GLOBAL ALLIANCE

U.S. and Japanese Pharmaco-genomics Partnership

Scientists from the U.S. and Japan have entered into a strategic partnership to study the genetic factors that influence the safety and effectiveness of medicines. Leaders from the U.S. National Institutes of Health and the Japanese Center for Genomic Medicine have signed a letter of intent creating a global alliance for pharmacogenomics. The goal is to identify genetic factors that contribute to individual responses to medicines, including rare and dangerous side effects. The results of such work will eventually help optimize the safety and effectiveness of drugs for each patient.

Initial projects will focus on:

- Understanding genetic factors that influence the effectiveness of breast cancer treatments (aromatase inhibitors)
- Determining the optimal length of treatment for two drugs used to treat early-stage breast cancer (cyclophosphamide and either doxorubicin or paclitaxel)
- Discovering new genetic factors linked to serious side effects from certain pancreatic cancer drugs (gemcitabine and bevacizumab)
- Exploring how genes contribute to drug-induced long QT syndrome, an irregular heart rhythm that can cause sudden cardiac arrest
- Working with the International Warfarin Consortium to tailor initial doses of the anti-clotting drug warfarin based on the genetic profiles of patients

A steering committee will manage the alliance and will meet twice a year to discuss progress, future directions, intellectual property issues, the approval of additional members, and communications with the public. Alliance members will share data and research results.

SOURCE: NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD.

THE OTC MARKET

Plop,Plop, Fizz, Fizz

Consumers are taking an increasingly active role in self-medication because of rising healthcare costs, a large uninsured population, and ever more choices in OTC products. Purchasing OTC drugs also is more convenient and money is saved avoiding doctor's visits. Recent studies have uncovered that up to **40%** of consumers do not fill a doctor's prescription, and instead substitute an OTC alternative. Ultimately, purchasing OTC drugs saves U.S. consumers around **$15 billion** annually, According to a new report by Kalorama Information's World OTC Pharmaceutical Markets report, OTC drug sales account for between **8% and 30%** of total pharma sales in the majority of world regions. In developed regions, such as the U.S. and the U.K., they accounted for **7.7% and 15.8%** respectively in 2007. Higher percentages of OTC sales are often found in regions that are less developed, such as India or China.

> Self-medication is one of many factors driving the OTC drug market to exceed $80 billion by 2012.

The world OTC sales in 2007 were **$68.4 billion**, with a **3.9% CAGR** since 2005.

This market should enjoy a **4.3% CAGR** through 2012.

SOURCE: KALORAMA INFORMATION, NEW YORK.

HELP WANTED

FDA to Hire 1,300

The FDA will fill more than 1,300 positions within the next several months. Biologists, chemists, medical officers, mathematical statisticians, and investigators are among the experts in demand as the FDA begins a multi-year hiring initiative.

In fiscal year 2008 alone, the FDA is looking to fill more than 600 new positions and to backfill more than 700 others to implement the FDA Amendments Act of 2007, the Food Protection Plan, and the Import Safety Action Plan. This almost triples the number of people hired from 2005 to 2007.

The critically needed occupations are medical officers, consumer safety officers, chemists, nurse consultants, biologists, microbiologists, health/regulatory/general health scientists, mathematical statisticians, epidemiologists, pharmacologists, pharmacists, and veterinary medical officers. Many of these positions are located in the Washington metropolitan area, specifically Rockville, Silver Spring, and College Park, Md., as well as across the country in the FDA's five regions, 20 districts, more than 179 resident posts, and the newly created FDA offices overseas.

For general information and to apply for one of the positions listed above, submit your questions and electronic curriculum vitae with a cover letter via e-mail at joinourteam@fda.gov.

SOURCE: FDA, ROCKVILLE, MD.

DTC REPORT CARD

GAO Gives FDA Failing Grade

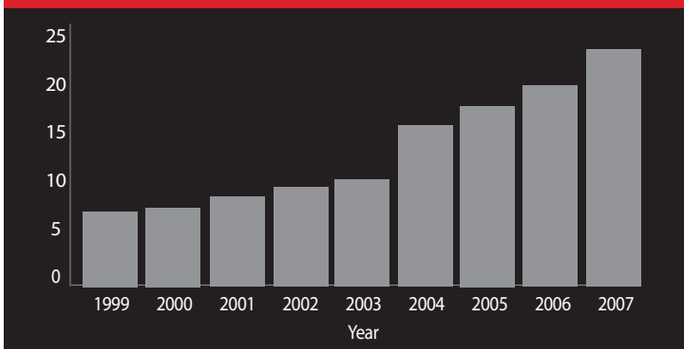
A recent report — Trends in FDA's Oversight of Direct-to-Consumer Advertising — based on the statements of Marcia Crosse, Director, Health Care, GAO, finds that the FDA's oversight of prescription drug advertising materials is lacking.

Highlights from the report include:

- The FDA reviewed a small portion of DTC materials and could not ensure it was reviewing the highest-priority materials.
- After the 2002 policy change (requiring legal review by OCC of all draft regulatory letters), the FDA's process for issuing regulatory letters took longer and the number of letters issued declined.
- Effectiveness of FDA regulatory letters at halting dissemination of violative DTC materials was limited.

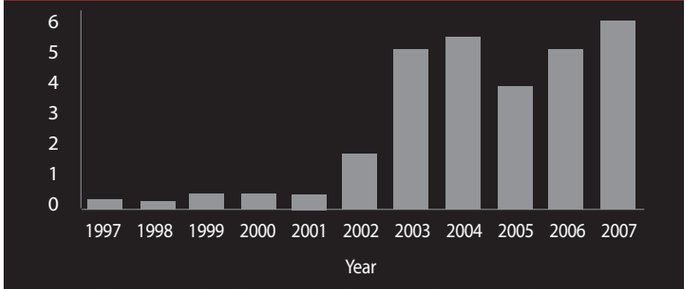
To access the full report, please go to: gao.gov/cgibin/getrip?GAO-08-758T.

Number of Materials Directed to Consumers Submitted to FDA — 1999 to 2007



Note: Numbers in thousands; Totals include final DTC materials, Internet materials — some of which may be directed to medical professionals — and materials.

Average Months to issue Regulatory Letters Citing Violative DTC Materials, 1997 through 2007



Notes: Months to issue regulatory letters (initial draft to issuance); for each letter, the GAO determined the number of months from the date on which a reviewer first began drafting a regulatory letter to the date the letter was issued. FDA does not track the date a violation was identified or the date it was determined that the violation merited a regulatory letter.

SOURCE: GAO ANALYSIS OF FDA DATA.

SOURCE: U.S. GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, D.C.

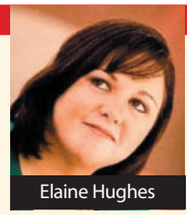
THE MONEY TREE

Record VC Investment in Life Sciences

Venture capitalists invested $29.4 billion in 3,813 deals in 2007 — marking the highest yearly investment total since 2001. The total invested in 2007 represents a 10.8% increase in dollars and a 5% increase in deal volume over 2006. The life-sciences sector (biotech and medical-device industries together) set an all-time record for venture capital investing in 2007, with $9.1 billion in 862 deals compared with $7.6 billion going into 786 deals in 2006. The most significant growth was in the medical-device industry, which rose 40% in 2007 to $3.9 billion going into 385 deals. For the year, life sciences accounted for 31% of all VC invested, which also represents an all-time high.

SOURCE: PRICEWATERHOUSECOOPERS, NEW YORK.

THE SURVEY SAYS ...


Elaine Hughes

PharmaVOICE would like to thank all of the participants who took the time to reply to inVentiv Health's sponsored survey: "Maximizing Efficiency through Sales and Marketing Integration."

The lucky winner of the iPod Touch is Elaine Hughes, Marketing Director, Account Management Team, Centocor Inc.

THE WINNER IS ...


Tom Mahony

PharmaVOICE would like to thank all of the attendees who took the time to stop by our booth at the 17th Annual CRO Partnerships conference in Las Vegas in April.

The conference drew hundreds of clinical research professionals and other life-sciences executives involved with clinical trials and drug-development activities.

We would like to offer our congratulations to Tom Mahony, Director Business Development, PPD, who was the lucky winner of the iPod Touch in a drawing sponsored by PharmaVOICE.

TUNING IN...

Featured Podcasts

- **Redefining the CRO**
  Featured Podcast Thought Leader: Bob Burford Ph.D., Managing Director, Aptuit Consulting
- **Corporate Volunteerism at Amgen**
  Featured Podcast Thought Leader: Eduardo Cetlin, Senior Manager of Corporate Contributions, Amgen
- **Improving Clinical Operations**
  Featured Podcast Thought Leader: Karen Gotting-Smith, Ph.D., VP, Business Performance and Continuous Improvement, formerly VP, U.S. Clinical Development, AstraZeneca
- **Corporate Volunteerism at Roche**
  Featured Podcast Thought Leader: Sherrie Pietranico, Ph.D., Research Leader, Discovery Chemistry, Roche