

Statement of Consumers Union
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Food and Drug Administration
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Reform of Prescription Drug Direct-to-Consumer Advertising

Mr. Chairman, Members of the Committee:

On behalf of Consumers Union, the independent, non-profit publisher of *Consumer Reports*, we urge the FDA to support major reforms in the advertising of pharmaceuticals. We believe this is a major consumer issue, particularly for the nation's seniors.

In answer to the first question posed for these hearings, we believe that all too often, current DTC promotions fail to present the benefits and risks of using medical products in an accurate, nonmisleading, balanced, and understandable way.

Consumers Union urges

--requiring a 2 or even 3 year moratorium on advertising of new drugs, because—to be frank—we really do not know how safe new drugs are, given the often accelerated approval procedures and recent breakdowns in the advisory committee process;

--pre-approval of all direct-to-consumer (DTC) and direct-to-provider (DTP) ads before they are presented to the public and providers, so as to end the long history of misleading marketing that overstates benefits and understates risks. If pre-approval is not possible, then there should be substantial penalties for misrepresentation of the safety risks;

--support of S. 930 (Grassley-Dodd) requiring that ads for those drugs approved on the condition of further studies publicly identify that safety concerns have been identified and are being investigated;

--support of legislation giving the FDA civil monetary penalty authority to effectively enforce truth-in-advertising and penalize repeat offenders;

--requiring an addition to all DTC ads, noting that all adverse reactions should be reported to 'your physician and the FDA at MedWatch' and give the toll-free telephone number and website of MedWatch;

--ensuring that if or when PDUFA is re-authorized in 2007, enough resources are dedicated to review of DTC and DTP ads so as to make the program truly effective; and

--developing a system where drug manufacturers may support a public service announcement fund to educate—through objective NIH, CDC, or AHQR materials—the public about under-treated and under-diagnosed diseases and conditions

Why we believe advertising reforms are needed: Moratorium on Advertisement of Newly Approved Drugs

It is clear that some drugs with unacceptable safety risks are being approved.¹

Lots of people have died and been injured under the current system, which emphasizes getting drugs to market, while giving short shrift to determining the safety of those drugs once they are used by millions of Americans.

The recent decision of the FDA Advisory Panel on psychiatric drugs October 25 illustrates this problem: rather than slow the entry of new drugs by requiring longer testing, the panel wanted—and the FDA appears to be agreeing—almost immediate approval. The result will be the marketing of more drugs that we do not fully understand and that may have higher risks (and fewer benefits) than we can detect in short trials.

The public wants quick access to drugs that may be life-saving. They want safe drugs. They also want more affordable drugs.

Achieving everything that the public wants is possible, but it will require the FDA to give as much organizational attention and resource to post-approval safety studies as it gives to speeding up the approval of new drugs. It also will require the FDA to acknowledge that during the two or three years after a drug has been introduced to the market, vital information is lacking as to whether these drugs are safe, if they should be used on older people, or those with co-morbidities, etc.

In short, we don't know if the new drugs are safe in the long-run on large masses of people, and we should not be advertising them to millions until we have a clearer understanding of risks that cannot happen from limited clinical trials..

Here's an ad from a patient database company that appeared about two months ago in a newsletter read by many in the drug world:

“How many prescriptions...

“How many weeks in market...

¹ While the final approval decision is unclear, the failure of the Advisory Committee process (and of the FDA to highlight problems for the Advisory Committee) in the recent Muraglitazar/Pargulva review is just one more example of on-going problems. Even when a safety problem is detected, the response can be inadequate from a consumer standpoint. For example, in October, 2005, in the case of pemoline (Cylert) with its unacceptable liver toxicity problem, remaining supplies will be allowed to be sold, rather than recalled and destroyed. We hope there will be no “final clearance” ads for this drug!

UNTIL YOU'RE CONFIDENT THAT YOUR DRUG IS SAFE?"

If you showed that ad to the average consumer on the street, they would be shocked. They assume and expect that FDA-approved drugs are safe. Vioxx—and almost weekly headlines for the past two years—have shaken their confidence. But the average consumer doesn't think they are the guinea pig this ad correctly describes. The public has no idea how few people are actually studied in many clinical trials.²

The only way to mitigate the damage of quick approval of drugs tested on a thin population base is to ban mass advertising for the first two to three years after a drug has been approved. Two-thirds of all drug withdrawals occur within the first three years of release, so a three-year moratorium would result in a major reduction in the use of drugs eventually found unacceptably risky.³ Therefore we support Senator Frist's call for a two-year moratorium on drug advertising. We support Rep. Sherrod Brown's bill (HR 3696) for a two-year moratorium, and Representatives Jo Ann Emerson and Rosa DeLauro's proposal for a three-year ban (HR 3950).

Of course, the Vioxx example is the poster child for why drugs approved for a limited problem should not be mass marketed to hundreds of millions until we know more about their effects over a longer period of time. It is possible that the dangers of this drug would have come to light after use by a much smaller population. Thousands of lives possibly would have been saved and tens of thousands of heart attacks avoided if the product had not been so aggressively marketed. And the company would be saving billions of dollars in litigation costs.

Limits on mass marketing of new drugs are particularly important for the senior community and people with disabilities. Attached is a fact sheet we have prepared on why drug safety is especially important for seniors and how the elderly are disproportionately impacted by adverse drug events. Advertising of newly approved drugs that have not been adequately tested on seniors and those with multiple conditions has—and will in the future—result in harm and even death. Until we understand better the impact of a drug on a large and diverse population and especially on seniors, its advertising should be limited.

Repeated, Continuing Violations of Ad Regulations Points to the Need for

² A recent example is the discussion in the Advisory Committee on Endocrinologic & Metabolic Drugs, September 8, 2005, where they discussed the safety of the inhaled insulin powder Exubera in lung patients, based on two tests on 27 and 30 patients, respectively. (*The Pink Sheet*, September 12, 2005, p. 7)

³ Matthew F. Hollon, MD., "Direct-to-Consumer Advertising: A Haphazard Approach to Health Promotion," *JAMA*, April 27, 2005. Vol. 293, No. 16, p. 2032.

Review and Approval of Advertisements Before They Are Used on the Public and Providers—and the Need for Civil Monetary Penalty Authority to Put Teeth into the Rules

It is the nature of for-profit companies to display their products in the best light possible and to minimize discussion of risks and downsides. The history of FDA-industry relations is a tale of companies pushing the limit, repeatedly overstating benefits and understating dangers. Given the incentives to earn the highest profits, that's not going to change. But since the health and safety of the public is at stake, it should be regulated.

Unlike some others who have spoken in the last two days, we do not believe there is a Constitutional right to harm your fellow citizens for profit. Just as I hope we all agree there is no right to yell fire in a crowded theater, there is no right to promise improved health but hide possible disastrous side effects.

Consumers Union has been working on the issue of drug ads for a long time, with a June 1996 report and a February 2003 report entitled, "*Free Rein for Drug Ads? A slowdown in FDA review has left consumers more vulnerable to misleading messages.*" This report details our analysis of FDA regulatory letters relating to ads, both direct-to-providers and direct-to-consumers (DTC), issued between January 1997 and November 2002.⁴ We found

a broad and disconcerting range of misleading messages: ads that minimized the product's risk...; exaggerated its efficacy; made false claims of superiority over competing products; promoted unapproved uses for an approved drug; or promoted use of a drug still in the experimental stage.

A reading of recent regulatory letters seems to indicate a welcome up-turn in strong warning letters, for which we congratulate the FDA. We particularly appreciate the emphasis on ensuring that the risks of a drug are given more prominence.⁵ But it appears that the overall level of policing of promotions is still down from the previous decade—and that nothing has changed in the type of abuses detected.

Companies are repeatedly warned about similar violations, all too often after the ad campaign has ended and the public damage done. In our 2003 report, we noted how the maker of Claritin had received a total of 11 regulatory letters about problems with their ads. With these kinds of repeat warnings, one gets the strong impression that many in the industry are just scoffing at the requirements, or as someone has said, 'the FDA is just playing a game of whack a mole,' as it tries to stop DTC and DPC abuses. This disregard for the rules and regulations is why the law should be changed to permit imposition of major civil monetary penalties (CMPs) violations, especially repeat violations.

⁴ We will be updating this study in the next few months.

⁵ The Pink Sheet, August 1, 2005, "FDA Ad Division Letter Shows Focus on Prominence of Risk Information. P. 7.

Since the industry has so consistently failed to comply with the rules and regulations, we urge that FDA review and pre-clearance of all DTC and DTP be required. If the FDA decides not to proceed with this recommendation, it should require corrective ads and take other enforcement action (and seek civil monetary penalty authority) for any violations of truth and accuracy so that all manufacturers will want to have pre-clearance.

We especially support legislation by Senators Grassley and Dodd (S. 930) that would, among a number of important safety provisions, require review of advertising materials for all drugs for which postmarket study requirements have not been fulfilled and require enhanced disclosures to the public about the safety uncertainties that may accompany the drug.⁶ Not only would this provision help consumers understand the possible risks of a drug, but it would be a major incentive to manufacturers to actually complete post-market study commitments.

Use DTC ads to promote MedWatch and the Improved Reporting of Adverse Drug Events

Currently, it is believed the adverse drug event reporting system catches only 1 to 10 percent of adverse incidents. In the long-term, we hope that increased availability and use of large medical data bases will bring more predictability to the detection of adverse events. But in the meantime, increased reporting and use of MedWatch would help in the earlier detection and better analysis of problems. All DTC ads should contain information on how patients should report unusual side effects to their doctor and/or the FDA MedWatch system.

Adequate Resources

The FDA needs more resources — and it certainly should not be part of any 1 or 2 percent across-the-board cut in government spending. Our recommendations for pre-approval and better, more aggressive monitoring of DTC and DPC will certainly require more dollars; even PhRMA's voluntary proposal is predicted to increase the FDA's workload. The current review program has consistently been "a day late" in catching problematic ads—in part because it is "a dollar short." In this case, many dollars short. We urge that you request additional resources in your FY 2007 budget to ensure safe and accurate promotions. But in the long-run, the Federal government faces enormous long-range funding problems. The Congressional Budget Office projects major deficits through 2015 while many analysts expect deficits to trend toward the half trillion dollar a year mark unless major policy changes are made. Relying on increased general Treasury funding in the next few years is probably unrealistic. Therefore, if and when PDUFA is

⁶ We also have endorsed the provision in S. 930 that would require review of advertising and promotional materials for new drugs for the first two years after approval and require improved risk communication to consumers in those materials. But as stated earlier, we also strongly support the much stronger proposal to prohibit such ads for the first two or three years a drug is on the market.

renewed in 2007, we hope you will propose that some of the user fee funding be used to ensure truthful, honest prescription drug promotion.

Public Service Announcements

It is said that ads help educate the public about health problems—for example, the serious problem of depression that has often been tragically hidden in our society. Consumers Union believes that ads which explain a condition or problem and urge people to check with their physician have a role, and some polls show that consumers like this kind of information. The recent study by Doctors Kravitz, Epstein, Feldman and others in the April 27, 2005 issue of JAMA makes this point:

The results of this trial sound a cautionary note for DTC advertising but also highlight opportunities for improving care of depression (and perhaps other chronic conditions) by using public media channels to expand patient involvement in care.

More bluntly, the researchers wrote:

One interpretation [of the study results] is that more neutrally couched [patient] requests, generated from noncommercial sources, might not produce so furious a rush [by doctors] to comply [with patient requests] in clinically equivocal situations [i.e., where it is not appropriate].⁷

As JAMA editorialized on the Kravitz research:

“Decisions to advertise a specific product to the public do not necessarily reflect superior safety, efficacy, or the interest of the public’s health but rather calculations of return on investment. Driven by this financial interest, the domination of health-related communication by companies with drugs to sell will, by its very nature, lead to problems unless balanced by educational efforts geared to public rather than private good.”⁸

Ideally, such ads about under-treated diseases and conditions would be run as public service announcements objectively developed by NIH or AHQR. They could be financed by contributions from the industry, assuming that manufacturers support a totally objective educational campaign. As the American College of Physicians recently testified

⁷ “Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial,” JAMA, April 27, 2005. Vol. 293, No. 16, p 1995ff. Today’s testimony of Commercial Alert in which more than 200 Medical School Professors Condemn DTC Advertising is even clearer:

“Prescription drug advertising is not educational. It is inherently misleading because it features emotive imagery and omits crucial information about drugs and their proper use, as well as about side effects and contraindications that can be found on the full FDA-approved label.

⁸ ⁸ Matthew F. Hollon, MD., “Direct-to-Consumer Advertising: A Haphazard Approach to Health Promotion,” JAMA, April 27, 2005. Vol. 293, No. 16, p. 2032.

before the Senate Special Committee on Aging on Sept. 29, a number of companies have made unrestricted grants for such educational work, and we hope more of this could be done in the future. We believe, however, that when ads push a particular drug, serious problems can and do follow (as demonstrated by the Kravitz research just cited).

DTC a Factor in Rising Health Care Costs

We also believe that advertising drives up costs—and health care costs are certainly one of the leading consumer issues of our times. Every dollar spent on advertising is a dollar added to America’s health care costs. We spend about 50% more of our GDP on health care than other industrialized nations, but with questionable results and benefits. Once the New Zealanders end their DTC, we will be the only Organization for Economic Co-operation and Development nation that still allows pill advertising – which may be one factor in explaining why our health costs are so high. We believe advertising increases sales of what are often the most expensive prescriptions and thus accelerates the rate of health inflation, which in turn compounds our nation’s health insurance and un-insurance problems. For example, the heavy advertisement of expensive brand drugs and their continued sales despite the availability of cheaper and comparable generics (which are almost never advertised) contributes to our nation’s health cost inflation.⁹

The Need to Help Consumers Choose the Most Effective, Safe Drugs: Consumer Reports Best Buy Drugs Campaign

Further, the drugs being promoted may or may not be the most effective and safest medicines. We believe that the government should require more scientific, evidence-based studies to help the public understand which drugs are truly effective and safe—and how drugs compare in effectiveness. Consumers Union has combined drug pricing information with the data from the Drug Effectiveness Review Project led by Oregon’s Health and Science University to make recommendations to consumers on what is the Best Buy Drug. We believe these recommendations can save consumers hundreds and thousands of dollars per year by encouraging the use of the most effective, safe, and best priced drugs.

The DERP project is being used by 14 states to assist in the development of their public program preferred drug lists (PDLs). This helps ensure that the most effective drugs are made available to Medicaid patients, state retirees, and others. A number of states have also shown how the use of these evidence-based PDLs can be used to save millions of dollars through competitive bidding procedures. To the extent the FDA can require good clinical comparative trials, you will help the DERP process and help the States improve the quality of their drug insurance programs, thus saving lives and dollars.

⁹ For data on the growth in prescriptions for the mostly heavily advertised drugs, see the Statement of the American College of Physicians to the Senate Special Committee on Aging, September 29, 2005. p. 2.

The Need for Supervision of Direct-to-Provider Promotions

While the subject of your hearing today is DTC, we believe the same types of problems are occurring in the direct-to-provider (DTP) advertising world, resulting in serious distortions in the quality of prescribing. It appears that DTP spending is about 6 to 7 times larger than DTC. The direct selling to doctors through armies of detail personnel is the unseen part of the drug advertising iceberg. It is an area where there have been frequent documented abuses. We hope that you will also focus on this often hidden world where so many billions are being spent to influence prescribing physicians.

Conclusion—and a Request for Urgency

In conclusion, we hope the FDA will immediately propose administrative changes and support legislative reforms in the area of DTC. There was one press report this August indicating that these hearings were the beginning of a process that might take four years. We hope there is a greater sense of urgency and that you will make regulatory changes—and support legislative changes—on a much faster timetable. We do believe that faster action will help prevent or minimize future Vioxx-type incidents, with their attendant deaths and injuries.

Thank you for your consideration of these recommendations that we believe will help improve the quality and safety of health care in the United States, and moderate the rate of health care inflation.

Attachment



Drug Safety & Seniors

ILLNESS AND INJURY AMONG SENIORS

- Eighty-eight percent of those over 65 years of age have at least one chronic health condition, such as heart disease, cancer, stroke, and diabetes.ⁱ Many suffer from multiple conditions—often known as the complex chronically ill. Arthritis and related conditions are the leading cause of disability in the U.S. affecting nearly 43 million Americans, most of them elderly.ⁱⁱ
- Older adults are at higher risk for many types of injuries that can lead to death or disability. Each year, about 35% to 40% of adults 65 and older fall at least

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once. Suicide rates increase with age and are very high among those 65 years and older. ⁱⁱⁱ

- More than 4.3 million voluntary visits to doctors and hospitals in 2001 were for treatment of adverse drug effect, compared to 2.7 million such visits in 1995. People over 65 were particularly impacted. Nationally 11-15 people per 1000 had an adverse event. For seniors, the figure was 56.8 per 1000 for those 65-74 and 34.7 per 1000 for those 75-plus. ^{iv}

PREScription DRUG USE AMONG SENIORS

- Seniors represent 13% of the total population, but account for about 34% of all prescriptions dispensed and 42% of all prescription drug spending. ^v
- Nine out of 10 seniors report taking at least one prescription drug and nearly half of those taking one drug report taking five or more different drugs daily. ^{vi}
- People over age 65 fill, on average, up to 4 times as many prescriptions annually compared to younger adults, and up to 5 times as many compared to patients under 19. ^{vii}
- Women over age 65, fill, on average 7 more prescriptions (27.2) annually compared to men of the same age (20.3). ^{viii}
- Fifty-four percent of all seniors have more than one prescribing physician and one-third have their prescriptions filled by more than one pharmacy. ^{ix} One study found that one in ten seniors was prescribed medications by more than *six* doctors and one in three used more than *four* different pharmacies. ^x
- Rates of metabolism and liver and kidney effectiveness change as people age. These rates can be further complicated by the number of drugs seniors take. ^{xi}

WHY DRUG SAFETY REFORM IS A SENIOR ISSUE

- **FDA's current pre-approval drug safety system fails to detect unique risks to seniors**
 - Pre-approval clinical drug trials (Phase II and III trials) are generally conducted using **younger, healthier subjects who are not taking any other prescription drugs**. Twenty-seven percent of patients treated for a common type of massive heart attack are older than 75, yet those over 75 make up only 15% of those in heart medicine clinical trials. ^{xii}
 - As a result, the trials may not detect safety problems likely to occur under conditions of actual use by an increasingly elderly patient population, such as:

- the potential for adverse interactions with other drugs commonly prescribed to seniors—a particular problem for seniors taking multiple medications and using multiple doctors.
- risks arising from the unique metabolism and excretion rates of the elderly.
- risks to patients with health problems other than the indication being tested in the trial. For the elderly with multiple chronic conditions, this presents significant risk. (For example, the VIGOR trial for testing gastrointestinal effects of Vioxx excluded patients with recent cardiovascular events or on aspirin, confounding results on cardiovascular risks of the drug.^{xiii} As a result, physicians treating arthritis patients with prior cardiac history or at high risk for a cardiac event were unaware the painkiller might increase the risk of heart attack.)
- Pre-approval trials are generally of short duration—a few weeks or months—and often fail to detect risks from the long-term use more likely among elderly patients with chronic conditions.
- **FDA’s weak postmarket surveillance program fails to detect drug risks to the elderly after a drug is on the market**
 - Though pre-approval trials are generally effective in evaluating efficacy, because they include a small number of subjects they often fail to detect safety risks that may become apparent from widespread use. For example, a strong, ‘black box’ warning was placed on certain antipsychotic drugs in April 2005, after an FDA analysis of 17 placebo-controlled clinical trials showed that elderly patients with dementia were 1.6 to 1.7 times more likely to die as those given the placebo.^{xiv}
 - Because the elderly are more likely to be prescribed more drugs, they effectively become test subjects for postmarket safety. “The elderly are basically unstudied guinea pigs in the most-market approval phase of drug distribution,” says Alta Charo, University of Wisconsin professor of medicine and bioethics.^{xv}
 - Once a drug is approved, FDA lacks authority to require drug sponsors to conduct postmarket safety or efficacy studies that could be used to evaluate unique issues facing elderly patients, such as:
 - Long-term trials to detect safety issues not found in pre-approval trials
 - Trials designed to test safety or efficacy in senior population
 - Trials or other scientific studies to test potential interactions of the drug with others commonly prescribed to seniors
 - In addition, once a drug is approved, FDA cannot require the drug sponsor to--

- monitor sales and usage to detect potential safety issues associated with widespread use by seniors;
 - change a label to address specific safety or efficacy questions associated with seniors;
 - conduct physician education to address unique senior-health issues;
 - limit distribution to assure use by patients for which the risk-benefit profile of the drug is acceptable; or
 - take other action to mitigate risk to senior populations.
- The already weak adverse event reporting system for drugs is even less effective at detecting adverse drug reactions in the elderly because seniors use multiple doctors who may not associate an event with a drug prescribed by another physician.

References

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- ⁱ King, Abby, et.al., "Physical Activity Interventions Targeting Older Adults," *Am J. Prev. Med* 1998;15(4):316-333.
- ⁱⁱ Center for Disease Control, National Center for Injury Prevention and Control, <http://www.cdc.gov/ncipc/olderadults.htm>
- ⁱⁱⁱ Ibid
- ^{iv} "Ambulatory Care Visits for Treating Adverse Drug Effects in the United States, 1995-2001," by Dr. Chunliu Zhan, et. al., *Journal on Quality and Patient Safety*, July 2005, p. 372.
- ^v Enough to Make You Sick: Prescription Drug Prices for the Elderly," Families USA, 2003.
- ^{vi} Safran, Dana et. al., "Prescription Drug Coverage and Seniors: Findings from a 2003 Survey," *Journal of Health Affairs*, April 19, 2005, www.healthaffairs.org.
- ^{vii} Kaiser Family Foundation, 2003, www.statehealthfacts.org
- ^{viii} Ibid
- ^{ix} Safran, op. cit.
- ^x Medco Health, 2003 Drug Trend Report, and Kaiser Family Foundation, "Survey Finds Four in 10 Seniors do not take Medications as Prescribed," April 19, 2005..
- ^{xi} Curtis, Lesley, et.al., "Inappropriate Prescribing for Elderly Americans in a Large Outpatient Population," *Arch Intern Med.* 2004;164:1621-1625. August 9, 2004
- ^{xii} "A bitter pill for older patients," by Steve Sternberg, *USA Today*, May 5, 2005. Another example is from the FDA Arthritis Advisory Committee meeting of September 8, 2005 (as reported in the September 12 *Pink Sheet*, during the discussion of Bristol-Myers Squibb's new rheumatoid arthritis therapy Orencia (abatacept). One panel member expressed "concern about the use of abatacept in elderly patients. The average age of patients in pivotal trials (early 50s) is likely significantly younger than the patient population who will be using the product, he noted. "Older people weren't studied here, kids weren't studied here and I think I would be real concerned about vulnerable people getting this therapy." There is a risk of high rates of infection in vulnerable patients, he added.
- ^{xiii} Psaty, Bruce, et.al., "COX-2 Inhibitors: Lessons in Drug Safety," *N Engl J Med* 2005; 352:1133-1135, Mar 17, 2005.
- ^{xiv} "Popular Drugs for Dementia Tied to Deaths," by Gardiner Harris, *New York Times*, April 12, 2005.
- ^{xv} Op.cit., *USA Today*.