OFFICE OF THE ATTORNEY GENERAL
CONNECTICUT

WILLIAM TONG
ATTORNEY GENERAL

October 5, 2020

Via Email

Vasant Narasimhan
Chief Executive Officer
Novartis Pharmaceuticals
One Health Plaza
East Hanover, NJ 07936

Re: *340B Medications*

Dear Dr. Vasant Narasimhan:

I write to urge Novartis to abandon its recent actions to unilaterally cease providing 340B medications to 340B covered entities using contract pharmacies and unreasonably demand claims data. These actions would directly undermine the 340B Drug Pricing Program, obstruct patient access to critical prescription medications, and devastate the financial stability of healthcare centers and hospitals serving vulnerable communities. Novartis's threats to flout federal requirements and discontinue appropriate 340B drug pricing are especially appalling given that these critical safety-net healthcare institutions are on the front lines of our nation's collective response to the ongoing COVID-19 pandemic. Moreover, low income patients suffering chronic conditions (including cancer, hypertension, heart disease, diabetes, HIV/AIDS, asthma, and arthritis), and those facing heightened COVID-19 risks, could be blocked from affordable lifesaving prescription medications due to Novartis's unlawful actions.

As you know, the 340B Drug Pricing Program, enacted by Congress as part of the Public Health Service Act, ("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 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."[1]

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

Federal law requires drug manufactures wishing to participate in Medicaid and Medicare Part B to offer outpatient prescription drugs to eligible safety-net healthcare centers and hospitals at a discounted "ceiling" price.[2] These "covered entities"[3] include children's hospitals, rural hospitals, federally qualified health centers, Ryan White HIV/AIDS clinics, and other hospitals and health centers that serve vulnerable patients.[4] The covered entities rely on 340B program savings to promote access to care for underserved populations. Restricting crucial discount pricing will reduce covered entities' access to program savings, thereby thwarting their safety-net missions and causing painful cutbacks to critical healthcare services.

Despite clear federal statutory requirements, Novartis has recently refused to send medications to covered entities using contract pharmacies. In addition, Novartis has stated that it will no longer distribute 340B discounted drugs to contract pharmacies unless covered entities using contract pharmacies provide broad claims data to Novartis's third-party platform, 340B ESP. These actions are outrageous. By refusing to provide 340B medications to covered entities, Novartis will disrupt 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. Novartis is also depriving covered entities of discounts necessary to continue serving low-income patients who may otherwise do without necessary healthcare.

Moreover, Novartis's actions will deprive patients of necessary medication at an affordable price during a time of great need. One covered entity in Connecticut reports that diabetic patients have been forced to change medications as a result of recent drug company actions restricting access to 340B discounted drugs – sometimes increasing the cost to patients to fill their prescriptions by hundreds of dollars. Similarly, underinsured patients who need inhalers to treat asthma or chronic obstructive pulmonary disease may have to pay $400 above the 340B cost. Patients who cannot afford these increased costs may be forced to stop taking their medications, thereby exacerbating their underlying conditions and putting them at risk for serious medical complications.

There is no legal basis for Novartis's actions. Denying outpatient access to appropriate 340B drug pricing is a clear violation of federal law. Nothing in the Act allows Novartis to impose conditions or restrictions on covered entities' access to 340B drug pricing, including requiring that data be provided to a third party for reasons unrelated to patient care and unrelated to any reasonable belief that any covered entity has acted improperly. Indeed, Novartis's surprise announcement that it will now refuse to ship most 340B drugs to outpatient contract pharmacies absent the provision of data

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[2] Specifically, 42 U.S.C. § 256b(a)(1) provides that drug manufacturers must "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."

[3] *See* 42 U.S.C. § 256b(a)(2)(B)(4).

[4] 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). In Connecticut, there are 111 covered entities. https://portal.ct.gov/DPH/Family-Health/Community-Health-Centers/Community-Health-Center-Programs--Services#:~:text=Six%20Community%20Health%20Centers%20in,340B%20facilities%20throughout%20the%20state.

contravenes decades-old policies of the U.S. Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA"), which has statutory authority to oversee the 340B Drug Pricing Program. Since 1996, HRSA has expressly allowed covered entities to contract with outpatient pharmacies to fill prescriptions for 340B eligible patients.[5] 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.[6] Moreover, HRSA's guidance expressly 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.[7]

Novartis's recent demands to covered entities for medications claims data present significant concerns. First, the demands for data are without basis in any law or regulation. Second, the deadline you have issued is arbitrary, unrelated to the core mission of the 340B program and unrelated to the covered entities' interactions with Novartis.[8] Third, the broad scope of the sought-after data, which includes Protected Health Information (PHI)[9] is concerning.[10]

Novartis's data demand, along with its abrupt disavowal of longstanding HRSA policy and well-established practice within the pharmaceutical industry of shipping 340B drugs to contract pharmacies that partner with safety-net hospitals and health centers, is deeply troubling especially given the ongoing COVID-19 health crises. Not only are Novartis's actions an attempt to disrupt long-settled expectations and existing contractual arrangements for dispensing 340B drugs, but Novartis is making this attempt during a historic pandemic and unprecedented economic crises. Indeed, HHS has called the timing of such unfortunate recent actions "*at the very least*, insensitive to the recent state of the economy."[11] Safety-net healthcare institutions are struggling to meet the dual challenges of responding to COVID-19 and maintaining long-term financial stability. And the needs of individual patients who will be directly harmed by a lack of accessible and affordable medications must not and cannot be ignored. Novartis's combined actions directly thwart the essence of the 340B program—ensuring that medicine and healthcare are provided to the underserved patients who need it most.

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

6 *See* 75 Fed. Reg. 10272 (March 5, 2010).

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

8 Novartis's notice that it requires this data is unrelated to any suggestion of improper 340B discounts to covered entities.

9 Protected Health Information is a term defined by federal regulation pursuant to the Health Insurance Portability and Accountability Act. 45 C.F.R. § 160.103.

10 The Department of Health and Human Services has stated that covered entities "may use and disclose protected health information for *its own treatment, payment, and healthcare operation activities.*" https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html , citing 45 C.F.R. § 164.506(c) (emphasis added). The purpose of Novartis's request exceeds the scope of such disclosure. Novartis and its 340B data collection agent have provided insufficient assurances regarding the protection of the PHI being demanded by your company.

11 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

My office will not stand idly by while Novartis and other drug companies prioritize profits over access to affordable prescription medications and other critical medical services for vulnerable communities. Therefore, I urge Novartis to abandon its unilateral and unlawful actions.

Very truly yours,

WILLIAM TONG

Cc: Robert P. Charrow
General Counsel
Office of the Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

OFFICE OF THE ATTORNEY GENERAL
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WILLIAM TONG
ATTORNEY GENERAL

October 5, 2020

Via Email

Kenneth C. Frazier
Chairman & Chief Executive Officer
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889

Re: *340B Medications*

Dear Mr. Frazier:

I write to urge Merck to abandon its recent actions to unilaterally cease providing 340B medications to 340B covered entities using contract pharmacies and unreasonably demand claims data. These actions would directly undermine the 340B Drug Pricing Program, obstruct patient access to critical prescription medications, and devastate the financial stability of healthcare centers and hospitals serving vulnerable communities. Merck's threats to flout federal requirements and discontinue appropriate 340B drug pricing are especially appalling given that these critical safety-net healthcare institutions are on the front lines of our nation's collective response to the ongoing COVID-19 pandemic. Moreover, low income patients suffering chronic conditions (including cancer, hypertension, heart disease, diabetes, HIV/AIDS, asthma, and arthritis), and those facing heightened COVID-19 risks, could be blocked from affordable lifesaving prescription medications due to Merck's unlawful actions.

As you know, the 340B Drug Pricing Program, enacted by Congress as part of the Public Health Service Act, ("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 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."[1]

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Federal law requires drug manufactures wishing to participate in Medicaid and Medicare Part B to offer outpatient prescription drugs to eligible safety-net healthcare centers and hospitals at a discounted "ceiling" price.[2] These "covered entities"[3] include children's hospitals, rural hospitals, federally qualified health centers, Ryan White HIV/AIDS clinics, and other hospitals and health centers that serve vulnerable patients.[4] The covered entities rely on 340B program savings to promote access to care for underserved populations. Restricting crucial discount pricing will reduce covered entities' access to program savings, thereby thwarting their safety-net missions and causing painful cutbacks to critical healthcare services.

Despite clear federal statutory requirements, Merck has recently refused to send medications to covered entities using contract pharmacies. In addition, Merck has stated that it will no longer distribute 340B discounted drugs to contract pharmacies unless covered entities using contract pharmacies provide broad claims data to Merck's third-party platform, 340B ESP. These actions are outrageous. By refusing to provide 340B medications to covered entities, Merck will disrupt 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. Merck is also depriving covered entities of discounts necessary to continue serving low-income patients who may otherwise do without necessary healthcare.

Moreover, Merck's actions will deprive patients of necessary medication at an affordable price during a time of great need. One covered entity in Connecticut reports that diabetic patients have been forced to change medications as a result of recent drug company actions restricting access to 340B discounted drugs – sometimes increasing the cost to patients to fill their prescriptions by hundreds of dollars. Similarly, underinsured patients who need inhalers to treat asthma or chronic obstructive pulmonary disease may have to pay $400 above the 340B cost. Patients who cannot

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[4] 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). In Connecticut, there are 111 covered entities. https://portal.ct.gov/DPH/Family-Health/Community-Health-Centers/Community-Health-Center-Programs--Services#:~:text=Six%20Community%20Health%20Centers%20in,340B%20facilities%20throughout%20the%20state.

afford these increased costs may be forced to stop taking their medications, thereby exacerbating their underlying conditions and putting them at risk for serious medical complications.

There is no legal basis for Merck's actions. Denying outpatient access to appropriate 340B drug pricing is a clear violation of federal law. Nothing in the Act allows Merck to impose conditions or restrictions on covered entities' access to 340B drug pricing, including requiring that data be provided to a third party for reasons unrelated to patient care and unrelated to any reasonable belief that any covered entity has acted improperly. Indeed, Merck's surprise announcement that it will now refuse to ship most 340B drugs to outpatient contract pharmacies absent the provision of data contravenes decades-old policies of the U.S. Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA"), which has statutory authority to oversee the 340B Drug Pricing Program. Since 1996, HRSA has expressly allowed covered entities to contract with outpatient pharmacies to fill prescriptions for 340B eligible patients.[5] 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.[6] Moreover, HRSA's guidance expressly 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.[7]

Merck's recent demands to covered entities for medications claims data present significant concerns. First, the demands for data are without basis in any law or regulation. Second, the deadline you have issued is arbitrary, unrelated to the core mission of the 340B program and unrelated to the covered entities' interactions with Merck.[8] Third, the broad scope of the sought-after data, which includes Protected Health Information (PHI)[9] is concerning.[10]

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8 Merck's notice that it requires this data is unrelated to any suggestion of improper 340B discounts to covered entities.

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10 The Department of Health and Human Services has stated that covered entities "may use and disclose protected health information for *its own treatment, payment, and healthcare operation activities.*" https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html , citing 45 C.F.R. § 164.506(c) (emphasis added). The purpose of Merck's request exceeds the scope of such disclosure. Merck and its 340B data collection agent have provided insufficient assurances regarding the protection of the PHI being demanded by your company.

Merck's data demand, along with its abrupt disavowal of longstanding HRSA policy and well-established practice within the pharmaceutical industry of shipping 340B drugs to contract pharmacies that partner with safety-net hospitals and health centers, is deeply troubling especially given the ongoing COVID-19 health crises. Not only are Merck's actions an attempt to disrupt long-settled expectations and existing contractual arrangements for dispensing 340B drugs, but Merck is making this attempt during a historic pandemic and unprecedented economic crises. Indeed, HHS has called the timing of such unfortunate recent actions "*at the very least*, insensitive to the recent state of the economy."[11] Safety-net healthcare institutions are struggling to meet the dual challenges of responding to COVID-19 and maintaining long-term financial stability. And the needs of individual patients who will be directly harmed by a lack of accessible and affordable medications must not and cannot be ignored. Merck's combined actions directly thwart the essence of the 340B program—ensuring that medicine and healthcare are provided to the underserved patients who need it most.

My office will not stand idly by while Merck and other drug companies prioritize profits over access to affordable prescription medications and other critical medical services for vulnerable communities. Therefore, I urge Merck to abandon its unilateral and unlawful actions.

Very truly yours,

WILLIAM TONG

Cc: Robert P. Charrow
General Counsel
Office of the Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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[11] 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

OFFICE OF THE ATTORNEY GENERAL
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WILLIAM TONG
ATTORNEY GENERAL

October 5, 2020

Via Email

Paul Hudson, Chief Executive Officer

Karen Linehan, Executive Vice President,
Legal Affairs and General Counsel

Gerald Gleeson, Vice President
Head, US Market Access Shared Services

Sanofi U.S.
55 Corporate Drive
Bridgewater, NJ 08807

Re: *340B Medications*

Dear Mr. Hudson, Ms. Linehan, and Mr. Gleeson:

I write to urge Sanofi to abandon its recent actions to unilaterally cease providing 340B medications to 340B covered entities using contract pharmacies and unreasonably demand claims data. These actions would directly undermine the 340B Drug Pricing Program, obstruct patient access to critical prescription medications, and devastate the financial stability of healthcare centers and hospitals serving vulnerable communities. Sanofi's threats to flout federal requirements and discontinue appropriate 340B drug pricing are especially appalling given that these critical safety-net healthcare institutions are on the front lines of our nation's collective response to the ongoing COVID-19 pandemic. Moreover, low income patients suffering chronic conditions (including cancer, hypertension, heart disease, diabetes, HIV/AIDS, asthma, and arthritis), and those facing heightened COVID-19 risks, could be blocked from affordable lifesaving prescription medications due to Sanofi's unlawful actions.

As you know, the 340B Drug Pricing Program, enacted by Congress as part of the Public Health Service Act, ("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 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,

165 Capitol Avenue
Hartford, Connecticut 06106

the committee has emphasized the importance of the 340B program in providing care to vulnerable Americans."[1]

Federal law requires drug manufactures wishing to participate in Medicaid and Medicare Part B to offer outpatient prescription drugs to eligible safety-net healthcare centers and hospitals at a discounted "ceiling" price.[2] These "covered entities"[3] include children's hospitals, rural hospitals, federally qualified health centers, Ryan White HIV/AIDS clinics, and other hospitals and health centers that serve vulnerable patients.[4] The covered entities rely on 340B program savings to promote access to care for underserved populations. Restricting crucial discount pricing will reduce covered entities' access to program savings, thereby thwarting their safety-net missions and causing painful cutbacks to critical healthcare services.

Despite clear federal statutory requirements, Sanofi has recently refused to send medications to covered entities using contract pharmacies. In addition, Sanofi has stated that it will no longer distribute 340B discounted drugs to contract pharmacies unless covered entities using contract pharmacies provide broad claims data to Sanofi's third-party platform, 340B ESP. Both actions are outrageous. By refusing to provide 340B medications to covered entities, Sanofi will disrupt 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. Sanofi is also depriving covered entities of discounts necessary to continue serving low-income patients who may otherwise do without necessary healthcare.

Moreover, Sanofi's actions will deprive patients of necessary medication at an affordable price during a time of great need. One covered entity in Connecticut reports that diabetic patients have been forced to change medications as a result of recent drug company actions restricting access to 340B discounted drugs – sometimes increasing the cost to patients to fill their prescriptions by hundreds of dollars. Similarly, underinsured patients who need inhalers to treat asthma or chronic obstructive pulmonary disease may have to pay $400 above the 340B cost. Patients who cannot

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afford these increased costs may be forced to stop taking their medications, thereby exacerbating their underlying conditions and putting them at risk for serious medical complications.

There is no legal basis for Sanofi's actions. Denying outpatient access to appropriate 340B drug pricing is a clear violation of federal law. Nothing in the Act allows Sanofi to impose conditions or restrictions on covered entities' access to 340B drug pricing, including requiring that data be provided to a third party for reasons unrelated to patient care and unrelated to any reasonable belief that any covered entity has acted improperly. Indeed, Sanofi's surprise announcement that it will now refuse to ship most 340B drugs to outpatient contract pharmacies absent the provision of data contravenes decades-old policies of the U.S. Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA"), which has statutory authority to oversee the 340B Drug Pricing Program. Since 1996, HRSA has expressly allowed covered entities to contract with outpatient pharmacies to fill prescriptions for 340B eligible patients.[5] 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.[6] Moreover, HRSA's guidance expressly 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.[7]

Sanofi's recent demands to covered entities for medications claims data present significant concerns. First, the demands for data are without basis in any law or regulation. Second, the deadline you have issued is arbitrary, unrelated to the core mission of the 340B program and unrelated to the covered entities' interactions with Sanofi.[8] Third, the broad scope of the sought-after data, which includes Protected Health Information (PHI)[9] is concerning.[10]

Sanofi's data demand, along with its abrupt disavowal of longstanding HRSA policy and well-established practice within the pharmaceutical industry of shipping 340B drugs to contract pharmacies that partner with safety-net hospitals and health centers, is deeply troubling especially

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10 The Department of Health and Human Services has stated that covered entities "may use and disclose protected health information for *its own treatment, payment, and healthcare operation activities.*" https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html , citing 45 C.F.R. § 164.506(c) (emphasis added). The purpose of Merck's request exceeds the scope of such disclosure. Merck and its 340B data collection agent have provided insufficient assurances regarding the protection of the PHI being demanded by your company.

given the ongoing COVID-19 health crises. Not only are Sanofi's actions an attempt to disrupt long-settled expectations and existing contractual arrangements for dispensing 340B drugs, but Sanofi is making this attempt during a historic pandemic and unprecedented economic crises. Indeed, HHS has called the timing of such unfortunate recent actions "*at the very least*, insensitive to the recent state of the economy."[11] Safety-net healthcare institutions are struggling to meet the dual challenges of responding to COVID-19 and maintaining long-term financial stability. And the needs of individual patients who will be directly harmed by a lack of accessible and affordable medications must not and cannot be ignored. Sanofi's combined actions directly thwart the essence of the 340B program—ensuring that medicine and healthcare are provided to the underserved patients who need it most.

My office will not stand idly by while Sanofi and other drug companies prioritize profits over access to affordable prescription medications and other critical medical services for vulnerable communities. Therefore, I urge Sanofi to abandon its unilateral and unlawful actions.

Very truly yours,

WILLIAM TONG

Cc: Robert P. Charrow
General Counsel
Office of the Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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[11] 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

OFFICE OF THE ATTORNEY GENERAL
CONNECTICUT

WILLIAM TONG
ATTORNEY GENERAL

October 5, 2020

Via Email

Pascal Soriot
Executive Director and Chief Executive Officer

Jeff Pott
General Counsel

Astra Pharmaceuticals, L.P.
1800 Concord Pike
Wilmington, DE 19803

Re: *340B Medications*

Dear Mr. Soriot and Mr. Pott:

I write to urge Astra Pharmaceuticals, L.P ("AstraZeneca") to abandon its recent action of unilaterally restricting access to low cost drug pricing by covered entities in Connecticut and other states. This action would directly undermine the 340B Drug Pricing Program, obstruct patient access to critical prescription medications, and devastate the financial stability of healthcare centers and hospitals serving vulnerable communities. AstraZeneca's threats to flout federal requirements and discontinue appropriate 340B drug pricing are especially appalling given that these critical safety-net healthcare institutions are on the front lines of our response to the ongoing COVID-19 pandemic. Moreover, low income patients suffering chronic conditions (including cancer, hypertension, heart disease, diabetes, HIV/AIDS, asthma, arthritis, and opioid use disorder), and those facing heightened COVID-19 risks, could be blocked from affordable lifesaving prescription medications due to AstraZeneca's unlawful actions.

As you know, the 340B Drug Pricing Program, enacted by Congress as part of the Public Health Service Act, ("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 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."[1]

Federal law requires drug manufactures wishing to participate in Medicaid and Medicare Part B to offer outpatient prescription drugs to eligible safety-net healthcare centers and hospitals at a discounted "ceiling" price.[2] These "covered entities"[3] include children's hospitals, rural hospitals, federally qualified health centers, Ryan White HIV/AIDS clinics, and other hospitals and health centers that serve vulnerable patients.[4] The covered entities rely on 340B program savings to promote access to care for underserved populations. Restricting crucial discount pricing would reduce covered entities' access to program savings, thereby thwarting their safety-net missions and causing painful cutbacks to critical healthcare services.

Despite clear federal statutory requirements, AstraZeneca has recently stated that it would no longer distribute 340B discounted drugs to contract pharmacies that partner with covered entities to ensure outpatient access to prescription medications. This is outrageous. By refusing to honor contract pharmacy orders, AstraZeneca would disrupt an essential mode used by many covered entities for dispensing 340B drugs to underserved and vulnerable patient populations who rely on these pharmacies in their communities to fill their prescriptions. AstraZeneca is also depriving covered entities of discounts necessary to continue serving low-income patients who may otherwise do without necessary healthcare.

Moreover, AstraZeneca's actions will deprive patients of necessary medication at an affordable price during a time of great need. One covered entity in Connecticut reports that diabetic patients have been forced to change medications as a result of recent drug company actions restricting access to 340B discounted drugs – sometimes increasing the cost to patients to fill their prescriptions by hundreds of dollars. Similarly, underinsured patients who need inhalers to treat asthma or chronic obstructive pulmonary disease may have to pay $400 above the 340B cost. Patients who cannot

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3 *See* 42 U.S.C. § 256b(a)(2)(B)(4).

4 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). In Connecticut, there are 111 covered entities. https://portal.ct.gov/DPH/Family-Health/Community-Health-Centers/Community-Health-Center-Programs--Services#:~:text=Six%20Community%20Health%20Centers%20in,340B%20facilities%20throughout%20the%20state.

afford these increased costs may be forced to stop taking their medications, thereby exacerbating their underlying conditions and putting them at risk for serious medical complications.

There is no legal basis for AstraZeneca's actions. Denying outpatient access to appropriate 340B drug pricing is a clear violation of federal law. Nothing in the Act allows AstraZeneca to impose conditions or restrictions on covered entities' access to 340B drug pricing, including discontinuing the longstanding practice of shipping drugs to contract pharmacies. Indeed, AstraZeneca's surprise announcement that it will now refuse to ship most 340B drugs to outpatient contract pharmacies contravenes decades-old policies of the U.S. Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA"), which has statutory authority to oversee the 340B Drug Pricing Program. Since 1996, HRSA has expressly allowed covered entities to contract with outpatient pharmacies to fill prescriptions for 340B eligible patients.[5] 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.[6] Moreover, HRSA's guidance expressly 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.[7]

AstraZeneca's abrupt disavowal of longstanding HRSA policy and well-established practice within the pharmaceutical industry of shipping 340B drugs to contract pharmacies that partner with safety-net hospitals and health centers is deeply troubling especially given the ongoing COVID-19 health crises. Not only is AstraZeneca attempting to disrupt long-settled expectations and existing contractual arrangements for dispensing 340B drugs, it is doing so during a historic pandemic and unprecedented economic crises. Indeed, HHS has called similar actions of another drug company "*at the very least*, insensitive to the recent state of the economy" and expressed "significant initial concerns with [the] new policy. . . ."[8] The contrast between safety-net healthcare institutions struggling to meet the dual challenges of responding to COVID-19 and maintaining long-term financial stability on the one hand, and drug companies callously chasing increased profits on the other, is striking. And the needs of individual patients who will be directly harmed by a lack of accessible and affordable medications must not and cannot be ignored. AstraZeneca's actions directly thwart the essence of the 340B program—ensuring that medicine and healthcare are provided to the underserved patients who need it most.

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6 *See* 75 Fed. Reg. 10272 (March 5, 2010).

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

8 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

My office will not stand idly by while AstraZeneca and other drug companies prioritize profits over access to affordable prescription medications and other critical medical services for vulnerable communities. Therefore, I urge AstraZeneca to abandon its unilateral and unlawful actions.

Very truly yours,

WILLIAM TONG

Cc: Robert P. Charrow
General Counsel
Office of the Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

OFFICE OF THE ATTORNEY GENERAL
CONNECTICUT

WILLIAM TONG
ATTORNEY GENERAL

October 5, 2020

Via Email

David A. Ricks
Chairman and Chief Executive Officer

Anat Hakim
Senior Vice President & General Counsel

Eli Lilly and Company
Corporate Center
Indianapolis, IN 46285

Re: *340B Medications*

Dear Mr. Ricks and Ms. Hakim:

I write to urge Eli Lilly and Co. ("Eli Lilly") to abandon its recent action of unilaterally restricting access to low cost drug pricing by covered entities in Connecticut and other states. This action would directly undermine the 340B Drug Pricing Program, obstruct patient access to critical prescription medications, and devastate the financial stability of healthcare centers and hospitals serving vulnerable communities. Eli Lilly's threats to flout federal requirements and discontinue appropriate 340B drug pricing are especially appalling given that these critical safety-net healthcare institutions are on the front lines of our response to the ongoing COVID-19 pandemic. Moreover, low income patients suffering chronic conditions (including cancer, hypertension, heart disease, diabetes, HIV/AIDS, asthma, and arthritis), and those facing heightened COVID-19 risks, could be blocked from affordable lifesaving prescription medications due to Eli Lilly's unlawful actions.

As you know, the 340B Drug Pricing Program, enacted by Congress as part of the Public Health Service Act, ("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 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,

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Hartford, Connecticut 06106

the committee has emphasized the importance of the 340B program in providing care to vulnerable Americans."[1]

Federal law requires drug manufactures wishing to participate in Medicaid and Medicare Part B to offer outpatient prescription drugs to eligible safety-net healthcare centers and hospitals at a discounted "ceiling" price.[2] These "covered entities"[3] include children's hospitals, rural hospitals, federally qualified health centers, Ryan White HIV/AIDS clinics, and other hospitals and health centers that serve vulnerable patients.[4] The covered entities rely on 340B program savings to promote access to care for underserved populations. Restricting crucial discount pricing would reduce covered entities' access to program savings, thereby thwarting their safety-net missions and causing painful cutbacks to critical healthcare services.

Despite clear federal statutory requirements, Eli Lilly has recently stated that it would no longer distribute 340B discounted drugs to contract pharmacies that partner with covered entities to ensure outpatient access to prescription medications.[5] This is outrageous. By refusing to honor contract pharmacy orders, Eli Lilly would disrupt an essential mode used by many covered entities for dispensing 340B drugs to underserved and vulnerable patient populations who rely on these pharmacies in their communities to fill their prescriptions. Eli Lilly is also depriving covered entities of discounts necessary to continue serving low-income patients who may otherwise do without necessary healthcare.

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

2 Specifically, 42 U.S.C. § 256b(a)(1) provides that drug manufacturers must "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."

3 *See* 42 U.S.C. § 256b(a)(2)(B)(4).

4 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). In Connecticut, there are 111 covered entities. https://portal.ct.gov/DPH/Family-Health/Community-Health-Centers/Community-Health-Center-Programs--Services#:~:text=Six%20Community%20Health%20Centers%20in,340B%20facilities%20throughout%20the%20state.

5 Eli Lilly indicated it would consider exceptions only for covered entities distributing to a single contract pharmacy where a covered entity lacks an in-house outpatient pharmacy. Limited Distribution Plan Notice for Eli Lilly and Company Products.

Moreover, Eli Lilly's actions will deprive patients of necessary medication at an affordable price during a time of great need. One covered entity in Connecticut reports that diabetic patients have been forced to change medications as a result of recent drug company actions restricting access to 340B discounted drugs – sometimes increasing the cost to patients to fill their prescriptions by hundreds of dollars. Similarly, underinsured patients who need inhalers to treat asthma or chronic obstructive pulmonary disease may have to pay $400 above the 340B cost. Patients who cannot afford these increased costs may be forced to stop taking their medications, thereby exacerbating their underlying conditions and putting them at risk for serious medical complications.

There is no legal basis for Eli Lilly's actions. Denying outpatient access to appropriate 340B drug pricing is a clear violation of federal law. Nothing in the Act allows Eli Lilly to impose conditions or restrictions on covered entities' access to 340B drug pricing, including discontinuing the longstanding practice of shipping drugs to contract pharmacies. Indeed, Eli Lilly's surprise announcement that it will now refuse to ship most 340B drugs to outpatient contract pharmacies contravenes decades-old policies of the U.S. Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA"), which has statutory authority to oversee the 340B Drug Pricing Program. Since 1996, HRSA has expressly allowed covered entities to contract with outpatient pharmacies to fill prescriptions for 340B eligible patients.[6] 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.[7] Moreover, HRSA's guidance expressly 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.[8]

Eli Lilly's abrupt disavowal of longstanding HRSA policy and well-established practice within the pharmaceutical industry of shipping 340B drugs to contract pharmacies that partner with safety-net hospitals and health centers is deeply troubling especially given the ongoing COVID-19 health crises. Not only is Eli Lilly attempting to disrupt long-settled expectations and existing contractual arrangements for dispensing 340B drugs, it is doing so during a historic pandemic and unprecedented economic crises. Indeed, HHS has called the timing of Eli Lilly's unfortunate actions "*at the very least*, insensitive to the recent state of the economy" and expressed "significant initial concerns with [Eli] Lilly's new policy. . . ."[9] The contrast between safety-net healthcare institutions

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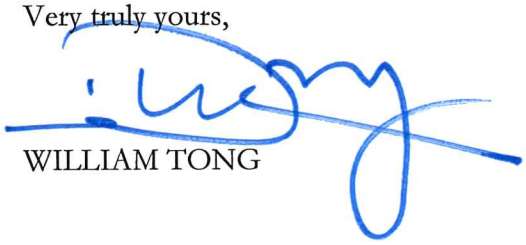
struggling to meet the dual challenges of responding to COVID-19 and maintaining long-term financial stability on the one hand, and Eli Lilly's unprecedented stock prices and profits in 2020[10] on the other, is striking. And the needs of individual patients who will be directly harmed by a lack of accessible and affordable medications must not and cannot be ignored. Eli Lilly's actions directly thwart the essence of the 340B program—ensuring that medicine and healthcare are provided to the underserved patients who need it most.

My office will not stand idly by while Eli Lilly and other drug companies prioritize profits over access to affordable prescription medications and other critical medical services for vulnerable communities. Therefore, I urge Eli Lilly to abandon its unilateral and unlawful actions.

Very truly yours,



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10 https://investor.lilly.com/stock-information/historic-stock-lookup