Congress of the United States
Washington, DC 20515

April 1, 2019

The Honorable Sanford D. Bishop, Jr.
Chairman
Subcommittee on Agricultural, Rural Development and Related Agencies
2407 Rayburn House Office Building
Washington, DC 20515

The Honorable Jeff Fortenberry
Ranking Member
Subcommittee on Agricultural, Rural Development and Related Agencies
1514 Longworth House Office Building
Washington, DC 20515

Dear Chairman Bishop and Ranking Member Fortenberry:

We write to respectfully request that you include the following bill language in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations legislation for Fiscal Year 2020:

> *Provided, none of the funds made available by this Act may be used to promulgate, propose, or implement any rule, or take any other action with respect to, allowing or requiring information intended for a prescribing health care professional, in the case of a drug or biological product subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)), to be distributed to such professional electronically (in lieu of paper form) unless and until a federal law is enacted to allow or require such distribution.*

This is identical to language that has been included in the Fiscal Year 2019 omnibus legislation that passed Congress earlier this year.

Despite Congress's clear bipartisan intent to stop the Food and Drug Administration (FDA) from implementing its proposed "Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products" rule, we are concerned that the agency will proceed unless this language is included for Fiscal Year 2020. This rule would jeopardize the health of the American people by eliminating hard copies of critical medicine prescribing information, upon which physicians, pharmacists, and other health care professionals rely.

According to a 2013 study by the Government Accountability Office (GAO), relying on electronic labeling as a complete substitute for paper labeling could adversely impact public health. In their study, the GAO notes that an absence of printed labels is particularly problematic for prescribers and patients in rural practice settings, deployed military practice settings, and in all areas in the event of a severe weather or man-made disaster. Further, a study by NERA Economic Consulting found that pharmacists prefer labels over the electronic version. As the GAO highlighted, when pharmacists have to print their own drug labels, they have less time available to counsel patients. For these

reasons, physician, pharmacy, and patient advocacy groups have repeatedly objected to the FDA's proposed rule.

Given demonstrated Congressional intent, we request your support in blocking this harmful proposed rule. Thank you for your consideration of this request.

Sincerely,

JARED GOLDEN
Member of Congress

PETER T. KING
Member of Congress

NYDIA M. VELAZQUEZ
Member of Congress

BRIAN FITZPATRICK
Member of Congress

ELIOT L. ENGEL
Member of Congress

BRIAN HIGGINS
Member of Congress

GREGORY W. MEEKS
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ANTHONY BRINDISI
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THOMAS MASSIE
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BLAINE LUETKEMEYER
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C. A. DUTCH RUPPERSBERGER
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BRENDAN F. BOYLE
Member of Congress