establishment of this center is Goal 18a which states the following: "Create campus-wide centers in critical research areas such as drug discovery (Center for Drug Discovery...)". Another collegiate goal (13a) with direct relevance to the Center states: "Increase substantially the academic relationships between departments within the College and within academic programs locally, regionally, nationally and internationally." Establishment of the CDD will allow the College to position itself as a world leader in the area of drug discovery, because of the expertise already existing in the College and the involvement of Eminent Scholars and other distinguished scientists from the University of Georgia, the Medical College of Georgia, Emory University, Georgia State University and Georgia Institute of Technology. Establishment of the Center is also consistent with the strategic plans of the University of Georgia.

Operational Procedures and Policies

The Center for Drug Discovery will report directly to the Dean of the College of Pharmacy and the Vice President for Research and Associate Provost of the University of Georgia. The structure of the Center will include the following participating personnel: Director, Faculty (Principal Investigators), Staff Investigators, Support Staff, and an Advisory Committee. Faculty Members of the CDD will be faculty actively involved in research in the chemical, biological, biomedical or clinical aspects of drug discovery. Faculty who want to be members of the Center will be expected to have major research grant support (e.g., NIH) in the general area of drug discovery (drug design and synthesis, enzymology, genomics and proteomics, mechanism of action, drug delivery, pharmacokinetics, toxicity, resistance, and clinical trials, among others) and be very actively involved in research in their respective fields. No FTE percentages will be administered by the Center. Affiliated faculty salaries will not be paid by the Center. Admission of faculty investigators to membership of the CDD will be made by the Advisory Committee. Admission of faculty members in the College of Pharmacy will also require approval of the Department Head, Center Director and the Dean. Admission of faculty members from outside the college will also require administrative approval from their departments and/or colleges. Membership in the Center will be for a five-year term. Re-admission after five years will require going through the same process. Assistant Professors accepted by the Advisory Committee will have Associate Membership in the Center initially until a positive promotion decision is accomplished, and at that time their application to full membership will be reviewed by the Advisory Committee. Center members should have normal appointments within their departments and are expected to meet their obligations to their departments in terms of scholarly activities, service and particularly teaching.

The designation, "Staff Members," will normally be applied to post-Ph.D. investigators associated with Principal Investigators who are members or associate members of the CDD. Staff members may be research scientists, postdoctoral associates or investigators in

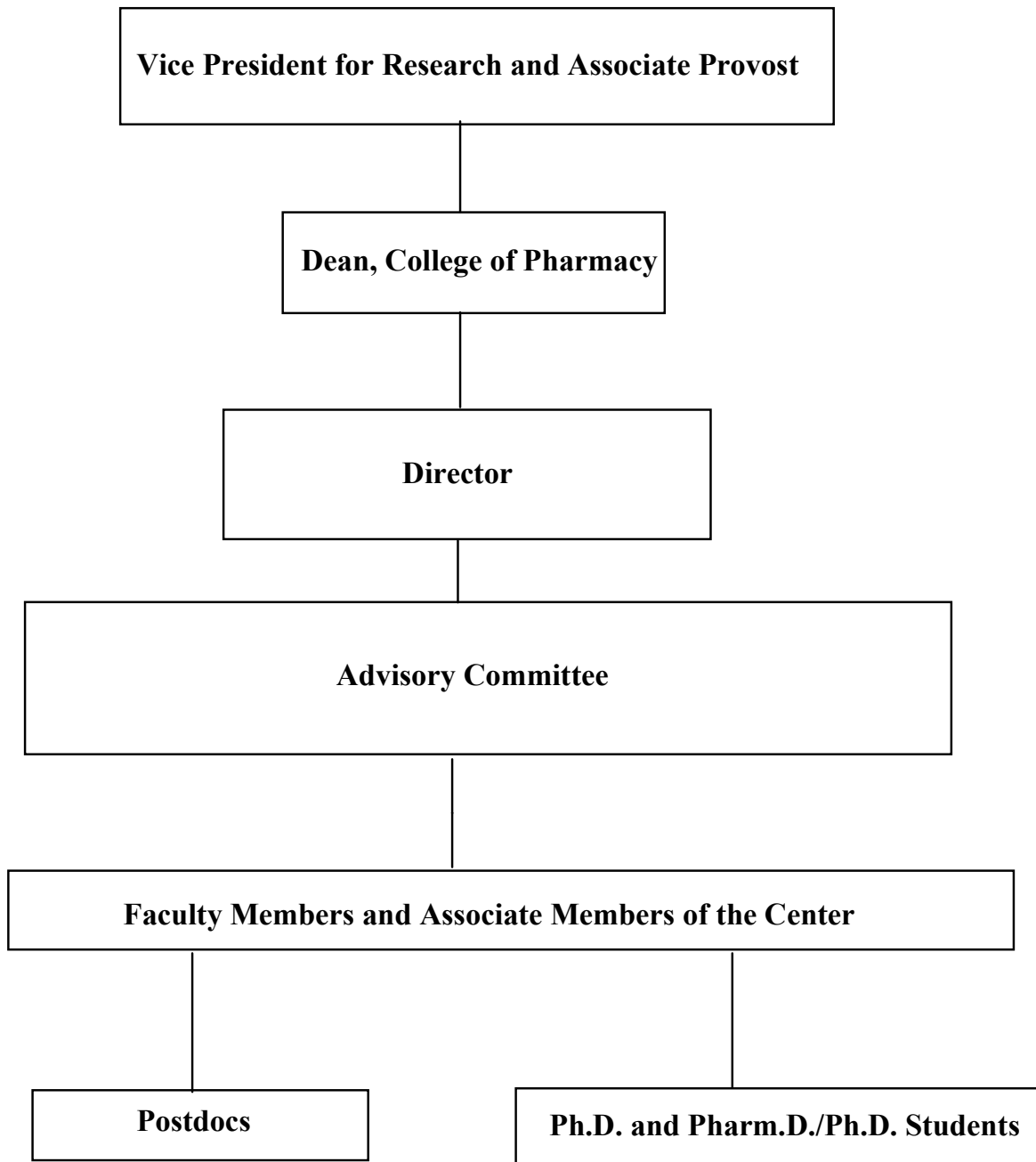
equivalent positions. Support Staff refers to secretarial or administrative personnel of the CDD.

Graduate students or Pharm.D. students will be designated as research assistants or equivalent and will be under the mentorship of the faculty member who is their major professor and who is a member of the CDD. In the first few years, research assistantships are not likely to be available through the Center. However, as funds for the Center increase, it may be possible to award some research assistantships. After the Center is established, it is expected that the Director will work with selected faculty members of the Center to apply for a NIH Training Grant in Drug Discovery and this mechanism will provide NIH support for the best pre-doctoral students in drug discovery.

Affiliated faculty and research staff investigators including assistants will conduct their research investigations individually or collaboratively in their departments and colleges and will be connected to the Center through individual or joint research projects in the drug discovery area, through coordinated seminars and research meetings, and through a yearly conference on drug discovery that will have poster and oral sessions.

The Director of the Center serves at the discretion of the Dean of the College of Pharmacy and the Vice President for Research. The Director will have a position on the CDD Advisory Committee and will preside over meetings involving Faculty Members of the Center, Staff Investigators, Support Staff and the Advisory Committee and any other formal meeting involving the CDD. The Advisory Committee for the Center will be appointed by the Dean of the College of Pharmacy with input from the Center Director and Faculty Members of the Center. The first Advisory Committee will be appointed by the Dean of the College of Pharmacy with input from the Center Director and the Vice President for Research.

Organizational Chart for the Center for Drug Discovery



Financial Resources to Initiate Center

Resources to initiate the Center already exist in the College of Pharmacy and this seed money from collegiate patent funds was included as part of the offer letter to Dr. Nair by the University of Georgia and specifically targeted to create a Center for Drug Discovery. The initial set up of the Center will require the following:

- (i) office space in the current Pharmacy Building and subsequently in the New Pharmacy Building which will be designated as the Central Office of the Center;
 - (ii) small renovation expenses for the office.....\$5,000;
 - (iii) equipment and office furniture (computer, printer, Fax machine, scanner, telephone, copy machine, cell phone, furniture, video facility for teleconferencing, furniture, file cabinets, office supplies, etc.).....\$15,000;
 - (iv) appointment of a full-time staff member who will act as the Center's Administrative Assistant (salary and benefits)\$42,000;
 - (v) funds for the creation of a website for the Center.....\$5,000;
 - (vi) funds to invite outstanding scientists from universities and pharmaceutical companies to present seminars on drug discovery.....\$8,000;
 - (vii) funds to organize the first UGA Conference on Drug Discovery.....\$15,000;
 - (viii) miscellaneous expenses for operating the Center Office.....\$10,000
- Total.....\$100,000**

After the first year, a total of at least \$75,000 per year would be needed to keep the Center operational in the following three years. Dr. Nair has a commitment for this amount for three years as a component of his offer letter to create the Center for Drug Discovery. This seed money to support years 2, 3 and 4 of the Center is currently available and comes from patent income of the College of Pharmacy in the area of drug discovery. During the first four years of the operation of the Center, fund raising from pharmaceutical companies and/or patent funds arising out of Center discoveries would generate sufficient money (expected

to be about \$100,000 per year by year 4) to supplement existing income to enhance the Center with respect to its stated goals and benefits. After four years, it is likely that the Center will be self-sufficient.

Anticipated Income of Center and Financial Arrangement of Center and Other Units

It is anticipated that patent funds, donations from pharmaceutical companies and former graduates and support from the Georgia Research Alliance will provide some income for the operation of the Center. Overhead returns from interdisciplinary grants submitted by members through the Center may also provide a source of funds for the Center. Extramural funding applications originating from the Center must be approved by the Center Director, Department Head(s), and Dean and must be in compliance with the College of Pharmacy and the University of Georgia Policies on Grants and Contracts. Grant submission will recognize the Center and department affiliation of faculty and staff. Any distribution of salary and indirect cost returns will follow established collegiate policies.

Formal Arrangements for Faculty Participation

Faculty who want to be members of the Center will be expected to have major research grant support (e.g., NIH) in the general area of drug discovery (drug design and synthesis, enzymology, genomics and proteomics, mechanism of action, drug delivery, toxicity, resistance, and clinical trials, among others) and be very actively involved in research in their respective fields. No FTE percentages will be administered by the Center. Affiliated faculty salaries will not be paid by the Center as the CDD will be administered as an appendage of an administrative structure, such as a department or college. In this case the main administrative structure is the College of Pharmacy. Thus, faculty salaries will not be

contained in the center budget. Admission of faculty investigators to membership of the CDD will be made by the Advisory Committee. Admission of faculty members in the College of Pharmacy will also require approval of the Department Head, Center Director and the Dean as set out in the “COP Collegiate Policy on Centers.” Admission of faculty members from outside the college will also require administrative approval from their departments and/or colleges. Membership in the Center will be for a five-year term. Re-admission after five years will require going through the same process. Center members will have normal appointments within their departments and are expected to meet their obligations to their department in terms of scholarly activities, service and particularly teaching.

Tentative and Initial List of Faculty Participating in the Center

Note: Faculty members in this initial list of participants have very active, funded research programs in the general area of drug discovery. They have excellent research laboratories and state-of-the-art equipment for this type of research work.

Svein Øie, Ph.D., Professor and Dean, College of Pharmacy, University of Georgia, Athens, GA

Vasu Nair, Ph.D., D.Sc., Department Head, William Henry Terry, Sr. Chair and Georgia Research Alliance Eminent Scholar in Drug Discovery, Department of Pharmaceutical and Biomedical Sciences, University of Georgia, Athens, GA

Michael Bartlett, Ph.D., Associate Professor and Associate Department Head for the Graduate Program, Graduate Coordinator, Department of Pharmaceutical and Biomedical Sciences, University of Georgia, Athens, GA

Brian Cummings, Ph.D., Assistant Professor, Department of Pharmaceutical and Biomedical Sciences, University of Georgia, Athens, GA

Will Taylor, Ph.D., Professor, Department of Pharmaceutical and Biomedical Sciences, University of Georgia, Athens, GA

Cory Momany, Ph.D., Assistant Professor, Department of Pharmaceutical and Biomedical Sciences, University of Georgia, Athens, GA

Alvin Terry, Ph.D., Professor, Department of Clinical and Administrative Pharmacy, University of Georgia, Athens, GA (Address: Medical College of Georgia, Augusta, GA)

Susan Fagan, Pharm.D., BCPS, FCCP, Professor, Department of Clinical and Administrative Pharmacy, University of Georgia, Athens, GA (Address: Medical College of Georgia, Augusta, GA)

Joseph DiPiro, Pharm.D., Panoz Professor, Department Head and Assistant Dean, Department of Clinical and Administrative Pharmacy, University of Georgia, Athens GA (Address: Medical College of Georgia, Augusta, GA)

James H. Prestegard, Ph.D., Professor of Biochemistry and Molecular Biology and Eminent Scholar, Complex Carbohydrate Research Center, University of Georgia, Athens, GA

Bi-Cheng Wang, Ph.D., Professor and Eminent Scholar, Department of Biochemistry and Molecular Biology, University of Georgia, Athens, GA

Rafi Ahmed, Ph.D., Professor and Eminent Scholar, Department of Microbiology and Immunology, Emory University, Atlanta, GA

Binghe Wang, Ph.D., Professor of Chemistry and Eminent Scholar, Georgia State University, Atlanta, GA

Stephen Dalton, Ph.D., Associate Professor and Eminent Scholar in Molecular Cell Biology, Animal and Dairy Science and Biochemistry and Molecular Biology, University of Georgia, Athens, GA

David Puett, Ph.D., Regents Professor and Department Head, Biochemistry and Molecular Biology, University of Georgia, Athens, GA

Raymond Schinazi, Ph.D., Professor & Director, Laboratory of Biochemical Pharmacology, Emory University, Medical Research-151, Decatur, GA

Dennis Liotta, Ph.D., Professor of Chemistry and (Former) Vice President for Research, Emory University, Atlanta, GA

Julia Hilliard, Ph.D., Professor of Biology and Eminent Scholar in Molecular Biotechnology, Georgia State University, Atlanta, GA

David Munn, M.D., Professor of Pediatric Oncology, Program in Molecular Immunology, Medical College of Georgia, Augusta, GA

Geert-Jan Boons, Ph.D., Franklin Professor of Chemistry, Complex Carbohydrate Center, University of Georgia, Athens, GA

Robert Phillips, Ph.D., Professor of Chemistry, University of Georgia, Athens, GA

Roberto Docampo M.D., Ph.D., Professor of Cellular Biology, Barbara and Sanford Orkin/Georgia Research Alliance Eminent Scholar in Tropical and Emerging Global Diseases, University of Georgia, Athens, GA

Alfred Merrill, Jr., Ph.D., Professor and Smithgall Chair in Molecular Cell Biology, Georgia Institute of Technology, Atlanta, GA.

Mark R. Prausnitz, Ph.D., Associate Professor, School of Chemical and Biomolecular Engineering, Georgia Institute of Technology, Atlanta, GA.

Harry Dailey, Ph.D., Professor of Microbiology and Director, Biomedical and Health Sciences Institute, University of Georgia, Athens, GA ([Liason with the BHSI](#)).

Michael Pierce, Ph.D., Professor, Biochemistry and Molecular Biology, Complex Carbohydrate Research Center, University of Georgia, Athens, GA ([Liason with the Cancer Center](#))

Concluding Statement on Establishment of the Center for Drug Discovery

Establishment of the Center for Drug Discovery is consistent with the strategic plan of the University of Georgia. Establishment of the CDD is also a stated goal in the strategic plan of the College of Pharmacy. As discussed previously, supporting references to establishment of the CDD are covered in a number of collegiate goals such as Goals 9, 9a, 9b, 9d, 13a, and very specifically, in 18, 18a. Establishment of the Center would provide further national and international recognition in state-of-the-art, interdisciplinary research in drug discovery, enhance interactions with pharmaceutical companies, increase research-based interactions and collaborations within the University of Georgia and among major research institutions in the state, contribute to the recruitment and retention of highly competent faculty, staff and students, facilitate the building of top quality graduate programs and contribute to providing excellence in teaching in the professional (Pharm.D.) and graduate (Ph.D.) programs at the University of Georgia. Finally, it is anticipated that the Center will serve as an “economic engine” for the State of Georgia in the area of pharmaceuticals and related biotechnology.

Appendix

Selected letters of support.

College of Pharmacy Strategic Plan



The University of Georgia

College of Pharmacy

2 November 2004

Dr. Arnett C. Mace, Jr.
Senior Vice president for Academic
Affairs and Provost
The University of Georgia
Administration Building

Dear Dr. Mace:

Enclosed please find a proposal on behalf of the College of Pharmacy to establish a Center for Drug Discovery that is being submitted for consideration by the University. I am very excited about the proposal and expect that it will become an important part of the University research profile when fully operational.

Drug discovery has been a longstanding research interest at the University of Georgia's College of Pharmacy. Moreover, it has become increasingly clear that the successful pursuit of modern drug discovery requires input from a large number of disciplines. To position Georgia as one of the leaders in the area of drug discovery, the College of Pharmacy realized the need to create an interdisciplinary and inter-university Center for Drug Discovery to serve as a hub that would bring together researchers throughout Georgia. As the initial step in the process, the College, with the help of the Georgia Research Alliance, established an Eminent Scholar position in the area of Drug Discovery—the William Henry Terry Sr. GRA Eminent Scholar in Drug Discovery. To help secure initial funding for the Center, a decision was made to set aside all College patent fund income in the area of drug discovery for this purpose which has as of today accumulated to well over \$300,000. The third step was to identify an outstanding scientist to lead the development of the Center. Vasu Nair was recruited to become the William Henry Terry Sr. GRA Eminent Scholar and he is uniquely qualified to direct the development and operation of the Center.

We expect that the Center when established will contribute positively to the University and to the State. The operational cost of the Center is expected to be funded mainly through continuous patent income, fundraising, industry support, granting agencies and contributions by the individual Center members.

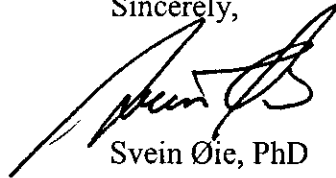
Dr. Nair has prepared a Drug Discovery Center proposal which received approval of the College of Pharmacy faculty at its regular Faculty meeting on May 10, 2004 in a formal vote of forty six (46) yeah and zero (0) nay in support of the proposal. The proposed center has support from the Vice President for Research as well as from a number of deans and directors on campus. The support letters are attached. Initial, limited space for the Center's administrative core will be

Dr. Arnett C. Mace, Jr.
2 November 2004
Page 2

provided by the College of Pharmacy. It is, however, expected that as the Center grows, additional space may have to be identified elsewhere on or off campus until the new Pharmacy Addition is funded and completed.

Please do not hesitate to contact me if you need additional information to complete the University's consideration of this proposal.

Sincerely,

A handwritten signature in black ink, appearing to read 'Svein Øie', written over a light blue horizontal line.

Svein Øie, PhD
Dean

Enc.



The University of Georgia

College of Agricultural and Environmental Sciences
Office of the Dean and Director

October 14, 2004

RECEIVED

Dr. Svein Øie, Ph.D.
Dean, College of Pharmacy
106 R.C. Wilson Pharmacy Building
CAMPUS

OCT 15 2004

University of Georgia
College of Pharmacy

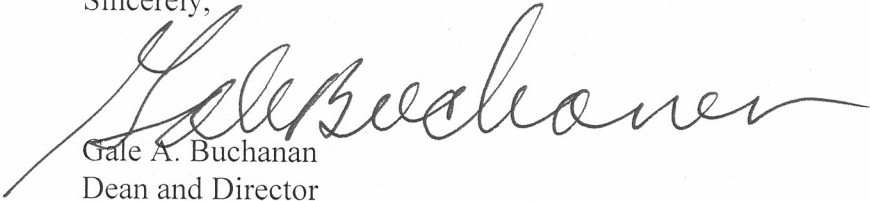
Dear Dr. Øie:

The College of Agricultural and Environmental Sciences has reviewed the College of Pharmacy proposal to establish a Center for Drug Discovery at UGA. We certainly see no conflicts with any of our programs, and believe there may be opportunities for collaboration in some instances, particularly in issues related to food safety and biotechnology.

I will certainly support the proposal in any way possible and suspect that the proposal will be approved by the University Council with little opposition.

Thank you for providing me the opportunity to review the proposal.

Sincerely,


Gale A. Buchanan
Dean and Director



The University of Georgia

The Center for Tropical and Emerging Global Diseases

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October 13, 2004

Svein Øie, Ph.D.
Dean, College of Pharmacy
106 Robert C. Wilson Pharmacy Building
The University of Georgia

OCT 14 2004

University of Georgia
College of Pharmacy

Dear Dr. Øie:

Thank you for providing me with the College of Pharmacy's proposal for the establishment of a Center for Drug Discovery at the University of Georgia. I was pleased to read through it, and to see the comprehensive plans you and Dr. Vasu Nair have generated on behalf of this important effort.

I fully believe that this initiative is overdue here at UGA, and that you have put together the critical ingredients for it to be established and successful. There are many investigators at UGA who will benefit by the coalition that you propose. I entirely agree that the Center for Drug Discovery will allow enhanced interactions of those involved, and this will, over time, yield substantial rewards for their research and UGA.

Having observed some of the activities of the Georgia Research Alliance, and knowing the goals of this unique institution, I am also struck by how closely aligned your proposal is with these goals. I believe this is an advantageous position that will provide strong emphasis on those enterprises that will be beneficial to the scientific and commercial interests of all involved.

I wish to make it very clear that I am in full support of the establishment of the Center for Drug Discovery at UGA. I look forward to the participation of several of the members of the Center for Tropical and Emerging Global Diseases in the activities of the Center for Drug Discovery, including our new Orkin/GRA Eminent Scholar, Dr. Roberto Docampo. Dr. Nair and I have discussed the synergies that we expect will flourish between our Centers, and I am excited by these plans.

I wish you the best in the approvals process and in the establishment of this Center.

Sincerely yours,

Daniel G. Colley, Ph.D.
Director, Center for Tropical and Emerging Global Diseases
Professor of Microbiology
The University of Georgia



The University of Georgia

Biomedical and Health Sciences Institute

220 Veterinary Medicine Bldg
Athens, GA 30602-7394
Telephone: (706) 542-5922
Fax: (706) 542-5285

Harry A. Dailey, Ph.D.
Professor and Director
Email: hdailey@uga.edu

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OCT 19 2004

October 18, 2004

University of Georgia
College of Pharmacy

Svein Øie, Ph.D.
Dean
College of Pharmacy
University of Georgia

Dear Svein,

Thank you for sharing with me the proposal to create a Center for Drug Discovery. I found the document describing the CDD to be very complete and informative. Since I have had several conversations with Vasu Nair and also you about your goals for the CDD, I feel well acquainted with what you hope to accomplish with this center.

As both the Director of the Biomedical and Health Sciences Institute and as an academic researcher with interests in the area of drug metabolism and discovery I strongly support the creation of a Center for Drug Discovery. I believe that the CDD can become a focus for research in this area and should help UGA to attain national status in the field of drug discovery.

I wish you well and look forward to strong collaborative interactions involving the CDD and the BHSI.

Sincerely,

Harry A. Dailey
Director, Biomedical and Health Sciences Institute



The University of Georgia

Complex Carbohydrate Research Center

Alan Darvill, Regents Professor and Director

adarvill@ccrc.uga.edu

706.542.4411

October 19, 2004

RECEIVED

OCT 20 2004

Svein Øie, Dean
College of Pharmacy
Pharmacy Building
Campus

University of Georgia
College of Pharmacy

Dear Svein:

Thank you for sending me a copy of the College of Pharmacy proposal to establish a Center for Drug Discovery. You and Professor Vasu Nair deserve great credit for proposing this Center that, undoubtedly, will add to the research credentials of the University. Please be assured that I support your initiative to establish the Center for Drug Discovery.

Sincerely yours,

Alan Darvill
Regents Professor and Director



The University of Georgia

Graduate School
Maureen Grasso, Dean

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October 5, 2004

OCT 08 2004

University of Georgia
College of Pharmacy

Dr. Svein Øie
Office of the Dean
College of Pharmacy
The University of Georgia
CAMPUS

Dear Dean Øie:

I fully support the establishment of a Center for Drug Discovery. It is clear from the proposal that the development of a world-class center to promote interdisciplinary scientific research and discoveries of this nature is an important strategic move for the University of Georgia. The Center not only will provide excellent research opportunities for graduate students, but also excellent opportunities for faculty to seek external funding. Finally, a Center for Drug Discovery will be a strong recruitment tool to attract the best faculty and prospective graduate students.

Sincerely,

Maureen Grasso

MG/rb



The University of Georgia

Sharon Y. Nickols
Dean

College of Family & Consumer Sciences
Office of the Dean

Dawson Hall
Athens, Georgia 30602-2622
Telephone (706) 542-4879
Fax (706) 542-4862

October 19, 2004

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Dr. Arnett C. Mace, Jr.
Senior Vice President
for Academic Affairs and Provost
Administration Building
University of Georgia

OCT 19 2004

University of Georgia
College of Pharmacy

Dear Dr. Mace:

On behalf of the College of Family and Consumer Sciences, I am writing to support the proposal to establish a Center for Drug Discovery in the College of Pharmacy. The proposal clearly presents justification for the Center, statements of mission and goals, and an outline for operational policies and procedures. It is impressive that financial resources have been designated to initiate the work without placing further strain on current scarce resources.

Faculty in the College of Family and Consumer Sciences have a history of collaborating with faculty in the College of Pharmacy. I can envision future collaboration as the opportunity arises, in particular, as related to nutraceutical products and testing the efficacy of drugs for dietary-related conditions, as well as diet-drug interaction.

The proposal presented by the College of Pharmacy presents a "compelling need" to seize the opportunity to establish the Center. It fits well into the College and University strategic plans. The careful planning and development of this proposal in consultation with the Medical College of Georgia, Emory University, Georgia State University, and various departments and centers at UGA, provides a sound basis for collaboration.

On behalf of the College of Family and Consumer Sciences, I offer our support for the establishment of the Center for Drug Discovery.

Sincerely,

Sharon Y. Nickols
Dean



The University of Georgia

RECEIVED

Gordhan L. Patel
Vice President and
Associate Provost

Office of the Vice President
for Research

OCT 20 2004

October 20, 2004

University of Georgia
College of Pharmacy

Dr. Svein Øie
Dean, College of Pharmacy
Office of the Dean
103 Pharmacy
CAMPUS

Dr. Vasu Nair
Eminent Scholar in Drug Discovery
College of Pharmacy
351 Pharmacy
CAMPUS

Dear Svein and Vasu:

Thank you for sharing with me your proposal for the Center for Drug Discovery. I believe this is a timely initiative, given the breadth and deep expertise of faculty members who have been long standing members, as well as those who have been recruited in recent years. This initiative also compliments the Biomedical and Health Sciences Institute that we have established.

Your proposal has my strong endorsement.

Best wishes,

Gordhan L. Patel
Vice President for Research
& Associate Provost

GLP/gm



The University of Georgia

Office of the Dean

College of Veterinary Medicine

Athens, Georgia 30602-7371
(706) 542-3461
Fax (706) 542-8254

October 19, 2004

RECEIVED

OCT 19 2004

Dr. Svein Øie, Dean
College of Pharmacy
103 Wilson Pharmacy Building
CAMPUS

University of Georgia
College of Pharmacy

Dear Dean Øie:

I have reviewed your proposal to establish a Center For Drug Discovery at UGA. On behalf of the College of Veterinary Medicine, I endorse the proposal. Opportunities for collaboration with or participation of our faculty appear to be numerous. Specifically, faculty in our Departments of Physiology and Pharmacology and Infectious Diseases will be interested. Furthermore, we have a growing number of faculty in several departments working in comparative oncology, and opportunities for trials in naturally occurring cancer are numerous.

Please keep me informed on your progress, and if you need more specific information, please let me know.

Sincerely,

Keith W. Prasse, DVM, PhD
Dean

KWP/tce

X-Auth-No:

To: soie@rx.uga.edu

From: Michael Pierce <hawkeye@uga.edu>

Subject: endorsement for Center for Drug Discovery

Date: Thu, 21 Oct 2004 15:11:43 -0400

X-Mailer: Apple Mail (2.619)

X-UgaRx-MailScanner: Found to be clean

X-UgaRx-MailScanner-SpamCheck: not spam, SpamAssassin (score=-3.5,
required 5, BAYES_10 -4.70, HTML_10_20 1.21,
USER_AGENT_APPLEMAIL 0.00)

Dear Dean Oie,

I am writing to enthusiastically endorse the establishment of the Center for Drug Discovery in the College of Pharmacy under the leadership of Dr. Vasu Nair. I have read the documents you forwarded to me, and I am impressed about the presence of this Center at the University of Georgia. This is truly an area in which UGA can build on past success to develop a cutting-edge research Center that will interact with many faculty and departments on campus. Please let me know if I can assist you in any way.

Sincerely,

Michael Pierce

Dr. Michael "Haw keye" Pierce
Director, University of Georgia Cancer Center
Complex Carbohydrate Research Center
& Department of Biochemistry and Molecular Biology
University of Georgia
315 Riverbend Road
Athens, Georgia 30605
Voice:706.542.1702; FAX:706.542.1759; Cell:706.338.5071



The University of Georgia

Graduate School
Maureen Grasso, Dean

RECEIVED

October 5, 2004

OCT 08 2004

University of Georgia
College of Pharmacy

Dr. Svein Øie
Office of the Dean
College of Pharmacy
The University of Georgia
CAMPUS

Dear Dean Øie:

I fully support the establishment of a Center for Drug Discovery. It is clear from the proposal that the development of a world-class center to promote interdisciplinary scientific research and discoveries of this nature is an important strategic move for the University of Georgia. The Center not only will provide excellent research opportunities for graduate students, but also excellent opportunities for faculty to seek external funding. Finally, a Center for Drug Discovery will be a strong recruitment tool to attract the best faculty and prospective graduate students.

Sincerely,

Maureen Grasso

MG/rb