

FDA bill: changes to FDA drug and device oversight

The Associated Press

The Senate passed a mammoth bill Thursday that would reshape how the Food and Drug Administration assures the safety of the drug supply, particularly medicines imported from overseas.

The underlying bill is a must-pass piece of legislation because it extends the 20-year program which helps fund the FDA's budget for reviewing new drugs and medical implants. But lawmakers added dozens of additional provisions influencing FDA policies and the drug industry itself. Here's a look at some of the key changes proposed by the bill:

BREAKTHROUGH DRUGS: Allows the FDA to speed up the approval of drugs that appear to have breakthrough potential by relaxing certain requirements. The agency would be able to approve drugs based on smaller, shorter clinical studies, in order to accelerate approval of innovative medicines for life-threatening diseases.

OUTSIDE INSPECTORS: Allows drugmakers to hire non-government inspectors to visit factories and assess whether they are meeting U.S. quality standards. While these would not take the place of FDA inspections, they could be submitted to regulators to bolster a company's safety profile.

DEVICE APPROVALS: The FDA would be required to provide a rationale for denying clearance of low-risk medical implants within 30 days of issuing a rejection. This provision was supported by medical device lobbyists who complain the FDA has become overly cautious and unpredictable when reviewing routine medical devices.

DRUG TRACKING SYSTEM: Lawmakers were unable to reach an agreement on a comprehensive network for tracking drug shipments which experts say is needed to combat drug counterfeiting and tampering.

For more than a decade, public safety advocates have pushed for a system that would track individual bottles and vials from the factory to the pharmacy using electronic tags or barcodes. Supporters of tracking system say it would help prevent counterfeit drugs from entering the system.

Despite much discussion, the system was not detailed in the bill due to disagreements between the FDA and industry over its scope and cost. Instead, lawmakers inserted placeholder language, in the hopes that an agreement can be reached in coming weeks.

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