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LOUISIANA
DEPUTY WHIP
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Immigration, Refugees and
Border Security Subcommittee
Deputy Chairman
Banking, Housing, and Urban Affairs

United States Senate
WASHINGTON, DC 20510

WASHINGTON, D.C.
Hart Senate Office Building
Suite SH-516
Washington, DC 20510
(202) 224-4623
Fax: (202) 228-5061

BATON ROUGE
858 Convention Street
Baton Rouge, LA 70802
(225) 383-0331
Fax: (225) 383-0952

Website with
E-Mail Access: vitter.senate.gov

September 28, 2015

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

Dear Acting Commissioner Ostroff:

The problem of soaring drug prices is receiving increased attention given its detrimental, direct impact on health care consumers and its contribution to the increasing cost of health care. Currently, there is a tremendous backlog of applications from manufacturers for approval by the Food and Drug Administration (FDA) of generic drugs. I urge you to make this issue a top priority and to dedicate enough resources to eliminate the backlog.

Most recently, we have seen the press accounts of the extreme jump in the price of the drug Daraprim (primethamine), which is used to treat a potentially life-threatening parasitic infection. Turing Pharmaceuticals LLC recently purchased this drug and increased its price from $13.50 per tablet to $750 a tablet, according to *The New York Times*, although the company has since indicated it has lowered the price somewhat. Previous owners of the drug also increased its price and there are other instances of huge price increases for other drugs by manufacturers.

While public pressure is being applied on Turing Pharmaceuticals over the exorbitant price increase for Daraprim, my concern is the functioning of a free market for pharmaceuticals and the role of the FDA in that market. Monopoly control over specific drugs does occur on occasion, and the solution is competition, especially from the generic drug industry. In this case, Daraprim was approved by the FDA in 1953 and, like other drugs that have long been off patent, it is a prime candidate for manufacture and distribution in its generic form, which brings me to my main point of concern.

Earlier this year, the *Wall Street Journal* reported that the FDA's Office of Generic Drugs had a backlog of over 3,000 applications from manufacturers for approval of a generic drug. As you know, an overly lengthy approval process is detrimental to drug manufacturers which must plan for product launches, but most importantly, it harms consumers who are forced to pay higher drug prices. The bottom line is that this extensive backlog serves as a major obstacle to a market-based, competitive response to manufacturers who choose to run up prices. This is unacceptable.

ACADIANA
2201 Kaliste Saloom Road
Suite 201
Lafayette, LA 70508
(337) 993-9502
Fax: (337) 993-9567

CENTRAL LOUISIANA
6501 Coliseum Boulevard
Suite 700-A
Alexandria, LA 71303
(318) 448-0169
Fax: (318) 448-0189

NORTHEAST LOUISIANA
1651 Louisville Avenue
Suite 148
Monroe, LA 71201
(318) 325-8120
Fax: (318) 325-9165

NORTHWEST LOUISIANA
920 Pierremont Road
Suite 113
Shreveport, LA 71106
(318) 861-0437
Fax: (318) 861-4865

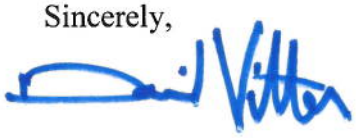
SOUTHEAST LOUISIANA
2800 Veterans Boulevard
Suite 201
Metairie, LA 70002
(504) 589-2753
Fax: (504) 589-2607

SOUTHWEST LOUISIANA
949 Ryan Street
Suite E
Lake Charles, LA 70601
(337) 436-0453
Fax: (337) 436-3163

Competition by drug manufacturers in an efficient, responsive market is the solution to the problem we currently see regarding unscrupulous players attempting to establish monopoly control over specific drugs. Downward pressure on prices through competition from generic drug makers is especially important, as evidenced by the fact that 86% of all prescription filled in the United State are for generics, according to the IMS Institute for Healthcare Informatics. I urge you to give this issue top priority and to focus the necessary agency resources on review and decision-making regarding the generic drug approval applications you have received.

Additionally, I urge that approval requests be fast tracked for generic drugs that may potentially provide immediate relief from high prices due to market manipulation or exploitation. Such action by the FDA will benefit American health care consumers in a time where such assistance is undoubtedly needed.

Sincerely,



David Vitter
U.S. Senator