Reps. Carney and Bucshon announce new bipartisan legislation to address prescription drug shortages

WASHINGTON — U.S. Representatives John Carney (D-DE) and Larry Bucshon (R-IN) today introduced the *Drug Shortage Prevention Act,* to address the scarcity of certain pharmaceutical drugs in the marketplace.

In 2005, there were 61 different drug shortages. In 2010, that number was 178. Last year, there were more than 230 different drug shortages. Cancer drugs, anesthesia drugs, and nutrition medicines are overwhelmingly affected by these shortages. Those drugs are delivered intravenously, as opposed to in a pill form, and the manufacturing process is complex, time-consuming, and highly precise. Many of these drugs have only one or two manufacturers in the market, so when a manufacturing problem occurs, it can quickly cause a shortage.

The legislation mandates expedited review of drugs vulnerable to shortage in order to prevent shortages in the first place and it requires FDA to a use more refined regulatory process that addresses manufacturing problems without instigating drug shortages. The bill also streamlines communications between FDA, manufacturers, distributors, providers, and patients to ensure that all parties have the information they need to act proactively – instead of reactively – to prevent shortages from occurring.

The Drug Shortage Prevention Act has been endorsed by the American Society of Clinical Oncology, the American Society for Parenteral and Enteral Nutrition, AstraZeneca, and the Hematology/Oncology Pharmacy Association.

“Since 2005, the number of drug shortages in the United States has quadrupled, and cancer patients have been disproportionately impacted by this troubling trend,” said Congressman Carney. “We must ensure that Americans have access to the critical drugs they need to stay healthy and fight back against deadly diseases. The Drug Shortage Prevention Act brings more efficiency to the manufacturing and distribution processes and requires the FDA to take action to prevent drug shortage problems before they begin impacting patients.”

“As a physician, drug shortages for patients who need specialized care is a critical issue that deals directly with the well-being of our citizens,” said Congressman Bucshon. “It is vital that we are proactive when it comes to preventing shortages and ensuring access to treatments that save lives and improve health. I am proud to work across the aisle with my colleague from Delaware on an issue of national importance that will truly improve the quality of life for the American people.”

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BACKGROUND INFORMATION

The *Drug Shortage Prevention Act* takes the following steps to solve the problems at the root of the drug shortage crisis:

- **Problem**: According to an October 2011 report by FDA, manufacturing problems and shortages of active pharmaceutical ingredients (API) were the primary causes of over half of the drug shortages between 2010 and 2011. However, FDA is not currently required to identify or perform special monitoring on drugs that are vulnerable to shortage (those with few manufacturers or API sites). Thus, FDA is reactive, rather than proactive, in preventing drug shortages.

  Solution: Requires FDA to work with stakeholders to develop a Critical Drug List, which will identify drugs that are vulnerable to shortage.

- **Problem:** While FDA works closely with the manufacturer of a drug in shortage, distributors of the drug often do not learn of a shortage until their requested shipment does not arrive. If distributors were made aware of imminent drug shortages, they could take steps to reallocate supply to postpone and mitigate the effects of a shortage.

  Solution: Requires FDA to notify distributors of an imminent critical drug shortage. Distributors will then be on the alert for secondary buyers who may be attempting to hoard drugs and sell them on the grey market. Distributors will be better positioned to keep the critical drug out of the hands of grey market participants. If a wholesale distributor is determined by the Attorney General to be participating in stockpiling, price gouging, or other unlawful activities related to the distribution of a critical drug, FDA must withhold notification to that distributor until the Attorney General determines that the distributor is no longer participating in such activities.

- **Problem:** Some physicians do not learn about a drug shortage until they attempt to use the drug on the operating table. Clinical trials across the country are facing disruption because hospitals do not learn of a critical drug shortage until the shipment fails to arrive at the hospital pharmacy.

  Solution: Requires FDA to develop a system to notify members of the public (doctors, patients, etc.) on an opt-in basis when a drug is added to the Critical Drug Shortage List.

- **Problem:** While FDA currently offers expedited processes for inspecting or approving manufacturing sites for drugs that are in shortage, this expedited review does not extend to drugs that are vulnerable to shortage. If a drug has only two manufacturing sites, and one manufacturing site shuts down, even temporarily, a shortage can ensue. To prevent a shortage, FDA needs to lower the barriers for manufacturing drugs or APIs that are vulnerable to shortage.

  Solution: Requires FDA to expedite the review of any application seeking approval of a critical drug (one that is vulnerable to shortage and on the critical drug list). Requires expedited review of any request by a manufacturer of a critical drug to approve a change to the manufacturing process or facilities of that drug or to approve an application for an alternate active pharmaceutical ingredient supplier.

- **Problem:** As a result of an inspection, a manufacturing site may be forced to completely halt operations until the problem is resolved. A regulatory action taken against a drug vulnerable to shortage can precipitate a shortage.

  Solution: Requires FDA to improve communications between the regulatory offices and drug shortage office within FDA. Requires FDA to communicate any new regulatory concern identified about a critical drug within 1 business day to the FDA drug shortage office. Requires FDA to communicate any new regulatory concern about a critical drug within 5 business days to the manufacturer of that critical drug.

- **Problem:** The Drug Enforcement Agency (DEA) currently sets quotas for controlled substances production. Some drug shortages involve these controlled substances, but manufacturers who have already manufactured their quota of that substance for the year can't continue producing the drug, despite the shortage. DEA currently has authority to raise quotas, but it has not done so consistently or in a timely manner during shortages.

  Solution: Requires FDA to notify DEA of any critical drug on the critical drug shortage list and provide information to the Attorney General to allow for the determination of whether it is appropriate to increase one or more quotas under the Controlled Substances Act in order to address the shortage. If a drug on the critical drug shortage list contains or is a controlled substance subject to a quota, DEA must increase the quota, in consultation with FDA, to address the critical drug shortage.

- **Problem:** The U.S. does not have a national contingency plan to cope with a drug shortage crisis like the one we are currently experiencing.

Solution: Requires the Secretary of Health and Human Services to conduct a feasibility study to determine the efficacy of and logistics associated with creating a national contingency plan in the event of a critical drug shortage, including the creation of a national stockpile of drugs or expanding an existing national stockpile to respond to potential critical drug shortages.

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