

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF THE U.S. TRADE REPRESENTATIVE

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SECTION 301 INVESTIGATION OF ACTS, POLICIES, AND
PRACTICES OF GERMANY RELATED TO PERSISTENT
UNDERPAYMENT FOR INNOVATIVE PHARMACEUTICAL
PRODUCTS

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TUESDAY
SEPTEMBER 22, 2026

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The Section 301 Committee convened at
the U.S. International Trade Commission, 500 E
Street SW, Washington, D.C., at 10:00 a.m.,
Philip Butler, Panel Chair, presiding.

PRESENT:

PHILIP BUTLER, Office of the U.S. Trade
Representative, Panel Chair
TRACY CARSON, Department of Health & Human
Services
WON CHANG, Department of Treasury
CYNTHIA ECHEVERRIA, Department of Homeland
Security
RACHEL HASANDRAS, Office of the U.S. Trade
Representative
STU HUFFMAN, Department of State
CHRISTINA OLSON, Office of the U.S. Trade
Representative
TOBIAS REYNOLDS, Department of Commerce

PANEL 1:

JEFFREY GERRISH, Schagrin Associates
KEVIN HANINGER, Pharmaceutical Research and
Manufacturers of America
THOMAS HWANG, Harvard Medical School, Brigham
and Women's Hospital
CHRIS ISRAEL, Alliance of U.S. Startups and
Inventors for Jobs
SATYA MARAR, Mercatus Center at George Mason
University
JAMES POOLE, Obelisk Tech Systems Inc.
FREDERIK ROEDER, Consumer Choice Center
PERRY SIATIS, AbbVie Inc.
MEGAN WHITEMAN, Public Citizen

ALSO PRESENT:

SHARON BELLAMY, U.S. International Trade
Commission

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P-R-O-C-E-E-D-I-N-G-S

(10:01 a.m.)

MR. BUTLER: Good morning and welcome.

The Office of the United States Trade Representative, in conjunction with the Interagency Section 201 Committee, is holding this public hearing in connection with the Section 301 investigation of Germany's persistent underpayment for innovative pharmaceutical products.

The United States Trade Representative initiated this investigation on June 18, 2026. Under a Federal Register Notice published on June 24th, 2026, announcing this investigation, USTR also invited written comments and announced this hearing.

The June 24 notice invited comment on a number of issues going to the question of whether the acts, policies, or practices at issue are actionable under the statute.

Under Section 301 of the Trade Act of 1974, actionable matters include acts, policies,

1 and practices of a foreign country that are
2 unreasonable and discriminatory, and burden or
3 restrict U.S. commerce.

4 The June 24 notice is available on the
5 USTR webpage under the Section 201
6 Investigations page, and is published in the
7 Federal Register at 91 Fed. Reg. 38072.

8 The purpose of this hearing is to
9 receive public testimony regarding the issues
10 raised in the June 24 notice. The Section 301
11 Committee will carefully consider today's
12 testimony, as well as all written comments in
13 response to the Federal Register Notice,
14 including post-hearing rebuttal comments.

15 Because this hearing will last one day,
16 all written comments, including post-hearing
17 comments, are due September 29, 2026.

18 Consistent with the rules and
19 procedures set forth in the June 24 Federal
20 Register Notice, witnesses have provided USTR
21 and the Section 301 Committee with a summary of
22 their testimony in advance of today's hearing.

1 As appropriate, witnesses have been advised in
2 advance that this hearing will not address
3 potential remedies under Section 301, which is a
4 separate inquiry.

5 After the Section 301 Committee has
6 completed its work, the committee will make a
7 recommendation to the United States Trade
8 Representative on whether the acts, policies,
9 and practices, and practices are actionable
10 under the statute.

11 If the Trade Representative determines
12 actionable acts, policies, and practices exist,
13 the United States Trade Representative will
14 determine whether action is appropriate and, if
15 so, what action to take, which would involve an
16 additional notice and comment period.

17 We are pleased to have international
18 trade and economic experts from a range of U.S.
19 Government departments and agencies here today.

20 We will go, first start with introductions, and
21 we'll start with State, please.

22 MR. HUFFMAN: I'm Stu Huffman, Senior

1 Trade Advisor, the Office of Multilateral Trade
2 Affairs, Department of State.

3 MS. CARSON: Good morning. My name is
4 Tracey Carson. I'm a Senior Advisor for Health
5 with the Office of Global Affairs at the
6 Department of Health and Human Services.

7 MS. OLSON: Christina Olson with the
8 Office of the United States Trade
9 Representative.

10 MR. REYNOLDS: Tobias Reynolds with the
11 Office of Trade Negotiations and Analysis at the
12 Department of Commerce.

13 MS. ECHEVERRIA: Good morning. Cynthia
14 Echeverria, Director for Trade Policy at the
15 Department of Homeland Security.

16 MR. CHANG: Hi. Good morning. Won
17 Chang, Department of the Treasury, Office of
18 International Trade and Investment Policy.
19 Thanks

20 MR. BUTLER: And I'm Philip Butler
21 with the Office of the United States Trade
22 Representative and Chair of the Section 301

1 Committee.

2 Before we proceed with the panel, I
3 will provide some procedural and administrative
4 instructions. Please note that no cameras, or
5 video, or audio will be allowed during the
6 hearing.

7 The hearing is scheduled to conclude
8 today, Tuesday, September 22. A written
9 transcript of this hearing will be posted on the
10 USTR website and on the Federal Register docket
11 as soon as possible after the conclusion of this
12 hearing.

13 We have one panel of witnesses with
14 nine individuals scheduled to testify. The
15 provisional schedule has been posted on the USTR
16 website.

17 Each witness appearing at the hearing
18 is limited to five minutes of oral testimony.
19 The light before you will be green when you
20 start your testimony, yellow means you have one
21 minute left, and red means your time has
22 expired.

1 After the testimony from the panel, the
2 Section 301 Committee will have an opportunity
3 to ask questions. All questions will be from
4 agency representatives. There will be no
5 questions accepted from the floor. Committee
6 representatives will generally direct their
7 questions to one or more specific witnesses.

8 Again, post-hearing comments, including
9 any written responses to questions from the
10 Section 301 Committee are due September 29,
11 2026. The rules and procedures for written
12 submissions are set out in the June 24 Federal
13 Register Notice.

14 We request that witnesses, when
15 responding to questions, be as concise as
16 possible. We, likewise, ask witnesses to be
17 understanding if and when the chair asks that a
18 witness conclude a response. In this regard,
19 witnesses should recall that they have the full
20 opportunity to provide more extensive responses
21 in their post-hearing submission.

22 Witnesses should please turn on their

1 microphone and speak directly into the
2 microphones with your testimony and to answer
3 any questions.

4 With that, we will begin. Can we seat
5 the panel, please?

6 (Pause.)

7 MR. BUTLER: Okay, thank you.

8 Mr. Israel, the floor is yours.

9 MR. ISRAEL: Good morning. I would
10 like to thank the members of the Section 301
11 Committee for the opportunity to testify today.
12 My name is Chris Israel, and I am the Executive
13 Director of The Alliance of U.S. Startups and
14 Inventors for Jobs, USIJ. We are coalition of
15 inventors, startups, entrepreneurs, research
16 institutions, and the venture investors who
17 support them. USIJ is committed to
18 strengthening America's innovation ecosystem.

19 I am here today to express our strong
20 support for the USTR's investigation into
21 Germany's underpayment for medicines. USIJ's
22 members fundamentally believe that intellectual

1 property protections are critical to any
2 innovation but hold little value when foreign
3 governments can strip away the economic rewards
4 they're designed to deliver. That's why this
5 investigation is so important.

6 The Administration has accurately
7 observed that Germany's pharmaceutical pricing
8 policies unfairly shift the cost of
9 pharmaceutical research and development onto the
10 United States.

11 Developing a successful therapy can
12 require years of research and billions of
13 dollars. Investors accept these risks only when
14 they believe that successful discoveries can
15 earn sufficient returns in global markets.
16 Germany's pricing policies weaken incentives to
17 invest in innovation.

18 When governments systematically drive
19 prices below market-based levels they reduce the
20 expected return on successful discoveries.
21 Lower expected returns make pharmaceutical
22 investment less attractive.

1 Germany's persistent underpayment
2 doesn't just affect Wall Street or Big Pharma.
3 The U.S. biopharmaceutical industry directly
4 employed more than a million works in 2022, and
5 supported more than 4.9 million jobs across the
6 economy. When Germany undermines innovation
7 incentives, it's hurting these workers,
8 researchers and venues.

9 Germany is hardly the only offender.
10 Most other wealthy nations similarly underpay
11 for medicines. Americans represent less than 5
12 percent of the world's population, but the U.S.
13 market generates roughly 75 per cent of global
14 pharmaceutical profits.

15 Earlier this year, the United States
16 and the United Kingdom reached an agreement that
17 showed we can work with these countries to
18 correct that imbalance. The agreement
19 recognized that countries benefitting from
20 innovative medicines must take responsibility
21 for sustaining the research ecosystem and the
22 intellectual property that produces them.

1 It also acknowledged that stronger
2 intellectual property protections and market-
3 based incentives encourage investment,
4 strengthen supply chains, and support high-
5 paying jobs. Germany can and should be next.

6 The effects of this investigation will
7 also extend well beyond Germany. Other
8 offenders, including trading partners like
9 Canada, Japan, and South Korea are watching
10 closely. The investigation will show them that
11 the United States is serious about making
12 wealthy partners pay fairly for American
13 discoveries.

14 And, if USTR secures meaningful reforms
15 in Germany, it will establish an important
16 precedent if the United States is prepared to
17 use its trade laws to defend American
18 intellectual property and protect the workers,
19 inventors, companies, and investors that produce
20 innovative new medicines.

21 We strongly support this investigation
22 and urge USTR to pursue meaningful reforms

1 without delay. Germany should be the first of
2 many countries that we push to end harmful
3 pharmaceutical pricing policies.

4 Thank you for your time and
5 consideration today.

6 MR. BUTLER: Thank you.

7 Ambassador Gerrish.

8 MR. GERRISH: Good morning, members of
9 the Section 301 Committee. My name is Jeff
10 Gerrish, and I served as Deputy United States
11 Trade Representative in the first Trump
12 administration. In that role, I saw firsthand
13 how unfair foreign trade practices harm American
14 companies and workers, our broader economy, and
15 our national security.

16 One particularly consequential problem
17 is that nearly all developed countries impose a
18 variety of direct and indirect price controls on
19 medicines. These policies allow foreign
20 countries to obtain innovative medicines, often
21 developed in the United States, at artificially
22 low prices. That forces American patients,

1 employers, and taxpayers to shoulder a
2 disproportionate share of the cost of
3 pharmaceutical research and development.

4 USTR's Section 301 investigation into
5 Germany's persistent underpayment for innovative
6 medicines is an important step toward addressing
7 one of the worst offenders. By thoroughly
8 examining Germany's practices and leveraging its
9 findings to secure fairer pricing commitments,
10 USTR can establish a clear template for
11 confronting similar practices around the globe.

12 President Trump has rightly recognized
13 foreign free-riding on U.S.-funded
14 pharmaceutical innovation as a serious and
15 pervasive problem. The United States represents
16 just over 4 percent of the world's population
17 and about one-quarter of global GDP. Yet, it
18 accounts for roughly half of worldwide
19 pharmaceutical R&D spending and three-quarters
20 of global pharmaceutical profits.

21 According to a 2023 analysis by the
22 Information Technology and Innovation

1 Foundation, if other developed countries had
2 paid U.S. market prices for innovative medicines
3 in 2018, biotechnology companies worldwide would
4 have earned an additional \$254 billion that
5 year.

6 Much of that additional revenue would
7 have flowed to American companies, supporting
8 greater investment in research and development,
9 more job creation, and the development of dozens
10 of additional medicines.

11 Germany is an especially egregious
12 offender when it comes to suppressing
13 pharmaceutical spending. Over the years, it has
14 used unfair policies and practices to keep its
15 spending on innovative pharmaceuticals at less
16 than half that of the United States on a per
17 capita GDP basis.

18 If Germany alone had paid U.S. prices
19 for medicines in 2018, biotechnology companies
20 would have earned nearly \$35 billion in
21 additional revenue. But rather than adopting
22 needed reforms to do its fair share, the Germany

1 Government has doubled down on its longstanding
2 price controls.

3 Recently, German lawmakers approved
4 even steeper mandated rebates on medicines. To
5 compound this problem as Europe's largest
6 economy and one of the world's largest
7 pharmaceutical markets, Germany's pricing
8 decisions set an example for countries
9 worldwide. This is precisely what makes USTR's
10 investigation into Germany such a crucial step.

11 A robust Section 301 investigation can
12 give the United States the leverage it needs to
13 bring Germany to the negotiating table and
14 secure meaningful reforms to its pharmaceutical
15 pricing and reimbursement policies. The
16 agreement USTR recently negotiated with the
17 United Kingdom, which committed to roughly
18 doubling its spending on innovative medicines as
19 a share of GDP, demonstrates how trade pressure
20 can compel foreign governments to adopt fairer
21 policies.

22 Securing a similar agreement with

1 Germany would send a powerful signal that
2 advanced economies must share the global R&D
3 burden more equitably.

4 Conversely, if the United States allows
5 Germany to get away with continued freeloading,
6 other governments will take notice and,
7 likewise, stonewall U.S. demands for reforms.

8 I urge USTR to complete this Section
9 301 investigation expeditiously, and to use
10 every tool available under Section 301 to secure
11 meaningful reforms from Germany.

12 But our efforts should not stop there.
13 Free-riding is a global problem, and solving it
14 will require the rest of America's trading
15 partners to more fairly contribute to the cost
16 of developing new medicines. For the sake of
17 American workers, taxpayers, and patients,
18 Germany should be the first country brought to
19 the negotiating table, but it certainly should
20 not be the last.

21 Thank you for the opportunity to
22 testify today. And I look forward to your

1 questions.

2 MR. BUTLER: Thank you.

3 Mr. Siatis.

4 MR. SIATIS: Good morning and thank you
5 for this opportunity to testify. I am Perry
6 Siatis, the Executive Vice President, General
7 Counsel, and Secretary of AbbVie, an American
8 biopharmaceutical company that researches,
9 discovers, and develops medicines that, once
10 approved, reach 74 million patients globally.

11 We strongly support the
12 Administration's efforts to gain agreement by
13 Germany to address their unreasonable and
14 discriminatory acts, policies, and practices
15 that burden U.S. commerce by cutting prices for
16 those medicines in Germany to unfair levels that
17 do not reflect a proportionate share of AbbVie's
18 R&D investment.

19 Since becoming an independent company
20 in 2013, AbbVie has invested more than \$85
21 billion in R&D in pursuit of life-changing
22 medicines addressing serious diseases like blood

1 and solid tumor cancers, and Parkinson's
2 Disease, among others. Our investments support
3 not only the medicines that succeed, but also
4 the many unsuccessful research efforts that are
5 an essential cost of discovering new treatments.

6 Unfortunately, many countries outside
7 the United States, including Germany, use their
8 laws to deny companies like AbbVie reasonable
9 prices that reflect our R&D investments and the
10 value these medicines deliver.

11 These countries fail to pay their fair
12 share for access to the world's best medicines
13 when compared to the United States.

14 Under Section 301 of the Trade Act of
15 1974, the U.S. Government may act against a
16 trading partner whose acts, policies, and
17 practices are unreasonable or discriminatory,
18 and burden or restrict U.S. commerce. That
19 standard is certainly met here.

20 I will highlight just a few examples.

21 First, the German health technology
22 assessment policy known as AMNOG Process, does

1 not correctly measure value and is inconsistent
2 with global norms. The result is chronic
3 underpayment for innovative medicines.

4 For instance, Germany regularly ignores
5 or rejects clinical evidence that regulatory
6 bodies, including the EMA and FDA, accept or
7 even request during the approval process to
8 prove value and benefit to patients.

9 Second, Germany's mandatory rebates are
10 used to force innovative manufacturers,
11 including AbbVie, to fund budget shortfalls that
12 are instead the responsibility of the Germany
13 Government. This practice cuts prices even
14 further.

15 Third, Germany quickly passed a new law
16 this year that is even more unreasonable and
17 discriminatory than historic laws. Despite
18 President Trump's attempts to get the rest of
19 the world to pay their fair share, Germany in
20 just 90 days proposed and passed a law that more
21 than doubled mandatory rebates, and added Focus
22 Lists, a new mechanism targeting medicines sold

1 primarily by American companies, including
2 AbbVie.

3 This will force new price reductions
4 through unfair tender procedures that will
5 further distort fair market competition.

6 Lastly, these acts, practices, and
7 policies work in combination to magnify their
8 negative impact. For example, Germany rejected
9 important clinical evidence when evaluating
10 AbbVie's innovative migraine treatment and
11 preventive medicine Aquipta.

12 Aquipta will be subject to mandatory
13 rebates, including at higher levels under the
14 new law. And it is a target of the new law's
15 initial Focus Lists. The compounding effect of
16 these laws puts Aquipta in jeopardy of its
17 already low price being forced to new
18 unjustified lows.

19 The facts we have outlined for the U.S.
20 Government are clear. In Germany the government
21 dictates the terms of price, access, and
22 reimbursement. AbbVie is unable to negotiate

1 price fairly and freely. Germany laws ensure
2 this outcome, with limited or often no legal
3 recourse for the manufacturing to challenge
4 Germany.

5 We support USTR's exercise of Section
6 301 and its statutory leverage to gain a swift
7 agreement with Germany.

8 To be clear, success is not simply
9 repealing this year's law. Germany's underlying
10 system must also change. At a minimum, Germany
11 should increase funding for innovative
12 medicines, not just early stage research, reform
13 its health technology assessment so that unfair
14 standards can no longer be used to justify
15 undervaluating innovative treatments, and
16 eliminate mandatory rebates.

17 Your recent agreement with the United
18 Kingdom offers a strong framework that can be
19 tailored here. Your resolution with Germany can
20 signal to the rest of Europe and major economies
21 what the U.S. Government expects from its
22 trading partners.

1 Thank you very much.

2 MR. BUTLER: Thank you.

3 Mr. Hwang.

4 MR. HWANG: Thank you to USTR, Mr.
5 Chair, and the Section 301 Committee for
6 organizing this hearing.

7 My name is Professor Thomas Hwang. I'm
8 a physician researcher and Director of the
9 Cancer Innovation and Regulation Initiative at
10 Harvard Medical School and the Brigham and
11 Women's Hospital in Boston. All views here are
12 my own.

13 Our systematic review of the evidence
14 does not support claims that the German
15 pharmaceutical system is unreasonable or
16 discriminatory under the meaning of Section 301,
17 or that they burden or restrict U.S. commerce.

18 My testimony today calls for USTR to
19 not make a positive determination in this
20 Section 301 investigation of the German
21 pharmaceutical pricing system.

22 Our research indicates that Germany is

1 among the top three countries of origin for
2 innovative medicine imports into the U.S. by
3 value, underscoring the importance for access to
4 medicines by U.S. patients.

5 The USTR's notice of initiation of
6 investigation highlights two policies that
7 concerns the committee:

8 First is the proposed dynamic or
9 variable pharmaceutical rebates, and;

10 Second is confidentiality of prices.

11 My comments are structured around five
12 key considerations on these two policies.

13 First, the variable pharmaceutical
14 rebates cited by USTR were excluded from the
15 final enacted legislation. The final German
16 legislative text instead includes an increased
17 statutory rebate of 15.5 percent, which applies
18 to all pharmaceutical companies regardless of
19 domicile, and is not unreasonable or
20 discriminatory within the meaning of Section
21 301.

22 In fact, this statutory rebate in

1 Germany is lower than comparable minimum
2 statutory rebates here in the United States.

3 For example, 23.1 percent is guaranteed
4 for Medicaid, 24 percent for the VA, and 25 to
5 60 percent for Medicare under the Inflation
6 Reduction Act.

7 Second, the second policy of concern,
8 the price confidentiality mechanism, is not
9 discriminatory and is rarely applied, therefore,
10 not burdening U.S. commerce. This voluntary
11 mechanism in the German system is available to
12 both domestic and foreign manufacturers and,
13 ultimately, rarely used.

14 Since its entry into force in 2025,
15 this mechanism has been invoked by manufacturers
16 for only two products. Given how rarely this
17 provision has been invoked, there is no evidence
18 that this provision or this policy has burden to
19 U.S. commerce.

20 Third, similar price confidentiality
21 policies are widely used here in the U.S. and in
22 other countries. In the U.S. system,

1 confidentiality of negotiated prices is a common
2 condition of pricing across public and private
3 payers. The expectation is that confidential
4 final prices reflect additional discounts
5 provided to research payers, such as
6 supplemental rebates in the Medicaid Program
7 that are available to the broader market.

8 In the Medicare Program, the Centers
9 for Medicare and Medicaid Services said that it
10 needed confidentiality to increase the chance of
11 effective and successful negotiation with
12 pharmaceutical companies. The President's
13 nominee for Deputy Secretary of Department of
14 Health and Human Services said in his recent
15 U.S. Senate confirmation hearing that
16 confidential negotiations were needed for the
17 Government's ability to negotiate with other
18 countries.

19 Fourth, conditions on price
20 confidentiality incentivize price transparency,
21 which benefits U.S. public programs and
22 taxpayers. The required discount for price

1 confidentiality in Germany may serve as a
2 deterrent against confidential prices, which
3 benefits U.S. public payers and taxpayers.

4 Following President Trump's May 2025
5 executive order, the Administration has
6 implemented or proposed Most-Favored Nation
7 pricing models in Medicaid and Medicare, all of
8 which include Germany as a reference country.

9 This provision of the German system,
10 therefore, allows the U.S. Federal Government
11 and taxpayers to benefit from lower prices in
12 Germany.

13 Fifth and finally, the evidence does
14 not support a positive determination in this
15 Section 301 investigation. Our research
16 suggests that most German-origin pharmaceutical
17 imports will be exempted from Section 332
18 pharmaceutical tariffs due to company-specific
19 agreements with the Administration.

20 We recommend that if USTR does pursue a
21 positive determination that the Trade
22 Representative not stack any Section 301 tariffs

1 on existing Section 332 duties.

2 In summary, we recommend that USTR not
3 make an affirmative determination in the Section
4 301 investigation and, instead, allow the
5 Administration to continue bilateral
6 negotiations with the German Government for
7 policies that reduce prices for new medicines in
8 both countries.

9 Thank you very much again for the
10 opportunity to present. I welcome any
11 questions.

12 MR. BUTLER: Thank you.

13 Mr. Marar.

14 MR. MARAR: Hi. Chairman and members
15 of the committee, thank you for the opportunity
16 to appear before you today for this important
17 inquiry.

18 My name is Satya Marar. I am a
19 research fellow at the Mercatus Center at George
20 Mason University specializing in competition,
21 innovation, and governance.

22 Our central point is straightforward:

1 Germany's pharmaceutical pricing system shifts
2 a disproportionate share of the cost of global
3 pharma research and development onto American
4 patients, taxpayers, employers, and private
5 health plans.

6 Germany's policies are, therefore, not
7 simply domestic health care choices, there are
8 significant consequences for U.S. commerce,
9 American IP, and the future supply of lifesaving
10 medicines.

11 The U.S. accounts for approximately 5
12 percent of the world's population and about 26
13 percent of global GDP. Yet, our market
14 generates roughly 75 percent of global
15 pharmaceutical profits.

16 Germany is the third largest
17 pharmaceutical market in the world, behind the
18 U.S. and China, but it produces only about 5
19 percent of global pharmaceutical profits,
20 approximately a 15th of the U.S. figure, even
21 though Germany's population and GDP are each
22 roughly one-fifth of the U.S.

1 Moreover, Germany's purchasing power
2 adjust GDP per capita is only about 16 percent
3 lower than America's.

4 These figures are difficult to
5 reconcile with Germany's low contribution to
6 pharmaceutical innovation. They suggest that
7 Germany is not merely paying less because it's
8 substantially poorer or because its citizens
9 have dramatically lower purchasing power,
10 rather, Germany is using government purchasing
11 power and regulatory mechanisms to suppress the
12 prices it pays for patented medicines below
13 competitive levels.

14 The German system illustrates this
15 clearly. Under AMNOG, manufacturers may
16 initially set prices for newly-approved
17 medicines. But those prices are subsequently
18 subject to therapeutic assessments and
19 negotiations with Germany's statutory health
20 insurance system which, in theory, are based on
21 an objective assessment of the therapeutic
22 value.

1 The outcome of these negotiations is
2 that these prices are typically about 25 percent
3 below the launch price.

4 Germany also conditions confidentiality
5 to negotiate prices on the acceptance of a 9
6 percent discount in relation to administration
7 costs.

8 Because 12 of 19 relatively high income
9 OECD countries using reference pricing systems
10 that include Germany, public disclosure of
11 prices can reduce the prices paid in other
12 countries as well. Meaning that this isn't
13 truly a voluntary mechanism, this is closure.

14 Germany's statutory health insurance
15 system covers approximately 90 percent of their
16 population. That gives the German Government
17 strong monopsony power. Manufacturers that
18 reject the these terms risk losing access to
19 most of the German market.

20 In turn, Germany is insulated from the
21 effects of its monopsony power because of the
22 high amount of pharmaceutical profits coming out

1 of the United States, which subsidize the global
2 public good of pharmaceutical innovation that
3 everyone benefits from.

4 Proposed legislation could impose
5 additional mandatory penalties and rebates
6 beginning in 2027, with one estimate suggesting
7 that the dynamic rebate could read 20 percent by
8 2030. What's more, manufacturers can't even
9 adjust their prices based on inflation without
10 incurring financial penalties under German law.

11 This matters because pharmaceutical
12 innovation is not released from the moment the
13 medicine reaches the markets. It depends on
14 expected future revenue to finance research,
15 field clinical trials, regulatory review, and
16 manufacturing investments.

17 Under one estimate from the CBO, a
18 pharma company has to make 60 percent of profit
19 margin on its blockbuster drugs to secure a 4
20 percent return on its overall assets because of
21 the high cost of many failed and -- failed
22 trials.

1 When Germany and other wealthy
2 countries suppress prices, they reduce the
3 expected returns on American pharmaceutical
4 patents. The result of is a three-way problem.

5 American consumers and taxpayers help finance
6 medicines benefitting patients worldwide while
7 foreign governments use their purchasing power
8 and monopsony power to capture a
9 disproportionate share of the savings.

10 The answer is not to impose foreign
11 price control in the U.S. or to force global
12 price uniformity. Research summarized by
13 forthcoming paper shows that when both branded
14 medicines and generics are considered, Medicare
15 and Medicaid pay approximately 18 percent less
16 on average than comparable systems in Germany,
17 U.K., Japan, France, and Canada. More than 90
18 percent of U.S. prescriptions are generic, and
19 U.S. generic prices are approximately 43 percent
20 less on average than comparable developed
21 economies.

22 A constructive solution of the trade

1 agreement that increases Germany's contributions
2 by creating reciprocal benefits for German
3 consumers and businesses.

4 The recent U.S.-U.K. pharma pricing
5 agreement demonstrates this approach is
6 achievable. In exchange for improved access to
7 the U.S. market, the U.K. agreed to raise
8 payments for U.S. medicines by 25 percent while
9 reducing other trade barriers. The agreement is
10 expected to improve access to new medicines and
11 strengthen the U.K.'s domestic life sciences
12 sector.

13 A similar framework could work with
14 Germany. The U.S. could also tab productions,
15 reduce long-term barriers, initial regulatory
16 recognition, or expedite FDA's pathways for
17 qualifying Germany products. In return, Germany
18 could roll back its pharmaceutical price
19 suppression mechanisms, pay more for U.S.
20 medicine, and strengthen protection of the I.P.
21 that makes those medicines possible.

22 MR. BUTLER: Thank you, Mr. Marar, your

1 time has expired.

2 MR. MARAR: Thank you.

3 MR. BUTLER: Thank you.

4 Mrs. Whiteman.

5 MS. WHITEMAN: Good morning.

6 Public Citizen is a nonprofit consumer
7 advocacy organization with more than one million
8 members and supporters across the United States.

9 The Access to Medicines Program advocates for
10 access to prescription drugs in the U.S. and
11 internationally.

12 Germany's drug pricing policies are not
13 unreasonable. Germany's Statutory Health
14 Insurance Contribution Rate Stabilization Act
15 passed earlier this year, and referenced in the
16 Section 301 investigation notice, includes
17 measures to address public insurers' projected
18 budget shortfall.

19 Among other suggestions, Germany's
20 Health Finance Commission recommended adjusting
21 the statutory rebate applied on patented
22 products. The commission had identified

1 pharmaceutical spending among areas where costs
2 have increased since 2024. Spending on patented
3 pharmaceuticals increased 8 percent annually on
4 average over 5 years, driven by higher prices of
5 new drugs rather than prescription volumes.

6 In other words, Germany's policies are
7 justified by the need to manage health care
8 costs, something that governments have a
9 responsibility to do in order to protect the
10 public and steward taxpayer resources.

11 Germany's policies are also not
12 discriminatory as they are applied equally to
13 foreign and domestic industry.

14 Price differences between the U.S. and
15 Germany are not evidence of price suppression.
16 These differences are better understood in the
17 context of the respective countries' health care
18 systems and pharmaceutical pricing policies.

19 In the U.S., the patent-based
20 pharmaceutical industry operate largely without
21 systems providing a check on rising prices.
22 Without such systems, companies seek to maximize

1 profit, pricing drugs based on what the market
2 will bear.

3 Insulated by patents and other
4 exclusivities, pharmaceutical companies charge
5 prices beyond what would be seen in a normal
6 competitive market, and this market power is
7 reflected in rising launch prices for new drugs
8 in both Germany and the United States.

9 In Germany, launch prices increased by
10 an average of 6 percent per year between 2011
11 and 2022.

12 In the United States, launch prices
13 increased by 20 percent per year between 2008
14 and 2021.

15 Pharmaceutical companies do not have a
16 right to these pricing excesses. Patents grant
17 the right to exclude competitors, a consequence
18 of which is their significant market power to
19 set high prices. Patents do not confer the
20 right to a particular price or pricing
21 authority.

22 U.S. courts have rejected industry

1 claims that the Medicare drug price negotiation
2 program infringes property rights by limiting
3 companies' ability to sell products at market
4 rates, concluding that there is no protected
5 property interest in selling to Medicare
6 beneficiaries at a price higher than what the
7 Government is willing to pay.

8 It's only in recent years that Medicare
9 has gained this authority to negotiate prices
10 with drug makers at all. Notably, our
11 negotiation framework policy represents a
12 similar framework to that used in other
13 countries, including in Germany.

14 There is no evidence that costs are
15 shifted onto the U.S. due to lower prices in
16 other countries. Research finds no association
17 between R&D costs and prices. The drug
18 companies receive 163 percent of their global
19 R&D costs just from the excess revenue generated
20 in the United States, underscoring that these
21 companies earn well beyond their R&D spending.

22 Revenues are also not synonymous with

1 greater or better innovation. The majority of
2 company revenue is not spent on R&D.

3 For example, between 2022 and 2025, the
4 15 publicly traded companies whose drugs were
5 selected for the first and second rounds of
6 Medicare price negotiations collectively spent
7 \$4.4 billion more on stock buybacks and
8 dividends than on research and development.

9 Allowing high prices and revenues alone
10 to guide R&D discussions can also distort
11 innovation incentives. According to one study,
12 fewer than half approved first indications for
13 new drugs in the U.S. and Europe added
14 substantial therapeutic value over existing
15 treatments.

16 Notably, Germany's drug price
17 negotiation framework is designed to reward
18 genuine innovation over these small "me too"
19 changes that extend profits without adding
20 value.

21 Treating high drug prices or private
22 sector revenues as directly synonymous with

1 innovation also fails to account for the
2 substantial public sector contributions to
3 innovation. In the United States, the National
4 Institutes of Health plays a critical role in
5 basic research and drug development. NIH
6 research contributed to virtually every new drug
7 approved by the FDA between 2010 and 2019.

8 Higher prices raise costs and can make
9 medicines harder to access. Four in ten
10 Americans struggle to afford their medicine.
11 Many sacrifice other needs in order to afford
12 the care they cannot do without.

13 The U.S. pharmaceutical pricing
14 agreement with the U.K. underscores the risks
15 posed to patients, with the deal expected to
16 redirect billions in health spending toward
17 patented drugs over other health services,
18 leading to an estimated 229,000 excess deaths
19 over 10 years.

20 We urge USTR to take no action and to
21 drop its investigation. Thank you for the
22 opportunity to testify.

1 MR. BUTLER: Thank you.

2 Mr. Haninger.

3 MR. HANINGER: Good morning and thank
4 you very much for this opportunity. My name is
5 Kevin Haninger, Senior Vice President for
6 International Advocacy at the Pharmaceutical
7 Research and Manufacturers of America.

8 PhRMA works on behalf of the innovative
9 industry to advance policies that encourage the
10 discovery of new medicines. We are one of the
11 most research-intensive industries in the United
12 States.

13 PhRMA supports the Administration's
14 efforts to eliminate foreign policies that
15 undervalue innovative medicines, shift the cost
16 of funding innovation onto the United States,
17 and restrict market access for U.S. innovators.

18 This investigation can help to ensure
19 that Germany, one of the world's wealthiest
20 economies, eliminates such policies and pays its
21 fair share for innovative medicines.

22 I will emphasize three main points

1 today. First, Germany's longstanding pricing
2 policies unreasonably undervalue innovative
3 medicines and burden U.S. commerce;

4 Second, new legislation enacted by the
5 German parliament will exacerbate this burden,
6 and;

7 Third, USTR should address this problem
8 by negotiating an agreement through which
9 Germany commits to increase its spending on
10 innovative medicines.

11 For more than a decade, Germany has
12 operated a price-setting regime to control
13 medicine costs for its statutory health
14 insurance system. In setting prices, Germany's
15 Federal Joint Committee, the G-BA, routinely
16 rejects clinical trial evidence, asserting that
17 55 percent of new medicines provide no
18 additional benefit over existing treatments,
19 even though many of these new medicines are
20 recognized as breakthrough therapies.

21 As a result, older, inferior medicines
22 and generics are often used as price benchmarks,

1 subjecting new medicines to unreasonably low
2 prices.

3 Germany also suppresses spending by
4 imposing mandatory rebates on all innovative
5 medicines, and maintaining a price freeze since
6 2010. These policies cause 10 to 15 percent of
7 new medicines to subsequently exit the German
8 market after launch.

9 Overall, Germany's public system
10 reimburses just 55 percent of new medicines
11 compared to 88 percent in the U.S. Medicare
12 program.

13 As a result of these policies, Germany
14 spends only .64 percent of GDP on innovative
15 medicines, compared to 1.32 percent in the
16 United States. This underspend burdens the U.S.
17 economy by suppressing needed innovations and
18 causing Americans to disproportionately pay an
19 additional \$39 billion annually for
20 pharmaceutical innovation.

21 Legislation enacted by the German
22 parliament in July mandates additional rebates

1 that will further reduce Germany's spending on
2 innovative medicines and worsen the burden on
3 U.S. commerce. The law increases the mandatory
4 rebate on innovative medicines from 7 to 15.5
5 percent, and adds a 9 percent rebate on
6 innovative vaccines, on top of existing rebates.

7 The law adds further rebates to a new
8 statutory formula for price volume agreements
9 which unreasonably targets successful treatments
10 that generate greater patient demand.

11 The law also allows insurers to use
12 tender-style rebate contracts to set prices,
13 directing physicians and patients away from
14 innovative medicines, even when G-BA
15 acknowledges their clinical benefits. U.S.
16 company products account for 70 percent of the
17 sales in the drug classes targeted by this new
18 mechanism.

19 The legislation will further reduce
20 Germany's spending on innovative medicines,
21 causing Americans to pay, in total, an
22 additional \$45 billion annually for

1 pharmaceutical innovation.

2 To eliminate the burden on U.S.
3 commerce, USTR should negotiate a bilateral
4 agreement that requires Germany to spend the
5 same share of its GDP on innovative medicines as
6 the United States, and corrects many of the
7 underlying policy problems.

8 When Ambassador Greer announced this
9 investigation he rightly called on Germany to
10 follow the U.K.'s example by negotiating a
11 pharmaceutical pricing agreement with the United
12 States. We support the U.S.-U.K. arrangement
13 and agree that Germany should follow suit.

14 Under the agreement, Germany should
15 increase net prices for prospective new
16 medicines while ensuring rapid access. Germany
17 should achieve this through specific reforms
18 through its benefit assessment and price-setting
19 policies, which are detailed in our written
20 submission.

21 Germany should also ensure that the
22 impact of these reforms are not offset by

1 statutory rebates, price volume agreements,
2 tender-style rebate agreements, or other
3 measures that lower net prices or restrict
4 access. Abolishing these cost containment
5 measures for all innovative medicines, not only
6 prospective new medicines, is necessary to
7 ensure that Germany sufficiently increases
8 spending.

9 In conclusion, our industry greatly
10 appreciates USTR's efforts and looks forward to
11 working constructively with both governments to
12 resolve these concerns. Thank you.

13 MR. BUTLER: Thank you.

14 Mr. Roeder.

15 MR. ROEDER: Thank you for the
16 opportunity to be here. My name is Frederik
17 Roeder and I'm a German health economist and
18 Managing Director of the Consumer Choice Center,
19 which, among many countries in the world, has
20 offices in the United States and Germany.

21 Germany and the U.S. are partners.
22 Sometimes among partners there are

1 disagreements. I think in the last couple of
2 years we could observe that in the area of
3 defense spending. And with the so-called site
4 investor in Germany there was actually an
5 understanding that Germany and the Europeans in
6 general need to spend more on defense and need
7 to stop the free-riding on U.S. defense
8 spending. A similar site investor is also
9 needed in spending on innovative medicines.

10 Germany's pricing policies are not just
11 a German budget measure. They affect American
12 commerce, European patient access, and the
13 global pipeline of future cures. The core
14 problem is simple: governments cannot suppress
15 the price of innovative indefinitely and expect
16 innovative to continue as before.

17 When reimbursement is pushed below a
18 medicine's fair market value, someone pays the
19 price. And, too often, that someone in the
20 patient who waits longer for a treatment, the
21 researcher whose project is never funded, or the
22 American patient who is expected to carry a

1 disproportionate share of the world's
2 pharmaceutical research and development burden.

3 Germany is a particularly important
4 case. It is Europe's largest economy and,
5 historically, one of the faster European markets
6 when it comes to access to medicine. But its
7 recent policy direction sends the wrong signal.

8 Mandatory discounts and proposed additional
9 rebates for patented medicines do not reward
10 innovation, they punish innovation.

11 USTR's notice correctly identifies the
12 concern: Germany's pricing practices can
13 suppress prices below fair market value and
14 contribute to reduced incentives for
15 pharmaceutical investment and R&D. That is an
16 actual risk.

17 Price controls rarely produce their
18 full damage on day one. They accumulate. They
19 make launches less attractive, turn investment
20 committees cautious, and gradually move
21 research, manufacturing, and first launches
22 elsewhere.

1 The interaction with the Most Favored
2 Nation policies makes this entire issue more
3 urgent. Low prices imposed by Europe are used
4 as benchmarks for the United States, then a
5 reimbursement decision made in Berlin can affect
6 expected revenues in the world's largest
7 pharmaceutical market: the U.S. Companies
8 respond rationally. They delay launches in low-
9 price markets or hold back until pricing
10 consequences become more clear. And that is bad
11 for everyone.

12 It's bad for American patients if they
13 remain the backstop for global R&D. It's bad
14 for German patients if innovative medicines
15 arrive late or not at all. It's bad for workers
16 if investment in German life science capacity is
17 scaled back.

18 Two examples of these recent scale-
19 backs in investments in the German
20 pharmaceutical sector were decisions by the
21 American company Eli Lilly to postpone an
22 investment, large investment, multi-billion

1 investment in Germany, and even the German
2 family-owned pharmaceutical manufacturer
3 Boehringer Ingelheim reported a withdrawal of
4 planned investments in Germany due to the most
5 recent pricing decisions and policies in
6 Germany.

7 The goal should not be a trade war
8 between Germany and the U.S. that leaves
9 consumers paying more for medicines than other
10 goods. The goal should be reform. We need a
11 more major style system for developed countries
12 to agree that there is joint burden sharing for
13 pharmaceutical R&D and drug prices.

14 USTR should use this investigation to
15 press Germany towards fair reimbursement,
16 predictable rules, and agreements that reward
17 medicines for the value they deliver to
18 patients.

19 The recent U.S.-U.K. pharmaceutical
20 pricing arrangement offers a useful model that
21 links fairer payment for innovation with better
22 access, stronger supply chains, and protection

1 from additional 301 measures. Germany should be
2 encouraged to pursue a similar path.

3 Again, as a German health economist, my
4 message is European patients do not benefit when
5 governments pretend innovation is costless.

6 American patients should not be forced to
7 subsidize that illusion. A fairer system would
8 protect patient access, reward medical
9 breakthroughs, and keep both side of the
10 Atlantic attractive for the next generation of
11 cures. Thank you very much.

12 MR. BUTLER: Thank you. Our next
13 witness is remote, so we'll just take a minute
14 before we start with him.

15 Thank you.

16 (Pause.)

17 MS. BELLAMY: Mr. Poole, are you able
18 to hear us?

19 MR. POOLE: I can hear you.

20 MS. BELLAMY: All right. Yes, sir, you
21 may begin.

22 MR. POOLE: I am James Poole, CEO of

1 Obelisk Tech Systems, Inc., a small business in
2 Georgia and a registered government contractor.

3 Germany's drug pricing practices are
4 actionable because they are unreasonable and
5 discriminatory and burden or restrict United
6 States commerce. Germany makes drug companies
7 accept a 9 percent discount and then pay extra
8 fees to keep their prices private. Germany's
9 health ministry also proposes a new rebate on
10 patented medicines in 2027, 3.5 percent, then a
11 formula that makes new medicines pay for the
12 health funds' overspending on all medicines.
13 Americans pay about 3.9 times what Germans pay
14 for brand-name drugs.

15 These rules are discriminatory in how
16 they work. They deny fair and equitable market
17 opportunities and push Germany's health costs
18 onto the United States commerce. This is not
19 normal bargaining; it is government price-
20 setting backed by law.

21 This is not just German health policy.
22 Section 301 looks at what a practice actually

1 does. No treaty violation is needed under
2 Section 301. This case falls under Section
3 301(b).

4 Germany's discriminatory practices
5 burden United States commerce through programs
6 created by the Social Security Act. For seniors
7 and disabled Americans, the burden reaches
8 Medicare under Title 18: prescription drugs
9 under Part D, drugs given in the doctor's office
10 under Part B, hospital and skilled nursing care
11 under Part A, and Medicare Advantage under Part
12 C.

13 For nursing home residents, it reaches
14 Medicare and Medicaid nursing home care and
15 federal nursing home rules in Sections 1819 and
16 1919 of the Social Security Act.

17 For low-income Americans, it reaches
18 Medicaid under Title 19 and the Medicaid Drug
19 Rebate Program under Section 1927.

20 For children, it reaches Medicaid's
21 EPSDT guarantee under Section 1905(r) and the
22 Children's Health Insurance Program under Title

1 21. It also reaches children's drug research
2 required by the Federal Drug, Food, and Cosmetic
3 Act and the Pediatric Research Equity Act.

4 These laws commit federal and state programs to
5 pay for medicines, needed treatment, hospital
6 care, and nursing care, and they require drug
7 companies to test medicines for children.

8 Germany's discriminatory pricing shifts
9 part of that cost onto American patients,
10 taxpayers, federal programs, state governments,
11 hospitals, pharmacies, and drug makers. This
12 burden on United States commerce falls on
13 seniors and children, and it is an egregious,
14 persistent pattern of conduct.

15 These programs are not separate
16 violations by Germany; they show where Germany's
17 discriminatory burden on United States commerce
18 lands, who bears it, and how USTR can manage it.
19 Missing data is a reason to get the data, not to
20 deny the burden.

21 Determine that Germany's practices are
22 unreasonable or discriminatory, that they burden

1 or restrict United States commerce, and that
2 they are actionable under Section 301. Monitor
3 Germany under Section 306. Measure the cost to
4 Medicare, Medicaid, CHIP, and nursing homes,
5 along with shortages, lost sales, and lost
6 research and factory investment. Work with HHS,
7 CMS, FDA, Commerce, Customs and Border
8 Protection, the International Trade Commission,
9 and the Department of Defense. Require Germany
10 to drop the proposed rebates. End the 9 percent
11 discount. Require fair payment by a firm
12 deadline. Keep duties, fees, procurement
13 limits, suspended trade benefits, and every
14 other appropriate and feasible action under
15 Section 301(c) ready to remove the burden.

16 That's all.

17 MR. BUTLER: Thank you, Mr. Poole.
18 Thank you to all the witnesses. We will now
19 proceed with questions. We have questions
20 directed to the individual panelists, as well as
21 a general question that we invite any panelist
22 to respond to.

1 Before the hearing ends, we will invite
2 a final round of comments from all speakers. At
3 that time, we invite you to comment on other
4 witnesses' testimony and to elaborate on the
5 extent to which Germany's unfair pricing
6 policies and practices related to pricing for
7 innovative pharmaceutical products result in
8 American patients paying a disproportionate
9 share of global R&D costs for innovative
10 pharmaceuticals.

11 So, for the first question, we will
12 start with State.

13 MR. HUFFMAN: Thank you. My question
14 is for Mr. Israel. Your public comments note
15 that investments by the U.S. pharmaceutical
16 companies is based on adequate expected returns
17 in global markets, and that Germany's pricing
18 policies weaken those incentives. Do you have
19 quantitative information on the impact of
20 Germany's policies on pharmaceutical
21 investments?

22 MR. ISRAEL: We can certainly try to

1 follow up with some quantitative information
2 that specifies that. I think our perspective is
3 looking at the early stage in the lifecycle of
4 this industry in particular. And one thing we
5 focus heavily on is the flow of entry capital
6 into that industry.

7 Right now, there's about \$30 billion
8 that's spent on early stage biotech innovation
9 and startup activity in the United States. So,
10 it is in that context that we look at this
11 question.

12 There's two things that are very, very
13 true, particularly about this industry: it's
14 extremely capital intensive, as I just noted,
15 and it's very intellectual-property-reliant, and
16 it always seeks a global market.

17 So, if there's disruptions or if
18 there's asymmetries in that global market, as
19 there are in Germany, it's our contention that
20 you'll ultimately have disruption in the flow of
21 primarily venture capital R&D and capital
22 formation into those types of companies, which

1 will be to the detriment of the U.S. innovation
2 cycle and the ability to invent new drugs and
3 sustain those companies here.

4 MS. ECHEVERRIA: Good morning. My
5 question is for Ambassador Gerrish. In your
6 testimony you focus on Germany's use of price
7 controls of medicine. Can you elaborate on how
8 Germany's price controls impact drug pricing in
9 the United States? Is there any data or
10 quantitative evidence that you could provide?

11 MR. GERRISH: Thank you very much. And
12 the way in which Germany's practices result in
13 higher prices here in the United States is by
14 the German Government's policies and practices
15 undervaluing innovation and not paying fair
16 prices through, you know, a series of
17 mechanisms. You've heard many of them talked
18 about here in terms of the mandatory rebates and
19 benchmarking prices to older, lower-cost
20 treatments. That results in less revenues going
21 to the pharmaceutical companies.

22 Of course, you know, the research and

1 development that has to go into developing these
2 new medicines, it's very expensive, it takes a
3 long time, there's a lot of risk involved in it.

4 So, these companies have to recoup their
5 investments in some way, so they have to charge
6 higher prices here in the United States, in many
7 cases, to recoup those investments and to
8 justify the risks that they incur in going down
9 the road of trying to develop new medicines,
10 which often take many years and, in some cases,
11 billions of dollars to develop.

12 So, with Germany and other countries
13 not paying fair prices, suppressing prices for
14 innovative medicines, those companies have to
15 recoup their revenues and their investments in
16 the United States. And that's resulted in the
17 United States funding roughly half of all
18 investments in R&D globally, and accounting for
19 75 percent of pharmaceutical companies' profits
20 here, despite the fact the United States is just
21 a little over 4 percent of the world's
22 population and only a quarter of the world's

1 GDP.

2 So, the fact is we're paying higher
3 prices because companies around the world are
4 suppressing prices in their markets through
5 their policies and practices. And Germany is
6 one of the most egregious offenders of that.

7 We can follow up with additional data
8 on that. There's been studies done on that to
9 show that, on a per capita basis or an overall
10 GDP basis, that Germany's paying far less than
11 the United States; in fact, half on a per capita
12 GDP basis of what U.S. patients pay for
13 medicines, for innovative medicines.

14 Ernst & Young has done a study on this
15 and shown how, you know, Germany pays less than
16 half than the United States. Other countries
17 are in similar situations as well. So, we can
18 provide that data for you.

19 MS. CARSON: Thank you. My next
20 question is for Mr. Siatis. So, your comments
21 touched on Germany's price volume agreement
22 rules, which require an additional rebate on

1 patented drugs that exceed a certain threshold
2 of sales. Could you quantify the effect of
3 these rules, including the new default statutory
4 calculation that applies in the absence of a
5 negotiated rebate?

6 For example, could you provide an
7 estimate of the number of drugs that will be
8 subject to the rebate, and, two, an estimate of
9 the savings that these price volume agreements
10 are expected to generate?

11 MR. SIATIS: Thank you for the
12 question. I will have to get back to you with
13 specific information. I can tell you, at a
14 macro level, the unfairness of a volume discount
15 like this. What it does, effectively, is it
16 basically says, if you have a successful product
17 that is treating a lot of patients that actually
18 is taking on more volume, you are actually going
19 to, essentially, have to pay a larger rebate,
20 which is, once again, disproportionately going
21 to put more of the burden on, effectively, the
22 American prices because of the big delta between

1 now more of our R&D investment isn't getting
2 recouped.

3 In terms of specifics, we're going to
4 have to get back to you in our post-hearing
5 comments.

6 MR. REYNOLDS: I have another question
7 for Mr. Siatis. In AbbVie's public comments
8 they say that new tender-style contracts for
9 innovative medicines will only affect one drug
10 manufactured by a German company. How many
11 drugs produced by non-German companies are
12 expected to be affected?

13 MR. SIATIS: Again, I'll have to get
14 back to you with a specific answer on the
15 number. But I can tell you it is a
16 disproportionately large number of American
17 companies. The reality is, essentially, the
18 tender system that is being set up was set up to
19 say we're going to take certain classes of
20 products, for example, CGRP antagonists, which
21 are migraines -- so, AbbVie's drug is in that,
22 in that class -- and JAK inhibitors, which

1 AbbVie's other drug is in that class. They
2 selected only certain drugs in these classes.
3 And these are largely American company drugs.

4 And that is the discriminatory aspect
5 of that focus list, which is a new, basically,
6 price control by Germany instituted after the
7 attempts by the Trump administration to actually
8 curb these types of abuses.

9 MS. CARSON: Thank you. So, Dr. Hwang,
10 this question is for you. What do you estimate
11 the difference to be between the prices that
12 manufacturers set when a drug is launched in
13 Germany versus the final prices for those same
14 drugs following the AMNOG process and the
15 application of all rebates, discounts, et
16 cetera? And if an estimate is not readily
17 available, we would welcome a post-hearing
18 submission on the subject.

19 Thank you.

20 MR. HWANG: Thank you for the question.
21 I think, like everyone else, I'll be submitting
22 that after the hearing. But I can tell you, in

1 general, the German system has different
2 formulas set based on the level of added
3 clinical benefit that's determined by the
4 Federal Joint Committee. And that formula
5 basically rewards therapeutically important
6 innovations by offering lower discounts on those
7 products, and escalating discounts on products
8 with more marginal value.

9 And so I think this system is actually
10 something that the Medicare program is also
11 trying to implement in its Medicare drug price
12 negotiation program. It's not unique to
13 Germany. But what Germans do better than most
14 is making that process transparent and evidence-
15 based.

16 MR. REYNOLDS: I have another question
17 for Dr. Hwang. Let's see. Oh, in your
18 testimony you state that manufacturers have only
19 invoked Germany's confidential pricing agreement
20 for three drugs. Could you share how you
21 determined the number of drugs, which
22 manufacturers invoked that confidential pricing

1 arrangement, and where we can find that
2 information, if it is publicly available?

3 MR. HWANG: Yeah. Great question.
4 Names of those products have been disclosed in
5 various press reports. The most recent was
6 Mounjaro, which is a weight loss medication.

7 MR. REYNOLDS: Thank you.

8 MR. HUFFMAN: This question is for Mr.
9 Marar. Your public comments state that
10 Germany's pricing and reimbursement policies
11 deflate patented drug prices below what exists
12 in a competitive market. Could you provide
13 evidence that shows that Germany's
14 pharmaceutical prices are below competitive
15 market levels?

16 MR. MARAR: Thanks. Well, one piece of
17 evidence is that U.S. drug prices, which are
18 pegged to the average or lowest private market
19 price insurers pay, significantly higher than
20 even the healthcare technology assessment
21 submitted prices that the German Government
22 comes up with prior to the rebates, and so on.

1 We can also see that, given that the
2 U.S. currently finances so much of the share of
3 the profits that fund future research and
4 development, and recoupment of its own costs,
5 given that Germany's benefitting from this
6 directly and is -- we can clearly see that they
7 are underpaying relative to what they are
8 clearly benefitting from, even given their
9 healthcare technology assessments.

10 Because that's ultimately the problem.

11 This is all funded by global revenue, so it's
12 very hard to then say, okay, you know, this
13 country is paying less for drugs, then that's
14 clearly just a free market negotiation, because
15 it isn't. They are benefitting from the fact
16 that other countries are paying so much more.

17 MS. ECHEVERRIA: I have a follow-up
18 question for Mr. Marar. You explain how German
19 drug prices affect prices in other countries
20 through reference pricing. If Germany agreed to
21 pay more for pharmaceutical would those other
22 countries generally recognize the increase or

1 would separate changes be needed?

2 MR. MARAR: Thanks. So, on page 3 of
3 my written testimony, of 19 OECD member
4 countries with GDP per capita at least 60
5 percent of the U.S. -- so that's Austria,
6 Belgium, Denmark, Finland, Germany, Luxembourg,
7 Netherlands, and so on -- 12 apply an
8 international referencing pricing model that
9 includes Germany. Which means that if German
10 prices go up, in many of these cases, the price
11 that those countries pay will automatically go
12 up.

13 So, the decision that Germany makes, as
14 the third largest pharmaceutical market by sales
15 in the world, does have a significant impact on
16 global revenues and also the prices that other
17 countries pay.

18 MS. OLSON: All right, this question is
19 for Ms. Whiteman. If Germany abandoned the
20 pharmaceutical pricing policies described in the
21 Notice of Initiation of this investigation, what
22 would be the impact on German drug prices? Do

1 you believe that there would be an impact on
2 drug prices for U.S. consumers? And is there
3 any data or quantitative evidence you can
4 provide?

5 MS. WHITEMAN: Thank you for the
6 question. Generally, the result of removing
7 policies that regulate the cost of medicines is
8 that they -- it will lead to greater spending on
9 medicines in Germany. But we -- there's no
10 reason to think that if Germany increased its
11 spending or increased its prices that the United
12 States would see our own prices go down. A
13 study from the Department of Commerce in 2004
14 came to the same conclusion when assessing a
15 similar issue.

16 I might have to get back to you on the
17 final question in a post-hearing comment, but
18 thank you for the question.

19 MR. REYNOLDS: This question is for Mr.
20 Haninger. Your public comments note that
21 Germany's drug pricing and reimbursement
22 policies reduce, quote, the expected return on

1 investment from the development of innovative
2 medicines and contribute to an unfair and
3 inequitable distribution of the global costs of
4 biopharmaceutical development.

5 Do you have any quantitative
6 information about how Germany's policies affect
7 innovative pharmaceutical development? For
8 example, changes in investment levels, or R&D
9 spending, employment, the number of laboratories
10 operating, et cetera?

11 (Off-microphone comments.)

12 MS. BELLAMY: Sir, is your microphone
13 on?

14 MR. HANINGER: I'm sorry. Thank you
15 very much.

16 We do. And I'm happy to provide that
17 in a post-hearing submission. But, in short,
18 Germany spends less than half, as a share of its
19 GDP after adjusting for purchasing power parity,
20 as the United States. It's new policies that
21 have been enacted we estimate will reduce that
22 spending by an additional 15 percent. So, these

1 are very substantial underpayments for new
2 medicines.

3 We've heard stories today about
4 companies pulling back on their investments in
5 Germany. And we can also model some of the
6 changes over time that provide evidence on
7 reduced economic activity in our sector
8 following some of the changes that have happened
9 historically.

10 I need to underscore that the problems
11 in Germany are not just ones that existed in the
12 past year or so. These are longstanding
13 policies that have shaped markets. And so,
14 there is a lot of evidence that we could provide
15 to substantiate those claims.

16 MR. REYNOLDS: Thank you so much.

17 MS. OLSON: All right. I have a
18 follow-up question for Mr. Haninger. We have a
19 question regarding spending on innovative
20 medicines that may be better addressed in a
21 post-hearing comment, which is: do you have any
22 updated estimates on spending on innovative

1 medicines in Germany and the United States as a
2 percent of GDP for both countries?

3 MR. HANINGER: We do. We're happy to
4 submit that. The estimates that we have
5 published were for 2023. We have estimates for
6 the most recent year. We're happy to provide
7 that as well.

8 MS. CARSON: Thank you. The next
9 question is for Mr. Roeder. In your written
10 submission you argue that USTR should prioritize
11 a negotiated outcome that pushes Germany towards
12 fairer reimbursement, lower mandatory rebates,
13 faster patient access, and innovative-based
14 agreements. Can you please describe what a
15 fairer reimbursement system in Germany would
16 look like and what types of policies would
17 address current unfair practices?

18 MR. ROEDER: Thank you for your
19 question. And my answer is not just for
20 Germany, but, in general, other developed
21 countries. There needs to be some conversion of
22 drug prices in developed economies that can be

1 maybe indexed by purchase power, or GDP, PPP.
2 But Germany and other developed economies need
3 to pay more for drugs than they currently do,
4 especially if it's the aim of United States
5 Government to bring drug prices down, and at the
6 same time safeguard medical innovation so we can
7 still find cures for all the diseases we can't
8 cure yet.

9 There needs to be sufficient
10 investments into drug prices. The prices need
11 to have a certain level. So, at the end of the
12 day, I think there needs to be an agreement to
13 pay more for innovative medicines in Germany.
14 And probably the U.K.-U.S. agreement can be a
15 blueprint for that.

16 MR. BUTLER: Okay, thank you. We're
17 going to turn to general questions now. Again,
18 we invite all the panelists to respond. We'll
19 go in the order that you gave your testimony.
20 If you want to respond, please do. If you
21 don't, just let us know and we'll move to the
22 next panelist.

1 So, the first question comes from
2 Treasury.

3 MR. CHANG: Hi. The general question
4 is: what are the effects of Germany's pricing
5 and reimbursement practices on drug pricing in
6 the United States? Can you provide examples
7 and/or data that show the impact of Germany's
8 pricing and reimbursement practices on
9 innovative pharmaceutical R&D, including at a
10 company level? Thank you.

11 MR. ISRAEL: I would start by just
12 making an observation, as I did in the
13 testimony, that, at a high level, it puts more
14 pressure, certainly, on the United States. It
15 puts more pressure to drive more costs into the
16 system and more revenue dedicated by the
17 American system into the R&D pipeline, more
18 global -- which is already globally dependent on
19 the United States.

20 So I would say any increase in revenue
21 or resources being dedicated to the R&D pipeline
22 globally is going to have the effect of reducing

1 the burden that's placed on the United States.

2 And I would make the additional
3 observation that -- and there was a question
4 earlier about the effect on pricing in the
5 United States just at a general level -- I
6 believe the statistic is that drug prices
7 overall in the United States decreased by about
8 3 percent last year.

9 So, I would say that at a high level,
10 sequencing of this approach, the idea of
11 addressing asymmetries in global pricing that
12 are driven by policy amongst our largest trading
13 partners -- we saw this in the U.K., we see this
14 now with the utilization of tools like Section
15 301 -- is exactly the right first step, because
16 it will have positive effect on both the pricing
17 in the United States and driving more resources
18 into the global R&D pipeline.

19 MR. GERRISH: I would certainly echo
20 Mr. Israel's comments on that. And, you know, I
21 think the data support the fact that the United
22 States is bearing a disproportionate burden of

1 the R&D investments that have to take place to
2 develop innovative medicines. And other
3 countries not paying their fair share results in
4 American patients paying more for innovative
5 medicines because that R&D investment needs to
6 be funded somewhere. It's very expensive. And
7 so, a larger burden is being placed on American
8 patients in paying more for medicines as a
9 result.

10 And, I mean, this is really just a --
11 it's a basic matter of fairness. We need other
12 countries to start paying their fair share and
13 not pursuing these policies that suppress drug
14 prices artificially. And we see this in a
15 number of countries. And, again, Germany is a
16 prime example. And, unfortunately, it's a
17 longstanding problem in Germany, and they're
18 moving in the wrong direction with their most
19 recent moves. And all that's going to do is
20 result, again, in more of the burden being
21 placed on the United States.

22 MR. SIATIS: I think it's important to

1 understand that pharmaceutical research is,
2 unfortunately, very expensive because, by
3 nature, we, as pharmaceutical companies, are
4 running, at a time, hundreds of products through
5 our scientific pipeline trying to find the drugs
6 that will actually treat disease. At times, it
7 takes years, sometimes over a decade, to figure
8 out whether these medicines work. The
9 unfortunate reality is the scientific process
10 results in a lot of failure. That means there's
11 a lot of expense that goes into R&D for
12 pharmaceutical companies.

13 I mentioned AbbVie alone has spent,
14 since 2013, \$85 billion on R&D. I could tell
15 you, I wish every drug we were researching
16 turned into a product for patients, but it
17 doesn't work that way. So, when products do get
18 to market, we need to be able to recoup
19 investment and have a sustainable rate of return
20 that effectively we can then put into our
21 pipeline for new products to come. This is the
22 pharmaceutical research model.

1 So, when companies -- I'm sorry, when
2 countries like Germany effectively put a set of
3 laws in place that simply drive the prices to
4 unfair low levels, what you have is the
5 disproportionate burden then falling on the --
6 you need to make up for that R&D revenue in the
7 U.S. And that is the reason we look here to the
8 USTR to find, basically, to find these laws that
9 are unfair and, essentially, unreasonable and
10 burden disproportionately U.S. commerce.

11 MR. HWANG: Thank you for the question.

12 I want to provide a slightly different
13 perspective.

14 So, as you know, the administration has
15 implemented or proposed Most Favored Nation
16 pricing models in Medicaid and Medicare. Last
17 Friday, we heard at the White House that all 50
18 states have signaled an interest in
19 participating in the Medicaid Most Favored
20 Nation pricing model, and that 40 U.S. states
21 have signed agreements to effectuate that
22 commitment.

1 So, to directly answer your question,
2 raising the benchmark price in Germany would
3 increase federal and state spending in Medicaid
4 as a result. And those costs should be
5 considered on balance.

6 MR. MARAR: Thanks for the question.

7 So, as other witnesses have noted,
8 there's increased pressure in the U.S. to fund
9 more pharmaceutical innovation by paying higher
10 prices when other countries decide to pay less
11 and they end up free-riding off the benefits of
12 that funding.

13 But, moreover, what gets lost often in
14 this conversation is the impact of overall
15 health care spending. So, about 9 percent of
16 the federal health care budget right now is
17 dedicated towards drugs. Three times that
18 figure is dedicated towards hospitalizations.
19 And since new drugs and new cures keep patients
20 out of the hospital and, therefore, help lower
21 those costs, the impact of less funding overall
22 for new drugs and new research is fewer new

1 cures, leading to greater hospitalizations
2 likely in the future. And that is something we
3 all end up paying for, either through our taxes
4 or through our healthcare premiums. So, in that
5 sense, when other countries underpay for
6 medicine and for medical research we all suffer,
7 and including the federal budget.

8 MS. WHITEMAN: I just want to say U.S.
9 prices are not rational. Germany does pay less
10 than the U.S., but that's not why U.S. prices
11 are so high. And R&D costs are also not why
12 U.S. prices are so high. Research has shown no
13 connection between R&D costs and drug prices.

14 So, I think to re-center the
15 conversation, it's important to recognize that,
16 you know, if Germany raised prices there's no
17 reason to think that the U.S. would spend less.

18 And that the conversation about R&D is more
19 narrow than I think is suggested by, like,
20 company revenues alone. Thank you.

21 MR. HANINGER: I think, in the
22 interests of time, I'll just make some brief

1 remarks here. I agree with some of the previous
2 panelists that, if you look over time, Americans
3 have increasingly shouldered a greater burden of
4 what it takes to bring new medicines to the
5 world. And that has happened as Germany has cut
6 its prices over time. And this hasn't happened
7 for just any old medicines; these are happening
8 for some of the most important medicines ever
9 to, you know, reach humanity.

10 So, yes, I think Germany's choices do
11 impact Americans. They put more pressure on
12 businesses. And I do think that this industry
13 would look very, very different if suddenly the
14 United States was contributing at the level that
15 Germany was. We just simply wouldn't have the
16 medicines that we need today.

17 MR. ROEDER: Yeah, price controls, no
18 matter in what sector of the economy, lead to
19 reduction of future supply. And in healthcare,
20 especially in biopharmaceutical innovation,
21 future supply -- a reduced future supply means
22 less cures in the future.

1 Right now, the U.S. basically funds
2 these future cures and Europeans free-ride on
3 it, or Canadians. And I second the other
4 statements here that if the U.S. would copy the
5 German approach then probably everyone who's
6 suffering from a disease, or whose loved one is
7 suffering from a disease where there's no cure
8 yet, can bury their hopes that there will be a
9 cure developed at German pharmaceutical pricing
10 levels.

11 MS. BELLAMY: Mr. Poole, would you like
12 to make a comment?

13 MR. POOLE: Yes. My comment is, other
14 than the price parity, the GDP, those numbers,
15 if we have all these confidentiality agreements,
16 how do we have price discovery on every
17 particular prescription? Because there may be
18 some that are distinguishable where they're way
19 overpriced, and there may be some that are fair.

20 So, to be precise, how are we going to
21 be able to measure it? If I take my pen and
22 it's confidential, is it a one-dollar pen, a

1 one-hundred-dollar pen, one penny? Who knows?
2 If it's confidential, we can't measure it. And
3 if it's not publicly available, there's no
4 disclosure, how are we going to make the choice
5 based upon which medicines and what supplies we
6 need, especially such as insulin and some of the
7 lifesaving variety of prescription medication?
8 How will we ever actually know, if it's not
9 publicly available?

10 MR. BUTLER: Thank you, Mr. Poole.

11 Okay. For our final question we would
12 like to invite all of the witnesses to make any
13 final comments you may have, including comments
14 on other witnesses' testimony.

15 So, we'll open it up. Again, we'll go
16 in the same order. Again, if you don't have
17 anything, that's fine.

18 MR. ISRAEL: Yeah, I'd just like to
19 close by thanking the panel for the time and the
20 great conversation this morning. Hopefully, it
21 was helpful to inform and guide the
22 investigation that will follow.

1 I would just close by stressing a
2 couple of a couple of fundamental points, and it
3 was picked up in some of the panel discussion as
4 well, just the tremendous capital resource,
5 intellectual resource, and entrepreneurial
6 energy and capability that it requires to build,
7 develop, and sustain this incredible industry.
8 And that it is very American in its global
9 positioning, and it's something we need to be
10 very cognizant of protecting and stimulating, I
11 think.

12 Having had the opportunity to visit
13 innovative pharmaceutical company startups and
14 large companies, the amount of capital and human
15 intelligence that's required to drive that
16 process is absolutely staggering.

17 To me, the notion that there is no
18 correlation between revenues that are generated
19 by great American innovative pharmaceutical
20 companies and the R&D capabilities that they are
21 able to expend doesn't seem to correlate, I
22 would question that. I do think there is an

1 absolute direct line between the ability to be
2 price competitive globally by American companies
3 and what they are able to dedicate in terms of
4 resources to R&D. It takes about a billion
5 dollars and perhaps a decade, usually, to bring
6 a new drug to market. And that is fundamentally
7 impacted by the position and the policies taken
8 by foreign governments and their willingness to
9 compensate at a fair level for that American
10 innovation.

11 MR. GERRISH: I'd just like to thank
12 the Section 301 Committee for the opportunity to
13 be here and testify today. And I want to
14 applaud USTR and Ambassador Greer for
15 undertaking this investigation and pursuing it.
16 And I would urge that USTR take very strong and
17 expeditious action here.

18 These are issues with unfair pricing
19 policies and practices in the pharmaceutical
20 space that, unfortunately, have been going on
21 for years and years and, in fact, decades. And,
22 you know, in my time at USTR I was trying to

1 address these problems with a number of
2 countries in my portfolio.

3 And, finally, USTR has taken the
4 necessary action to pursue this. And I think
5 it's incredibly important for strong action to
6 be taken as a result of this investigation. I
7 think doing so will send a message. It will
8 address the problem with Germany. It will send
9 a message to other countries to start taking
10 effective action to address the problems that
11 they have in countries like Japan, France,
12 Switzerland, and others.

13 And, you know, I think it's something
14 that's long overdue. And I think you have a
15 template. You have a framework with the deal
16 that was done with the United Kingdom. That's
17 something that can set, you know, the framework
18 for a negotiation with Germany as well to try to
19 address these problems.

20 But if they're not willing to take the
21 necessary actions, I think strong action under
22 Section 301 is going to be necessary. Otherwise,

1 countries will continue to stonewall the United
2 States, and we'll be dealing with this for years
3 and years to come.

4 And we need these, you know, the
5 necessary investments to be made. And the way
6 to do that is to get every country to pay its
7 fair share in doing that. And Germany certainly
8 is not doing that right now. And I applaud USTR
9 for taking this action and urge you to take
10 strong action as a remedy here as a result of
11 the investigation. Thank you again.

12 MR. SIATIS: Yes, on behalf of AbbVie,
13 I would also like to thank the panel, the 301
14 Committee, for considering these very important
15 issues in your questions today.

16 To close, I would just like to make a
17 few comments about the systems and the
18 differences between our U.S. system and the
19 system in Germany. And I think it's important
20 to understand that the U.S. system is set up for
21 market-based -- essentially market-based prices
22 in the pharmaceutical industry.

1 I do reject the notion that we could
2 just price our products for anything. We
3 actually negotiate with pretty significant and
4 very well-versed insurance companies in the U.S.
5 that negotiate prices with us. We have
6 competition in the U.S. But, ultimately, we end
7 up with a market-based price. And that market-
8 based price allows us to have -- we have the
9 time in the United States to recover and,
10 ultimately, sustain a rate of return that helps
11 us invest in continued R&D at significant
12 levels, which is what we need in this industry.

13 In Germany, for a long time, there have
14 been nothing but laws and practices and
15 policies, and even more recently new ones, that
16 drive the price down. The effect of these laws
17 is to do nothing but reduce the price of each of
18 these products. And it's very important to
19 understand that system isn't going to help the
20 R&D and the future of R&D in our industry.
21 Which is why it has a disproportionate impact, a
22 negative impact, on the U.S.

1 To me, the examples that have been
2 cited around, you know, the Medicare and
3 Medicaid, they are differentiated with Germany.
4 For example, in Medicaid, it's a specific
5 patient population where there is a percentage
6 rebate. That's a specific population, not the
7 entire population. We still have the commercial
8 market, Medicare markets.

9 In Medicare, there are certain products
10 that are negotiated, but after a certain period
11 of time, seven to 10 years, depending on the
12 type of molecule. Whereas, in Germany,
13 everything is negotiated six months after the
14 product's been on the market at these very low
15 prices.

16 It's a very different system. And
17 there's multiple of these discounts stacked on
18 each other in Germany, for all patients, for the
19 majority of the products, and especially,
20 disproportionately, larger American products.

21 I agree with the U.K. is a framework.
22 It's a floor, in our view. Increasing the

1 budget for innovative medicines is necessary.
2 It's also necessary to retool the AMNOG process
3 in Germany to make sure that the appropriate
4 clinical evidence is considered in evaluating
5 these innovative medicines. It's important to
6 get rid of the mandatory rebates, the volume
7 rebates.

8 But it doesn't -- U.K. doesn't go far
9 enough, because Germany has additional
10 restrictions, like these focus lists in the new
11 law, for example, that also create further
12 negative prices for the American companies that
13 have these innovative products in these focus
14 list classes. That has to be eliminated as
15 well. So, there's a great starting point in the
16 U.K. And we do commend the USTR for the great
17 work getting that agreement done. But we need
18 to go further with Germany.

19 So, I'll just finish by saying, again,
20 thank you for the opportunity and we appreciate
21 the consideration. We do believe the evidence
22 supports a finding that Germany is, basically,

1 in violation of the 301.

2 MR. HWANG: Thank you, Mr. Chair and
3 the Section 301 Committee, for this opportunity
4 to present and discuss these important issues.

5 I wanted to highlight that some of the
6 very companies that are speaking before you on
7 this panel put out press releases as soon as
8 last week basically commending the German system
9 as comprehensive, vigorous, and patient-
10 centered. It's hard to square some of their
11 testimony with those separate press releases as
12 anything but company rent-seeking. An objective
13 review of the facts here does not support claims
14 that the German pharmaceutical system is unfair
15 or discriminatory under the meaning of Section
16 301, or that they unfairly burden U.S. commerce.

17 The tenders that were mentioned in some
18 of these hearing proceedings are also being
19 subject to formulary controls by U.S. from U.S.
20 formularies. And those very same products and
21 very same manufacturers are subject to those
22 same negotiations here in the U.S.

1 I want to conclude by saying trade in
2 medicines should be fair and should be free.
3 There's longstanding legal and moral norms
4 against imposition of trade duties on medicines
5 and other lifesaving goods. And I commend the
6 USTR for pursuing bilateral negotiations at the
7 government level to lower prices for drugs in
8 both countries and to increase spending on
9 research and development for new medicines.

10 Thank you.

11 MR. MARAR: Thanks for the opportunity,
12 again, to give comments.

13 So, in a competitive market, fully
14 profit-interested businesses will allocate their
15 resources towards satisfying demand, meeting the
16 healthcare needs of society. And when we don't
17 have competitive market conditions, that money
18 and those resources will tend to go towards
19 other activities. So, this is one possible, at
20 least partial, explanation for why firms right
21 now may be deciding to spend more money on stock
22 buy-backs and things of that nature rather than

1 R&D.

2 And given the fact that current
3 investments in R&D are correlated to expected
4 future revenues, it tracks quite well that, as
5 proposals such as MFN pricing and negotiations
6 under the IRA and foreign governments' decisions
7 to expand their price controls even further, it
8 tracks quite well that these announcements have
9 been followed by less investment in R&D.

10 For a big pharma company, that might
11 mean spending more money on things other than
12 R&D. For small, cash-strapped startups that are
13 research intensive, that means difficulty
14 attracting external financing. So, many of
15 those companies may not even get off the ground.

16 So, American entrepreneurs and researchers are
17 being short-changed in the long run.

18 Now, while Section 301 focuses
19 generally on the ability of the U.S. Government
20 to have targeted tariffs against countries who
21 unfairly burden U.S. commerce and penalize U.S.
22 companies, there is a win/win situation here.

1 Beyond the possible stick of a targeted tariff,
2 which, you know, if the end result of that is
3 that other countries raise the price that they
4 pay and the tariffs are done away with, that
5 might be a worthwhile outcome. But, in the
6 short term, while those are in effect, they are
7 mostly being paid for by American taxpayers and
8 American patients who rely on the foreign
9 medicine.

10 Another way of doing this would be to
11 approach Germany and to offer carrots. So, for
12 example, we already have expanding international
13 cooperation on things like drug trials and
14 approval processes. Expanding those further
15 would lower the costs of researching,
16 developing, and bringing a new drug to the
17 market. It would be a reward for Germany
18 manufacturers because they would have easier
19 access to the U.S. market. American patients
20 benefit from more access to medicine.

21 And the American industry will benefit,
22 too, because there would be reciprocity, so they

1 would have an easier time getting into foreign
2 markets and lower costs, which could be passed
3 on to consumers and patients through lower
4 prices.

5 And the good part about doing it this
6 way is that, in the long run, as more jobs and
7 factories and innovation clusters are created in
8 Europe and elsewhere, that creates a political
9 constituency. Because going back on these
10 agreements would result in harm to existing
11 jobs, existing manufacturing, and existing
12 waterways.

13 This is a much stronger sell for German
14 politicians to make to their voting public than
15 to say simply, well, if we pay more money, then,
16 in the future, we'll have more drugs. Patients
17 don't immediately see that benefit. It takes
18 years to manifest.

19 So, you know, we think this is a pro-
20 consumer, pro-innovation approach to securing
21 higher foreign drug prices and reducing the
22 free-riding, while benefitting patients,

1 taxpayers, and our healthcare system.

2 MS. WHITEMAN: Thank you to the panel
3 today. Of course, companies want to make more
4 money in every market. They want to treat any
5 policy that reduces their revenue as unfair.
6 They make the same claims in the U.S. against
7 our policies that seek to make medicines more
8 affordable for people here. But treating this
9 reduction in revenue as our standard for
10 unreasonable policies inevitably results in
11 higher costs that will quickly become
12 unmanageable and is not sustainable.

13 I also wanted to comment that drug
14 prices are just one way to pay for innovation.
15 So, when we're talking about what other company
16 -- other countries should do to contribute to
17 global innovation, it's more than just spending
18 going to the private sector. Of course, the
19 private sector does do research and development
20 and invests in developing new cures. But that's
21 not the only player that invests. Ignoring the
22 massive public sector contributions would be a

1 mistake considering, for example, that NIH has
2 contributed to every new drug that has come to
3 the market, or nearly every new drug.

4 Thank you.

5 MR. HANINGER: So, I'd like to conclude
6 by thanking the committee for the opportunity
7 today, and also commending the U.S. Government
8 for looking at these longstanding and undeniably
9 challenging issues. We very much believe that
10 the evidence shows that Germany's policies are
11 unfair, that they are inequitable, and that they
12 also do not create reciprocal opportunities for
13 U.S. companies accessing the German market.

14 I also wanted to just address some
15 comments that have been made today and in
16 written testimony that really speak to the
17 differences between the U.S. and German systems.

18 One claim that has been made is that
19 rebates are much higher in the U.S. than they
20 are in Germany on a percentage basis. And while
21 that is true in certain sections of our
22 pharmaceutical system, I need to underscore the

1 point that the rebates in Germany are off of
2 already government-set low prices. And so, it's
3 exacerbating the situation. Even after we
4 adjust for purchasing power parity, even after
5 we look at differences in our pharmaceutical
6 systems and adjust for net prices, Germany's
7 just spending a lot less. And they're spending
8 a lot less in a way that is burdening U.S.
9 commerce and Americans.

10 So, we look forward to working on these
11 issues more, providing whatever evidence the
12 committee or others may need. And thank you,
13 again, for the opportunity today.

14 MR. ROEDER: And maybe just closing
15 this by teaching everyone a German term.
16 Zwangsrabatt is what you nicely call a mandatory
17 rebate; but, actually, Zwangsrabatt literally
18 translates to coercive discount. And I think
19 that should answer the question if there is,
20 like, coercive behavior by the German health
21 policymakers.

22 MS. BELLAMY: Mr. Poole, did you have

1 any final comments?

2 MR. POOLE: Yes. There has been a lot
3 said about the U.K. agreement with America and
4 how that's gone. And one of my concerns is that
5 the precedent could go in the other direction
6 where allowing Germany to use this rebate
7 system, they're passing more legislation.
8 Somebody like France, with another large
9 economy, could do the very same thing. This
10 could become an even bigger problem.

11 And so I think that the other way to
12 see this is that if the USTR did not take action
13 under Section 301, that it could set the
14 precedent for other EU countries, which the
15 United Kingdom is not a part of the EU, those EU
16 countries could do the very same thing and put
17 even more burden on U.S. commerce in the future.

18 And I also wanted to thank you for
19 allowing me to come digitally to this hearing.
20 It's a very professional, great staff, great
21 help. And please take action under Section 301
22 against Germany so we can have less burden on

1 U.S. commerce.

2 MR. BUTLER: Thank you. Okay. So, I
3 think that concludes us for the hearing for
4 today. I'd like to thank the witnesses for
5 their testimony and for time and participation
6 in this hearing.

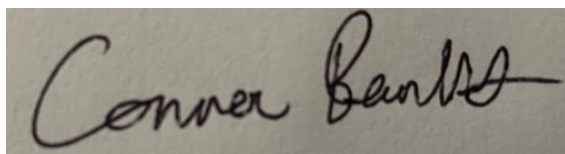
7 As a reminder, written post-hearing
8 comments are due September 29, 2026. Should any
9 witness wish to supplement answers provided to
10 the panel today, please do so in your post-
11 hearing comments. They will be submitted on the
12 USTR portal according to the instructions in the
13 Federal Register Notice.

14 So, this concludes today's hearing.
15 Thank you again, and I hope you have a good day.

16 (Whereupon, the above-entitled matter
17 went off the record at 11:35 a.m.)
18
19
20
21
22

C E R T I F I C A T E

This is to certify that the foregoing transcript was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings; and that I am neither counsel for, related to, nor employed by any of the parties to this action in which this matter was taken; and further that I am not a relative nor an employee of any of the parties nor counsel employed by the parties, and I am not financially or otherwise interested in the outcome of the action.

A handwritten signature in black ink on a light-colored background. The signature is written in a cursive style and appears to read "Connor Banks".

Connor Banks

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\$254 16:4	1919 54:16	22 8:8	4
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