New US legislation aims to curb cancer drug shortages (Update)

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A critical shortage of generic drugs in the United States, particularly in cancer care, could be curbed with legislation now being hammered out by the US House and Senate, doctors said on Monday.

Similar versions have passed each chamber and may be reconciled in time for President Barack Obama to sign them this month or next, said a panel of experts at the American Society of Clinical Oncology (ASCO) annual meeting.

The law would require generic drug makers to pay user fees to federal regulators for the first time -- a payment that pharmaceutical companies already make for brand name drugs -- in exchange for the promise of faster drug approval.

It would also require manufacturers to notify the US Food and Drug Administration six months in advance of any potential shortage.

However, a provision to impose cash penalties on companies that do not comply has gained little traction on Capitol Hill and is not likely to be included, said Richard Schilsky, chair of ASCO's government relations committee.

"We are never exactly sure when a generic drug is suddenly going to go out of supply and that creates a tremendous amount of uncertainty, anxiety for our patients, (and) great difficulty in planning if you are a physician," said Schilsky, a medical oncologist at the University of

Chicago.

"We have concerns about the fact that if there are no teeth in that legislation some companies may decide not to report as required," he said.

But Schilsky said the addition of generic drug user fees for the first time would likely "bring about 1.5 billion dollars to the FDA in additional resources over the next several years.

"That should reduce the review time for a new drug application to market a generic drug from about 30 months to 10 months or less, which would be a huge step forward in terms of getting new manufacturers into the game and getting drugs onto the market."

While the shortage situation has improved slightly in recent months, experts say the market remains volatile due to economic concerns and manufacturing woes that can suddenly remove a much-needed cancer drug from the US market.

The FDA has said the number of shortages of prescription drugs nearly tripled between 2005 and 2010.

Often, the drugs affected are generics that have been on the market for many years, and some have no acceptable medical substitutes, which can threaten patient care.

"Manufacturing and drug quality problems have accounted for and continue to account for the majority of drug shortages," said Sandra Kweder, deputy director of the FDA's Office of New Drugs.

Kweder said the closure of a single facility due to quality problems can spark dozens of shortages at the same time.

Popular chemotherapy drugs Mustargen, paclitaxel, and fluorouracil are among those recently affected by shortages, experts said.

"There have been problems in many of these products with things like particles of glass or metal shavings in the vials. Those are not quality problems that can be tolerated on any large scale or for any individual patient," she said.

"No patient should ever be exposed to risks of those sorts. It is not acceptable."

Obama signed an executive order in October 2011 to boost the FDA's power to predict and tackle potential shortages of prescription drugs and to halt illegal price gouging of life-saving medicines during supply shortfalls.

Kweder said the measure had prevented more than 150 drug shortages, and hailed "important progress" made by FDA in the last six months.

However, she said the FDA remains "extremely concerned about all of the current and potential drug shortages" in oncology care.

"We are not out of the woods yet by any measure," said Michael Link, a doctor at the Stanford University School of Medicine.

"Over past two years, 22 oncology therapies are or have recently been in short supply," added Link, who is the president of ASCO.

"We are seeking long-term solutions to ensure that the shortages are no longer a threat to patients."