Improving Generic Competition – Collins Amendment

On average, generic drugs cost 80 to 85 percent less than brand name drugs. Increasing generic drug competition is one of the most successful ways to lower prescription drug prices and reduce drug spending. This amendment aims to provide more regulatory certainty to enhance generic competition and improve transparency.

The amendment takes a number of steps to foster a competitive marketplace to help keep drug prices down and improve access to affordable prescription drugs for patients.

- First, the amendment would set a clear timeframe of no more than eight months for the FDA to prioritize the review and act on applications where there is inadequate generic competition. This would capture drug shortages and circumstances where there are not more than three approved drug products being marketed. The Aging Committee's investigation into sudden price spikes last year found that older drugs with only one manufacturer and no generic competitor are particularly vulnerable to dramatic and sudden price increases.
- Second, through new reporting requirements, the amendment would improve visibility of the backlog and pending generic applications, priority review applications, average approval times, and facility inspection timeliness, helping to ensure that Congress can perform more oversight of the generics program.
- Third, to provide additional support and improve communication with certain applicants to help improve the quality of applications from the beginning, the amendment would establish a process for communications in advance of the actual ANDA submission.
- Finally, the amendment would set a clear timeframe for FDA to act on facility inspections after an applicant has notified FDA that they have taken necessary actions to resolve identified issues.

The amendment sets forth a priority review timeline for generic applications, provides enhanced communications with eligible sponsors, improves transparency, and sets clear expectations about facility inspections. By taking these steps, Congress will improve certainty for generic drug companies, help prevent future shortages, increase competition to lower prices and avoid monopolies, and deter practices that can lead to exorbitant price hikes on drugs that had been affordable for decades.

Summary

Improving generic access with set timelines for priority review. Under this section, FDA would be required to prioritize the review of certain generic applications within eight months (240 days), including for: (1) a drug where there are not more than three approved drug products; or (2) a drug that is on the drug shortage list. Applicants would be required to submit complete, accurate information regarding facilities involved in manufacturing processes and testing 60 days prior. Under this section, the Secretary could allow for the inspection or re-inspection of a manufacturing facility to be expedited. Finally, FDA would be required to provide generic applicants with status updates, including when an application is awaiting final regulatory action.

Improve transparency in FDA reporting about the backlog and pending generic applications, priority review applications, and facility inspections. This section would require that FDA make public on a quarterly basis:

- The number of ANDA applications filed prior to October 1, 2014, that are still pending (this includes applications without goal dates); the average and median time such applications have been pending; the number of such applications that contain a "paragraph iv" certification; and the number of such applications that are subject to priority review.
- The number of ANDAs withdrawn in each reporting month; the tentative approval times for applications approved in the quarter; and the number of applications where FDA has taken action under the new expedited review.

FDA would be required to report annually to the relevant committees:

- The number of applications subject to priority review, including first generics, sole-source, and shortage drugs.
- The time it takes to schedule and complete facility inspections.

Expediting generic drug development. This section would establish a process for improving communication with the sponsor to help accelerate the approval process in advance of the actual ANDA submission for a drug with three or fewer competitors. At the request of a sponsor, FDA would expedite the review of an application, including through additional communications between FDA and the applicant, as appropriate. This would include meetings, as appropriate, prior to the submission of the application; timely advice and communication to ensure collection of data necessary for approval is as efficient as practicable; for complex products, it would mean assigning a cross-disciplinary project lead to facilitate efficient, collaborative, cross-disciplinary review. A sponsor of drug expedited under this section would report to FDA one year following approval on whether the drug has been marketed.

[Closing a loophole in the priority review voucher program for neglected tropical diseases that Mr. Shkreli tried to exploit. The amendment seeks to ensure that a voucher is only granted to a company that did substantial new research, not for research that was done decades ago by another company.]

[***List of actively marketed drugs***.]

Suitability petitions. This section includes a sense of the Senate that FDA fulfill its existing statutory requirement by responding to suitability petitions within 90 days. It would also require FDA to report publicly on a quarterly basis on the number of pending petitions and the number that have been pending longer than 180 days. (Note: a suitability petition is a process used by an applicant to allow for changes from the original reference listed drug (RLD), including a different active ingredient in a combination product in which the other active ingredients match those of the RLD, or for a different route of administration, dosage form, or strength.)

Inspections. This section aims to help applicants have a clear timeframe for FDA's response back to them after an applicant has taken corrective action in response to a facility assessment issue identified by FDA. Under this section, in circumstances where an applicant has responded to an inspection finding indicating that necessary changes have been made to the facility, FDA would be required to either re-inspect the facility or make a determination about the applicant's response and whether to approve the application. This would only be for cases where the only obstacle to approval of an application is the inspection funding or where FDA has determined that approving an application is a public health benefit.