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Review of Multi-State Letter Signed by Attorneys General

**Presented to the 2021 Special Committee on Federal 340B Drug Program
by Steve Anderson, Medicaid Inspector General**

October 20, 2021

Chair Concannon and Members of the Committee:

Thank you for the opportunity to appear today and discuss the Multi-State letter signed by Attorneys General. My name is Steve Anderson, Medicaid Inspector General.

Last year, Attorney General Derek Schmidt joined former California Attorney General Xavier Becerra (now of U.S. Secretary of Health and Human Services), Connecticut Attorney General William Tong, and Nebraska Attorney General Doug Peterson in leading a bipartisan coalition of attorneys general of 27 states and the District of Columbia urging the U.S. Department of Health and Human Services (HHS) to hold accountable drug manufacturers that are unlawfully refusing to provide discounts to federally qualified health centers, hospitals, and other providers that serve vulnerable patient populations through the 340B Drug Pricing Program.

The multi-state letter dated December 14, 2020, which is attached to my testimony, concerning drug manufacturer's actions violating 340B drug pricing program requirements, was signed by attorneys general from California, Connecticut, Kansas, Nebraska, Colorado, Delaware, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia and addressed to Alex Azar, Secretary of the HHS at that time.

In the letter, the attorneys general argue that by withholding or threatening to withhold these critical discounts, drug manufacturers Eli Lilly & Company, AstraZeneca PLC, Sanofi SA, Novartis Pharmaceuticals, Merck & Co., United Therapeutics Corp., and others, put low-income patients at risk of losing access to affordable medications while communities continue to battle

the COVID-19 pandemic. HHS was urged to create a binding administrative dispute resolution (ADR) process under which 340B health center could seek to remedy some the unlawful conduct of the drug companies. The ADR process was finalized by HHS.

It was also noted in the letter that HHS has the authority to address these ongoing violations of § 340B of the Public Health Service Act, 42 U.S.C § 256b. Specifically, HHS has the authority to issue civil monetary penalties, and to issue guidance articulating the statutory responsibilities of drug manufacturers. The illegal actions of drug manufacturers during this time of urgent need to compel HHS to utilize its authority to maintain and support the purpose and execution of the 340B Drug Pricing Program.

On December 30, 2020, Robert Charrow, General Counsel, HHS, issued Advisory Opinion 20-06 On Contract Pharmacies Under the 340B Program. In the opinion, it was concluded that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.

On May 17, 2021, Acting Health Resources and Services Administration (HRSA) Administrator Diana Espinosa sent letters to six pharmaceutical manufacturers outlining each manufacturer's violation of statutory 340B Program requirements by refusing to sell, without restriction, covered outpatient drugs at 340B prices to covered entities that dispense medications through contract pharmacy arrangements. The letter directed each manufacturer to submit a plan to come into compliance with the law. In their responses, the manufacturers refused to comply and did not provide such plans.

On June 16, 2021, Delaware District Court Judge Leonard P. Stark, issued an opinion that Advisory Opinion 20-06 differs from the 2010 HRSA guidance document (and earlier guidance), as the Advisory Opinion "is the first document in which HHS explicitly concluded that drug manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies." Stark also determined that the Advisory Opinion is "legally flawed" because "there is more than one permissible interpretation of the 340B statute."

On June 18, 2021, the HHS Office of General Counsel issued its Notice of Withdrawal of Advisory Opinion 20-06 with an explanation it was done "in the interest of avoiding confusion and unnecessary litigation."

On September 22, 2021, HRSA sent letters to each manufacturer alerting them that, in light of their refusal to comply, the matter has been referred to the HHS Office of Inspector General

(OIG) in accordance with the 340B ceiling Price and Civil Monetary Penalties Final Rule.¹ The full text of the letters can be found on the HRSA Program Integrity Page at <https://www.hrsa.gov/opa/program-integrity/index.html>.

As a condition of having their drugs covered by Medicaid and Medicare Part B, Congress has required drug manufacturers to enter into pricing agreements with the HHS secretary to limit the cost of medications for public hospitals, community health centers and others serving indigent patients. The agreements require companies to offer the medications “at or below the applicable ceiling price.”

Thank you for your time. I will be happy to answer questions.

¹ <http://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf>



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December 14, 2020

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Via Email and U.S. Mail

Administrator Thomas J. Engels
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Re: Drug Manufacturers' Actions Violating 340B Drug Pricing Program Requirements

Dear Secretary Azar and Administrator Engels:

We, the undersigned State Attorneys General of California, Connecticut, Kansas, Nebraska, Colorado, Delaware, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia, write to urge the U.S. Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) (collectively HHS), to address drug manufacturers' unlawful refusal to provide critical drug discounts to covered entities, such as community health centers, under the 340B Drug Pricing Program. The 340B statute requires manufacturers that want to participate in Medicare Part B and Medicaid to "offer each covered entity covered outpatient drugs for purchase at or below the

applicable ceiling price.”¹ Yet,—amid the ongoing COVID-19 pandemic—drug manufacturers Eli Lilly & Company, AstraZeneca PLC, Sanofi SA, Novartis Pharmaceuticals, Merck & Co., and United Therapeutics Corp. have threatened the loss of or have already refused to provide drug discounts for drugs shipped to contract pharmacies that administer 340B drugs on behalf of some of our nation’s most impactful safety-net providers. We applaud HHS’s recent promulgation of regulations establishing the required Alternative Dispute Resolution (ADR) process, but urge HHS to provide immediate relief to the health centers and hospitals that have already lost significant cost savings, by making immediate determinations that manufacturers’ actions violate the terms of their participation in the Medicare Part B and Medicaid Programs.

HHS has the authority to address these ongoing violations of § 340B of the Public Health Service Act, 42 U.S.C. § 256b. Specifically, HHS has the authority to issue civil monetary penalties, and to issue guidance articulating the statutory responsibilities of drug manufacturers. The illegal actions of drug manufacturers during this time of urgent need compel HHS to utilize its authority to maintain and support the purpose and execution of the 340B Drug Pricing Program.

We understand that HHS has now issued a final rule to create a binding administrative dispute resolution process under which 340B health centers could seek to remedy some of this unlawful conduct.² Still, because the ADR process will not become effective until January 14, 2021, we urge the department to seriously consider the vital role played by contract pharmacies and to prohibit drug manufacturers from dictating whether and how a covered entity can access 340B pricing for their contract pharmacies.

Each day that drug manufacturers violate their statutory obligations, vulnerable patients and their healthcare centers are deprived of the essential healthcare resources that Congress intended to provide. Drug manufacturers are, without justification, flouting discounted pricing requirements for low-income patients and/or unreasonably conditioning 340B pricing on data demands, depriving such patients of affordable medications to the detriment of the health centers and hospitals that serve these vulnerable communities. During a national public health crisis, these actions are especially egregious and cannot be ignored.

A. The States and 340B Covered Entities Share a Common Purpose

The partnership between the States and 340B covered entities is not only a matter of public policy but enshrined in federal law. To ensure that public hospitals, community health centers, and others serving indigent patients, including state-run hospitals, have necessary resources, Congress directed the Secretary to enter into agreements with drug manufacturers to limit the amount required to be paid for drugs purchased by such covered entities. The Medicaid statute requires that drug manufacturers participate in the 340B pricing program as a condition of

¹ 42 U.S.C. § 256b(1).

² See 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, RIN 0906-AB26 (Dec. 12, 2020), <https://public-inspection.federalregister.gov/2020-27440.pdf> (to be published in the Federal Register on Dec. 14, 2020).

having their drugs covered under Medicaid and Medicare Part B.³ The statute requires drug manufacturers to enter into Pharmaceutical Pricing Agreements (PPAs) with HHS regarding outpatient medications covered by the Medicaid program.⁴ The PPAs “*shall require* that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.”⁵

As Congress explained, 340B “provides protection from drug price increases to specified federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans.”⁶ The purpose of the statute is “to enable” 340B entities “to obtain lower prices on the drugs that they provide to their patients,” thus “reaching more eligible patients and providing more comprehensive services.”⁷ To that end, covered entities treating vulnerable patient populations can “stretch scarce federal resources as far as possible, reaching more eligible patients.”⁸ Without these lower prices, community health centers may be forced to restrict healthcare services provided to at-risk patients in a time of great need.

Thus, the States and the 340B covered entities work in partnership to provide individuals access to affordable healthcare, including prescription drugs. Both the States and the 340B entities benefit when covered entities receive the price discounts to which they are entitled. In addition to discounted drugs, 340B enables covered entities to stretch resources to support underserved patients and provide comprehensive services beyond the reach of state Medicaid programs. In this way, 340B entities provide additional services to low-income communities.

The more medical care 340B covered entities can provide with their limited resources and state reimbursement, the further state-Medicaid budgets will go in serving the States’ uninsured and underinsured residents. 340B prices are a vital lifeline for safety-net providers across the country. These savings ensure that medication and primary care are affordable for low-income patients, making care accessible to persons below 100% of the poverty level for no more than a nominal fee, and ensure that patients between 101-200% of the poverty level are charged on a sliding fee scale. These critical benefits allow covered entities to expand access to medication and other services, such as supporting in-house pharmacies, including extending pharmacy hours and pharmacy staff, providing automated systems that electronically dispense prescribed medication to patients in remote areas, mail-order prescription delivery programs, and

³ 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 1396r-8(a)(2018).

⁴ 42 U.S.C. §§ 256b(a)(1);1396r-8(a)(5).

⁵ 42 U.S.C. § 256b(1)(emphasis added). The ceiling price is defined as being “equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter,” which is then reduced by a rebate percentage calculated by Medicaid. 42 U.S.C. § 256b(a)(1)-(2).

⁶ H.R. Rep. No. 102-384(II), at 12 (1992).

⁷ H.R. Rep. *supra*, note 4 at 7, 12.

⁸ *Id.*

funding behavioral health, OBGYN, and dental services that are co-located to help create a continuum of care for patients.

Moreover, 340B helps support non-billable services by covered entities that lead to improved public health outcomes. For example, many 340B covered entities provide robust care coordination for HIV and Hepatitis C patients, as well as STI prevention, and play a key role in expanding access to preventive services for men and women's reproductive health. Among many other benefits, the 340B pricing helps health centers, already stretched thin, to develop infrastructure necessary to care for underserved populations. This means the ability to modernize their IT infrastructure, improve electronic health records, expand their service capacity by building additional exam rooms, and train employees to use data that improve clinical and operational measures.

B. Congress Required HHS to Regulate and Oversee Compliance with the 340B Program

As you know, the 340B Drug Pricing Program, enacted by Congress as part of the Public Health Service Act, and signed into law by President George H. W. Bush in 1992, has provided low-income patients access to reduced-price prescription drugs for decades. The 340B "covered entities"⁹ include crucial community health providers such as children's hospitals, rural hospitals, federally qualified health centers, Ryan White HIV/AIDS Program funded-recipients, and other hospitals and health centers that have served vulnerable patients for years.¹⁰

HHS should use the enforcement mechanisms Congress has provided to immediately address flagrant and clear statutory violations by the drug manufacturers. For example, if a manufacturer overcharges a covered entity, HHS may require the manufacturer to reimburse the covered entity, and HHS may also terminate the manufacturer's PPA,¹¹ which also terminates the drug manufacturer's eligibility for Medicaid coverage of its drugs.¹²

In 2010, Congress also underscored the requirement of drug manufacturer compliance, adding the imposition of civil monetary penalties for any instance in which a manufacturer overcharges a 340B covered entity for a 340B drug.¹³ Congress provided that the HHS's regulatory authority over the 340B Program includes the ability to impose civil monetary

⁹ See 42 U.S.C. § 256b(a).

¹⁰ There are over 12,000 covered entities nationwide. U.S. House of Representatives, Committee on Energy & Commerce, Subcommittee on Oversight & Investigations, 115th Congress, email from U.S. Dept. of HHS to Committee Staff (Dec. 21, 2017).

¹¹ § 1396r-8(b)(4)(B)(i), (v). See also Dep't. of Health and Human Servs., Health Resources and Servs. Admin., Healthcare Systems Bureau, *Pharmaceutical Pricing Agreement*, OMB No. 0915-0327, § IV(c), <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf>.

¹² 42 U.S.C. § 1396r-8(a)(1), (5).

¹³ 42 U.S.C. § 256b(d)(1).

penalties, with HHS issuing a Civil Monetary Penalties Regulation in 2017.¹⁴ Both Congress and HHS have made clear that civil monetary penalties are available when participating manufacturers overcharge covered entities, with a separate penalty of up to \$5,000.00 for each individual medication order.¹⁵

In addition, throughout the years, HRSA has repeatedly issued guidance regarding the 340B Program. Since 1996, HRSA has stated that the law expressly allows covered entities to contract with outpatient pharmacies to fill prescriptions for 340B eligible patients.¹⁶ In 2010, HRSA released additional guidance making clear that covered entities can use multiple external contract pharmacies as they work to fulfill the mission of providing healthcare to underserved populations.¹⁷ HRSA's guidance specifically allows contract pharmacies to receive 340B drugs under a "bill to/ship to" model, whereby the drug manufacturer sends invoices to the covered entity, but ships drugs to the contract pharmacy.¹⁸ The actions of some drug manufacturers both violate the law and abruptly disavow longstanding HRSA policy and well-established practice for carrying out the vital mission of the program.

Notwithstanding clear legal requirements, some drug manufacturers have brazenly ceased providing 340B pricing to covered entities using contract pharmacies and others have unilaterally imposed conditions on 340B pricing.¹⁹ HRSA recently expressed "significant concerns" with this unilateral conduct on the part of at least one manufacturer.²⁰ Similar concerns have been expressed by at least one state Attorney General directly to Eli Lilly, Astra Zeneca, Merck, Novartis and Sanofi.²¹ Some drug manufacturers have stated that they will provide 340B pricing to covered

¹⁴ See 42 C.F.R. § 10.11 and 42 C.F.R. Part 1003. See also *Pharm. Research & Manufacturers of America v United States Dept. of Health & Human Services*, 43 F. Supp.3d 28, 41 (D.D.C. 2014).

¹⁵ 42 U.S.C. § 256b(d)(1); 42 C.F.R. § 10.11(b).

¹⁶ See 61 Fed. Reg. 43,549 (Aug. 23, 1996).

¹⁷ See 75 Fed. Reg. 10,272 (March 5, 2010).

¹⁸ See 61 Fed. Reg. 43,549 (Aug. 23, 1996).

¹⁹ This conduct by drug manufacturers is not a just recent problem. As early as 2015, Celgene, now owned by Bristol Myers Squibb, implemented a policy that limited the distribution network for Revlimid®, Pomalyst®, and Thalomid®, such that 340B pricing was not available to all 340B covered entities. Celgene provided notice to covered entities of this policy implementation in 2015 through HRSA. See <http://www.hrsa.gov/opa/programrequirements/manufactureletters/2015/celgeneletter.pdf>.

²⁰ September 21, 2020 letter from Robert Charrow, General Counsel to the Secretary of Health and Human Services, to Eli Lilly and Company. <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf>.

²¹ <https://portal.ct.gov/AG/Press-Releases/2020-Press-Releases/AG-Tong-Demands-Drug-Makers-Abandon-Unlawful-Actions-Imperiling-Access-to-Affordable-Prescriptions>.

entities using contract pharmacies but are conditioning such pricing on unacceptable terms.²² The imposition of these additional requirements has no basis in the text of the Public Health Service Act, is untethered to maintaining 340B Program integrity, and serves only to increase costs for covered entities. Moreover, these actions are disrupting an essential method used by many covered entities to dispense 340B drugs to underserved and vulnerable patient populations who rely on these pharmacies in their communities to fill their prescriptions. These actions also deprive or threaten to deprive 340B pricing necessary to enable covered entities to continue serving low-income patients who may otherwise do without necessary healthcare.

C. The 340B Program Enjoys Strong Bipartisan Support, Confirming the Importance of Access to Affordable Prescription Drugs for All Americans

Congress has expressed bipartisan support for the 340B Program as it has operated for years. The House of Representatives Committee on Energy and Commerce noted in 2018 that the 340B Program “is an important program that enjoys strong bipartisan support in Congress. . . . On numerous occasions, the committee has emphasized the importance of the 340B program in providing care to vulnerable Americans.”²³

Most recently, Congress has issued letters decrying the conduct of drug manufacturers who unilaterally seek to impose conditions without legal basis and take other steps to undermine the 340B Program. In September, a bipartisan group of 246 U.S. Representatives urged HHS to continue to comply with 340B Program requirements without imposing baseless restrictions regarding the use of contract pharmacies.²⁴ On November 13, 2020, a bipartisan group of 217 members of the U.S. House of Representatives issued a letter to HHS expressing “grave concern” regarding measures being considered by drug manufacturers which “threaten ‘safety net providers’ lawful access to discounted drugs through the 340B Program.”^{25, 26}

²² For example, some manufacturers are illegally conditioning 340B pricing on the provision of claims data to an agent of the manufacturer with insufficient assurance of compliance under the Health Insurance Portability and Accountability Act. In addition, some manufacturers are requiring covered entities to sign documents stating that they are not entitled to receive 340B pricing through a contract pharmacy in order to receive 340B pricing.

²³ https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf.

²⁴ https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf.

²⁵ https://spanberger.house.gov/uploadedfiles/201113_final_340b_hhs_letter.pdf (addressing recent actions to shift the 340B Program from a discount to a rebate formula).

²⁶ A smaller group of senators similarly urged that HHS not ignore noncompliance by drug manufacturing companies which harms underserved patients. https://www.blumenthal.senate.gov/imo/media/doc/2020.09.15_Letter%20to%20PhRMA%20on%20340B%20Contract%20Pharmacies%20FINAL%20SIGNED.pdf.

Such strong bipartisan support, even decades after its inception, confirms Congress' unwavering commitment to protect the purpose of the 340B Program and underscores the importance of providing access to affordable prescription drugs to all Americans.

D. Drug Manufacturers' Actions Exacerbate the Harms Brought On by the COVID-19 Pandemic and Undermine HHS's Efforts to Support 340B Covered Entities

These recent actions by the drug manufacturers are deeply troubling, particularly given the ongoing COVID-19 health crisis. Not only are the manufacturers' actions an attempt to disrupt long-settled expectations and existing contractual arrangements for dispensing 340B drugs, but they have been taken when millions of Americans in our respective States are already reeling from the grave health and financial consequences caused by a historic pandemic and unprecedented economic crisis. Indeed, HHS has called the timing of such unfortunate recent actions "*at the very least, insensitive to the recent state of the economy.*"²⁷ We urge HHS to do more than decry these unlawful practices and provide immediate relief, beyond the new ADR process, to halt these actions now.

Safety-net healthcare institutions are struggling to meet the dual challenges of responding to COVID-19 while maintaining financial stability. As you know, this unprecedented effort requires providing covered entities with flexibility and additional resources to combat the virus. HRSA recently issued a number of COVID-19 resources aimed at assisting 340B covered entities in maintaining 340B Program compliance throughout the COVID-19 outbreak.²⁸ Allowing 340B entities regulatory flexibility, such as the use of abbreviated health records, the expansion of 340B-eligible child sites, the relaxation of the prohibition on acquiring covered outpatient drugs through group purchasing organizations due to shortages, and the encouraged use of telemedicine platforms as a critical way of treating COVID-19 patients, confirm that your office understands the serious challenges many healthcare centers are facing. The States applaud these actions, as there is a critical need for the expansion of healthcare coverage to help those who have lost their jobs and those in need of care in response to COVID-19.

However, drug manufacturers' concerted efforts to cut off, threaten, or belabor discounted drug distribution to contract pharmacies utilized by covered entities undermines HRSA's efforts to support these safety-net providers. We urge you to provide immediate relief, not only because it is critical to the community providers that serve low-income patients, but also because it is more necessary than ever now as many of these Americans are also the hardest hit by the COVID-19 pandemic.

The drug manufacturers' combined actions directly thwart the essence of the 340B Program—ensuring that medicine and healthcare are provided to the underserved patients who

²⁷ September 21, 2020 letter from Robert Charrow, General Counsel to the Secretary of Health and Human Services, to Eli Lilly and Company. <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf>.

²⁸ Health Res. and Servs. Admin., *COVID-19 Resources*, <https://www.hrsa.gov/opa/COVID-19-resources> (last visited Nov. 20, 2020).

need it most—and it is the duty of HHS, not the drug manufacturers, to ensure the integrity of the 340B Program.

* * * * *

While we were pleased to learn that HHS has finalized the long-delayed ADR rule and we continue to review it in its entirety, we urge you to provide clarity to all 340B stakeholders regarding these important issues as soon as possible. In addition, it is our hope that your final rule will provide a substantive enforcement mechanism for covered entities and that implementation is undertaken with haste. The landscape has altered considerably in the last several years, and the events of 2020 have sharpened the need for discounted pricing afforded by the 340B Program. The undersigned Attorneys General welcome any opportunity to provide input, either formally or informally, with regard to the final rule or the content of this letter. In the meantime, HHS should use its authority and any available measures, including imposition of civil penalties where appropriate, to hold those drug manufacturers in violation of the law directly accountable. The vulnerable and underserved patients of 340B covered entities of our States and nationwide deserve no less.

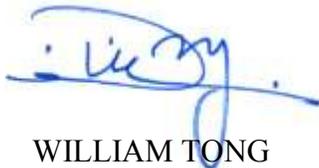
Sincerely,



XAVIER BECERRA
Attorney General of California



DEREK SCHMIDT
Attorney General of Kansas



WILLIAM TONG
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cc: Robert P. Charrow
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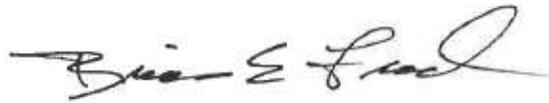
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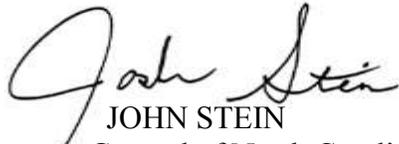
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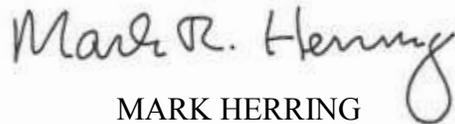
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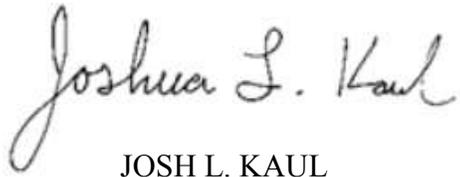
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December 14, 2020

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A handwritten signature in cursive script that reads "Joshua L. Kaul". The signature is written in black ink and is positioned above the printed name.

JOSH L. KAUL
Attorney General of Wisconsin