Questions for the Record from Representative Issa for Krista Carver

"Medicines and IP: Balancing Innovation and Access"

June 4, 2026

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1. If a generic company is properly applying a "skinny label," why do extraneous statements by that manufacturer matter?

    a. Follow on question: How do you respond to the argument that suing generic manufacturers for applying "skinny labels" undermines an important pathway to market entry for generics under Hatch-Waxman?

2. Based on your understanding of current U.S. law, can a generic manufacturer produce generics exclusively for export to markets in which either the drug is not under patent or certain uses of that drug are off-patent?

Question for the Record from Representative Ross for Krista Carver

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1. How should the Supreme Court's decision in *Hikma v. Amarin* inform this Committee's thinking about the need for H.R. 6485, the Skinny Labels, Big Savings Act?

Questions for the Record from Representative Johnson for Krista Carver

"Medicines and IP: Balancing Innovation and Access"

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1. You stated in your opening remarks that "[b]iopharmaceutical companies have brought more than 900 new medicines to American patients since 2000." Please provide peer-reviewed data to support this claim and briefly summarize the methodology used to obtain it.

2. In your opening remarks, you stated that 90% of all drugs dispensed in the United States are generic, compared to just 41% in comparable OECD countries. Please provide the peer-reviewed data supporting these figures along with a brief summary of the methodology used to produce them.

3. In your opening remarks, you estimated that 60% to 75% of cancer drugs are later approved to treat additional cancer types beyond their initial indication. Please provide peer-reviewed research supporting this figure and a brief summary of the methodology used to reach it.

4. In response to one of my questions, you estimated that pharmaceutical companies have invested more than $850 billion in R&D over the last decade. Please provide peer-reviewed data supporting this claim and briefly summarize the methodology the authors used.

    a. Additionally, please estimate what share of that investment went toward clinical development of medicines that had not yet received regulatory approval versus those already approved for at least one indication, and what share went toward researching treatments that already held patents versus those that did not.

5. In response to a question from Chairman Darrell Issa, you stated that American patients have access to 85% of new medicines, on average, compared to an average of 38% across G-20 countries. Please provide peer-reviewed data supporting this statement and briefly summarize the methodology used to obtain these figures.

July 7, 2026

Answers to Questions for the Record from Representative Issa for Krista Carver
"Medicines and IP: Balancing Innovation and Access"

1. If a generic company is properly applying a "skinny label," why do extraneous statements by that manufacturer matter?

Statements outside properly drafted "skinny labeling" may induce infringement of a method-of-use patent. Specifically, "[t]o prevail on a theory of induced infringement, a plaintiff must prove (1) direct infringement and (2) 'that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute infringement.'"[1] As the Supreme Court recently emphasized in *Hikma*, "the key question is whether a defendant actively encouraged infringement *through its statements*."[2] Those statements may be found in generic drug labeling or elsewhere, such as promotional materials, press releases, or other communications. In short, "extraneous" statements outside the generic drug labeling matter because those statements may constitute the affirmative acts that induce infringement. In addition, such statements may supply the requisite evidence of intent necessary to establish inducement, even where the labeling itself properly omits the patented use.[3] In this respect, the law provides incentives for further study of approved medicines through method-of-use patents while enabling generic manufacturers to avoid inducement liability if they refrain from actively encouraging the patented use.

a. <u>Follow on question</u>: How do you respond to the argument that suing generic manufacturers for applying "skinny labels" undermines an important pathway to market entry for generics under Hatch-Waxman?

I disagree with this argument and believe that the recent Supreme Court decision in *Hikma* underscores that the skinny labeling pathway remains an important pathway for generic market entry. Lawsuits against generic manufacturers that fail to adequately carve out patented uses or that make extra-label statements that actively encourage the generic drug's use for the patented method do not undermine the skinny-labeling pathway. Rather, these lawsuits enable courts to ensure that the pathway functions as Congress intended.

The Hatch-Waxman Amendments reflect a deliberate balance between facilitating generic entry for unprotected uses of the innovator drug and preserving incentives for innovation, including through method-of-use patents. If the innovator has listed a method-of-use patent for its drug in FDA's Orange Book, the generic applicant may challenge the patent,[4] wait for its expiry,[5] *or* file a "section viii statement" averring that the listed patent "does not claim a use for which the applicant is seeking approval."[6] If the generic applicant chooses the

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[1] *Genentech, Inc. v. Sandoz, Inc.*, 592 F. Supp. 3d 355, 364 (D. Del. 2022) (quoting *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018)), *aff'd*, 55 F. 4th 1368 (Fed. Cir. 2022).

[2] *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 146 S. Ct. 1391, 1400 n.3 (2026) (emphasis added).

[3] *See, e.g.*, *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642, 647 (D. Del. 2022).

[4] FDCA § 505(j)(2)(A)(vii)(IV).

[5] *Id.* § 505(j)(2)(A)(vii)(III).

[6] *Id.* § 505(j)(2)(A)(viii).

last option, it assumes the obligation to ensure that the patented use is, in fact, properly omitted from its labeling.[7] To avoid inducement liability, the generic company must not actively encourage use of the generic drug for the patented use within or outside the bounds of its labeling. Because FDA plays only a "ministerial role" with respect to patent issues and does not assess whether a generic applicant's statements induce infringement, the courts are best equipped to evaluate disputes about inducement. As the Supreme Court's opinion in *Hikma* reinforces, courts must engage in a fact-specific inquiry that considers "whether a defendant actively encouraged infringement through its statements," including both explicit and implicit statements.[8] The *Hikma* opinion shows that generic applicants may prevail on these issues at the motion-to-dismiss stage and highlights the continued viability of the skinny labeling pathway.

2. Based on your understanding of current U.S. law, can a generic manufacturer produce generics exclusively for export to markets in which either the drug is not under patent or certain uses of that drug are off-patent?

Under 35 U.S.C. § 271(a), manufacturing a patented invention within the United States constitutes infringement, even if the product is made solely for export. Accordingly, a generic manufacturer producing a drug in the United States may be liable for infringing a composition patent or a method of manufacture patent regardless of where the product is ultimately sold or used. For method of treatment patents, manufacture of the drug in the United States does not itself constitute infringement. Liability would depend on whether the claimed method is practiced (direct infringement), typically by physicians, and whether the relevant conduct occurs within the United States or otherwise gives rise to indirect infringement liability.

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[7] FDA, Letter to Dexmedetomidine Hydrochloride Injection NDA Holder/ANDA Applicant, Docket No. FDA-2014-N-0087, at 5 (Aug. 18, 2014) (citing 21 C.F.R. §§ 314.92(a)(1) and 314.94(a)(12)(iii)); *see also* 72 Fed. Reg. 21,266, 21,269 (Apr. 30, 2007).

[8] *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 146 S. Ct. 1391, 1400 n.3 (2026).

Question for the Record from Representative Ross for Krista Carver
"Medicines and IP: Balancing Innovation and Access"

1. **How should the Supreme Court's decision in *Hikma v. Amarin* inform this Committee's thinking about the need for H.R. 6485, the Skinny Labels, Big Savings Act?**

The Supreme Court's decision in *Hikma* highlights that the Skinny Labels, Big Savings Act, H.R. 6485 is unnecessary to ensure the availability of the skinny labeling pathway. Moreover, H.R. 6485 would undermine incentives for further study of approved medicines in novel new uses that may benefit patients and grant abbreviated applicants special treatment compared to companies operating in all other fields of technology.

H.R. 6485 would create a novel liability shield for abbreviated applicants that seek to use "skinny labeling" by protecting them from inducement liability in specified circumstances. In relevant part, the bill would provide that the following "shall not be acts of direct, induced, or contributory infringement" of a method-of-treatment patent listed in the Orange Book: (1) submitting an abbreviated application that includes a section viii statement with proposed skinny labeling; (2) promoting or commercially marketing a drug product "with the [approved] labeling"; and (3) describing the drug "as a generic of, or therapeutically equivalent to, the listed drug."[9] The safe harbor applies "only if" the applicant's labeling, promotion, or commercial marketing "does not reference" the patented use that was the subject of the section viii statement.[10] The bill includes an analogous liability shield for biosimilar applications.

The *Hikma* opinion reinforces that H.R. 6485 is not needed to ensure the viability of skinny labeling. The Court emphasized that "the key question is whether a defendant actively encouraged infringement through its statements."[11] Employing a fact-specific analysis, the Court found that, "Amarin's allegations, whether viewed together or separately, fail to establish that Hikma took any affirmative steps to encourage infringement."[12] For example, the Court found that Hikma's labeling and statements that its product was the "generic equivalent" of Amarin's product did not induce infringement. The Court determined that Amarin's complaint could not withstand Hikma's motion to dismiss. In other words, the Court affirmed a generic applicant's ability to make the types of statements described in H.R. 6485, as long as it does not cross the line into active inducement.

Contemporaneous reactions to *Hikma* underscore that no legislative intervention is required. The decision has been described as "a decisive win for the generic industry that affirms skinny labeling as a shield against method-of-use liability."[13] Hikma's General Counsel said the company is grateful that the Supreme Court "unanimously upheld Hikma's right to continue providing millions of American patients with safe, affordable, high-quality generic

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[9] Skinny Labels, Big Savings Act, H.R. 6485, 119th Cong. § 2(a)(2) (2025).

[10] *Id.*

[11] *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 146 S. Ct. 1391, 1400 n.3 (2026).

[12] *Id.* at 1401.

[13] C. Landmon et al., Supreme Court Hands Generics a Unanimous Win on Skinny Labels in Hikma v. Amarin, Polsinelli Publications (June 4, 2026).

medicines."[14] These characterizations reflect a consensus that the carve-out pathway remains viable under existing law without the need for legislation.

Moreover, the bill is overbroad to address the purported aim of affirming that appropriate skinny labeling does not trigger inducement liability. It would create a categorical, unique liability shield for abbreviated applicants who pursue labeling carve-outs, even if they actively encourage infringement of valid method-of-use patents. For example, manufacturers of software and telecommunications equipment benefit from no shield from inducement liability.[15] The bill also would fail to ensure that there is a neutral arbiter of disputes concerning the adequacy of a labeling carve-out. Even though FDA does not assess inducement issues,[16] the bill would strip courts of the ability to find inducement in the bill's specified circumstances. If the courts cannot review the adequacy of skinny labeling, innovators will have no recourse where generic applicants adopt labeling strategies with known inducement problems, as they have in the past.[17]

The bill's proviso that the liability shield applies only if the abbreviated drug applicant "does not reference" the patented use appears insufficient to address these concerns. In *Hikma*, the Court noted that a defendant can achieve active inducement through implicit, rather than explicit, encouragement.[18] In contrast, under the bill, it is unclear if an *implicit* reference to the patented use that, when evaluated with all other facts, amounts to inducement under current law would nevertheless be protected under the bill's liability shield. If so, the bill would enable "wink-and-nod" messages designed to spur infringing uses while staying just shy of an explicit instruction. The bill also unnecessarily provides a liability shield for section 505(b)(2) applications and biosimilar applications, which need not have the same labeling as the listed drug or reference product and were not the subject of *Hikma*. Indeed, the prevalence of biosimilars with skinny labeling suggests that biosimilar companies have not encountered challenges executing labeling carve-outs. Per one publication, two-thirds of approved biosimilars had skinny labeling.[19] Therefore, there is no basis to provide section 505(b)(2) and biosimilar applicants with a shield from inducement liability.

Rather than clarifying the law, the bill would displace the fact-specific inquiry that *Hikma* reaffirms and upset the balance Congress established in Hatch-Waxman between facilitating generic entry and protecting innovation. The bill would fundamentally undermine patents directed to methods of treatment by providing abbreviated drug applicants with a shield from inducement liability. Protecting IP rights is critical to maintaining the balance that

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[14] B. Brittain, US Supreme Court Backs Generic Drugmaker in 'Skinny Label' Patent Case, Reuters (June 4, 2026).

[15] *See, e.g.*, *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321-22 (Fed. Cir. 2009); *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 700 (Fed. Cir. 2008).

[16] 68 Fed. Reg. 36676, 36683 (June 18, 2003).

[17] *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059 (Fed. Cir. 2010).

[18] *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 146 S. Ct. 1391, 1401 (2026).

[19] A.C. Egilman et al., Frequency of Approval and Marketing of Biosimilars With a Skinny Label and Associated Medicare Savings, 183 JAMA Internal Med., 82 (2022).

Congress struck in Hatch-Waxman between encouraging generic market entry and incentivizing continued clinical research on approved products.

Questions for the Record from Representative Johnson for Krista Carver
"Medicines and IP: Balancing Innovation and Access"

1. **You stated in your opening remarks that "[b]iopharmaceutical companies have brought more than 900 new medicines to American patients since 2000." Please provide peer-reviewed data to support this claim and briefly summarize the methodology used to obtain it.**

Researchers from Tufts Medical Center published an article in *Health Affairs Scholar* on this issue.[20] The authors "identified novel drug and biologic approvals from 2000 to 2024 in the FDA's New Molecular Entity database," excluding withdrawn products.[21] The article reports that "[b]etween 2000 and 2024, the FDA approved 897 novel drugs" and that the agency approved 50 novel drugs in 2025.[22] Added together, these sources show that 947 drugs were approved between 2000 and 2025, without counting those medicines approved to date in 2026. Moreover, because the Tufts researchers relied on an FDA database that includes only medicines approved by FDA's Center for Drug Evaluation and Research, not those approved by the Center for Biologics Evaluation and Research,[23] this figure reflects a conservative estimate of new medicines approved by FDA since 2000.

2. **In your opening remarks, you stated that 90% of all drugs dispensed in the United States are generic, compared to just 41% in comparable OECD countries. Please provide the peer-reviewed data supporting these figures along with a brief summary of the methodology used to produce them.**

A RAND Corporation analysis supports this statement.[24] Using IQVIA MIDAS 2022 data, RAND found that unbranded generics accounted for approximately 90% of prescription-drug volume in the United States versus 41% in the comparison OECD countries.[25] Table 2.2 of the report lists shares of volume for unbranded generics for the studied comparable OECD countries, which were Australia, Austria, Belgium, Canada, Chile, Colombia, Czechia, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom.[26]

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[20] S.E. Knox et al., FDA Approvals of Specialty Drugs, 2000-2024, 4 Health Affs. Scholar 1, 1 (Feb. 2026).

[21] *Id.*

[22] *Id.*

[23] FDA, Compilation of CDER New Molecular Entity (NME) Drug and New Biologic Approvals (content current as of May 12, 2026) (last visited July 6, 2026).

[24] A.W. Mulcahy et al., International Prescription Drug Price Comparisons, RAND Corp., at v (Feb. 2024) ("U.S. unbranded generics, which we found account for 90 percent of U.S. prescription volume, were on average cheaper at 67 percent of prices in comparison countries, where on average only 41 percent of prescription volume is for unbranded generics.").

[25] *Id.* at 12–13.

[26] *Id.* at 12.

The 90% figure is also supported by the following: (1) an FDA statement that "generic drugs account for more than 90% of prescriptions filled in the U.S";[27] (2) an Association for Accessible Medicines September 2025 report;[28] and (3) published literature such as "The Price to Consumers of Generic Pharmaceuticals: Beyond the Headlines," which notes that "90% of all retail prescriptions sold in the United States are generic drugs."[29]

3. In your opening remarks, you estimated that 60% to 75% of cancer drugs are later approved to treat additional cancer types beyond their initial indication. Please provide peer-reviewed research supporting this figure and a brief summary of the methodology used to reach it.

This statement was drawn from a study by Patterson et al. published in *Therapeutic Innovation & Regulatory Science*.[30] This article discusses both past studies on oncology drug development as well as a new cross-sectional study conducted by the authors.[31]

First, the Patterson et al. article states that "[a]s many as 60–75% of new oncology drugs are approved for multiple indications," citing two prior sources for this proposition.[32] The first is a report of a study on small molecule drugs that received an initial FDA approval between January 1, 2006, and December 31, 2012.[33] The authors examined product labeling and approvals from FDA's website to count approvals of new indications.[34] The authors reported that, of the studied oncology drugs, 61% received at least one post-approval indication.[35] Patterson et al. also reference an analysis by the IQVIA Institute for Human Data Science using IQVIA datasets.[36] This analysis found that "[o]f all targeted treatments in oncology, 75% are used in multiple indications, and in particular, the checkpoint inhibitors span 10 indications, including a pan tumor approval."[37]

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[27] FDA, 40th Anniversary of the Generic Drug Approval Pathway (Sep. 23, 2024).

[28] Ass'n for Accessible Meds., The U.S. Generic & Biosimilar Medicines Savings Report, at 10–13 (Sep. 2025).

[29] R.G. Frank et al., The Price to Consumers of Generic Pharmaceuticals: Beyond the Headlines, 78 Med. Care Rsch. & Rev. 649, 649 (May 29, 2021).

[30] J.A. Patterson et al., Subsequent Indications in Oncology Drugs: Pathways, Timelines, and the Inflation Reduction Act, 59 Ther. Innov. Regul. Sci. 102, 103 (2025).

[31] *See generally id.*

[32] *Id.* at 103.

[33] P'ship for Health Analytic Rsch., Implications of the Inflation Reduction Act Price Setting Provisions on Post-Approval Indications for Small Molecule Medicines, at 4 (June 2023).

[34] *Id.*

[35] *Id.* at 12.

[36] IQVIA Institute for Human Data Science, Global Oncology Trends 2018, at 8, 56 (May 2018).

[37] J.A. Patterson et al., Subsequent Indications in Oncology Drugs: Pathways, Timelines, and the Inflation Reduction Act, 59 Ther. Innov. Regul. Sci. 102, 110 (2025) (citing IQVIA Inst., Global Oncology Trends 2018, at 8 (May 2018)).

Second, the cross-sectional study conducted by Patterson et al. evaluated novel oncology drugs first approved by the FDA from 2008 to 2018.[38] The authors relied on FDA databases for approval dates and FDA-approved labeling changes.[39] The authors reported that "[o]ut of 86 drugs initially approved from 2008 to 2018 for an oncology indication, 56 drugs (65.1%) had at least one subsequent indication."[40] The authors further report that multi-indication drugs "were approved for a median of two subsequent indications and often gained indications in an additional cancer type (60.7%), new line of therapy (50.0%), or combination (41.1%)."[41]

4. In response to one of my questions, you estimated that pharmaceutical companies have invested more than $850 billion in R&D over the last decade. Please provide peer-reviewed data supporting this claim and briefly summarize the methodology the authors used.

These figures are based on the R&D expenditures of members of the Pharmaceutical Research and Manufacturers of America ("PhRMA") trade association. These investments are captured through an annual member survey by PhRMA. Therefore, they are inherently conservative because they do not capture R&D expenditures of biopharmaceutical companies who are not members of PhRMA. Specifically, PhRMA's member companies invested $104.3 billion in R&D in 2024 and over $850 billion in the search for new treatments and cures over the last decade.[42] PhRMA members are part of the broader biopharmaceutical industry, which saw 4,191 companies investing $276 billion in R&D in 2021.[43] Just 14% of those companies were commercial stage, but they contributed 74% of that investment amount.[44] Further, U.S. headquartered companies accounted for 55% of the R&D investment, and in the aggregate, companies re-invested 27% of their revenue into R&D globally and 34% in the United States.[45]

a. Additionally, please estimate what share of that investment went toward clinical development of medicines that had not yet received regulatory approval versus those already approved for at least one indication, and what share went toward researching treatments that already held patents versus those that did not.

A study published in the *Journal of Health Economics* estimates that the capitalized cost of developing a drug to first approval was about $2.59 billion (in 2013 dollars), rising to about $2.87 billion when post-approval R&D is included.[46] The difference suggests that post-approval

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[38] *Id.* at 102, 103.

[39] *Id.*

[40] *Id.* at 104.

[41] *Id.* at 107.

[42] PhRMA, 2025 PhRMA Annual Membership Survey, at 3 Table 1 (July 2025).

[43] A. Chandra et al., Comprehensive Measurement of Biopharmaceutical R&D Investment, 23 Nature Revs. Drug Discov. 652, 652 (2024).

[44] *Id.*

[45] *Id.* at 653.

[46] J.A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20, 20 (May 2016).

R&D—such as research supporting additional uses after initial FDA approval—accounts for roughly 10% of total R&D spending, with the remaining approximately 90% directed toward achieving initial approval. The paper attributes roughly $1.5 billion in average costs to those incurred during clinical trials, with the remaining approximately $1 billion getting consumed on research and translation into the clinic.[47]

With respect to novel indications in particular, these require substantial R&D investments with no guarantee of success. New indications often require large, expensive Phase 3 trials. Based on trial data from both new and existing molecules, some analyses estimate that the outlay for a Phase 3 clinical trial is $31.3 million to $214.4 million across therapeutic areas.[48] This outlay represents the expense of running a trial and does not incorporate whether the trial is a success or failure. Other estimates set the mean total outlay for a Phase 3 trial at $255.4 million based on data from new molecules.[49]

I am not aware of comprehensive industry-wide data on pharmaceutical R&D spending by patent status. Patents are ultimately necessary to sustain R&D on otherwise inefficient and failure-prone investments. On average, it takes an innovator between ten and fifteen years and investments of approximately $2.6 billion to develop a single new medicine, with only 12% of new molecular entities entering clinical trials ultimately receiving FDA approval.[50] IP is critical to enable biopharmaceutical companies to recoup their investments in this lengthy, costly, and highly risky R&D process and to reinvest revenues toward R&D for more new therapies for patients.

5. In response to a question from Chairman Darrell Issa, you stated that American patients have access to 85% of new medicines, on average, compared to an average of 38% across G-20 countries. Please provide peer-reviewed data supporting this statement and briefly summarize the methodology used to obtain these figures.

The source for this figure is the Global Access to New Medicines Report by PhRMA, dated April 2023.[51] This report describes an analysis of IQVIA MIDAS® and country regulatory data from October 2022.[52] New medicines were defined as new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and

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[47] *Id.* at 25, Figure 2.

[48] *See* A. Sertkaya et al., Costs of Drug Development and Research and Development Intensity in the US, 2000–2018, 7 JAMA Network Open 1, 7 (2024) (using 2018 dollars).

[49] J.A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20, 24 (2016) (using 2013 dollars).

[50] *Id.* at 20 (2013 dollars); PhRMA, Research and Development Policy Framework (last visited July 6, 2026).

[51] PhRMA, Global Access to New Medicines Report, at 11 (Apr. 2023).

[52] *Id.*

December 31, 2021.[53] The report states that, out of the 460 new medicines launched in this time window, 85% were launched in the United States compared to the 38% G20 average.[54]

[53] *Id.*

[54] *Id.*