TOM COTTON
ARKANSAS

SUITE SR-B33
RUSSELL SENATE OFFICE BUILDING
WASHINGTON, DC 20510
PHONE: (202) 224-2353
FAX: (202) 228-0908

United States Senate

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February 25, 2016

Robert Califf, MD
Acting Commissioner
U.S. Food and Drug Administration
10901 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Califf:

In light of Arkansans facing rising costs of prescription drugs, I'm writing to express my support for FDA's critical role in increasing competition in the generic drug market to lower the costs of life-saving pharmaceutical treatments. Prescription drug costs in Arkansas have increased to more than to $2.5 billion in 2014, and more market competition could relieve some of this burden on hard-working Arkansans.

Academic studies and experience has shown that every time a new generic drug enters the market, prices significantly drop. After the second generic is approved by the FDA, prices often decline by more than half.

Currently, there are roughly 3,875 Abbreviated New Drug Applications (ANDAs) pending approval at the FDA Office of Generic Drugs. This backlog has the affect of limiting market competition and contributes to the increase in prescription drug costs.

Since the enactment of the Generic Drug User Fess (GDUFA) in 2012, FDA has collected $1.5 billion in revenue, hired over 1,000 new employees, and created the Office of Generic Review to ensure timely reviews and increase ANDA approvals. However, contrary to the intention of GDUFA, we have seen a decrease in generic drug approvals and an increase in the average review time over the last 3 years.

As an urgent matter of public health, I ask for clarification on this so Congress may better address this pressing issue.

I. Backlog Definitions

- The agency has stated its goal to eliminate the backlog – how are you defining elimination?
- If the Agency is defining elimination in terms of actions beyond approval or withdrawal of an application (such as a tentative approval (TA) or complete response letter (CRL)), how long does the Agency anticipate it will take to respond to each of the current 3,875 ANDAs with either an approval, a rejection, or a withdrawal of the application?
- To what extent does the Agency identify and prioritize approving the second, third, and fourth generic to increase the number of generic competitors?

JONESBORO
300 SOUTH CHURCH, SUITE 338
JONESBORO, AR 72401
PHONE: (870) 933-6223
FAX: (870) 933-6590

SPRINGDALE
1108 SOUTH OLD MISSOURI ROAD
SUITE B
SPRINGDALE, AR 72764
PHONE: (479) 751-0879
FAX: (479) 927-1092

LITTLE ROCK
11809 HINSON ROAD
SUITE 100
LITTLE ROCK, AR 72212
PHONE: (501) 223-9081
FAX: (501) 223-9105

EL DORADO
106 WEST MAIN STREET, SUITE 410
EL DORADO, AR 71730
PHONE: (870) 864-8582
FAX: (870) 864-8571

II. Backlog Data

- How many first generic applications and shortage applications are currently in the backlog?
- How does the expedited review process differ than the standard review process? Are there substantive differences during the actual review, or only a change in order within the queue?
- What is the average approval time for applications going through the expedited review process vs. the standard review process? How has this changed in recent years?

III. Resources & Funding

- Can you provide an accounting of how FDA has spent the fees it has received through GDUFA? What proportion of these fees have gone towards personnel costs?

Thank you for your prompt response to these important questions.

Sincerely,

Tom Cotton

Tom Cotton
United States Senator