Public Doubts Strengthening FDAs Oversight of Prescription Drug Industry Will Make A Difference

Contributed by Harris Interactive
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The Public is Doubtful that Strengthening the FDAâ€™s Oversight of the Prescription Drug Industry Will Make a Difference.

The publicâ€™s confidence in the U.S. Food and Drug Administration (FDA) appears to be rebounding after two years of declining confidence, but the agency has more work to do. Half of all adults in the U.S. still believe that the FDA is doing a fair or poor job when it comes to ensuring the safety and efficacy of new prescription drugs. Nearly six in ten give the agency negative ratings on ensuring that truly innovative drugs come to market more quickly.

These are some of the results of an online survey of 2,482 U.S. adults, ages 18 and older, conducted by Harris InteractiveÂ® between May 22 and 24, 2007 for The Wall Street Journal Onlineâ€™s Health Industry Edition (www.wsj.com/health).

Legislators on Capitol Hill are actively seeking to address the publicâ€™s concerns. New provisions were recently passed by the U.S. Senate as part of the Food and Drug Administration Revitalization Act that would give the FDA new powers, including the ability to issue fines to drug companies if they fail to do follow-up safety studies or use false or misleading advertising. The Senate also passed legislation that would establish electronic networks to scan medical and prescription drug records for indications of drug safety issues. The FDAâ€™s expanded mandates will be funded by increased user fees paid by prescription drug companies.

The publicâ€™s perceptions of these initiatives, on the whole, are ambivalent at best; half of all adults are confident that that these oversight mechanisms would help improve drug safety.

The public is more dubious about legislation passed in the U.S. House of Representatives that would provide funding to the Agency for Healthcare Research and Quality (AHRQ) to compare prescription drugs in order to determine which are most cost effective. Only one in five adults is confident that cost-effectiveness comparisons would help contain healthcare costs for the U.S as a whole or help to contain costs for individuals like themselves. One in three adults is confident that cost-effectiveness comparisons would help ensure that patients receive safe and effective prescription drug treatments.

Public opinion is split as to whether or not allowing the FDA to issue fines would limit peopleâ€™s access to new and innovative treatments. Equally large numbers of adults worry that establishing systems to scan medical and pharmacy records for indications of safety issues would limit innovation. More than half of all adults are concerned the cost effectiveness comparisons will limit the publicâ€™s access to new and innovative prescription drugs.

The pubic is skeptical about the relying on user fees to fund these new oversight activities. Six in ten adults agree that the agencyâ€™s reliance on user fees could lead to less rigorous scrutiny when reviewing new prescription drugs. Less than one in three adults believe that having the industry fund these activities is a good way to save taxpayers money.TABLE 1RATING THE FDA"Based on what you know or have heard, how good a job do you think the FDA (Food and Drug Administration) does onâ€¦?"

Base: All AdultsÂ Â Positive*ExcellentGoodNegative**FairPoorNot Sure

Ensuring the safety as well as the efficacy of new prescription drugs2004%56144337271072006%3672958352362007%457374929206

Ensuring that truly innovative prescription drugs come to market more quickly2004%2942562342892006%2241870343782007%343305831269

*Excellent or good. **Fair or poor.

Note: Percentages may not add up exactly to 100% due to rounding.TABLE 2PUBLIC PERCEPTIONS OF POTENTIAL FDA REFORMS"The U.S. Senate recently passed a bill that would provide the FDA with new responsibilities. How confident are you that the following measures would help improve drug safety?"

Base: All AdultsÂ Extremely/ Very Confident/ Confident (NET)Extremely ConfidentVery ConfidentConfidentNot Very/ At All

Confident (NET)Not Very ConfidentNot at All ConfidentNot Sure

Establishing a computerized network to scan insurance and pharmacy records for indications of safety issues with new prescription drugs%526123437261011

Increasing fines for pharmaceutical companies who fail to comply with FDA requests for label revisions or additional studies of prescription drugs%528123237251211

Allowing the FDA to fine pharmaceutical companies for false or misleading ads%549143136241210

Note: Percentages may not add up to 100% due to rounding.TABLE 3PUBLIC PERCEPTIONS OF COST-EFFECTIVENESS COMPARISONS"The U.S. House of Representatives recently passed a bill that would provide $3 billion to the Agency for Healthcare Research and Quality to compare prescription drugs in order to determine which are the most cost-effective. Funding would come from the federal government, health plans and employers. Health plans would then use this information to help decide which therapies are most appropriate for their plan members. How confident are you that these kinds of cost-effectiveness comparisons wouldâ€¦?"

Base: All AdultsÂ Extremely/ Very Confident/ Confident (NET)Extremely ConfidentVery ConfidentConfidentNot Very/ At All Confident (NET)Not Very ConfidentNot at All ConfidentNot Sure

Help contain healthcare costs in the U.S.%22241667412710

Help contain healthcare costs for people like you%23241766392711

Help ensure that patients receive safe and effective prescription drug treatments%31152558352311

Note: Percentages may not add up to 100% due to rounding.TABLE 4POTENTIAL IMPACT OF REFORMS ON INNOVATION"How concerned are you that the following measures would limit peopleâ€™s access to new and innovative prescription drugs in the future?"

Base: All AdultsÂ Extremely/ Very Concerned/ Concerned (NET)Extremely ConcernedVery ConcernedConcernedNot Very/ At All Concerned (NET)Not Very ConcernedNot at All ConcernedNot Sure

Establishing a computerized network to scan insurance and pharmacy records for indications of safety issues with new prescription drugs

%476103139291014

Increasing fines for pharmaceutical companies who fail to comply with FDA requests for label revisions or additional studies of prescription drugs

%465103141301113

Allowing the FDA to fine pharmaceutical companies for false or misleading ads

%43682945311412

Funding federal research to provide health plans with cost-effectiveness data for prescription drugs

%551013313122914

Note: Percentages may not add up to 100% due to rounding.TABLE 5PUBLIC PERCEPTIONS OF USER FEES"Currently some of the FDAâ€™s drug review activities are funded by user fees paid by pharmaceutical companies. To what extent do you agree or disagree with the following statements about these user fees?"

Base: All AdultsÂ Strongly/ Somewhat Agree (NET)Strongly AgreeSomewhat AgreeNeither Agree Nor DisagreeStrongly/ Somewhat DisagreeSomewhat DisagreeStrongly Disagree

Having pharmaceutical companies fund FDA activities is a good way of saving taxpayers money

%2972134371720

Having pharmaceutical companies fund FDA activities means that the FDA wonâ€™t be as rigorous as it should be when reviewing new prescription drugs.

%5726312815104

Note: Percentages may not add up to 100% due to rounding.

Methodology

Harris InteractiveÂ® conducted this online survey within the United States between May 22 and 24, 2007 among a national cross section of 2,482 adults, ages 18 years and over. Figures for age, gender, race/ethnicity, education, income and region were weighted where necessary to align with population proportions. Propensity score weighting was also used to adjust for respondents' propensity to be online.

All surveys are subject to several sources of error. These include: sampling error (because only a sample of a population is interviewed); measurement error due to question wording and/or question order, deliberately or unintentionally inaccurate responses, nonresponse (including refusals), interviewer effects (when live interviewers are used) and weighting.

With one exception (sampling error) the magnitude of the errors that result cannot be estimated. There is, therefore, no way to calculate a finite "margin of error" for any survey and the use of these words should be avoided.

With pure probability samples, with 100 percent response rates, it is possible to calculate the probability that the sampling error (but not other sources of error) is not greater than some number. With pure probability samples of 2,482 one could say with a ninety-five percent probability that the results would have a sampling error of +/- 3 percentage points. Sampling error for data based on sub-samples would be higher and may vary. However, that does not take other sources of error into account. This online survey is not based on a probability sample and therefore no theoretical sampling error can be calculated.

About The Wall Street Journal Online

The Wall Street Journal Online at WSJ.com, published by Dow Jones & Company (NYSE: DJ; www.dowjones.com), is the largest paid subscription news site on the Web. Launched in 1996, the Online Journal continues to attract quality subscribers who are at the top of their industries, with 931,000 subscribers world-wide as of Q1, 2007. The Wall Street Journal Online network includes CareerJournal.com, OpinionJournal.com, StartupJournal.com, RealEstateJournal.com and CollegeJournal.com.

The Online Journal provides in-depth business news and financial information 24 hours a day, seven days a week, with insight and analysis, including breaking business and technology news and analysis from around the world. It draws on the Dow Jones network of nearly 1,900 business and financial news staff â€“ the largest network of business and financial journalists in the world.

In 2007, the Online Journal received the Webby Award for Best Website in the Financial Services category. Â In 2005, the Online Journal was awarded a Codie Award for Best Online News Service for the second consecutive year, and its Health Industry Edition was awarded Best Online Science or Technology Service for the third consecutive year.

About Harris Interactive

Harris Interactive is the 12th largest and fastest-growing market research firm in the world. The company provides innovative research, insights and strategic advice to help its clients make more confident decisions which lead to measurable and enduring improvements in performance. Harris Interactive is widely known for The Harris Poll, one of the longest running, independent opinion polls and for pioneering online market research methods. The company has built what it believes to be the worldâ€™s largest panel of survey respondents, the Harris Poll Online. Harris Interactive serves clients worldwide through its United States, Europe and Asia offices, its wholly-owned subsidiaries Novatris in France and MediaTransfer AG in Germany, and through a global network of independent market research firms. More information about Harris Interactive may be obtained at www.harrisinteractive.com.

To become a member ofÂ the Harris Poll Online and be invited to participate in online surveys,Â register at www.harrispollonline.com.

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