United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

June 29, 2026

Robert M. Davis
Chairman and CEO
Merck & Co., Inc.
126 East Lincoln Avenue
Rahway, NJ 07065-4646

Dear Mr. Davis:

I write today to request information on the ways in which Merck's decision to develop and deploy a new injectable version of the cancer drug Keytruda could impact cost and patient access for this lifesaving medication. As you know, Keytruda in its intravenous (or IV) form remains one of the most widely prescribed oncology therapies in the world,[1] with significant benefits for patients, and the injectable form promises improvements to the patient experience as well. However, I continue to have serious concerns about how Merck's anti-competitive practices have boosted profits at the expense of patients.

At a February 2024 hearing of the Senate Committee on Health, Education, Labor, and Pensions, I questioned you about how Merck has maintained a high annual list price for Keytruda – more than $190,000 at the time – by filing frivolous patents that block low-cost alternative medications from reaching the market.[2] Specifically, I noted that Merck had filed 168

[1] Between 2014 and 2025, Keytruda reportedly generated $146 billion in sales for Merck and accounted for nearly half of the company's revenue as of 2025. *A New Shot for Cancer Is Convenient, but Poised to Keep Prices High*, New York Times (Sept. 19, 2025) (www.nytimes.com/2025/09/19/health/keytruda-merck-cancer-patents.html).

[2] Senator Maggie Hassan: *Senator Hassan Presses Pharmaceutical CEOs on Using 'Gimmicks and Loopholes' to Keep Medication Prices Sky-High* (Feb. 8, 2024) (www.hassan.senate.gov/news/press-releases/senator-hassan-presses-pharmaceutical-ceos-on-using-gimmicks-and-loopholes-to-keep-medication-prices-sky-high). In 2024, the list price for Keytruda was $11,337.36 for a dose every three weeks or $22,674.72 for a dose every six weeks. *See* GoodRx, *How Much Does Immunotherapy Cost? Prices, Insurance, and Resources for Saving* (Sept. 19, 2024) (goodrx.com/drugs/biologics/resources-for-affording-immunotherapy). Based on these standard treatment schedules, the total list prices for both dosages for a 12-month period exceeded $190,000 in 2024. Keytruda currently has a list price of around $208,000 for a 12-month period. *See* Keytruda, Cost, Insurance & Financial Help (www.keytruda.com/financial-support/) (accessed Mar. 6, 2026).

patents for Keytruda and that nearly half of these patents referred to the process the company used to manufacture the drug and not factors related to treating patients.[3] I noted that these kinds of patent gimmicks have allowed Merck to "delay other companies from selling lower cost versions of this medication, all while raising the price of Keytruda in the U.S. year after year."[4]

In two years, however, key patents on Keytruda will begin to expire, which should allow for competition from "biosimilar" products.[5] In response to other questioning during the hearing about this potential competition, you stated that "we do believe that biosimilar competition and generic competition is core to the system. We need the patent protection, and then we need a robust biosimilar and generic market."[6] You further stated that "when the composition of matter patents expire on our drug Keytruda, I fully expect, and I will not try to stop a biosimilar IV [intravenous] version of Keytruda coming on to the marketplace."[7]

Despite these statements, existing patents for IV Keytruda and a new form of the medication may help block or minimize competition from biosimilars for years. An expert testifying at the February 2024 hearing predicted, for example, that biosimilar competition for IV Keytruda would not occur until 2034 due to protracted litigation from Merck.[8] Similarly, a February 2026 analysis from *Bloomberg Intelligence* found that Merck could avoid biosimilar competition for IV Keytruda in the United States until 2033 given its patent portfolio.[9]

Further threatening competition, in October 2025, Merck introduced a new injectable form of Keytruda that "will preserve its exclusivity and could box out lower-cost rivals for Keytruda, which last year made $29.5 billion globally," according to *Bloomberg Law.*[10] According to this reporting, you have suggested that the new version could buffer competition

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[3] Senator Maggie Hassan: *Senator Hassan Presses Pharmaceutical CEOs on Using 'Gimmicks and Loopholes' to Keep Medication Prices Sky-High* (Feb. 8, 2024) (www.hassan.senate.gov/news/press-releases/senator-hassan-presses-pharmaceutical-ceos-on-using-gimmicks-and-loopholes-to-keep-medication-prices-sky-high).

[4] *Id*.

[5] *Focus: Merck Could Keep its Patent Edge by Shifting Keytruda Cancer Drug to a Simple Shot*, Reuters (Dec. 2, 2022) (www.reuters.com/business/healthcare-pharmaceuticals/merck-could-keep-its-patent-edge-by-shifting-keytruda-cancer-drug-simple-shot-2022-12-02/).

[6] Senate Committee on Health, Education, Labor, and Pensions, *Hearing on Examining the Cost of Prescription Drugs*, 118th Cong. (Feb. 8, 2024) (S. Hrg. 118-320) (www.congress.gov/118/chrg/CHRG-118shrg55849/CHRG-118shrg55849.pdf).

[7] *Id*. at 69.

[8] *Id*. at 89.

[9] *Merck's Keytruda Likely Has a Few Extra Years of Dominance, With Billions on the Line*, BioSpace (Feb. 24, 2026). An April 2026 analysis also found that 50 active U.S. patents held by Merck on Keytruda "could protect aspects of Keytruda's dominance through at least 2042, about 14 years beyond the expiration of its core patents." *How Merck Uses Patents to Help Maintain Keytruda's Exorbitant Price*, International Consortium of Investigative Journalists (Apr. 13, 2026) (www.icij.org/investigations/cancer-calculus/keytruda-evergreening-patents-merck/).

[10] *Merck's New Keytruda Shot Is a Rare Real-Time 'Product Hop*,*'* Bloomberg Law (May 7, 2025) (news.bloomberglaw.com/ip-law/mercks-new-keytruda-shot-is-a-rare-real-time-product-hop).

from biosimilars as Merck looks ahead to the 2028 expiration of patents behind IV Keytruda.[11] Similarly, the *New York Times* has noted that "[d]rug pricing experts say that Merck's new shot will most likely slow the adoption of cheaper copycat infusions, keeping prices higher for longer at the expense of Americans who pay in the form of taxes and health insurance premiums."[12] In response to these concerns, a company spokesperson has stated that Merck "does not expect any patent protection specifically directed to [the new formulation] to impact the potential marketing of a biosimilar intravenous form of Keytruda."[13]

Nevertheless, experts have expressed concern that by "product hopping" between intravenous and injectable forms of Keytruda, Merck could maintain monopoly pricing for the medication at the expense of patients.[14] In the "product hopping" process, according to the Federal Trade Commission, "a brand-name pharmaceutical company seeks to shift demand from a brand-name drug that faces generic competition to newly patented and/or exclusivity protected drugs that do not face generic competition."[15] In the case of Keytruda, the "product hop" could serve to switch patients to the new, patent-protected injectable version before patents on the IV version expire in 2028, shielding the Keytruda franchise from biosimilar competition for years.[16] An ICIJ report in April 2026, for example, cited a finding from industry experts that this move "could help Merck generate billions of dollars and delay competition into the 2030s."[17] Notably, while you have publicly estimated that the injectable version of Keytruda could capture 30 to 40 percent of Keytruda's total U.S. patient base, Merck Chief Medical Officer Dr. Eliav Barr stated in 2022 that, in theory, the injectable "could replace everywhere that Keytruda currently is used."[18]

Recent changes in legislation have also impacted price and patient access for Keytruda. Given Keytruda's status as one of the highest-spend drugs in the Medicare program – costing the federal government $5.6 billion in 2023 – Medicare drug pricing negotiation would likely have

[11] *Id*.

[12] *A New Shot for Cancer Is Convenient, but Poised to Keep Prices High*, *supra* note 1.

[13] *Merck's New Keytruda Shot, supra* note 10.

[14] *Id*.; *Focus: Merck Could Keep its Patent Edge, supra* note 5; I-MAK, *Keytruda Qlex: Where's the Invention?* (Oct. 17, 2025) (www.i-mak.org/2025/10/17/keytruda-qlex-wheres-the-invention/).

[15] Federal Trade Commission, *Report on Pharmaceutical Product Hopping* (Oct. 2022) (www.ftc.gov/reports/federal-trade-commission-report-pharmaceutical-product-hopping).

[16] DrugPatentWatch, *A Strategic Guide to Biologic Patent Exclusivity and Competitive Advantage* (Nov. 20, 2025) (www.drugpatentwatch.com/blog/a-strategic-guide-to-biologic-patent-exclusivity-and-competitive-advantage/); *see also A New Shot for Cancer Is Convenient, but Poised to Keep Prices High*, *supra* note 1.

[17] *How Merck Turned its Wonder Drug Into a Blockbuster — and Priced Out Cancer Patients Worldwide*, International Consortium of Investigative Journalists (Apr. 13, 2026) (www.icij.org/investigations/cancer-calculus/merck-keytruda-cancer-drug-price/).

[18] *Focus: Merck Could Keep its Patent Edge, supra* note 5.

reduced expenses for patients and taxpayers in connection with this treatment.[19] However, due to changes Congressional Republicans implemented through the One Big Beautiful Bill Act, the Centers for Medicare & Medicaid Services (CMS) could not include Keytruda in the third cycle of the Medicare Prescription Drug Price Negotiation Program in January 2026.[20] As a result, patients will not receive the same cost savings that Medicare price negotiation has achieved for other medication. For example, if CMS could negotiate a 22 percent discount for Keytruda – in line with the average 22 percent net price discount from the first round of price negotiation – Medicare beneficiaries could receive annual savings of around $3,300.[21] This unnecessary exemption from Medicare drug price negotiation will further delay savings and underscores the need to address pharmaceutical industry patent strategies that can blunt the impact of biosimilars and delay meaningful price competition.

The injectable form of Keytruda represents a clear step forward for patients, with faster administration and a less burdensome treatment experience. At the same time, these gains should not come at the expense of robust biosimilar competition for the IV formulation, which will be essential to delivering lower drug costs over time. As a June 2025 study noted, "[t]he benefits of subcutaneous hyaluronidase versions" – like injectable Keytruda – "must be balanced against the challenges that come with higher prices if these versions are introduced before biosimilar competition begins for the original versions."[22]

To aid the Senate Finance Subcommittee on Health Care - Minority in understanding competition, price, and access dynamics for Keytruda, please provide responses to the following information requests:

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[19] *People with Medicare Will Face Higher Costs for Some Orphan Drugs Due to Changes in the New Tax and Budget Law*, KFF (Oct. 20, 2025) (www.kff.org/medicare/people-with-medicare-will-face-higher-costs-for-some-orphan-drugs-due-to-changes-in-the-new-tax-and-budget-law/).

[20] Centers for Medicare & Medicaid Services: *CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program, Including First-Ever Part B Drugs* (Jan. 27, 2026) (www.cms.gov/newsroom/press-releases/cms-announces-selection-drugs-third-cycle-medicare-drug-price-negotiation-program-including-first); *People with Medicare Will Face Higher Costs for Some Orphan Drugs Due to Changes in the New Tax and Budget Law*, KFF (Oct. 20, 2025) (www.kff.org/medicare/people-with-medicare-will-face-higher-costs-for-some-orphan-drugs-due-to-changes-in-the-new-tax-and-budget-law/).

[21] *People with Medicare Will Face Higher Costs for Some Orphan Drugs Due to Changes in the New Tax and Budget Law*, KFF (Oct. 20, 2025) (www.kff.org/medicare/people-with-medicare-will-face-higher-costs-for-some-orphan-drugs-due-to-changes-in-the-new-tax-and-budget-law/). Beneficiaries could receive even larger savings if the net price discount of 44 percent from the second round of price negotiation applied. *See* Centers for Medicare & Medicaid Services, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027* (Nov. 2025) (www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf).

[22] John Kim et al., *Medicare Spending and Use of Subcutaneous Biologic Formulations with Hyaluronidase*, The Oncologist (June 14, 2025) (pmc.ncbi.nlm.nih.gov/articles/ PMC12166118/); *see also* Merck: *FDA Approves Merck's KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph) Injection for Subcutaneous Use in Adults Across Most Solid Tumor Indications for KEYTRUDA® (pembrolizumab)* (Sept. 29, 2025) (www.merck.com/news/fda-approves-mercks-keytruda-qlex-pembrolizumab-and-berahyaluronidase-alfa-pmph-injection-for-subcutaneous-use-in-adults-across-most-solid-tumor-indications-for-keytruda-pem/) (noting that the injectable version of Keytruda includes "a variant of human hyaluronidase").

1. Please provide a complete list of all U.S. patents and patent applications currently held or asserted by Merck relating to IV Keytruda (original pembrolizumab), injectable Keytruda (subcutaneous pembrolizumab formulations), and related manufacturing processes and methods of use;

    a. For each patent or application, please state whether Merck anticipates asserting it against biosimilar applicants or other competitors and explain how these patents would affect the timeline for biosimilar market entry;

    b. Please provide any internal Merck estimates for when biosimilar competition for IV Keytruda will occur in the United States, given the company's patent portfolio and anticipated litigation;

2. Has Merck assessed whether the introduction of injectable Keytruda will delay or influence the commercial viability of biosimilar versions of IV Keytruda? If so, please provide any findings from this assessment;

    a. Please summarize any market analyses Merck has conducted that estimate the extent to which a shift from IV to injectable Keytruda could diminish uptake of potential biosimilar IV competitors;

3. Please describe how Merck anticipates positioning injectable Keytruda relative to the IV formulation in terms of clinical use, formulary placement, insurer reimbursement policies, and patient out-of-pocket costs;

    a. Please describe Merck's plans, if any, to encourage prescribers to transition patients from IV to injectable Keytruda, including through consumer and prescriber marketing campaigns, sales force guidance, or educational materials;

    b. Please provide any clinical evidence indicating better medical outcomes for patients receiving injectable Keytruda compared to patients receiving the IV formulation;

4. Will Merck commit to maintaining IV Keytruda as a fully supported product until there is a biosimilar available?

5. Please describe any communications or agreements between Merck and any company developing or considering development of a biosimilar version of IV Keytruda, including but not limited to any agreement Merck has entered that would delay market entry of FDA-approved biosimilar versions of IV Keytruda.

Please provide your responses as soon as possible but in no event later than July 20, 2026. If you have any questions related to this request, please contact Jasmine Masand at jasmine_masand@hassan.senate.gov. Please send any official correspondence relating to this request to jasmine_masand@hassan.senate.gov.

Sincerely,

Margaret Wood Hassan
Ranking Member
Senate Finance Subcommittee on Health Care

cc: Todd Young
Chairman