US cancer research strategy revised

Thirty years after Richard Nixon declared 'war on cancer', researchers have presented a revised approach to eradicating the disease in the 21st century that includes a request to increase the National Institute of Cancer (NCI) budget to \$5 billion. The NCI is already the richest government biomedical research body with an FY 2001 budget of \$3.7 billion.

The proposal, entitled 'Conquering cancer: a national battle plan to eradicate cancer in our lifetime', was presented on 8 November in Washington DC by the National Cancer Legislation Advisory Committee (NCLAC). It states that although the National Cancer Act of 1971 led to a better understanding of cancer, many discoveries are stalled by 'structural bottlenecks' that slow or stop the translation of basic discoveries into the clinic.

The report, prepared by the National Cancer Legislation Advisory Committee

(NCLAC) for congress and the president, recommends building a network of multi-disciplinary 'translational centers' to increase the speed at which new drugs and technologies are moved into clinical trials. They cite the Specialized Programs of Research Excellence (SPORes), which groups translation researchers by disease at various sites, and Rapid Access to Intervention Development (RAID), which provides resources for moving academic discoveries into the clinic, as examples of pre-existing models.

The committee also suggests that the Food and Drug Administration's (FDA) approval system for cancer drugs should be streamlined, partly by starting a specialized FDA division of oncology drug products to accelerate approval of priority drugs. They cite the FDA record approval time for STI-571 (Gleevec) of 2.5 months, as opposed to years for other drugs, as an

example of how quickly the system can move.

The proposal recommends that the federal government fund research at private companies that are developing cancer drugs, and states that although there is the possibility of curing many cancers if they are detected sufficiently early, the US does not provide enough access to prevention and early detection services. The committee suggests creation of a government-funded a National Cancer Screening Initiative and National Cancer Prevention Initiatives be launched to reduce tobacco use and improve nutrition.

Finally, the report recommends increasing funding for the National Cancer Clinical Trials System and continuing the effort to double the NIH budget by FY 2003. The NCLAC is a group of 21 cancer researchers, survivors, patient advocates, health providers, non-profit leaders and biotechnology executives.

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Confusion reigns over breast cancer

Britain's two leading cancer charities are urging women not to pull out of a trial to test Tamoxifen's preventative effects on breast cancer following fresh reports that the drug can substantially increase endometrial cancer and some cardiovascular diseases. The fear coincides with news that breast cancer has overtaken lung cancer as the most common form of the disease in the United Kingdom.

A large American study of the preventative effects of Tamoxifen—the Breast Cancer Prevention Trial (BCPT-P-1)—was stopped prematurely in 1998 when it was revealed that the drug causes a 49% reduction in the chance of high-risk but otherwise healthy women developing breast cancer. However, that report concluded that treatment also carries an increased risk of endometrial cancer, a finding that has since fuelled debate over the safety of using the drug in women who might never develop breast cancer.

Now, a paper in the *British Journal of Cancer* describing computer simulations of women who conform to the eligibility criteria of the BCPT-P-1 trial reinforces that concern (*BJC* 85, 1280; 2001). It states, "although Tamoxifen has a substantial benefit in reducing breast cancer

incidence and mortality, the detrimental effects...on endometrial cancer, coronary heart disease, stroke and deep vein thrombosis may counter-balance the protective effect Tamoxifen has on breast cancer for the majority of the women meeting the eligibility criteria."

The UK's Cancer Research Campaign (CRC) and Imperial Cancer Research Fund (ICRF) are part-funding a multi-center trial of the preventative effects of the drug in otherwise healthy females with a family history of breast cancer. Women in the International Breast Cancer Intervention Study (IBIS) are located in the UK, Australia and New Zealand, and results are due to be reported next year.

Kate Law, Head of Clinical Trials at the CRC points out that the *BJC* paper models women similar to those in the BCPT-P-1 trial which includes women defined as high-risk simply by nature of their age being over 60 years. However, the IBIS trial has recruited only women with a family history of the disease. In these women, it is presumed that the benefits of preventing possible breast cancer outweigh the risks of adverse events. According to Law, endometrial cancer is rare, occurring in only 3 of

10,000 women, and this increases with Tamoxifen treatment to only 6–9 of 10,000. Yet this strategy too is at odds with a new paper published by ICRF researchers, which states that most women with a family history of breast cancer will never develop the disease themselves (*Lancet* 358, 1389; 2001).

The incident highlights the confused messages on breast cancer that women receive. For example, while the UK is persevering with screening programs, some Scandinavian countries are convinced that mammography is ineffective in reducing mortality (*Lancet* 358, 1340; 2001). This paper also prompted the ICRF to post a statement on its website this October—officially the month of breast cancer awareness—alleging the findings to be "misleading."

Last month, the UK's Office of National Statistics released its latest data (for 1998), which show that 39,500 cases of breast cancer are now diagnosed in the UK each year. Although it affects women predominantly, this form of cancer has overtaken lung cancer—which affects both men and women—for which there are 38,900 cases annually. Researchers are presently at a loss as to explain why there has been such a rise in breast cancer and propose general hormonal changes, such as girls beginning to menstruate at an earlier age, women having children later in life and going through menopause later.

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