

# WSJ: Just-in-Time Inventories Make U.S. Vulnerable in a Pandemic

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Margin of Safety  
Just-in-Time Inventories Make U.S. Vulnerable in a Pandemic  
Low Stockpiles at Hospitals Boost Efficiency but Leave No Extras for  
Flu Outbreak  
A Run on Protective Masks

By BERNARD WYSOCKI JR. and SARAH LUECK  
Staff Reporters of THE WALL STREET JOURNAL  
January 12, 2006; Page A1

Like many big hospitals, the University of Utah Hospital carries a 30-day supply of drugs, in part because it would be too costly or wasteful to stockpile more. Some of its hepatitis vaccine supply has been diverted to the hurricane-ravaged Gulf, leaving it vulnerable should an outbreak occur closer to home. About 77 other drugs are in short supply because of manufacturing and other glitches, such as a drug maker shutting down a factory.

"The supply chain is horribly thin," says Erin Fox, a drug-information specialist at the Salt Lake City hospital.

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In the event of a pandemic flu outbreak, that chain is almost certain to break. Thousands of drug-company workers in the U.S. and elsewhere could be sickened, prompting factories to close. Truck routes could be blocked and borders may be closed, particularly perilous at a time when 80% of raw materials for U.S. drugs come from abroad. The likely result: shortages of important medicines -- such as insulin, blood products or the anesthetics used in surgery -- quite apart from any shortages of medicine to treat the flu itself.

The very rules of capitalism that make the U.S. an ultra-efficient marketplace also make it exceptionally vulnerable in a pandemic. Near-empty warehouses are a sign of strong inventory management. Production of drugs takes place offshore because that's cheaper. The federal government doesn't intervene as a guaranteed buyer of flu drugs, as it does with weapons. Investors and tax rules conspire to eliminate redundancy and reserves. Antitrust rules prevent private companies from collaborating to speed development of new drugs.

Most fundamentally, the widely embraced "just-in-time" business practice -- which attempts to cut costs and improve quality by reducing inventory stockpiles and delivering products as needed -- is at odds with the logic of "just in case" that promotes stockpiling drugs, government intervention and overall preparedness.

A report issued last month by the Trust for America's Health, a public-health advocacy group in Washington, concluded that 40% of the states lack enough backup medical supplies to cope with a pandemic flu or other major disease outbreak.

"Most if not all of the medical products or protective-device companies in this country are operating almost at full capacity," says Michael Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota. "That's the reality of today's economy: just-in-time delivery with no surge capacity."

The U.S. government says it is trying to address the problem, elevating the possibility of a flu outbreak to a national security concern. Rajeev Venkayya, a special assistant to President Bush for biodefense, says the pandemic flu threat calls for a national response similar to a "moonshot," alluding to the successful 1960s Apollo program.

President Bush has vowed to spend \$2.8 billion to help jump-start development of a next-generation cell-culture flu vaccine. Currently flu vaccine production relies on a decades-old process of growing viruses in individual fertilized chicken eggs. The viruses are inactivated to make a vaccine.

Cell-culture technology means the viruses are grown in living cells --

often mammalian kidney cells — that multiply on their own. The technology is already used in producing vaccines against hepatitis, chickenpox and shingles. In theory, cell-culture technology should allow manufacturers to produce enough flu vaccine for every American within six months of the start of a pandemic.

The Securities and Exchange Commission recently said it will allow companies to book revenue on sales of vaccines or bioterrorism remedies to the government, even if the companies hold onto the stockpile — as the U.S. government often prefers. Under current accounting rules, companies must ship the product to record the revenue, a major disincentive for vaccine manufacturers.

Yet those steps largely fail to address weaknesses in the supply chain. The severe acute respiratory syndrome outbreak in 2003 in Canada offers a case in point. When SARS hit, the country's largest nurses' union complained about a shortage of N95 masks after much of the existing supply was shipped to Asia, where the disease hit hardest.

These masks protect against contracting flu by filtering out at least 95% of certain airborne materials during normal breathing. Some nurses in Canada had to use less-protective masks when caring for SARS patients. Others were rationing the supply. In some cases, they were told to save their masks in plastic bags and reuse them from one shift to the next, Barbara Wahl, former president of the Ontario Nurses' Association, told a Canadian commission investigating SARS in 2003.

The main companies that manufacture the masks — 3M Co. and Kimberly-Clark Corp. — had to scramble to meet the sudden demand because, like many companies, they didn't have an existing stockpile.

The outbreak was relatively brief and limited in location — a minor blip compared with what would likely happen with pandemic flu.

'Albertson's Syndrome'

Supply-chain breakdowns are one reason the economy could go into a tailspin should there be a pandemic flu outbreak. A Congressional Budget Office study of the economic impact of a severe pandemic, released late last year, estimated a nearly \$700 billion hit to the U.S. economy, or about a 5% decline in economic output during a one-year span, about equal to a medium-sized recession.

One significant concern is what Michael Leavitt, the secretary of health and human services, described in an interview as the "Albertson's syndrome," referring to the grocery-store chain. At the first sign of panic, all supplies disappear from shelves, something that routinely happens when there is the threat of even a modest storm.

The Grocery Manufacturers Association, which represents food retailers

and distributors, estimates that the time it takes for manufacturers and wholesalers to deliver on a retailer's order has shortened to fewer than four days from nearly eight days in 1999. Respondents to an association survey "are targeting even shorter cycle times of three days," the survey said. Rick Blasgen, a former ConAgra Inc. executive and chief executive of the Council of Supply Chain Management Professionals, says food retailers and producers "can't afford just-in-case inventory."

The issue of stockpiling extends beyond food to vaccines. The U.S. government has generally been reluctant to pay companies to produce extra vaccines and create a reserve capacity. It's one reason so many companies have dropped out of vaccine manufacturing. In the case of flu vaccines, there is too much wasted medicine in "good" years, when the flu season isn't severe and people choose not to get vaccinated. Vaccines are tossed away at a loss for the corporations.

"Investors punish companies for having excess capacity they don't use," says Dr. Osterholm.

Today's worrisome flu strain, known as H5N1, has infected and killed millions of poultry, and killed about 70 humans in Asia. Recently it has spread to Turkey and infected at least 15 people there. Nobody knows if the H5N1 virus will mutate in ways that promote human-to-human transmission, which is what health officials fear would trigger a pandemic. A vaccine produced by Sanofi-Aventis SA has proved effective against H5N1 in early trials in humans, but the company hasn't scaled up manufacturing of it. Food and Drug Administration-approved antiviral medications, which could treat exposed individuals, are in short supply.

To some former Pentagon officials working on biodefense on Capitol Hill, the only way for the country to prepare for a possible pandemic is to think of health-care preparedness in military terms. This means moving away from a just-in-time system to planning for a just-in-case scenario in the manner of national-security policy makers.

The Pentagon, for instance, goes through intense planning and pays for reserves of everything from bullets to jet fuel. It even forces rivals to collaborate on Pentagon projects and wields its clout as a buyer of weapons.

Some steps are in motion to take pages out of the Pentagon playbook. A bill introduced last fall by North Carolina Republican Sen. Richard Burr would provide some relaxation of the antitrust laws. It would allow the government to convene meetings with drug makers to discuss manufacturing and distributing biodefense products including those related to pandemic flu.

Current Law

Industry executives say they feel that under current law, companies can't share basic knowledge that would be helpful in planning for an outbreak. "What we're suggesting to the administration is something discretionary and only under declaration of an emergency," says Billy Tauzin, a former congressman from Louisiana who now heads the pharmaceutical industry's leading trade organization.

Mr. Tauzin, though, also hinted at going a tad further, saying it would be helpful if "the administration determines to allow two of our companies to collaborate on a product — an antiviral or vaccine or similar product." Such proposals might raise worries about collusion in an industry that already enjoys considerable pricing power and patent protection on its products.

Some experts suggest the U.S. government should promise to purchase a fixed amount of flu vaccine — despite the cost and the likelihood that some of the money would end up being wasted. Canada, for instance, has contracts with vaccine makers to cover most of its population. The largest contract is with ID Biomedical Corp. (recently acquired by GlaxoSmithKline PLC) for about eight million flu vaccine doses per year. That takes much of the risk out of the company's business, but still lets it manufacture additional doses for the private market or for other needy buyers.

Dr. Osterholm has called for a program of "critical product continuity" to see the U.S. through the worst of pandemic disruption. He proposes identifying items that are essential to people's health and safety and then finding a way, possibly through government funding or tax incentives, to create emergency stocks or extra production capacity for them. High on his list of "critical products" are tools for fighting flu itself, such as face masks, ventilators to help the sickest patients survive and syringes to administer a vaccine if one becomes available.

In a pandemic, Dr. Osterholm says, "if we don't sell automobiles or jewelry...that wouldn't be the same as running out of critical medicines." He likens his idea to the well-equipped fire departments at international airports, which don't respond to many crises but are ready if a plane crashes.

Dr. Osterholm, who also is associate director of the Department of Homeland Security's National Center for Food Protection and Defense, says the country also needs reliable supplies of food and water, the ability to keep heat working in northern climates and medical products for non-flu-related illnesses. The U.S. has 105,000 ventilators, most of which at any given time are in use. The federal stockpile of medical products has about 4,500 more. In a pandemic, tens of thousands more would be needed.

The federal government has allocated grants worth \$5 billion over three

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years to states and hospitals to increase medical preparedness, including surge capacity at hospitals. But the money was used for other priorities as well, such as improving medical labs and disease surveillance. Not all of it has been spent.

"You can't plan for a surge capacity in an emergency room of 500 or 1,000 patients from the 20 you see in a day," says Michael Bishop, a Bloomington, Ind., emergency physician who used to be on the board of directors for the national trade association for emergency physicians. "Nobody could afford to do that. You can't have 10 doctors and 100 nurses sitting around waiting for something to happen."

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• ***Follow-Ups:***

◆ ***Re: WSJ: Just-in-Time Inventories Make U.S. Vulnerable in a Pandemic***

◇ *From:* johngohde@xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

◆ ***Re: WSJ: Just-in-Time Inventories Make U.S. Vulnerable in a Pandemic***

◇ *From:* chamgroup

• Prev by Date: ***Re: Acid, Base, Water & Temp. Balance?***

• Next by Date: ***Does anyone know if mucus is biodegradable (does it break down)?***

• Previous by thread: ***Corpus et Animus news (body and soul news)***

• Next by thread: ***Re: WSJ: Just-in-Time Inventories Make U.S. Vulnerable in a Pandemic***

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