Congress of the United States
Washington, DC 20515

November 15, 2013

Mrs. Sylvia Mathews Burwell, Director
Office of Management and Budget
Eisenhower Executive Office Building, Room 251
1650 Pennsylvania Avenue, NW
Washington, DC 20503

Dear Director Burwell:

We write to express our concerns regarding the Office of Management and Budget's (OMB) decision to sequester the Food and Drug Administration's (FDA) medical product user fees, and encourage you to revisit this decision immediately in order to return these non-tax revenues to FDA for the benefit of patients in need. The impact of OMB's misinterpretation is severely impacting the FDA's ability to fulfill its critical public health mission by fostering timely patient access to safe and effective innovative and generic medicines and medical devices. This cut to the user-fees poses a serious threat to the FDA's ability to meet its obligations when it comes to the Agency's human drug, medical device, biologics, biosimilars, and generic drug review programs.

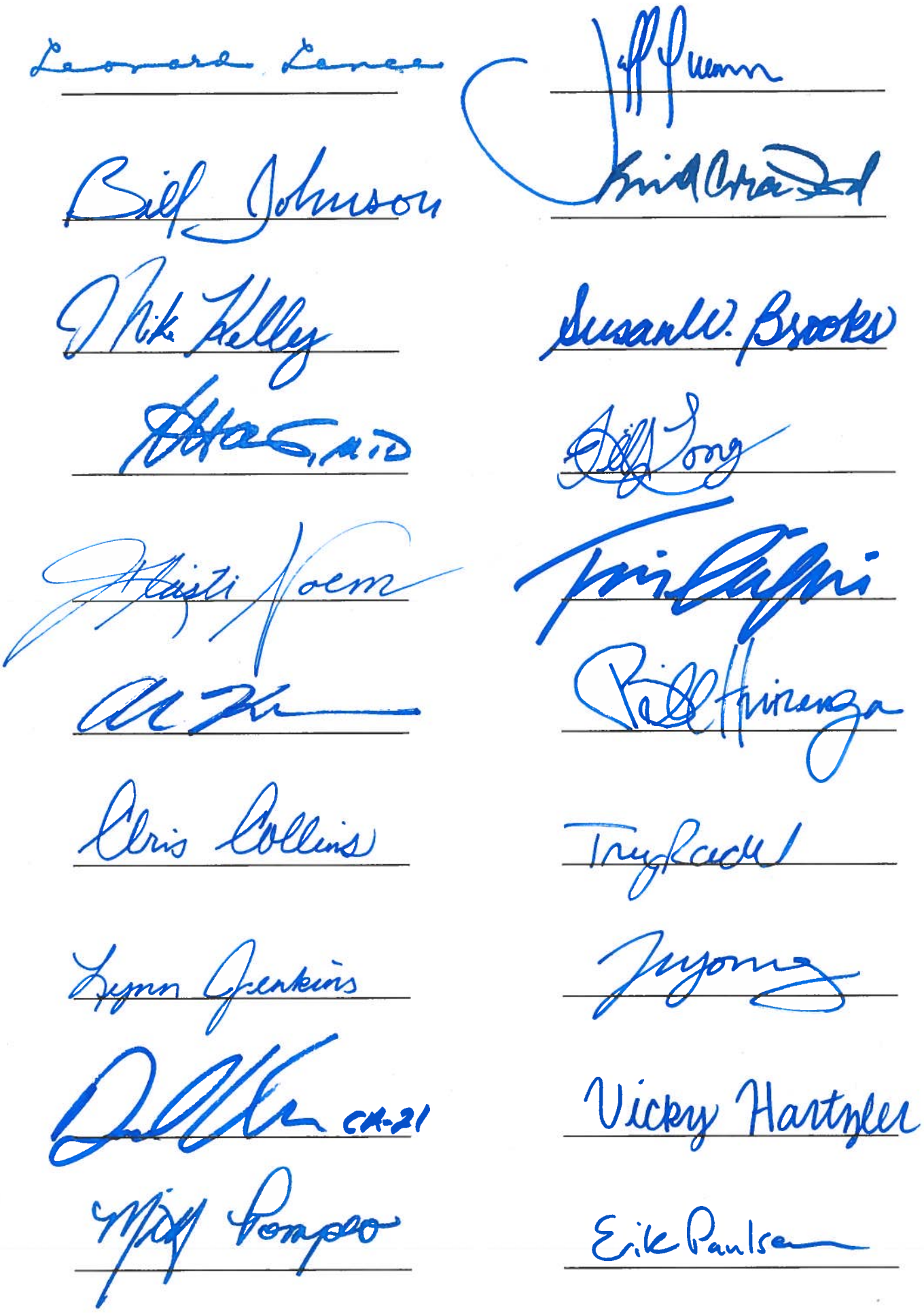
As you know, when sequestration took effect on March 1 of this year, it triggered a 5.1% across-the-board cut to most domestic discretionary spending, including a $209 million cut to FDA's $4.1 billion budget. OMB incorrectly interpreted sequestration to apply to both appropriations and user fees, resulting in $82 million in reduced user fee spending for FDA including $36.6 million in prescription drug and biologics user fees under the Prescription Drug User Fee Act (PDUFA), $15.25 million under the Generic Drug User Fee Act (GDUFA) user fees, and $2.85 million under the Medical Device User Fee Act (MDUFA) programs. These user fees cannot lawfully be used for any purpose other than to support the FDA's human drug or medical device review programs. Their sequestration does not decrease the nation's deficit, but only serves to exacerbate the severe budgetary constraints of a historically underfunded agency. This is detrimental to patients, regulatory science, and public health.

Additionally, we believe OMB's decision to sequester these private dollars goes against the fundamental intent of the Budget Control Act, which was to reduce government spending. These user fees are paid as part of an agreement negotiated between medical product applicants and the FDA, and ratified by Congress to supplement scarce government resources. Sequestering them not only compromises the good faith of industries that chose to enter into such an agreement, but also has the potential to cripple an essential public health agency that relies on outside resources for well over 60 percent of its drug review budget.

House and Senate Appropriators both have called upon OMB and FDA to release sequestered user fees in their respective draft FY14 appropriations bills. Additionally, H.R. 2725 (the FDA Safety Over Sequestration Act of 2013) and S. 1413 (FDA User Fee Protection Act) have bipartisan support in both chambers of Congress.

Therefore, we urge OMB to reverse its ruling on the sequester of FDA medical user fees in order to adhere to the original intent of the Budget Control Act and to preserve the integrity of the Food and Drug Administration Safety and Innovation Act for the benefit of patients, regulatory science and public health.

Sincerely,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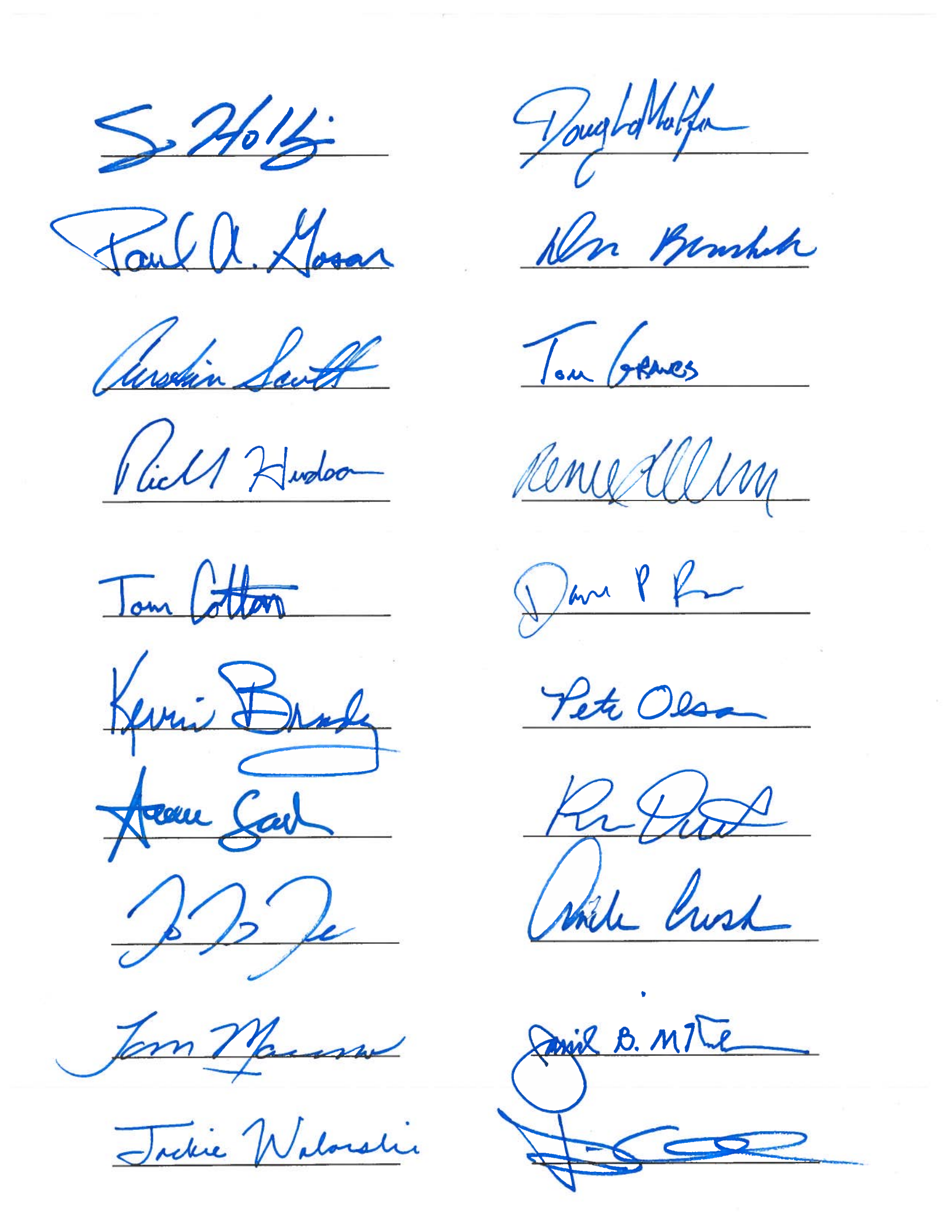

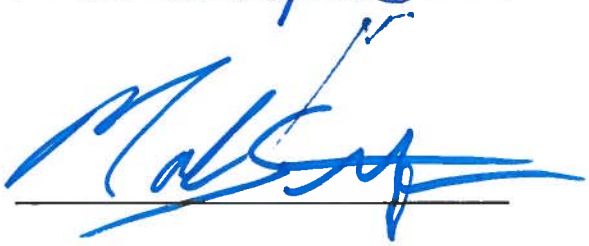

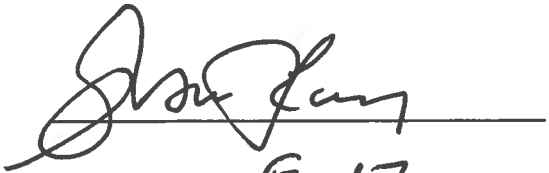
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