



UNIVERSITY OF MARYLAND

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CHANCELLOR'S OFFICE

MEMORANDUM

**TO:** William E. Kirwan, Ph.D.  
Chancellor

**FROM:** David J. Ramsay, D.M., D.Phil.  
President, University of Maryland, Baltimore

**DATE:** April 12, 2007

**RE:** Third Quarter Report on Exemptions Granted Pursuant  
To the Public-Private Partnership Act

A handwritten signature in black ink, appearing to be "D. Ramsay", written over the "FROM:" line of the memorandum.

There were two (2) exemptions granted to UMB personnel between January 1, 2007 and March 31, 2007, pursuant to the Public-Private Partnership Act.

Supporting documentations are enclosed.

EMPLOYEE	INTEREST	ENTITY	DATE OF EXEMPTION
Michael Kleinberg, M.D., Ph.D.	Paid Speaker	Pfizer, Inc.	3/13/2007
Jun Hayashi, Ph.D.	Equity, Employee/Manager, Spouse Equity, Spouse Employee/Manager	A&G Pharmaceutical, Inc.	3/15/2007

If any further information is required, please do not hesitate to contact Mr. Joe Giffels in the Office of the Vice President of Academic Affairs at (410) 706-1853.

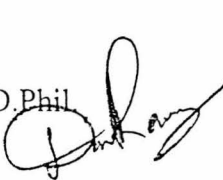
**PC:** Mr. Joe Giffels  
Dr. Malinda Orlin  
State Ethics Commission



## UNIVERSITY OF MARYLAND

### MEMORANDUM

**TO:** Michael Kleinberg, M.D., Ph.D.  
Associate Professor  
Division of Infectious Diseases  
Department of Medicine  
School of Medicine

**FROM:** David J. Ramsay, D.M., D.Phil.  
President 

**RE:** Conflict of Interest Disclosure #02-07-002  
Pfizer Pharmaceuticals, Inc.

**DATE:** March 13, 2007

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated February 26, 2007, involving paid speaking engagements sponsored by, and a research agreement with, Pfizer Pharmaceuticals, Inc., Inc. as described in your exemption request. Your association with Pfizer Pharmaceuticals, Inc. will facilitate research and development. I have determined that your relationship with Pfizer Pharmaceuticals, Inc. would not be a harmful interest, as described in the USM Board of Regents' Policy on Conflicts of Interest in Research and Development. This exemption permits your association with Pfizer Pharmaceuticals, Inc. as described in your exemption request. In the absence of this exemption, your association with Pfizer Pharmaceuticals, Inc. would conflict with Maryland law, including, but not limited to, Sections 15-504 and 15-507 of the Maryland Public Ethics Law and University policy.

The conditions of this exemption follow:

- Your business and financial relationship with Pfizer Pharmaceuticals, Inc. must be disclosed by you to anyone (including, but not limited to, collaborating faculty, staff, trainees and subjects) participating in your Pfizer Pharmaceuticals, Inc. funded research or related research. Your relationship with Pfizer Pharmaceuticals, Inc. must also be disclosed when you publish or speak on the Research. While this latter requirement is already standard with most professional journals and scientific meetings, in the interest of mitigating your conflicts, it must also be applied to presentations made on campus.

- Information about your research plans and outcomes must not be disclosed to Pfizer Pharmaceuticals, Inc. prior to the time that such information is made available to the scientific community as a result of publication, except as specified in any research, licensing, material transfer or other agreements between the University and Pfizer Pharmaceuticals, Inc. or except as necessary to the development of collaborative research proposals involving the University and Pfizer Pharmaceuticals, Inc..
- All of the research you propose, all of the findings that result from or affect your Pfizer Pharmaceuticals, Inc. activities, and the conflict of interest issues surrounding your Pfizer Pharmaceuticals, Inc. relationship must be disclosed to and discussed with your Department Chair on a regular basis to ensure the integrity of the science proposed and the publications prepared. Your discussions should be documented by you in writing and include an implementation plan for any changes suggested by your Department Chair. Copies of this documentation must be promptly submitted to the School of Medicine Dean's Office and the UMB Conflict of Interest Officer. These requirements are intended to diminish any perception that your research plans, results or publications may be biased as a result of your relationship with Pfizer Pharmaceuticals, Inc..
- If graduate students or postdoctoral fellows join your laboratory to conduct research sponsored by Pfizer Pharmaceuticals, Inc. under your direction and mentorship, it will be necessary for a faculty member uninvolved with your academic division or research to monitor the student's academic progress and research work and publications to assure that your financial interests in Pfizer Pharmaceuticals, Inc. do not adversely affect the student's academic needs. Your Department Chair will be responsible for identifying the faculty monitor and assuring that this provision is met.
- It is assumed that your Pfizer Pharmaceuticals, Inc.-sponsored research activities are related to your speaking activities only as described in the disclosure documentation you provided, and that mechanisms for ensuring the integrity of the research (including its design and conduct, and the collection, analysis and reporting of data) are in place. Further, it is assumed that any other University research activities undertaken by you are unrelated to your speaking activities for Pfizer Pharmaceuticals, Inc.. You must inform the Conflict of Interest Officer and your Department Chair immediately if these assumptions are incorrect or the facts change. Your consulting activities for Pfizer Pharmaceuticals, Inc. shall not involve the use of University funds or facilities, or personnel other than yourself, as described.
- All research personnel and activities in your laboratory must be supported according to their level of effort and use, respectively, on various projects, supported by the standard departmental review and approval of related documentation (such as University Grant Routing Forms and Time and Effort

Reports). Pfizer Pharmaceuticals, Inc. must pay full compensation for the time of personnel and for other research costs, and must pay full facilities and administrative costs unless waivers or reductions have been approved in accordance with University policy.

- You file timely annual reports with the Conflict of Interest Officer.

Note that this exemption may be voided by me in the event of your failure to satisfy all of the foregoing conditions. Procedural questions regarding this exemption should be directed to the UM Conflict of Interest Officer, Mr. Joe Giffels (x6-1853), or to my office.

This exemption permits your association with Pfizer Pharmaceuticals, Inc. in a manner that comports with the requirements of the Maryland Public Ethics Law and University policy, provided that the conditions of the exemption are observed. Any significant change in your planned relationship with Pfizer Pharmaceuticals, Inc., as disclosed in your exemption request, must be promptly disclosed to the University (through your Department Chair and Dean), so that the effect of the change in circumstances may be determined. I recommend you disclose and discuss proposed changes prospectively to avoid potential withdrawal of this exemption.

PC:       Dr. F. Calia  
          Mr. J. Giffels  
          Mr. J. Hughes  
          Dr. M. Orlin  
          Dean A. Reece

FILE COPY

EXEMPTION REQUEST FORM  
DISCLOSING CONFLICT OF INTEREST  
RELATED TO RESEARCH OR DEVELOPMENT

PART TWO:

DISCLOSURE AND EXEMPTION REQUEST

Please provide all information in boldface type.

Section One. Directory Information. Supply the requested information about yourself, as the employee requesting the exemption, and about the entity with which your relationship is proposed:

A. About You

Name: Michael Kleinberg

University Title: Associate Professor of Medicine

Division/Department or Administrative Unit: Infectious Diseases/Medicine

FTE: Full-time Annual Salary: \$131,742

University Business Address: 22 S. Greene St. Rm. N9E05

Phone Number: 410-328-2679

Facsimile: 410-328-6896

E-mail Address: mkleinbe@umaryland.edu

B. About Your Immediate Supervisor

Name: Dr. Robert Redfield

University Title: Head, Division of Infectious Diseases, Professor

University Business Address: Rm. N545 UMBI

Phone Number: 6-4613

Facsimile: 6-4619

E-mail Address: redfield@umbi.umd.edu

C. About the Entity

Name: Pfizer

Form of Organization: corporation  
(e.g., LLC, corporation, partnership)

State in which it is organized: New York

General nature of its business activities: \_\_\_\_\_  
pharmaceuticals

Any other names under which it does business, and the names of any wholly owned subsidiaries, or corporate parents (companies which own the entity) which conduct business similar to the entity's business, or which also have relationships with UM or you. None known to me

A Contact Person: Give the name and title of an officer or other person at the entity or its parent who is informed about the proposed relationship:

None

Give the person's business address: \_\_\_\_\_  
\_\_\_\_\_

Telephone Number: \_\_\_\_\_

Facsimile Number: \_\_\_\_\_

E-Mail Address: \_\_\_\_\_

D. Additional Information

Is the entity an ongoing business concern? X yes \_\_\_no

If the entity is to be established, (a) when do you think it will be created? \_\_\_\_\_ (give month and year)  
(b) What state will it be organized in? \_\_\_\_\_

**Section Two.** Your Conflict of Interest Concerns. Supply information about the potential or actual conflict of interest and your proposal to mitigate it.

A. Description of Conflict of Interest. Describe in your own words the potential or actual conflict of interest which you or others have identified which led you to file this exemption request. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

The potential conflict of interest arises where I give educational lectures at outside hospitals where I receive a speaker's fee directly from Pfizer, the sponsor of the lectures. This situation arises frequently where divisional and even department seminars choose not to file for CME activity even though the seminars are purely educational and not promotional. Pfizer markets several anti-infectives including one that is used extensively in infected cancer patients.

Pfizer is also a sponsor of research I am conducting on fungal infections in cancer patients.

B. Steps to Mitigate Conflict. Describe in your own words what steps you think UM could take to ensure that the integrity of your UM work is not compromised by your relationship with the entity. Be thorough. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

Requests for my lecturing are driven by the requesting educational institution. Requestors are unaware, and have no stake, in the outcomes of the proposed research. I have never participated in any industry-funded lecture or talk that I considered to be promotional and not educational. I continue to take that position independent of this CoI review.

The research activity is an outcome study using retrospectively collected data from Greenebaum Cancer Center patients admitted to the

inpatient unit over the last four years. The purpose of the study is report outcomes of cancer patients with fungal infections. A Pfizer drug is one of the workhorse agents we use to treat fungal infections. The proposed study, however, will not be limited to the Pfizer drug but will capture outcomes and experiences with all anti-fungal agents used in the study period. Analysis methods to judge outcomes are independent of treatment. Our retrospective study is not a comparative study and therefore no comparative conclusions will be made favoring any drug, even the Pfizer agent. We as investigators are acutely aware of bias. Our data collection and analysis plans are all designed and set in advance before we are aware of outcomes. This and the robustness of the database itself are important and powerful built-in guards against injection of the type of bias that would raise CoI concerns.

Publications arising from this study will all be multi-authored. That and journal review are the mechanism that will detect and prevent unintended reporting bias.

Have you discussed these suggestions with the entity (y/n)?  N

Is the entity prepared to pay the costs associated with implementing these suggestions (y/n)?  Robust scientific methodology is built into the direct costs for the trial funded by the grant from Pfizer

**Section Three.** Research and Development Activities. Explain how, in your view, the exemption will advance the research and development goals of the Public-Private Partnership Act. What are the research and development activities of the entity? In providing this information, remember that the UM Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development define "research" and "development" as basic or applied research or development, including (A) the development or marketing of university-owned technology or intellectual property; (B) the acquisition of services of an official or employee by an entity for research and development purposes; or (c) participation in State economic development programs. Research does not have to be sponsored research in order for relationships with entities to be eligible for Public-Private Partnership Act exemptions.

N/A

As a recognized expert in infections in cancer patients, I am in demand as a requested speaker for these educational seminars.

This exemption would allow my expertise to be shared through lectures. At the same time, research at UMB in the field of fungal infections in cancer patients would be funded by Pfizer.

Section Four. Details of Relationship. Provide information about the entity's relationship, present and/or proposed, with UM, and the entity's present or proposed interest in your work at UM.

A. Sponsored Research Agreements. Describe any present or proposed sponsored research agreements with the entity, as sponsor or as subcontractor to UM, involving you or your laboratory or academic group. Give the approximate budget, the Principal Investigator, the title of the project, and the name of the UM grants and contracts administrator most familiar with the project.

Research agreement concerns a clinical research project.

Direct budget \$157,800 (direct \$125,238)

Title: Fungal Infections in Neutropenic Patients: Responses of Voriconazole Assessed by Serial CT Scanning; PI Michael Kleinberg, MD

UM Grants Administrator - Dawn Wilkins <dwilk001@umaryland.edu>

B. Options or License Agreements. Describe any present or proposed options or license agreements known to you between UM and the entity if such agreements relate to inventions or other intellectual property developed by you or in your laboratory or academic group, giving the title of the subject intellectual property.

None anticipated

C. Entity Interest in Outcome. If, to your knowledge, the entity is interested in the outcome of your research or academic work, but is not a sponsor of your work, explain why the entity has such interest, in your opinion.

N/A -- Entity is a sponsor.

D. Gifts or Grants. If the entity has made gifts or grants to UM or the University of Maryland Foundation (UM Fund) in support of your work at UM, give information about the dates and amounts of the gifts or grants, including whether or not the funds were used for any purpose related to your proposed relationship with the entity.

None.

Section Five. Ownership Information. If you are requesting an exemption permitting you to have an ownership interest in an entity, provide the requested information, and attach a copy of any written proposal or offer covering the ownership interest.

A. What "units" you will or may own. (E.g., stock, warrants, limited partnership interest, LLC interest.)

None.

B. Ownership.

Individual \_\_\_\_\_ Joint \_\_\_\_\_

If joint, name of co-owner: \_\_\_\_\_

C. Value of your Ownership Interest. Current estimated dollar value \_\_\_\_\_. Percent of total ownership \_\_\_\_\_.

D. Conditions of Ownership. Describe any conditions or encumbrances affecting your ownership interest. (E.g., will you be prohibited from exercising options or selling stock for a certain period of time, or until certain events occur?)

E. Will you purchase the ownership interest? (Y/N) \_\_\_\_ If so, what will you pay for it? \_\_\_\_\_ How does that price compare with the market value, if there is a market value?

F. If you are not purchasing the ownership interest, what is the consideration for the ownership interest?

G. From what person or organization will you acquire your ownership interest?

**Section Six.** Your Employment Relationship. If you are requesting an exemption for an employment relationship (including both traditional compensated employment and other relationships e.g., consulting, office or executive responsibility in the entity's operations, board membership, royalties, etc.), attach a copy of any written proposal or offer covering the employment relationship and provide the requested information:

A. What position will you hold? What duties will you have on behalf of the entity? Be as specific as possible. In particular, if you will be conducting any research or scientific work for the entity, address what you will be doing, where you will do it, and the relationship, if any, to your work at UM.

Title: Lecturer

Responsibilities: Provide lectures on anti-infectives in cancer patients at the invitation of health/educational institutions.

B. How much time per biweekly period \_\_\_\_\_, month \_\_\_\_\_, year \_\_\_\_\_  
X will you be providing to the entity? 6 days

C. What compensation, if any, do you expect from the entity?

< \$10,000/year

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) Y If no, please

explain.

My participated in these seminars is not on University time. I will take annual leave.

E. Are you requesting a leave of absence or change in level of FTE at UM in order to make your time available to the entity? (Y/N) N  
If available, attach a copy of the request you have made and the approval.

F. If you are an externally funded investigator, what percentage of your FTE is budgeted to grants and contracts at this time?

20%

**Section Seven. Gifts.** Describe any gifts for which you are requesting an exemption because of your relationship with the donating entity, or that entity's interest in your work.

If you are seeking permission to accept a gift or honorarium from an entity which has a relationship with you, or an interest in your work, provide the nature and value of the gift. You need to give this information whether you are considering a gift directly to you which you plan to retain, a gift you plan to give to another person or entity (e.g., assigning the gift to the UM Fund), or a gift arranged through you but directed to the UM Fund or other UM affiliates which can hold and administer funds for the benefit of your work.

Give the nature and value of the gift (cash, stock, etc.,; market value or face value), and attach a copy of any written offer.

None.

**Section Eight.**

A. **Other Relationships with the Entity.** Provide information about any other relationship with the entity which has not been discussed above, but which may require an exemption to be lawful. Include here matters such as employment of a spouse or dependent child by the entity, ownership of an interest in the entity by a spouse, dependent child, or other dependent, or relationships between the entity and other organizations with which you or your spouse or dependent child have ownership or employment relationships. In describing ownership

interests, give details, including percentage interest and value. In describing employment, give levels of effort and salary.

**No other relationships.**

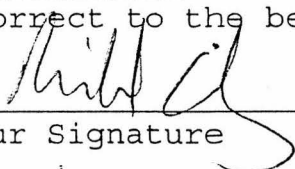
B. Relationship with other organizations. Describe any employment, ownership, or business relationship held by you or a spouse or dependent child in any business which could be affected (positively or negatively) by your relationship, or the results of your work, for the entity discussed in this exemption request.

None

**Section Nine. Signature and Approvals.**

Before routing this form, execute it here. Please remind other reviewers to consider this form thoughtfully, complete their sections below, and execute the form if they are forwarding your request with a positive recommendation. Omit any steps of review which are not applicable to you. Be sure the last reviewer forwards the exemption request to the Conflict of Interest Officer.

A. I hereby make oath or affirm that the contents of this Exemption Request are true and correct to the best of my knowledge, information and belief.

  
\_\_\_\_\_  
Your Signature

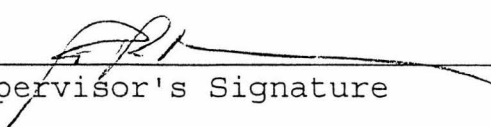
2/5/07  
\_\_\_\_\_  
Date

**B. Supervisor's Statement**

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: N/A

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Feb 5 2007  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Supervisor's Signature

**C. Statement of Division Head or Director**

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: N/A

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Feb 5 2007  
Date

[Signature]  
Signature of Division Head or Director

D. Statement of Chairperson or Assistant/Associate Vice President

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here:

Financial support by Pfizer must be disclosed at every lecture they sponsor

\_\_\_\_\_  
Date

[Signature]  
Signature of Chairperson or Assistant/  
Associate Vice President

E. Statement of Vice Dean for Research and Academic Affairs

I have reviewed this exemption request. I am aware of the nature of the conflict and the proposed measures to mitigate it. I am forwarding it to the Conflict of Interest Advisory Committee for its review, comments and suggestions.

2/26/07  
Date

[Signature]  
Signature of Vice Dean

F. Statement of Dean

I have reviewed this exemption request. I am aware of the nature of the conflict and the proposed measures to mitigate it. I am forwarding it to the Conflict of Interest Advisory Committee for its review, comments and suggestions.

\_\_\_\_\_  
Date

[Signature]  
Signature of Dean


FORWARD THIS FORM VIA CAMPUS MAIL TO J. JOSEPH GIFFELS, UMB CONFLICT OF INTEREST OFFICER, ACADEMIC AFFAIRS, FOURTH FLOOR, PACA-PRATT BUILDING.



## UNIVERSITY OF MARYLAND

### MEMORANDUM

**TO:** Jun Hayashi, Ph.D.  
Associate Professor  
Department of Pharmaceutical Sciences  
School of Pharmacy

**FROM:** David J. Ramsay, D.M., D.Phil.  
President 

**RE:** Conflict of Interest Disclosure #01-07-001

**DATE:** March 15, 2007

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated January 16, 2007. That request involves your relationships with A&G Pharmaceutical, Inc. As part of the strategy for mitigating the conflicts of interest arising from your financial relationship with A&G Pharmaceutical, Inc. and your University research activities, you propose taking an unpaid leave of absence for the period January 16, 2007 through January 15, 2008. As you know, that request has also been approved. Your association with A&G Pharmaceutical, Inc. will facilitate research and development. I have determined that your relationship with A&G Pharmaceutical, Inc. would not be a harmful interest, as described in the USM Board of Regents' Policy on Conflicts of Interest in Research and Development. This exemption permits your association with A&G Pharmaceutical, Inc. as described in your exemption request. In the absence of this exemption, your association with A&G Pharmaceutical, Inc. would conflict with Maryland law, including, but not limited to, Sections 15-504 and 15-507 of the Maryland Public Ethics Law and University policy.

The conditions of this exemption follow:

- It is presumed that you will be returning to your faculty position in the School of Pharmacy on January 16, 2008, as indicated in your leave of absence approval memorandum. You will be required to seek and receive an exemption request to continue any relationships with A&G Pharmaceutical, Inc. when you return to the University.

- Your relationships with A&G Pharmaceutical, Inc. must be disclosed when you publish or speak on any research conducted in your capacity as a University faculty member.
- Information about future University research plans and the outcomes of research already conducted must not be disclosed to A&G Pharmaceutical, Inc. prior to the time that such information is made available to the scientific community as a result of publication, except as specified in any research, licensing, material transfer or other agreements between the University and A&G Pharmaceutical, Inc. or except as necessary to the development of collaborative research proposals involving the University and A&G Pharmaceutical, Inc..
- All of the research you propose to conduct at the University following your return in January, 2008, all of the findings that result from or affect research conducted in your capacity as a UMB faculty member, and the conflict of interest issues surrounding your A&G Pharmaceutical, Inc. relationship must be disclosed to and discussed with your Department Chair on a regular basis to ensure the integrity of the science proposed and the publications prepared. Your discussions must be documented by you in writing. You must document and implement any changes suggested by your Department Chair. Copies of this documentation must be promptly submitted to the School of Pharmacy Dean's Office and the UMB Conflict of Interest Officer. These requirements are intended to diminish any perception that your research plans, results or publications may be biased as a result of your relationship with A&G Pharmaceutical, Inc..
- Your service as an employee of, and Vice President for Research and Development for, A&G Pharmaceutical, Inc. is approved, as described in your exemption request. As an A&G Pharmaceutical, Inc. employee and officer, you must recuse yourself from all discussions of and votes on decisions involving the University. You also must recuse yourself from consideration of business issues involving licensing of University of Maryland technologies.
- It is understood that your existing University research activities and your existing graduate student advising activities have been reassigned to other School of Pharmacy faculty as described in your exemption request.
- You have stated, and it is understood that the estimated current value of A&G Pharmaceutical, Inc. stock owned by you and/or your spouse is \$3.18 million and represents approximately 53% of the total equity in A&G Pharmaceutical, Inc.. As a condition of this exemption, you and your spouse must hold the stock until the earliest of the following trigger events:
  - upon arms-length acquisition of all the stock or assets of A&G Pharmaceutical, Inc. in return for cash; or
  - two years from the first commercial sale of a product embodying any of the licensed inventions developed, in whole or in part, in your University research laboratory; or

- upon approval by the President of a written request for permission to sell the stock.

These precautions are intended to mitigate criticism that inappropriate financial motivation may cause bias in your research.

Note that this exemption may be voided by me in the event of your failure to satisfy all of the foregoing conditions. Procedural questions regarding this exemption should be directed to the University Conflict of Interest Officer, Mr. Joe Giffels (x6-1853), or to my office.

This exemption permits your association with A&G Pharmaceutical, Inc. in a manner that comports with the requirements of the Maryland Public Ethics Law and University policy, provided that the conditions of the exemption are observed. Any significant change in your planned relationship with A&G Pharmaceutical, Inc., as disclosed in your exemption request, must be promptly disclosed to the University (through your Department Chair and Dean), so that the effect of the change in circumstances may be determined. You must disclose and discuss proposed changes prospectively to avoid potential withdrawal of this exemption.

Finally, I would like to thank you for your patience and continued cooperation throughout this process.

PC: Dr. Natalie Eddington  
Mr. J. Giffels  
Mr. J. Hughes  
Dean David A. Knapp  
Dr. M. Orlin

12/8/06

EXEMPTION REQUEST FORM  
DISCLOSING CONFLICT OF INTEREST

COPY

RELATED TO RESEARCH OR DEVELOPMENT

**PART TWO:**

**DISCLOSURE AND EXEMPTION REQUEST**

**Print or type all information.**

**Section One.** Directory Information. Supply the requested information about yourself, as the employee requesting the exemption, and about the entity with which your relationship is proposed:

A. About You

Name: Jun Hayashi

University Title: Associate Professor

Division/Department or Administrative Unit: \_\_\_\_\_

Dept. Pharmaceutical Sciences

FTE: 1.0 Annual Salary: \$90,801

University Business Address: 20 N. Pine St

Phone Number: 6-8295

Facsimile: \_\_\_\_\_

E-mail Address: jhayashi@rx.umaryland.edu

B. About Your Immediate Supervisor

Name: Dr. Natalie Eddington

University Title: Chair of PSC Dept.

University Business Address: Same as above

Phone Number: 6-6710

Facsimile: 6-7388

E-mail Address: neddingt@rx.umaryland.edu

C. About the Entity

Name: A&G Pharmaceutical Inc

Form of Organization: Corporation

(e.g., LLC, corporation, partnership)

State in which it is organized: DE

General nature of its business activities: Cancer diagnosis and therapy, monoclonal antibody development service

Any other names under which it does business, and the names of any wholly owned subsidiaries, or corporate parents (companies which own the entity) which conduct business similar to the entity's business, or which also have relationships with UM or you. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

A Contact Person: Give the name and title of an officer or other person at the entity or its parent who is informed about the proposed relationship:

Dr. Ginette Serrero, CEO

Give the person's business address: \_\_\_\_\_

9130 Red Branch Rd. Columbia, MD 21045

Telephone Number: 410-884-4100

Facsimile Number: \_\_\_\_\_

E-Mail Address: gserrero@agrx.net

D. Additional Information

Is the entity an ongoing business concern? XX yes no

If the entity is to be established, (a) when do you think it will be created?

\_\_\_\_\_ (give month and year)

(b) What state will it be organized in? \_\_\_\_\_

**Section Two.** Your Conflict of Interest Concerns. Supply information about the potential or actual conflict of interest and your proposal to mitigate it.

A. Description of Conflict of Interest. Describe in your own words the potential or actual conflict of interest which you or others have identified which led you to file this exemption request. Use

the space provided, or attach a statement. You may attach supporting documents as helpful.

**I am a co-founder, with my wife Dr Ginette Serrero, the CEO of A&G. I have served as A&G's Vice President for Research and Development. To date, my responsibilities have been minimal, including representing A&G at scientific conferences, attending formal business events as an A&G founder, and transporting research samples between UMB and A&G's laboratories for projects on which other faculty are working.**

**I would like to take a 12-month unpaid leave of absence from UMB to participate in A&G research and business activities. While I will not be conducting any research at UMB, I will still be associated with the University and will be completing research (primarily data analysis) under a TEDCO grant to UMB. My financial interests in A&G constitute a conflict of interest because of anticipated relationships between A&G and UMB. These relationships include a MIPS grant involving A&G and UMB, with Dr Paul Shapiro as UMB PI; a TEDCO grant, on which Dr Natalie Eddington will serve as the administrative PI for UMB; and a potential license agreement between A&G and UMB for intellectual property developed by me at UMB. Both the MIPS and the TEDCO grants are on a small molecule Lck inhibitor discovered at, and patented by, UMB. An STTR grant in collaboration with A&G is planned, with Drs Alex Mackerell, Andy Coop and Michael Shapiro as UMB investigators.**

B. Steps to Mitigate Conflict. Describe in your own words what steps you think UM could take to ensure that the integrity of your UM work is not compromised by your relationship with the entity. Be thorough. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

**By taking an unpaid leave of absence from UMB, I will not be conducting any research at UMB. There will, therefore, be no research activity at UMB which may be influenced by my financial interests in A&G. My research will be conducted at A&G. Any research collaboration between UMB and A&G will involve other UMB investigators (not me). Dr Paul Shapiro and/or Dr Natalie Eddington and/or Drs Andy Coop, Michael Shapiro, and Alex Mackerell will serve as UMB PI for the research collaborations between A&G and UMB.**

**Graduate students currently under my mentorship will be mentored by Dr Paul Shapiro. The graduate students' dissertation committees will be constituted in consultation with the Program Director and the UMB Graduate School to assure the academic integrity of the students' experience.**

Have you discussed these suggestions with the entity (y/n)?   Yes  \_\_\_\_\_

Is the entity prepared to pay the costs associated with implementing these suggestions (y/n)?

**No costs are anticipated**

**Section Three. Research and Development Activities.** Explain how, in your view, the exemption will advance the research and development goals of the Public-Private Partnership Act. What are the research and development activities of the entity? In providing this information, remember that the UM Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development define "research" and "development" as basic or applied research or development, including (A) the development or marketing of university-owned technology or intellectual property; (B) the acquisition of services of an official or employee by an entity for research and development purposes; or (c) participation in State economic development programs. Research does not have to be sponsored research in order for relationships with entities to be eligible for Public-Private Partnership Act exemptions.

**Allowing me to conduct research as an employee of A&G during my leave of absence from UMB would advance technologies of mutual interest to A&G and UMB, as evidenced by the research collaborations in the MIPS and TEDCO grants.**

**Section Four. Details of Relationship.** Provide information about the entity's relationship, present and/or proposed, with UM, and the entity's present or proposed interest in your work at UM.

A. **Sponsored Research Agreements.** Describe any present or proposed sponsored research agreements with the entity, as sponsor or as subcontractor to UM, involving you or your laboratory or academic group. Give the approximate budget, the Principal Investigator, the title of the project, and the name of the UM grants and contracts administrator most familiar with the project.

**MIPS: Involves research on a UM-owned technology -- a small molecule inhibitor of Lck kinase; Title – Novel Immunomodulators for Autoimmune Disease;” PI – Dr Paul Shapiro; \$77,778**

**TEDCO: Involves nearly-completed research on a UM-owned technology – a small molecule inhibitor of Lck kinase; Administrative PI – Dr Natalie Eddington; title -- “Novel Small Molecule Inhibitors for Rheumatoid Arthritis;” \$50,000**

**A&G-sponsored grant: A fellowship sponsored by A&G to support Tesfom Abrahale, a graduate student to be advised by Dr Paul Shapiro. The research this student is conducting is not related to my research; \$24,272**

**STTR: A partnership between A&G (Dr Randy Barton) and UMB co-investigators Drs Alex Mackerell, Andy Coop and Michael Shapiro. The research that is the subject of this STTR involves the structure and chemistry of the small molecule inhibitor, but I am not involved in the project at all.**

B. Options or License Agreements. Describe any present or proposed options or license agreements known to you between UM and the entity if such agreements relate to inventions or other intellectual property developed by you or in your laboratory or academic group, giving the title of the subject intellectual property.

**UMB and A&G are currently negotiating a license for small molecular weight modulators for cellular phosphorylation.**

C. Entity Interest in Outcome. If, to your knowledge, the entity is interested in the outcome of your research or academic work, but is not a sponsor of your work, explain why the entity has such interest, in your opinion.

**N/A – I will be conducting no research at UMB during the 12-month leave of absence**

D. Gifts or Grants. If the entity has made gifts or grants to UM or the University of Maryland Foundation (UM Fund) in support of your work at UM, give information about the dates and amounts of the gifts or grants, including whether or not the funds were used for any purpose related to your proposed relationship with the entity.

**A&G has provided no gifts and no grants to support my research, but A&G is supporting research projects directed by Drs Katherine Tkaczuk and Olga Ioffe, via a MIPS grant. I have not been involved in the research work of those grants.**

**Section Five.** Ownership Information. If you are requesting an exemption permitting you to have an ownership interest in an entity, provide the requested information, and attach a copy of any written proposal or offer covering the ownership interest.

**I am not requesting ownership interest. I am a co-founder. I already have an ownership.**

A. What "units" you will or may own. (E.g., stock, warrants, limited partnership interest, LLC interest.)

B. Ownership.

Individual \_\_\_\_\_ Joint See Section Eight

If joint, name of co-owner: \_\_\_\_\_

C. Value of your Ownership Interest. Current estimated dollar value \$1.32 million \_\_\_\_\_.

Percent of total ownership 22 \_\_\_\_\_.

D. Conditions of Ownership. Describe any conditions or encumbrances affecting your ownership interest. (E.g., will you be prohibited from exercising options or selling stock for a certain period of time, or until certain events occur?)

E. Will you purchase the ownership interest? (Y/N) No If so, what will you pay for it? \_\_\_\_\_ How does that price compare with the market value, if there is a market value?

F. If you are not purchasing the ownership interest, what is the consideration for the ownership interest? **As founder; I already own this interest.**

G. From what person or organization will you acquire your ownership interest?

**Section Six.** Your Employment Relationship. If you are requesting an exemption for an employment relationship (including both traditional compensated employment and other relationships e.g., consulting, office or executive responsibility in the entity's operations, board membership, royalties, etc.), attach a copy of any written proposal or offer covering the employment relationship and provide the requested information:

N/A

A. What position will you hold? What duties will you have on behalf of the entity? Be as specific as possible. In particular, if you will be conducting any research or scientific work for the entity, address what you will be doing, where you will do it, and the relationship, if any, to your work at UM.

Title: Vice President for Research and Development

Responsibilities: Minimal, to date. See explanation in Section Two A

**During my leave of absence from the university, I will supervise the monoclonal antibody division of A&G Pharmaceutical inc. I will also participate in the technology transfer once the licensing agreement is put in place between UMB and A&G regarding the screening of small molecule Lck inhibitors in vitro and assist the in vivo studies if needed.**

B. How much time per biweekly period \_\_\_\_\_, month \_\_\_\_\_, year \_\_\_\_\_ will you be providing to the entity? 12 months, full time

C. What compensation, if any, do you expect from the entity?

**A full time salary approximately equivalent to my current UMB salary (approximately \$100,000). The exact amount has not yet been determined, pending approval by A&G's Board, which is contingent upon the granting of this exemption.**

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) No If no, please explain. **I am requesting an unpaid leave of absence from UMB for 12 months**

E. Are you requesting a leave of absence or change in level of FTE at UM in order to make your time available to the entity? (Y/N) Yes If available, attach a copy of the request you have made and the approval.

F. If you are an externally funded investigator, what percentage of your FTE is budgeted to grants and contracts at this time?

**Section Seven.** Gifts. Describe any gifts for which you are requesting an exemption because of your relationship with the donating entity, or that entity's interest in your work.

If you are seeking permission to accept a gift or honorarium from an entity which has a

relationship with you, or an interest in your work, provide the nature and value of the gift. You need to give this information whether you are considering a gift directly to you which you plan to retain, a gift you plan to give to another person or entity (e.g., assigning the gift to the UM Fund), or a gift arranged through you but directed to the UM Fund or other UM affiliates which can hold and administer funds for the benefit of your work.

N/A

Give the nature and value of the gift (cash, stock, etc.,; market value or face value), and attach a copy of any written offer.

N/A

### **Section Eight.**

A. Other Relationships with the Entity. Provide information about any other relationship with the entity which has not been discussed above, but which may require an exemption to be lawful. Include here matters such as employment of a spouse or dependent child by the entity, ownership of an interest in the entity by a spouse, dependent child, or other dependent, or relationships between the entity and other organizations with which you or your spouse or dependent child have ownership or employment relationships. In describing ownership interests, give details, including percentage interest and value. In describing employment, give levels of effort and salary.

**Dr. Ginette Serrero, CEO of A&G, is my wife. She is also a co-founder of A&G. She currently owns ~31% of A&G. I am also a co-founder. I own ~22% of A&G. Currently A&G is valued at \$6 million. Therefore, Ginette's ownership is \$1.86 million, and my ownership is \$1.32 million at least on paper. Together, we own ~53% of A&G, valued at \$3.18 million, on paper.**

B. Relationship with other organizations. Describe any employment, ownership, or business relationship held by you or a spouse or dependent child in any business which could be affected (positively or negatively) by your relationship, or the results of your work, for the entity discussed in this exemption request.

**None**

### **Section Nine. Signature and Approvals.**

Before routing this form, execute it here. Please remind other reviewers to consider this form thoughtfully, complete their sections below, and execute the form if they are forwarding your request with a positive recommendation. Omit any steps of review which are not applicable to you. Be sure the last reviewer forwards the exemption request to the Conflict of Interest Officer.

A. I hereby make oath or affirm that the contents of this Exemption Request are true and correct

to the best of my knowledge, information and belief.

Jim Hayashi  
Your Signature

Dec 18 2006  
Date

B. Supervisor's Statement

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Date

\_\_\_\_\_  
Supervisor's Signature

C. Statement of Division Head or Director

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Division Head or Director

D. Statement of Chairperson or Assistant/Associate Vice President

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

1/5/07  
Date

Natalie D. Edgett  
Signature of Chairperson or Assistant/Associate Vice President

E. Statement of Dean or Vice President

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: \_\_\_\_\_

\_\_\_\_\_

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1-16-07  
Date

David Knepp  
Signature of Dean or Vice President

FORWARD THIS FORM TO J. JOSEPH GIFFELS, UM CONFLICT OF INTEREST OFFICER, FIFTH FLOOR, LOMBARD BUILDING, 515 WEST LOMBARD STREET, BALTIMORE, MD 21201.