

instruments, including product lines adjacent to the 3Q GC-MS and ICP-MS businesses. As a result, Bruker has a significant existing global infrastructure that will enable it to quickly support additional business expansion and replace the loss of competition posed by Agilent's acquisition of Varian.

Pursuant to the Consent Agreement, Inficon will receive the assets necessary to replicate Agilent's Micro GC instrument business, and Bruker will receive the assets necessary to replicate Varian's 3Q GC-MS and ICP-MS instrument businesses. In addition to ensuring that the employees of the relevant businesses will continue their employment with the acquirers, the Consent Agreement requires Agilent to provide Inficon and Bruker with access to additional Agilent employees who may be needed to facilitate the transition of the assets associated with each of the Products. The Consent Agreement also requires Agilent to transfer all relevant intellectual property and all contracts and confidential business information associated with each of the Products. Combined, these provisions ensure that Inficon and Bruker fully and immediately restore the competition that will be eliminated by the acquisition.

The Commission may appoint an interim monitor to oversee the divestiture of the Products at any time after the Consent Agreement has been signed. In order to ensure that the Commission remains informed about the status of the proposed divestitures, the proposed Consent Agreement requires the parties to file periodic reports with the Commission until the divestiture is accomplished. If the Commission determines that Agilent has not fully complied with its obligations under the Decision and Order within ten days after the date the Decision and Order becomes final, the Commission may appoint a divestiture trustee to divest the Micro GC, 3Q GC-MS, and ICP-MS assets to a Commission-approved acquirer.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

By direction of the Commission.

**Donald S. Clark**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Advisory Committee on Blood Safety and Availability

**AGENCY:** Department of Health and Human Services, Office of the Secretary.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood Safety and Availability (ACBSA) will hold a meeting. The meeting will be open to the public.

**DATES:** The meeting will take place Thursday, June 10 and Friday, June 11, 2010, from 8:30 a.m. to 5 p.m.

**ADDRESSES:** The Universities at Shady Grove, 9630 Gudelsky Drive, Rockville, Maryland 20850, Phone: 301-738-6000.

**FOR FURTHER INFORMATION CONTACT:** Jerry A. Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 250, Rockville, MD 20852, (240) 453-8803, FAX (240) 453-8456, e-mail [ACBSA@hhs.gov](mailto:ACBSA@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Advisory Committee on Blood Safety and Availability (ACBSA) provides advice to the Secretary and the Assistant Secretary for Health on a range of policy issues that impact (1) Definition of public health parameters around safety and availability of the blood supply and blood products, (2) broad public health, ethical and legal issues related to transfusion and transplantation safety, and (3) the implications for safety and the availability of various economic factors affecting product cost and supply.

Current Food and Drug Administration (FDA) policy recommends that men who have had sex with another man (MSM) even one time since 1977 should be deferred indefinitely from donating blood. The deferral of MSM began prior to the availability of tests for HIV in early 1985. The deferral has existed in its current form since September 1985. This and other related FDA policies are designed to address the major sources of known risk to the blood supply as well as the theoretical risk of emerging infectious disease (EID) transmission. FDA has reviewed the policy periodically, most recently at a meeting of the FDA Blood Products Advisory Committee in 2000 and in an FDA-sponsored public scientific workshop in

2006. After considering both public discussions FDA retained its policy. FDA has noted its commitment to continue to review its donor deferral recommendations.

Data from the Centers for Disease Control and Prevention (CDC) indicate that HIV and other blood borne pathogens are not randomly distributed in the population, but are concentrated within specific subgroups, including those whose sex partners have risk behavior(s) associated with a higher prevalence of transfusion transmitted diseases (TTDs). MSM have an increased incidence and prevalence of several currently recognized transfusion-transmitted diseases (*e.g.* HBV, HIV, syphilis, and CMV). There is a theoretical concern that MSM populations may also be at increased risk for other unrecognized transfusion-transmitted agents.

Although today's blood supply is screened using highly sensitive tests, screening tests can be falsely negative during the "window period," defined as the interval between the time when an infected individual may transmit the disease and the time when screening tests become positive. A period of deferral is needed after high-risk exposure to prevent false negative tests from "window period" collections. Deferral of donors with high-risk exposure depends upon reliable responses to a donor questionnaire, which are never 100 percent accurate. Therefore, despite highly sensitive testing and current deferral policies, failures to identify infected donors may occur.

In addition, unsuitable blood may be released inadvertently through inventory control errors. This increased risk is believed to be primarily related to human errors resulting in the release of infected units from quarantine. This is based on the assumption that due to higher infectious disease prevalence in MSM, greater numbers of infected units would be collected, leading to a small overall increase in quarantine release errors. These quarantine release errors would likely be reduced if computerized inventory controls were in place in all blood facilities.

At the June 10-11, 2010 meeting, the HHS ACBSA will hear presentations and engage in deliberations on the current MSM deferral policy. Specifically, the ACBSA will be asked to discuss the following: what are the most important factors (*e.g.* societal, scientific, and economic) to consider in making a policy change; is the currently available scientific information including risk assessments sufficient to support a policy change at this time;

what studies, if any, are needed before implementing a policy change; what monitoring tools or surveillance activities would need to be in place before implementing a policy change; what additional safety measures, if any, are needed to assure blood safety under a revised deferral policy?

The public will have opportunity to present their views to the Committee on the second day. A public comment session has been scheduled for June 11, 2010. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session should contact the Executive Secretary no later than June 8, 2010. It is requested that those who wish to have printed material distributed to the Committee provide thirty (30) copies of the document to be distributed to the Executive Secretary, ACBSA, prior to close of business June 8, 2010. If it is not possible to provide 30 copies of the material to be distributed, then individuals are requested to provide at a minimum one (1) copy of the document(s) to be distributed prior to the close of business June 8, 2010. It also is requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Executive Secretary prior to close of business June 8, 2010. Electronic comments must adhere to disability accessibility guidelines (Section 508 compliance).

Dated: May 4, 2010.

**Jerry A. Holmberg,**

*Executive Secretary, Advisory Committee on Blood Safety and Availability.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

[30 Day-10-10BT]

#### **Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of

information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

#### **Proposed Project**

National Quitline Data Warehouse—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### *Background and Brief Description*

Tobacco use remains the leading preventable cause of disease and death in the United States, resulting in approximately 440,000 deaths annually and contributing to \$92 billion annually in lost worker productivity. Although the prevalence of current smoking among adults decreased significantly since its peak in the 1960s, overall smoking prevalence among U.S. adults has remained virtually unchanged during the past five years. Large disparities in smoking prevalence continue to exist among members of racial/ethnic minority groups and individuals of low socioeconomic status.

The National Tobacco Control Program (NTCP) was established by CDC to help reduce tobacco-related disease, disability, and death. The NTCP provides funding for state Quitlines, which provide telephone-based tobacco cessation services to help tobacco users quit. Quitlines overcome many of the barriers to tobacco cessation classes and traditional clinics because they are free and available at the caller's convenience. Quitline services in all states can be accessed through a toll-free national portal number at 1-800-QUIT-NOW. According to CDC's Best Practices for Comprehensive Tobacco Control, approximately six to eight percent of tobacco users potentially can be reached successfully by Quitlines; however, currently, only one to two percent of tobacco users contact Quitlines.

With funding authorized by the American Recovery and Reinvestment Act of 2009 (ARRA), CDC has provided additional support for the expansion of tobacco Quitline services. CDC is therefore requesting OMB approval to establish a National Quitline Data Warehouse (NDQW), and to collect information from the 50 states, the District of Columbia, Puerto Rico, and Guam. The principal information collection will be based on a uniform Minimum Data Set (MDS) developed collaboratively by the North American Quitline Consortium and other tobacco control organizations.

Quitline service providers will use a common interview instrument to collect information from all callers. A one-minute interview will be conducted with callers who contact the Quitline to obtain information on another person's behalf. Callers who contact the Quitline to obtain information or services for themselves will be asked to participate in a 10-minute interview. A random sample of callers who receive a Quitline service will be asked to participate in a short, voluntary follow-up interview seven months after intake.

In addition, to monitor and evaluate the expenditure of Recovery Act funding, CDC will collect a quarterly report about each Quitline program from the designated Tobacco Control Manager. These reports will be used to quantify improvements in the capacity of the Quitlines to assist tobacco users over time.

The information collected in the NDQW will be used to determine the role Quitlines play in promoting tobacco use cessation, measure the number of tobacco users being served by state Quitlines, determine reach of Quitlines to high-risk populations (*e.g.*, racial and ethnic minorities and the medically underserved), measure the number using each state Quitline who quit, determine whether some combinations of services contribute to higher quit rates than others, and improve the timeliness, access to, and quality of data collected by Quitlines.

Information will be collected electronically for a two-year period. There are no costs to respondents other than their time. The total estimated annualized burden hours are 90,563.