Medicine and the market: the Vioxx and flu vaccine debacles

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Two events of the past week have further exposed the official lie—endlessly propounded by the corporate media and the politicians of the Democratic and Republican parties—that "the market" can provide a rational and effective solution to the deepening crisis of health care in the United States.

Last Thursday, September 30, the huge drug company Merck, long one of the most profitable US corporations, announced it was recalling its arthritis drug Vioxx, used by more than two million people worldwide. Merck took the action after a study confirmed what has long been suspected by cardiologists: the drug is associated with a sharply increased risk of heart attack and stroke.

Five days later, on October 5, Chiron Corp. announced that its entire production run of flu vaccine had to be scrapped because of contamination problems, cutting the US supply of vaccine in half only days before the start of the flu season. Federal health officials immediately issued guidelines for cutting back the scope of vaccination campaigns, suggesting a focus on selected high-risk groups, including infants between 6 and 23 months, the elderly, and those suffering from asthma and other respiratory problems.

What connects these two events, which threaten the health of millions of people? Both are byproducts of the subordination of the health care system to the profit motive.

In the case of Vioxx, it is questionable whether the drug should ever have been released to the public. The class of drugs of which it is part, called COX-2 inhibitors, have little demonstrated medical superiority over such proven over-the-counter pain relievers as aspirin and acetaminophen, though they cost 100 times more.

Once they received FDA approval in 1999, Vioxx and its counterparts like Pfizer's Celebrex were heavily promoted as anti-inflammatory wonder drugs free of the gastrointestinal side effects experienced by some aspirin users. Overstated claims were backed by marketing muscle: by one report, a staggering $3.2 billion was spent on advertising and other promotional efforts for COX-2 inhibitors in 2003 alone.

Merck spent $100 million on direct-to-consumer Vioxx advertising in 2003, aimed at pushing arthritis sufferers to ask their doctors to prescribe the drug. It expended $500 million more to promote the drug to doctors and pharmacists and in medical journals. Far more was spent to sell the drug than to conduct research on its safety and efficacy.

The reason is clear: a successful "best-selling" drug is a profit bonanza. Vioxx generated $2.5 billion in worldwide sales for Merck in 2003, 11 percent of the firm's total revenues. A measure of its importance to the company's bottom line is that the news of its withdrawal sparked a sell off in shares that slashed the company's stock market valuation by $27 billion in a single day.

Almost from the beginning, medical professionals have raised questions about the safety of COX-2 inhibitors, particularly for heart patients. Since the drug is believed to work by inhibiting cells that produce anti-clotting factors in the blood, the implications in terms of possible heart attack and stroke are fairly obvious. But no studies on the effects of the drug on heart patients have been done. Nor did the FDA mandate any study of the long-term effects, limiting the required study period for this class of new drugs to 6 to 12 months.

The longer study that produced the latest evidence was commissioned by Merck itself, in an effort to demonstrate that Vioxx had positive effects in reducing the risk of polyps in the colon—a feature that would have have increased the drug's commercial value. But the researchers found such an alarming increase in heart problems after use of Vioxx for 18 months that they urged the company to call off the study and take immediate action.

The study found that the risk of heart attack, stroke or blood clots doubled with the use of Vioxx, compared to patients taking a placebo. News accounts have described the increased risk as "small," but the numbers do not bear this out.

Those taking Vioxx experienced 15 heart-related incidents per thousand people over three years, compared to 7.5 events for those not taking Vioxx. Given that 2 million people currently take the drug, that suggests an additional 15,000 heart attacks, strokes or blood clots over a three-year period. Even Merck's own chief scientist described the finding as "stunning" and urged immediate recall of the product.

According to a paper released October 6 by the *New England Journal of Medicine*, the toll from Vioxx may be even higher. Co-author Eric Topol wrote that "it is possible that there are tens of thousands of patients who have had major adverse events attributable to" the drug. In a subsequent comment to the press, Dr. Topol put the number at 30,000 to 100,000.

The other factor in the recall decision was the rising number of lawsuits by patients alleging harm from the drug. More than 200 lawsuits had been filed before Vioxx was recalled.

Despite these legal actions, critical articles in medical journals and studies that suggested, but did not conclusively prove,

heightened cardiac risks, the FDA merely required Merck to add a warning about possible heart complications to its warning label. The agency did not order any safety studies, despite the large number of prescriptions—more than 84 million—issued for the drug.

This is in keeping with the Bush administration's general approach to regulation of business, which has been to sabotage federal oversight when it cannot abolish it altogether. Though spending on drug promotion has increased relentlessly, the FDA has cut the number of warning letters issued for misleading drug advertising from 82 in 2000 to 24 in 2003. While 11 prescription drugs were recalled for safety reasons in 1997-2001, no drug had been recalled since then, until Merck voluntarily recalled Vioxx last week.

In the case of influenza vaccine, the immediate cause of the supply disruption, according to Chiron Corp., the manufacturer, was accidental contamination at its plant in Liverpool, England. Chiron initially reported that it was discarding a lot containing 6 to 8 million doses, but after British regulators visited the plant the whole production line was shut down pending further investigation. The contaminant was a bacteria called Serrati, which can cause severe and even fatal infections.

Chiron CEO Howard Pien blamed the contamination on human error in the drug's processing. But there is no question that profit considerations underlie the debacle, which has wiped out half of the 100 million doses of injectable vaccine required for the US flu season.

There are only two companies licensed by the FDA to make flu vaccine for the US market, Chiron and Adventis-Pasteur of France.

Vaccine production is an inherently marginal business for a profit-making company, because of the long lead times required in the production process—it takes about six months to grow live viruses in chicken eggs—and because demand varies erratically based on the intensity and scope of the flu season worldwide.

The big US drug company Wyeth stopped making injectable flu vaccine several years ago, focusing instead on a nasal spray vaccine developed by its MedImmune subsidiary. The nasal spray costs five times as much and is not approved as safe for small children or the elderly, the most critical target group for flu vaccination.

Many vaccines for other diseases also have a similarly fragile infrastructure, with a few suppliers, or only a single one, for similar reasons: market forces prevail over the enormous social need for an adequate supply. It is not commercially profitable to produce additional vaccine to assure that there will always be enough on hand, even in case of an epidemic.

The flu vaccine supply crisis underscores the hypocrisy of the Bush administration's opposition to allowing the American public to purchase prescription drugs from foreign suppliers, especially those based in Canada. Tommy Thompson, Bush's secretary of health and human services, claims that the FDA cannot assure that drugs from Canadian pharmacies are safe, and the FDA has threatened prosecution of cities, states and individuals who have sought to purchase such drugs by mail-order or over the Internet.

The reality is that pharmaceuticals are a global market and the big drug companies operate without regard to national boundaries. Chiron, for instance, based in California, acquired the British company PowderJect last year and invested heavily to ramp up production at the Liverpool plant, 90 percent of it exported back to the US. Chiron is itself 40 percent owned by Novartis, the huge Swiss-based pharmaceutical maker.

The Bush administration policy has nothing to do with safety. It has a crass commercial purpose: to protect the profits of the US-based drug manufacturers, who have a captive market in the American population, compelled to pay prices two or three times the level elsewhere.

The common thread in both of these episodes is that medical professionals have repeatedly issued warnings. They were disasters not only foreseen, but foretold over and over again, but to no avail.

Dr. Topol, head of cardiology at the Cleveland Clinic, a leading heart institute, wrote scathing critiques of Vioxx more than three years ago, arguing that the COX-2 inhibitors were essentially worthless, offering "marginal efficiency, heightened risk, and excessive cost" compared to aspirin and other cheap alternatives. Similar warnings were made about the insufficiency of the supply system for flu vaccine.

Such alerts, even from the most prestigious medical authorities, counted for little compared to the profits of giant transnational corporations. As Dr. Topol noted in a column last week in the *New York Times*, there is "a conflict between the interests of the public and the interests of a company with a blockbuster drug that had sales of $2.5 billion in 2003."

This conflict is inherent in the profit system. It can be resolved only by putting an end to that system, and placing the provision of medical care on a civilized and humane basis. Medical care, including the supply of prescription drugs, must be a basic human right, provided free to all who need it, at state expense. This program of socialized medicine requires placing the pharmaceutical companies and the other giant corporations that dominate health care—insurance, medical supply, hospital management, etc.—under public ownership and democratic control.