The University of Virginia Tobacco Research Program

May 27, 2008

SUMMARY

In October 2007, the University of Virginia (UVA) established a Tobacco Research Program focused on medical and scientific research. This program has been created with an initial \$10 million gift from Philip Morris USA (PM USA), with another \$10 million pledged. The University and PM USA signed a precedent-setting agreement on October 22, 2007 confirming the independence of UVA's Tobacco Research Program and identifying an initial list of research topics. An independent peer-review process is underway to allocate the research funds, with oversight from a National External Advisory Board. (The program structure is described in more detail below.)

PROGRAM RATIONALE

The University of Virginia believes that this new agreement creates a model for funding important scientific research that has the potential to significantly improve public health. Smoking-related diseases are a major public health concern in this country and throughout the world. At the same time, financial support for tobacco control, and for tobacco-related research, is shrinking. State funding is limited, competition for National Institutes of Health (NIH) funding is intense, and fewer foundation monies are available for these purposes.

A recent report of the Institute of Medicine, *Ending the Tobacco Problem: Blueprint for the Nation* (2007), urged governments at all levels and all public and private institutions to intensify their efforts to reduce tobacco use. In this context, the University of Virginia should be ready to play a meaningful role in this overall effort to benefit public health. By harnessing its own scientific resources, the University will identify key areas of biomedical and social science research directed at preventing or treating the illnesses caused by cigarettes in the U.S. and internationally.

Both parties are mindful that concerns have been raised about scientific research conducted at universities with funding from tobacco companies. Through this agreement, PM USA was willing to make a substantial gift to enable the University to mount such a research program and to give UVA complete independence in conducting its tobacco research program and in reporting its results. This program involves no direct contact of UVA investigators with PM USA and the investigators have complete control over all decisions related to publication. It is also the case that some other funders, such as the American Cancer Society, preclude investigators who receive tobacco-company funding from competing for research monies from their organization. The University of Virginia ensures that investigators applying for funds are fully informed about this and encourages them to verify restrictions with their other funding sources.

The University of Virginia Tobacco Research Program

Under these circumstances, the University concluded that the agreement reached with PM USA preserves the University's institutional integrity, and that accepting the PM USA gift is in the public interest. As a strong service-oriented research university, our goal is to conduct high-quality independent research that contributes to the public good.

PROGRAM STRUCTURE

The UVA Tobacco Research Program will be conducted with complete independence from PM USA, in accordance with an internal peer-review process and under the oversight of an independent external advisory board.

The agreement states that funding from the gift will be awarded to investigators only through a rigorous peer-review process administered independently by UVA. UVA School of Medicine Senior Associate Dean for Research Erik Hewlett, M.D. will oversee this process and participate as a member of the review panel. As an addendum to the agreement, the University and PM USA determined an initial list of research topics, including the biologic origins, early detection, and identification of genetic and environmental susceptibility factors for lung cancer and other smoking-related illnesses; the relationship between inflammation caused by smoke and the development and progression of lung cancer and other smoking-related illnesses; the development of criteria that could be used to substantiate reduced risk in certain tobacco products; and approaches to preventing high-risk behaviors, including smoking, in adolescents.

The agreement also calls for an independent National External Advisory Board for oversight and public accountability. This arrangement is similar to that used by many states when distributing funding provided by tobacco companies under the Master Settlement Agreement. UVA Executive Vice President and Provost Arthur Garson, Jr., M.D., M.P.H. and Richard J. Bonnie, Harrison Foundation Professor of Medicine and Law and Director of the Institute of Law, Psychiatry & Public Policy at UVA, will both serve as non-voting, *ex officio* members of the National External Advisory Board. Recruitment is in progress for the National External Advisory Board. Its members may not be currently or previously affiliated with UVA, any tobacco company, or any other person or entity that presents a conflict of interest with the University or PM USA.

For more information, please contact:

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Statement on UVA agreement with Philip Morris

The University of Virginia established a Tobacco Research Program in October 2007 with an initial gift of \$10 million from Philip Morris USA (PM) with another \$10 million pledged. UVA's independence in research is confirmed within the agreement. Research will focus on several topics, to include lung cancer and other smoking related diseases and smoking cessation.

Why Undertake Tobacco Research?

A report of the Institute of Medicine, *Ending the Tobacco Problem: Blueprint for the Nation* (2007), urged governments at all levels and all public and private institutions to intensify their efforts to reduce tobacco use. In this context, UVA wants to play a meaningful role in this overall effort to benefit public health. Under its program UVA will identify key areas of biomedical and social science research directed at preventing or treating the illnesses caused by cigarettes in the U.S. and internationally.

What Does UVA Agreement Say?

The agreement contains several safeguards to maintain the independence of UVA and its researchers from Philip Morris, such as encouraging UVA to publish the results of research BEFORE sharing the results with Philip Morris. While UVa will send annual progress reports sent to Philip Morris, the agreement states that "In no event shall the progress report disclose any results of the research that have not been made available to the general public through publication or otherwise."

The agreement also states that UVA will have sole control over all publication of research results, and in no event shall PM influence any publications. It goes on to say that UVA will have the right to copyright, publish, disclose, disseminate, and use, in whole and in part, any data and information developed or received by the University under the agreement. It does, however, stipulate that UVA will include appropriate attribution of the funding source for the research.

The agreement makes it clear that UVA is in no way approving or endorsing any method, procedure, or product developed by PM. And PM will not claim such.

UVA Administration of the Gift

UVA established an independent National External Advisory Board for oversight and public accountability. This arrangement is similar to that used by many states when distributing funding provided by tobacco companies under the Master Settlement Agreement. UVA Executive Vice President and Provost Arthur Garson, Jr., M.D., M.P.H., is to serve as an *ex officio* member of the National External Advisory Board, and Richard J. Bonnie, Harrison Foundation Professor of Medicine and Law and Director of The Institute of Law, Psychiatry & Public Policy at UVA, is to serve in an *ex officio* capacity. Members of the National External Advisory Board may not be currently or previously affiliated with UVA, any tobacco company, or any other person or entity that presents a conflict of interest with the University or PM USA.

Review of initial grant proposals is underway and awards are expected to be made in June.

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In October 2007, the University of Virginia (UVA) established its Tobacco Research Program with an initial gift of \$10 million from Philip Morris USA (PM) with another \$10 million pledged. The university is aware that tobacco industry funding of tobacco-related research is controversial. Therefore, UVA was insistent that the terms of the agreement confirm its independence in research. The research will focus on topics including lung cancer and other smoking related diseases and smoking cessation. Smoking-related diseases are a major public health concern in this country and throughout the world, so financial support for tobacco control, and for independent tobacco-related research, is vital.

Mechanisms in the Tobacco Research Program guaranteeing the independence of UVA's research include:

- Grant recipients are encouraged to publish or otherwise disclose to the public the results of their research before sharing their results with PM.
- UVA retains control over the publication of research results.
- Research projects will be funded following an independent peer-review process that includes independent external and internal scientists.
- The program involves no direct contact of UVA investigators with PM.
- Under the agreement, UVA is in no way approving or endorsing any method, procedure, or product developed by PM; PM will not claim such.

The agreement with PM also calls for the establishment of an independent National External Advisory Board for oversight and public accountability. This arrangement is similar to that used by many states when distributing funding provided by tobacco companies under the Master Settlement Agreement. UVA Executive Vice President and Provost Arthur Garson, Jr., M.D., M.P.H. and Richard J. Bonnie, Harrison Foundation Professor of Medicine and Law and Director of the Institute of Law, Psychiatry & Public Policy at UVA, will both serve as non-voting, ex officio members of the National External Advisory Board. Board members may not be currently or previously affiliated with UVA, any tobacco company, or any other person or entity that presents a conflict of interest with the University or PM USA. The Board will review the administration of the grants program, including its review process.

In January 2008, the initial <u>request for applications</u> (SOM intranet) under this program was sent to all School of Medicine faculty and to the deans of the other UVA schools. An initial group of projects is expected to be funded in June 2008.

Related documents:

Program press release, May 2008 Program description, May 2008 Administration of the Tobacco Research grant program (SOM intranet)

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