UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE GENERAL HOSPITAL CORPORATION D/B/A MASSACHUSETTS GENERAL HOSPITAL, THE BRIGHAM AND WOMEN'S HOSPITAL, INC., NORTH SHORE MEDICAL CENTER, INC. D/B/A SALEM HOSPITAL, UMASS MEMORIAL MEDICAL CENTER, INC., and UMASS MEMORIAL HEALTH – HARRINGTON HOSPITAL, INC., *Plaintiffs,* v. ELI LILLY AND COMPANY, *Defendant*.	Civil Case No.

COMPLAINT

Plaintiffs The General Hospital Corporation d/b/a Massachusetts General Hospital ("**MGH**"), The Brigham and Women's Hospital, Inc. ("**BWH**"), North Shore Medical Center, Inc. d/b/a Salem Hospital ("**SH**"), UMass Memorial Medical Center, Inc. ("**UMass Memorial**"), and UMass Memorial Health – Harrington Hospital, Inc. ("**Harrington**") (referred to together as "**Plaintiffs**") seek injunctive and other relief against Defendant Eli Lilly and Company ("**Defendant**" or "**Lilly**") for engaging in unlawful, unfair, unjust, and deceptive conduct by imposing illegal terms and conditions on discounted drug pricing that it is statutorily required to offer to Plaintiffs pursuant to the 340B Drug Pricing Program, 42 U.S.C. § 256b (the "**340B Program**").

INTRODUCTION

1. This case is about corporate extortion. Lilly, the largest pharmaceutical company in the world and the first in history to achieve a trillion-dollar market capitalization, is using its monopoly power to hold vital 340B drug savings hostage—forcing five of Massachusetts' leading nonprofit hospitals to choose between surrendering highly valuable, privacy-protected patient claims data and confidential business operations information on unconscionable terms, or losing access to 340B savings and paying exorbitant, illegally inflated drug prices that deprive them of resources essential to serving their most vulnerable patients.

2. The 340B Program reflects a straightforward bargain: pharmaceutical manufacturers like Lilly gain access to the enormous Medicare and Medicaid markets and, in exchange, they voluntarily agree to sell covered outpatient drugs at discounted prices to 340B "**Covered Entities**" like Plaintiffs.

3. Plaintiffs use these congressionally mandated discounts to fund charity care, medication assistance programs, community health services, and care for uninsured and underinsured patients across the Commonwealth.

4. In January 2026, Lilly instituted a new policy (the "**Policy**") demanding that Covered Entities submit in-house pharmacy and medical claims data regarding 340B drug dispenses to their patients (the "**Claims Data**") through a unilaterally selected, private-equity-owned third-party platform ("**340B ESP**") as a condition of continued access to the federally mandated "**Ceiling Price**" under the 340B Program. But the Policy is not a good-faith compliance initiative. It is a coercive mechanism designed to extract commercially valuable data from Covered Entities without compensation while shifting all attendant risk to them.

5. The Claims Data demanded is protected health information ("**PHI**") under the

Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, "**HIPAA**"). Although 340B ESP is used to de-identify the Claims Data, the platform's own expert determination does not establish that the Claims Data will remain de-identified after submission and even suggests that it can be re-identified once in the hands of Lilly. Yet 340B ESP's non-negotiable terms (the "**Terms**") establish Lilly as a third-party beneficiary; limit the aggregate direct liability of 340B ESP's owner and its affiliates to the unconscionable sum of $100; grant Lilly and its vendor perpetual, sublicensable rights to use the Claims Data for broad purposes extending far beyond Medicaid "**Duplicate Discount**" or "**Diversion**" review;[1] and permit unilateral and even retroactive modification of terms—all while forcibly shifting the full burden of privacy, cybersecurity, and regulatory compliance risk to Plaintiffs.

6. Lilly has thus intentionally abused its substantial market power to create an untenable "Sophie's choice": Plaintiffs must capitulate to Lilly's demands, incur higher operational costs, and surrender valuable privacy-protected Claims Data on non-negotiable Terms, or forgo their 340B savings, absorb substantially higher upfront drug costs, and jeopardize services for vulnerable patients.

7. Plaintiffs rightfully refused to comply with Lilly's Policy. In response, Lilly retaliated by unlawfully terminating Plaintiffs' access to the 340B Ceiling Price for its covered outpatient drugs by directing the wholesalers through which Plaintiffs make 340B purchases to cease offering the 340B Ceiling Price to Plaintiffs.

8. Lilly's conduct forced Plaintiffs to forgo vital 340B savings and purchase drugs at

[1] Under 42 U.S.C. § 256b(a)(5)(C), manufacturers participating in the 340B Program have the right to audit Covered Entities under specific circumstances regarding their compliance with the program's two key prohibitions: (1) Duplicate Discounts (*e.g.*, receiving 340B pricing on a drug paid for by Medicaid FFS) and (2) Diversion (*e.g.*, reselling or transferring a 340B discounted drug to anyone who is not a "patient" of the Covered Entity). However, the statutory scheme does not give manufacturers the unfettered right to subject Covered Entities to a permanent, ongoing audit, as imposed by the Policy.

exorbitant prices—to the ultimate detriment of their patients and the Massachusetts communities they serve—while Lilly has been unjustly enriched.

9. Through the 340B ESP platform, Lilly has created a data dragnet that, so far, has been free from public scrutiny. Lilly's asserted justification of preventing Duplicate Discounts is pretextual. Congress and the Health Resources and Services Administration ("**HRSA**") have established a comprehensive audit and Administrative Dispute Resolution ("**ADR**") process for that very purpose, as well as for addressing suspected Diversion of 340B drugs. Those safeguards require reasonable cause, government oversight, limited scope, and good-faith notice before a Covered Entity must disclose its records. Lilly's Policy bypasses every one of these protections. It imposes a standing, across-the-board data demand untethered to any particular claim, patient, or compliance concern, then enforces compliance through the threatened—and now actual—denial of 340B pricing. Program integrity is a legitimate objective, but that objective does not authorize Lilly's coercive self-help.

The harm to Plaintiffs is irreparable in both directions. If they capitulate, they permanently surrender control over protected, commercially valuable Claims Data that cannot be clawed back, unwound, or adequately valued, while assuming ongoing HIPAA and other compliance burdens and risks to the benefit of Lilly. If they refuse—as Plaintiffs rightfully have—Lilly cuts off their statutory 340B Ceiling Price access, depleting resources Congress intended them to use for underserved communities. Plaintiffs collectively face tens of millions of dollars in annual losses that would otherwise fund uncompensated care, medication access programs, behavioral health services, oncology programs, and community health initiatives for Massachusetts residents. Neither that care nor the Claims Data can be reclaimed if pricing is later reinstated.

10. Lilly's conduct violates Massachusetts law. It is unconscionable, immoral, unfair,

and deceptive to use monopoly power and leverage the 340B Program to extort Claims Data from nonprofit hospitals under the guise of a routine corporate compliance policy, impose non-negotiable Terms that strip hospitals of control and shift all risk to them, and then punish them with crippling penalties when they refuse to comply. Through this conduct, Lilly is prioritizing its own profits over the health interests of Massachusetts citizens while maintaining access to the lucrative Medicare and Medicaid markets it receives as part of its bargain. The direct and inevitable result of Lilly's actions is increased healthcare costs and decreased access to healthcare services for Massachusetts citizens.

11. Plaintiffs do not ask this Court to administer the 340B Program or substitute itself for HRSA (as Lilly has done). They seek relief for Lilly's independent violations of Massachusetts law: using market power and leveraging the 340B Program to impose non-statutory conditions, extracting valuable, privacy-protected and confidential Claims Data without compensation,[2] shifting privacy and cybersecurity risk to Plaintiffs through adhesive terms, and severely penalizing Plaintiffs when they refused to submit to Lilly's extra-legal demands. Plaintiffs seek injunctive relief to return the parties to the status quo prior to Lilly's enforcement of its Policy. In further support of their Complaint, Plaintiffs state and allege the following.

PARTIES

12. Plaintiffs are not-for-profit hospitals that primarily serve the greater Boston and central Massachusetts areas.

13. Plaintiff MGH is a Massachusetts not-for-profit corporation and a citizen of the Commonwealth of Massachusetts, with its principal place of business located at 55 Fruit Street,

[2] Plaintiffs would not sell non-regulated elements of Claims Data to Lilly at any price but, nevertheless, Lilly's attempt to extract commercially valuable Claims Data from Plaintiffs at Plaintiffs' own expense is unlawful, unjust, and unconscionable.

Boston, Massachusetts.

14. Plaintiff BWH is a Massachusetts not-for-profit corporation and a citizen of the Commonwealth of Massachusetts, with its principal place of business located at 75 Francis Street, Boston, Massachusetts.

15. Plaintiff SH is a Massachusetts not-for-profit corporation and a citizen of the Commonwealth of Massachusetts, with its principal place of business located at 81 Highland Avenue, Salem, Massachusetts.

16. Plaintiffs MGH and BWH are world-renowned Harvard Medical School-affiliated teaching hospitals and founding members of the Mass General Brigham health care system. Each provides a broad range of advanced inpatient and outpatient services through its major academic medical center, physician practices, outpatient surgical centers, specialty programs and institutes, community health centers, and community-based care initiatives that serve patients in the greater Boston area, across Massachusetts, nationally, and from around the world. MGH and BWH consistently are ranked among the top ten hospitals in the country, and each uses savings from its participation in the 340B Program to support patient care, community health, and services for patients regardless of their ability to pay. Combined, Plaintiffs MGH and BWH conduct more than 6.5 million outpatient visits annually.

17. Plaintiff SH is a disproportionate share hospital and a prominent nonprofit community teaching hospital within the Mass General Brigham health care system. It is a 371-bed acute care hospital that operates a Level III trauma center and a dedicated 120-bed behavioral health center. SH serves a large population of uninsured and underinsured patients from its surrounding communities. In fiscal year 2025, approximately 70 percent of SH's patients were covered by Medicare or Medicaid or were self-pay. SH uses savings from its participation in the

340B Program to support patient care, community health, and services for its patients regardless of their ability to pay. SH provides annual community benefit grants to local community health centers to achieve meaningful improvements in health outcomes that increase life expectancy, reduce premature mortality, and enhance quality of life in the communities SH serves. SH also has supported these centers with substantial capital support, including $5 million in 2026. SH has used savings from its participation in the 340B Program to invest in infrastructure and programs to address health-related social risks, such as a recent $2.8 million investment in the Phoenix Food Hub in downtown Lynn.

18. Plaintiff UMass Memorial is a Massachusetts not-for-profit corporation and a citizen of the Commonwealth of Massachusetts, with its principal place of business located at 55 Lake Avenue North, Worcester, Massachusetts.

19. UMass Memorial is the largest safety-net provider in Central Massachusetts and relies on savings generated through the 340B Program to support critical patient care services, community health programs, medication assistance initiatives, and access-to-care programs for vulnerable populations. These savings are not excess revenue. They are reinvested directly into programs that improve access to healthcare for Medicare, Medicaid, uninsured, and underinsured patients throughout the region.

20. Plaintiff Harrington is a Massachusetts not-for-profit corporation and a citizen of the Commonwealth of Massachusetts, with its principal place of business located at 100 South Street, Southbridge, Massachusetts.

21. Plaintiff Harrington is a member of the UMass Memorial Health hospital system. Harrington serves a particularly vulnerable safety-net population and relies on 340B savings to sustain essential services that are often difficult to support through reimbursement alone.

22. In a given fiscal year, Plaintiffs provide hundreds of millions of dollars in uncompensated care, thousands of prescriptions at no cost, and millions of dollars in community benefits. Through numerous programs, Plaintiffs provide vital services to Massachusetts residents made possible through participation in the 340B Program.

23. Plaintiffs qualify and are each registered as Covered Entities under the 340B Program. They are therefore entitled to purchase covered outpatient drugs from manufacturers like Lilly at the 340B Ceiling Price.

24. Defendant Eli Lilly and Company is a citizen of the State of Indiana. Defendant is incorporated under the laws of the State of Indiana and maintains its principal place of business and headquarters at 893 S. Delaware Street, Indianapolis, Indiana.

25. Lilly is the largest drug manufacturer in the world, a publicly traded Fortune 100 company with over $65 billion in annual revenues, and the first drug manufacturer in history with a market capitalization of over one trillion dollars.

JURISDICTION AND VENUE

26. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a), because complete diversity of citizenship exists between the parties and the amount in controversy exceeds $75,000, exclusive of interest and costs.

27. Venue lies in this district under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred in this district.

FACTUAL ALLEGATIONS

THE 340B DRUG PROGRAM

28. Congress established the 340B Program in 1992 pursuant to the Veterans Health Care Act, 42 U.S.C. § 256b. The Program's primary purpose is to allow certain approved Covered Entities like Plaintiffs "to stretch scarce federal resources as far as possible, reaching more eligible

patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). The 340B Program accomplishes this goal by requiring pharmaceutical manufacturers like Lilly to sell covered outpatient drugs at discounts to qualifying healthcare organizations as a condition of participating in and receiving payment from Medicare and Medicaid, which combined represent an approximately $200 billion annual market. When it was initially passed, the 340B statute only limited the price that manufacturers could charge Covered Entities for their drugs. Congress later added a mandate, affirmatively requiring that manufacturers offer their drugs to each Covered Entity "if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). The Program allows safety-net providers to furnish critical medical care to their communities, including uninsured and underinsured patients, without requiring additional federal resources.

29. The 340B Program reflects a longstanding policy judgment that manufacturers benefiting financially from taxpayer-funded healthcare programs must help support entities providing a disproportionately high level of care for low-income, uninsured, and underserved populations.

30. Covered Entities include disproportionate share hospitals, children's hospitals, cancer hospitals, critical access hospitals, rural referral centers, federally qualified health centers, and other safety-net providers. *See* 42 U.S.C. § 256b(a)(4).

31. The 340B Program enables Covered Entities to purchase covered drugs administered or prescribed in outpatient settings at a discount. This pricing applies when the drug is prescribed in an outpatient setting and filled at the Covered Entity's pharmacy or at a "**Contract Pharmacy.**" The Covered Entity receives the usual payment from the patient and/or insurer, then purchases a replacement drug at the discounted 340B price, giving the Covered Entity and its underserved patients the financial benefit of the difference.

32. This discounted price is essential because Covered Entities operate on thin or negative margins and cannot be compelled to wait for drug manufacturers to grant—or deny—pricing based on unilaterally imposed requirements. Large for-profit pharmaceutical companies like Lilly, which have access to a massive market of government-insured patients, are better situated to absorb the cost of a discount rather than introducing burdensome, extra-statutory conditions that delay needed savings. In the event of suspected Duplicate Discounts or Diversion, manufacturers have a remedy, including the right to seek an audit pursuant to HRSA guidelines and to participate in ADR to resolve disputed purchases.

33. The 340B Program requires participating manufacturers to enter into a pharmaceutical pricing agreement ("**PPA**") with the Secretary of the U.S. Department of Health and Human Services ("**HHS**"). The PPA mandates that the price Covered Entities must pay for 340B drugs "does not exceed" the 340B Ceiling Price. 42 U.S.C. § 256b(a)(1). When a manufacturer signs a PPA, it opts into the 340B Program and agrees to the statutory requirement that prices charged to Covered Entities will not exceed the 340B Ceiling Price. Congress has conditioned coverage of manufacturers' outpatient drugs by Medicare Part B and Medicaid on participation in the 340B Program. Lilly willingly accepted that bargain for the benefit of its bottom line but now seeks to reap the full financial benefit of Medicare's and Medicaid's coverage of its drugs without fulfilling its commitment to support the health care safety net via the 340B Program.

34. The statutory calculation for the 340B Ceiling Price typically yields discounts significantly below the wholesale acquisition cost. For 340B providers like Plaintiffs, these discounts generate savings that fund patient care programs, charity care, and community health services. The statutory and contractual requirement that manufacturers sell drugs at or below the

340B Ceiling Price is not qualified, restricted, or dependent on receipt of any claims data.

35. HRSA, an agency of HHS, administers the 340B Program. Not Lilly. To become a Covered Entity, Plaintiffs were required to meet specific eligibility criteria and register with HRSA, which allows HRSA to verify that statutory requirements are met before participation. As Covered Entities, Plaintiffs are subject to HRSA audit and submit annual Medicare cost reports and IRS forms detailing the community benefits and charity care they provide.

36. HRSA has affirmed that Covered Entities may use the savings obtained by retaining the difference between the "actual acquisition cost" of 340B-discounted drugs and the usual market reimbursement "to reach more eligible patients and provide more comprehensive services." 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996). In 2010, HRSA reaffirmed that "the benefit of the program was intended to accrue to the covered entities." 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010).

APPLICABLE REGULATORY GUIDANCE

37. In 1994, HRSA issued its Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992. 59 Fed. Reg. 25,110–114 (May 13, 1994).

38. The 1994 guidance states that a manufacturer "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective." *Id*. at 25,111–12.

39. The 1994 guidance includes a narrow exception for contract provisions that "address customary business practice, request standard information, or include other appropriate contract provisions." *Id*. at 25,114. The phrase "standard information" was used in reference to "routine information necessary to set up and maintain an account." *Id*. at 25,112. The 1994 guidance explicitly barred manufacturer demands for "drug acquisition" and "purchase" information—the exact kind of information demanded by Lilly's Policy. *Id*. at 25,113–14.

40. Routine account setup information is categorically different from recurring patient-level Claims Data. Standard information needed to establish or maintain an account does not include a continuing feed of claim-level utilization, payor, dispensing, administration, replenishment, and reimbursement information that can be combined with other datasets and used for purposes extending beyond preventing Duplicate Discounts.

41. The 1994 guidance also expressly prohibits manufacturers from requiring a Covered Entity to provide assurances that it will comply with 340B provisions as a condition of receiving 340B pricing. *Id*. In other words, Lilly may not require Plaintiffs to submit Claims Data in order to assure Lilly of Plaintiffs' compliance with the 340B Program.

42. In 1996, HRSA issued Manufacturer Audit Guidelines, 61 Fed. Reg. 65,406 (Dec. 12, 1996) (the "**Guidelines**"). The Guidelines establish exclusive procedural mechanisms for manufacturer-initiated audits. *See* 42 U.S.C. § 256b(a)(5)(C).

43. Under the 2010 Contract Pharmacy Guidance, 75 Fed. Reg. 10,272 (Mar. 5, 2010), HRSA reinforced that manufacturer access to Covered Entity dispensing records is limited to the formal audit process. HRSA declined to require the automatic submission of compliance data to anyone, including HRSA itself.

44. When manufacturers specifically asked that audit results be made available to manufacturers, HRSA refused. 75 Fed. Reg. at 10,274.

45. On January 5, 2017, HRSA issued a Final Rule entitled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation." 82 Fed. Reg. 1210 (Jan. 5, 2017). In this Final Rule, HRSA rejected manufacturer requests to charge a Covered Entity a price above the 340B Ceiling Price "when a manufacturer acted on credible evidence that a covered entity is engaged in diversion of 340B drugs." *Id*. at 1223. The Final Rule states:

"Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *Id*. "Manufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." *Id*.

46. On April 19, 2024, HRSA issued a Final Rule establishing the ADR process to resolve claims by Covered Entities that they have been overcharged by manufacturers, along with claims by manufacturers, after conducting an approved audit, that a Covered Entity has violated the statutory prohibition on Diversion or Duplicate Discounts. *See* 89 Fed. Reg. 28,643 (Apr. 19, 2024). The ADR process addresses the very issues Lilly pretextually has asserted its Policy and data demands are designed to identify—Diversion or Duplicate Discounts—rendering Lilly's extraordinary self-help measures unnecessary.

47. The established audit framework permits Lilly to pursue a lawful, tailored audit if it has reasonable cause. The audit framework does not permit Lilly to bypass those safeguards by converting a limited audit right into an ongoing condition of sale applicable to every covered outpatient drug and every 340B-eligible claim. Covered Entities are entitled to both procedural and privacy protections in the audit process, none of which are present in the Policy or the Terms.

48. Manufacturers' auditors: must be independent public accountants (61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996)); must follow Generally Accepted Government Auditing Standards (*id.*); and must not disclose patient information or proprietary information to the manufacturer (*id.* at 65,409–10). Manufacturers must maintain confidentiality for audit information and any related information they receive. Pharmaceutical Pricing Agreement, § V(b).

49. The existence of the audit and ADR processes demonstrates that Lilly's self-help—in the form of denying Covered Entities the 340B Ceiling Price unless and until they provide

burdensome and voluminous Claims Data while assuming all risks associated with the subsequent acts or omissions of Lilly or its agents—is neither contemplated nor authorized by the 340B statute or any implementing rule.

50. Lilly cannot have it both ways. It cannot insist that only HRSA may address manufacturer and Covered Entity disputes under the 340B statute while at the same time bypassing HRSA's audit and ADR processes and imposing its own private enforcement regime as a condition of honoring the 340B Ceiling Price. Lilly's unilateral self-help is precisely the sort of conduct that makes state-law relief necessary and appropriate.

PLAINTIFFS' RELATIONSHIP WITH LILLY

51. For years, Lilly sold covered outpatient drugs to Plaintiffs at or below the applicable 340B Ceiling Price without requiring Plaintiffs to submit recurring Claims Data through 340B ESP or agree to its owner's non-negotiable Terms. Plaintiffs purchase those drugs through wholesalers, but Lilly manufactures the drugs, sets the prices, and is legally obligated under 42 U.S.C. § 256b to make the 340B Ceiling Price available to Covered Entities. Lilly's Policy disrupted this longstanding course of dealing.

52. Plaintiffs purchase millions of dollars of drugs from Lilly annually. Lilly manufactures top-selling drugs like Mounjaro for type 2 diabetes, Zepbound for obesity, Verzenio for certain types of advanced breast cancer, and Retevmo for certain cancers. Lilly is a single-source or monopoly supplier of numerous drugs for which there is significant demand, and Plaintiffs have no choice but to purchase them from Lilly to serve their patient populations, including their numerous Medicare and Medicaid patients.

53. This demonstrates the impossible dilemma Plaintiffs face: give Lilly the commercially valuable and privacy-protected Claims Data it unlawfully demands, while bearing all the risks of downstream use of that data, or enrich Lilly by forgoing vital 340B discounts and

purchasing drugs at the undiscounted wholesale acquisition cost, while depleting resources needed to continue serving their underserved patient populations.

54. Consistent with Congress's intent, Plaintiffs historically have used 340B savings to subsidize services that otherwise would not be possible. Without the 340B Program and corresponding savings, Plaintiffs would need to reduce these services, and if Lilly's unlawful conduct continues, eventually discontinue some services altogether.

LILLY'S UNLAWFUL POLICY AND TERMS

55. Under the 340B Program, manufacturers that increase drug prices faster than inflation must provide correspondingly larger discounts via the 340B Ceiling Price. The Ceiling Price is calculated as the drug's average manufacturer price ("**AMP**") minus the Medicaid unit rebate amount ("**URA**"). By law, the URA increases when manufacturers increase drug prices above the rate of inflation. 42 U.S.C. § 1396r-8(c)(2). As the URA increases, the 340B Ceiling Price drops. If the URA equals the AMP, manufacturers must charge no more than one penny ("**Penny Pricing**"). 42 C.F.R. § 10.10(b). Manufacturers who knowingly and intentionally do not honor the 340B Ceiling Price "may be subject to a civil monetary penalty not to exceed $5,000 for each instance of overcharging." 42 C.F.R. § 10.11(a).

56. In recent years, Lilly deliberately raised the prices of many drugs at rates far exceeding inflation. For example, between 1996 and 2019, Lilly increased the list price of Humalog, its top-selling insulin product, by approximately 1,200 percent.[3] Rather than accept the consequences of its pricing decisions, Lilly implemented extra-statutory conditions to restrict Covered Entities' access to the 340B Ceiling Price (which is as low as the Penny Price for drugs for which Lilly increased prices by more than the rate of inflation). Lilly restricted the use of

[3] Maureen Testoni, *Pursuit of Profits Is Driving Drug Companies to Break the 340B La*w, STAT News (June 10, 2022), https://www.statnews.com/2022/06/10/pursuit-of-profits-is-driving-drug-companies-to-break-the-340b-law/.

Contract Pharmacies, demanded pharmacy claims data, and created a constantly shifting patchwork of requirements not authorized by any law, rule, or regulation. These changes were a fundamental departure from decades of practice by Lilly. When HRSA attempted to stop it, Lilly sued—and lost. *See Eli Lilly & Co. v. Kennedy,* No. 21-CV-02608 (DLF), 2025 WL 1423630 (D.D.C. May 15, 2025), *appeal dismissed in part sub nom. Novartis Pharms. Corp. v. Kennedy*, No. 25-5177, 2025 WL 3779095 (D.C. Cir. July 18, 2025), *and aff'd sub nom. Novartis Pharms. Corp. v. Kennedy*, 182 F.4th 1027 (D.C. Cir. 2026).

57. In January 2026, Lilly instituted the Policy requiring Covered Entities to submit Claims Data as a condition of purchasing Lilly's covered outpatient drugs at the legally mandated 340B Ceiling Price.[4] Under the Policy, Covered Entities must submit the Claims Data through the third-party 340B ESP web platform unilaterally chosen by Lilly. 340B ESP is owned through Second Sight Solutions LLC ("**Second Sight**") by private-equity-backed Berkeley Research Group ("**BRG**"), a for-profit consulting company that supports the pharmaceutical industry.

58. BRG has conducted several studies funded by the Pharmaceutical Research and Manufacturers of America ("**PhRMA**"), the main pharmaceutical industry trade group. 340B ESP's Founder and Business Development Lead, Aaron Vandervelde, a Managing Director at BRG, has authored studies about the 340B Program on behalf of PhRMA. Upon information and belief, Second Sight has used Covered Entities' data to advocate for policies that harm them. Lilly's unilateral choice of vendor creates a clear conflict of interest.

59. The Policy states that Lilly "is committed to compliance with the 340B statute" and "will continue to offer all covered entities its 340B medicines at or below the 340B ceiling price, consistent with the 340B statute, as long as the covered entity provides the minimal, standard

[4] Update to Lilly's 340B Distribution Program for In-House Pharmacies (January 15, 2026), available at https://340besp.com/resources.

business information outlined in this notice." This characterization of the data demands as "minimal, standard business information" is false and deceptive. Covered Entities are not required to provide Claims Data to drug manufacturers in any other context. The Claims Data is voluminous, operationally and financially burdensome, and subject to broad commercially and competitively valuable use by Lilly and its vendor. In fact, some of it is not even standardized, much less "standard." For example, Lilly demands "claim number" and "claim line number" fields that are not assigned by the Covered Entity and can change during the adjudication of a medical claim.

60. Lilly's Policy does more than unlawfully deny Plaintiffs access to the 340B Ceiling Price; it exploits Plaintiffs' participation in the 340B Program to force them to pay Lilly's highest price and thereby further increase Lilly's profits. But for Plaintiffs' participation in the 340B Program, Plaintiffs ordinarily could purchase Lilly's drugs through group purchasing organizations ("**GPO**") at negotiated prices generally below the wholesale acquisition cost ("**WAC**"). As a condition of 340B participation, however, Plaintiffs (except BWH) are prohibited from obtaining covered outpatient drugs through a GPO. 42 U.S.C. § 256b(a)(4)(L)(iii). Lilly deliberately leveraged that statutory constraint twice: first, by conditioning access to the 340B Ceiling Price on Plaintiffs' surrender of Claims Data; and second, when Plaintiffs refused that unlawful condition, by directing wholesalers to deny not only the 340B Ceiling Price but also the otherwise available GPO price and instead charge WAC. Lilly thus used a statutory restriction applicable to Covered Entities (not to Lilly) as a mechanism to make Plaintiffs' refusal more costly, magnify Lilly's windfall, and coerce acceptance of its extra-statutory data demands.

61. The Policy demands Claims Data that Lilly has never requested and that Plaintiffs have never submitted. The Policy goes much farther in the volume, breadth, and number of data

elements demanded than Lilly's 2023 policy. No court or agency (including HRSA) has analyzed or approved a demand like Lilly's Policy.

62. Use of 340B ESP requires Plaintiffs to agree to 340B ESP's owners' and their affiliates' non-negotiable Terms designating Lilly as a third-party beneficiary. The Terms are unconscionable and unfair. They enable Second Sight and Lilly to use the Claims Data for broad purposes that extend beyond the pretextual justification of confirming compliance with the statutory Diversion and Duplicate Discount prohibitions. For example, the Terms:[5]

- Require Plaintiffs to grant Second Sight a "worldwide, sublicensable, non-exclusive, royalty-free, perpetual, irrevocable license to collect, process, disclose, create derivative works of and otherwise use the Covered Entity Claims Data ('Data License') for the purposes set forth herein. … This Data License survives after termination of the Agreement and shall survive as to any Covered Entity Claims Data that you have submitted on behalf of the Covered Entity or that a TPA (as defined herein) has submitted on behalf of the Covered Entity after such respective dates of submission.";

- Require Plaintiffs to agree that "Second Sight may enable Covered Entity Claims Data to be combined with rebate data remitted to Participating Pharmaceutical Manufacturers by payors (including Medicaid, Medicare, TRICARE and commercial payors) ('Rebate Data') in order to identify Ineligible Rebates and evaluate compliance with Participating Pharmaceutical Manufacturers' policies." Critically, "Ineligible Rebates" are defined as "duplicate Medicaid, Medicare, TRICARE and commercial payor rebates that are not eligible for reimbursement by Participating Pharmaceutical Manufacturers," a definition that far exceeds the statutorily prohibited Duplicate Discounts;

- Shift all risk associated with data security and data privacy to Plaintiffs;

- Establish Lilly as a third-party beneficiary to enforce the Terms against Plaintiffs (while granting no parallel enforcement rights to Plaintiffs against Lilly);

- Permit 340B ESP to unilaterally and even retroactively modify the Terms as it sees fit—a condition that is particularly concerning given Covered Entities are saddled with simply relying upon the data security and HIPAA compliance assurances Second Sight provides;

- Require Plaintiffs to agree to "monitoring," including but not limited to "grant[ing]

[5] 340B ESP Covered Entity Portal Terms of Use (last updated October 4, 2024) (last accessed October 27, 2026), available at https://340besp.com/terms-of-use.

[Second Sight] the right to … report any activity that we suspect may violate any law or regulation to regulators, law enforcement officials or other persons or entities that we deem appropriate." In essence, Second Sight is requiring Plaintiffs to acknowledge a non-existent authority for it (and Lilly) to audit claims and report findings to regulators like HRSA, all while circumventing the Guidelines;

- Limit the direct liability for damages under the Terms of Second Sight and its affiliates to the unconscionable aggregate amount of $100; and

- Shift liability to Plaintiffs in the event that it is subsequently determined that 340B ESP's data sharing model violates privacy laws.

THE POLICY AND TERMS SUBJECT PLAINTIFFS TO UNACCEPTABLE DATA PRIVACY AND CYBERSECURITY RISK

63. The Policy and Terms unilaterally imposed by Lilly expose Plaintiffs to substantial financial and operational risk and raise serious HIPAA compliance, data privacy, and data integrity concerns that Lilly has refused to address. Plaintiffs attempted to negotiate the Terms without success.

64. The Claims Data that Lilly demands is PHI under HIPAA.[6] While Lilly claims the data is de-identified upon submission, the expert determination on which Lilly relies (the "**Expert Opinion**") acknowledges that manufacturers may be able to re-identify the data. The Expert Opinion does not resolve whether the Claims Data remains de-identified once in the hands of Lilly, which may then combine the data with other reasonably available information in order to re-identify it.

65. HIPAA prohibits Covered Entities from disclosing PHI absent a valid legal basis. Disclosing PHI without a HIPAA-compliant purpose could violate Plaintiffs' duties to safeguard patient data, exposing them to civil suits, civil or criminal penalties, and regulatory audits, investigations, and fines (for example, if the HHS Office for Civil Rights independently

[6] Properly de-identified patient data is not considered PHI under HIPAA. However, "[d]isclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of PHI[.]" 45 C.F.R. § 164.502(d)(2)(i).

investigates the nature or legitimacy of these disclosures). Lilly has not provided Plaintiffs reasonable assurances that Plaintiffs' disclosure of the Claims Data complies with HIPAA's use and disclosure or de-identification requirements.

66. Lilly has identified no legal mandate requiring Plaintiffs to disclose PHI outside the audit and ADR framework established by Congress and HRSA. The 340B statute and HRSA's manufacturer audit guidelines provide a process for resolving legitimate Duplicate Discount concerns; they do not authorize a private, manufacturer-controlled data clearinghouse that compels broad preemptive disclosure of Claims Data as a condition of statutory 340B access. In fact, even in the context of a legitimate audit, HRSA's audit guidelines provide that "confidential patient information" will not be disclosed to the manufacturer, and require the audit work plan to include procedures for protecting patient information from improper disclosure. 61 Fed. Reg. at 65,409–10.

67. No HIPAA exception permits disclosure of the requested Claims Data in this context. Even if one existed, the Policy's Claims Data demands raise serious questions as to compliance with HIPAA's requirement that entities make reasonable efforts to limit use or disclosure of PHI to the "minimum necessary" information to accomplish a particular purpose—questions Lilly has not answered. Lilly cannot justify the Claims Data disclosure it demands by invoking generalized concepts of payment, health care operations, or program integrity. Lilly is demanding broad, preemptive Claims Data as a condition of statutory pricing, without the public safeguards, limited scope, minimum-necessary protections, government oversight, or good-faith process that would accompany a lawful audit.

68. Under the Terms, Plaintiffs bear all data security and privacy risk—including any failure of the de-identification structure—while Lilly and Second Sight reserve broad, perpetual,

and unilaterally modifiable rights to use the Claims Data.

69. Second Sight and Lilly reserve the right to use the Claims Data for commercial purposes—without compensation to Plaintiffs for non-regulated data elements that Plaintiffs would not voluntarily provide. The compelled disclosure of the Claims Data on Lilly's non-negotiable Terms deprives Plaintiffs of control over a commercially valuable information asset and exposes them to legal and reputational risks that cannot be measured solely in dollars and that cannot be retroactively remedied.

70. In a June 24, 2026 email to MGH, Lilly admitted it conducted "[a]n analysis of the claims data covered entities already have submitted under Lilly's current terms" to support its Policy, and that Second Sight "studied the pace of replenishment." This confirms that Lilly and Second Sight are already using claims data for analytics functions far beyond the stated purpose of Duplicate Discount integrity review.

71. Lilly has offered no meaningful explanation or assurances regarding: why the Claims Data submission is necessary; why the Policy demands more data than minimally necessary to address Duplicate Discounts; how the data will be kept confidential; whether and how manufacturers can re-identify it; what downstream uses will be permitted; and whether Lilly or Second Sight may use the Claims Data to deny claims, support lobbying, inform commercial rebate positions, create derivative analyses, or otherwise extract commercial value from Plaintiffs' information.

72. By unilaterally selecting 340B ESP and requiring Plaintiffs to agree to the Terms under threat of losing access to the 340B Ceiling Price, Lilly compels Plaintiffs to accept a contract of adhesion. The 340B statute "does not permit drug manufacturers, including Lilly, to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities," yet

Lilly's actions effectively condition 340B Program participation on compliance with manufacturer-imposed requirements that extend far beyond the statutory framework established by Congress. *See* Amended Partial Final Judgment, *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs*., No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Apr. 14, 2022).

THE POLICY CREATES UNLAWFUL AND UNREASONABLE BURDENS FOR PLAINTIFFS

73. The Policy imposes substantial administrative, operational, financial, and legal burdens on Plaintiffs that Lilly has refused to acknowledge.

74. Lilly characterizes the Claims Data submission as "minimal" and "standard business practice across the industry." Both characterizations are false. Plaintiffs do not routinely provide Claims Data to drug manufacturers, and the Policy requires Plaintiffs to operationalize a continuing data-transfer mechanism that implicates privacy, cybersecurity, legal, compliance, and data-governance functions across their entire health systems.

75. Before disclosing Claims Data outside their ordinary treatment, payment, and healthcare operations channels, Plaintiffs must evaluate the purpose of the disclosure, who will access the Claims Data, how it will be retained, whether it may be combined with other datasets, what downstream uses are permitted, and what privacy, cybersecurity, contractual, regulatory, and data-governance obligations arise. The fact that certain data elements exist in Plaintiffs' internal systems or are transmitted to payors for reimbursement purposes does not make the demanded disclosure of the Claims Data to Lilly, Second Sight, or other manufacturer-aligned recipients risk-free or "standard."

76. These burdens are especially acute for medical-benefit claims. Medical-benefit claim information originates in hospital clinical, charge-capture, billing, and revenue-cycle systems, while 340B eligibility, accumulation, purchasing, and replenishment determinations are

maintained in separate systems and workflows. Producing a manufacturer-ready file therefore requires Plaintiffs to query and link claim information from different data sources, including electronic health records systems, to separate 340B records, reconcile discrepancies, address reversals and corrected claims, validate the resulting dataset, confirm that disclosure is appropriately authorized, and maintain a recurring submission process. Data relating to in-house dispensing and outpatient administrations is spread across multiple recordkeeping systems, and reconciling those systems adds significant complexity and cost.

77. Compliance with the Policy also would require Plaintiffs to create new procedures with the numerous third-party administrators who assist with 340B claim submission, processing, and adjudication. This includes further oversight of third-party administrators, consolidation of information across multiple platforms, reconciliation of transaction volumes and timing differences, validation of reporting capabilities, staffing to support recurring submissions, and dedication of significant resources to address queries from Lilly or its vendor. In sum, compliance would divert significant staff time and resources from patient care and impose additional administrative burdens on Plaintiffs to provide Claims Data that is not legally mandated or required under the 340B statute or any implementing rule, and not necessary for Lilly's pretextual purpose of preventing Duplicate Discounts.

78. Beyond these administrative burdens, acquiescence to Lilly's demands would require Plaintiffs to assume continuing monitoring, compliance, and breach-response obligations for a data flow that Lilly designed for its own commercial benefit. These obligations expose Plaintiffs to substantial legal and regulatory risk if Lilly's or Second Sight's handling of the Claims Data is later deemed inconsistent with HIPAA, state privacy law, or Plaintiffs' independent commitment to safeguard patient information.

LILLY'S COMPLIANCE JUSTIFICATION FOR THE POLICY IS A PRETEXT TO EXTRACT VALUABLE COMMERCIAL DATA, DENY 340B PRICING, AND INCREASE ITS PROFITS

79. Lilly's stated justifications for its Claims Data demands are pretextual. The Policy is designed to extract commercially valuable Claims Data from Plaintiffs while shifting all attendant risk to them—not to address legitimate Duplicate Discount or Diversion concerns.

80. The Policy allows Lilly improper access to an unprecedented volume of Claims Data—including utilization, payor, reimbursement, timing, dispensing, and replenishment information—that manufacturers, consultants, data brokers, payors, pharmacy benefit managers, and researchers otherwise would have to obtain, license, or approximate through costly commercial channels. The Terms grant Lilly and Second Sight broad rights to use, combine, analyze, and derive commercial value from this Claims Data, while Plaintiffs bear all privacy, cybersecurity, compliance, and reputational risk. Lilly gains valuable commercial intelligence at no cost; Plaintiffs gain only exposure.

81. Lilly claims its demands are necessary to "identify the full universe of duplicate discounts and other program abuses, preserve our ability to initiate audits, and expand transparency even further…." But the Policy far exceeds any legitimate Duplicate Discount purpose. It demands Claims Data for all payors—not just Medicaid and Medicare—and permits uses extending well beyond statutory compliance.

82. HRSA has established a comprehensive system to address manufacturer concerns about Diversion or Duplicate Discounts: manufacturers may conduct an HRSA-approved audit or submit a claim through the ADR process. Under 42 U.S.C. § 256b(a)(5)(C), this audit right requires reasonable cause, HRSA-approved audit plans, manufacturer payment of audit expenses, and 30 days' notice for good-faith resolution. These existing mechanisms render Lilly's self-help demands unnecessary.

83. "Reasonable Cause" is defined as circumstances where "a reasonable person could believe that a covered entity may have violated a requirement of section 340B(a)(5)(A) or (B) of the PHS Act." 61 Fed. Reg. at 65,409. Before initiating an audit, the manufacturer must submit an audit plan to HRSA for review and approval. *Id*. at 65,410.

84. Lilly's Policy abandons these safeguards entirely. Instead of seeking information through lawful, tailored, HRSA-approved audits, Lilly has imposed a standing, across-the-board Claims Data demand—untethered to any particular claim, patient, transaction, audit plan, or reasonable-cause determination—and used its market power and denial of 340B discounts as leverage to compel compliance. This converts a limited statutory audit mechanism into a standing, manufacturer-controlled Claims Data collection regime that subjects Plaintiffs to perpetual audit without meeting statutory requirements.

85. Upon information and belief, Lilly has not established reasonable cause for an audit of Plaintiffs, submitted an audit plan to HRSA, or obtained HRSA approval. Lilly admits the Policy is designed to "produce the evidence required by HRSA to initiate audits" and "preserve [its] ability to continue to initiate audits." On June 1, 2026, Lilly told HRSA the Claims Data was necessary to "audit covered entities."

86. The pretextual nature of Lilly's actions is underscored by the timing: its Claims Data demands followed closely on the heels of setbacks to Lilly's legal and regulatory efforts against the expansion of 340B eligibility and the rejection of its rebate model. *See, e.g., Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021); *Eli Lilly & Co. v. Kennedy*, No. 1:24-cv-03220, 2025 WL 1423630 (D.D.C. May 15, 2025). Having failed to dismantle the 340B Program through litigation and regulatory advocacy, Lilly turned to unilateral Claims Data demands as an alternative mechanism to withhold

discounts and realize the full acquisition price.

87. The Claims Data demanded by Lilly has substantial, undisclosed commercial value. Upon information and belief, Lilly intends to monetize this Claims Data far beyond any Duplicate Discount purpose, including by:

- Challenging or denying valid claims—either through outright denial or by creating administrative burdens that deter submission or cause Plaintiffs to abandon valid claims;
- Identifying commercial "duplicate discounts" that are not statutory Duplicate Discounts—*i.e.*, carving out claims from payment under unrelated commercial rebate agreements Lilly has negotiated with third parties,[7] extracting enormous value from Plaintiffs' Claims Data while Plaintiffs bear all compliance costs;
- Developing derivative analyses for policy or lobbying purposes without making the Claims Data available to Plaintiffs to respond;
- Creating, licensing, or otherwise deriving commercial value from analyses based on the Claims Data—with any resulting financial gain flowing to Lilly and its vendor while Plaintiffs bear all financial loss and risk; and
- Obtaining access to Claims Data—including information that facilitates manufacturers' marketing practices—for which Lilly otherwise would have to pay third-party data vendors.

88. In sum, Lilly intends to monetize Plaintiffs' Claims Data for its own financial gain. Lilly avoids expenses it otherwise would incur and extracts commercial intelligence it has no right to demand while forcing Plaintiffs to bear all privacy, cybersecurity, compliance, and financial risk. To be clear, Plaintiffs would not sell this Claims Data to Lilly at any price. But by coercively demanding it for no compensation, Lilly is unjustly enriching itself at Plaintiffs' expense.

LILLY ENFORCES ITS UNLAWFUL POLICY AGAINST PLAINTIFFS

89. On or around April 23 and 24, 2026, Lilly sent identical form letters to Plaintiffs MGH, BWH, and UMass Memorial claiming they were out of compliance with Lilly's Policy

[7] Proposed Brief of 340B Expert Aaron Vandervelde as Amicus Curiae in Support of Neither Party, No. 3:21-cv-00634-FLW-LGH, ECF No. 99 (D.N.J. Sept. 28, 2021).

because they had refused to send the requested Claims Data. Lilly stated that compliance with its Policy "is a condition of Lilly's offer of its products at 340B ceiling prices" and threatened Plaintiffs: "[t]o accept Lilly's offer and maintain access to 340B pricing, your organization must fulfill this requirement without further delay … We strongly urge you to take the following actions immediately to accept Lilly's offer and purchase Lilly products at the 340B ceiling price … upload all outstanding claims level data."

90. On or around May 4, 2026, Lilly sent Plaintiffs MGH, BWH, and UMass Memorial identical emails reiterating its position and threatening that "adhering to the terms of Lilly's offer is important … if you do not respond, Lilly may assume that you have decided to reject its 340B offer."

91. On October 1, 2026, Lilly sent SH a letter from Derek Asay, Senior Vice President, Government Strategy and Federal Accounts, demanding that SH submit all outstanding Claims Data for 340B dispenses, including in-house dispenses, dating back to February 1, 2026, by October 12, 2026. The letter stated that, if SH did not submit the data by that deadline, Lilly would deem SH to have rejected Lilly's 340B offer and would notify wholesalers that, effective October 21, 2026, 340B pricing for Lilly products would no longer be accessible to SH. Lilly cited HRSA's Notice Regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48,883, 48,894 (Aug. 3, 2026), in support of its position regarding the legality, administrative burden, and privacy implications of its Claims Data requirement.

92. On or about October 1, 2026, Lilly sent a letter to Harrington stating that, effective October 21, 2026, Harrington would be denied 340B discounts for Lilly's drugs.

93. Plaintiffs undertook substantial efforts to confer with Lilly, and in each case, Lilly refused to answer straightforward questions or provide sufficient information.

LILLY REFUSED TO PROVIDE SUFFICIENT INFORMATION OR ASSURANCES IN RESPONSE TO UMASS MEMORIAL'S AND HARRINGTON'S REASONABLE INQUIRIES

94. On May 7, 2026, UMass Memorial responded to Lilly and expressed "significant concerns regarding the scope and framework of the requested data submission requirements." Specifically, UMass Memorial explained that there is no legal requirement that Covered Entities submit Claims Data and reiterated that Lilly's Policy raises HIPAA concerns and significant administrative burdens. UMass Memorial also expressed concerns about the potential for incomplete or inaccurate conclusions arising from retrospective data analysis in complex health-system environments involving mixed-use settings, multiple care sites, timing variances between dispensing and replenishment activity, and both pharmacy and medical benefit workflows.

95. Lilly responded in writing on June 1, 2026, dismissing UMass Memorial's concerns and failing to provide additional information. Instead, Lilly threatened to cut off UMass Memorial's access to the 340B Ceiling Price if it did not capitulate within five business days.

96. On October 9, 2026, Harrington wrote to Lilly, stating that it remains "committed to full compliance with all applicable 340B Program requirements" but that it is not prepared to submit claims-level data for its 340B utilization, as that falls outside the framework requirements for compliance with the 340B Program. Harrington also expressed "significant concerns" with the Claims Data requirement in the Policy, including the lack of statutory authority, patient privacy and data governance risks, and administrative and operational burdens. Lilly did not respond.

LILLY REFUSED TO PROVIDE SUFFICIENT INFORMATION OR ASSURANCES IN RESPONSE TO MGH'S, BWH'S AND SH'S REASONABLE INQUIRIES

97. MGH attempted to confer with Lilly, but Lilly refused to engage in good faith. Representatives of MGH met with Lilly telephonically on May 21, 2026. During that call, MGH explained that legality under HIPAA was a threshold concern with the Policy. Lilly acknowledged

that MGH was not the only Covered Entity to raise this issue, said it took MGH's concern seriously, and promised to follow up with additional analysis. It never did so.

98. Subsequently, MGH and BWH each responded to Lilly in writing with additional requests for information.

99. On or around June 2, 2026, BWH sent Lilly a letter explaining that "[s]ince the policy may require the production of data in a manner prohibited by law and under unreasonable, non-negotiable terms and conditions, we do not believe Lilly's proposal is a bona fide offer … If Lilly's offer requires us to violate the law, it is not a bona fide offer." BWH reiterated that the Policy carried substantial HIPAA concerns with no appropriate assurances, and advised Lilly that BWH lacked sufficient assurance that Claims Data could not be improperly re-identified. Lilly never responded to BWH's letter; its next action was to terminate BWH's access to the 340B Ceiling Price.

100. On June 17, 2026, Lilly sent a letter to MGH that failed to address MGH's concerns or answer its straightforward questions. Instead, the letter reiterated that "to accept Lilly's offer and maintain access to 340B pricing you must submit your outstanding data within 5 business days of the date of this letter." While Lilly contended that it could not re-identify the Claims Data, Plaintiffs understood Second Sight's own Expert Opinion to raise a contrary re-identification concern.

101. Representatives for MGH and Lilly then exchanged emails. Lilly threatened that "Lilly intends to proceed as its June 17 letter describes. We sincerely hope, however, that your client will reconsider its decision to reject Lilly's offer. That offer remains open on the same terms and your client can accept it by submitting the outstanding claims data through Second Sight Solutions." Lilly also confirmed that it and Second Sight would use the Claims Data for purposes

beyond Duplicate Discount prevention, admitting that it and/or Second Sight already had conducted "[a]n analysis of the claims data covered entities already have submitted under Lilly's current terms [which] shows that, in 2026, 93% of claims arrive within the 45-day window."

102. On June 25, 2026, representatives for MGH responded, explaining that Lilly had failed to answer basic questions about the Policy, including why "Second Sight's expert determination states that manufacturers re-identify patients' data." To date, Lilly has not even attempted to answer this basic question.

103. MGH and BWH also asserted that Lilly has not explained why it is selectively enforcing the Policy against some Covered Entities but not others. They expressed willingness to "engage in good faith dialogue on a lawful structure for any data exchange that has a statutory or regulatory basis and that resolves the HIPAA question previously raised." Lilly failed to respond.

104. On October 8, 2026, SH responded in writing to Lilly in a letter from Rafic Nehme, Executive Director, 340B Pharmacy & Business Development, Mass General Brigham, transmitted to Lilly by email on October 12, 2026, copying HRSA's Office of Pharmacy Affairs. SH contested Lilly's statutory authority to condition access to 340B pricing on submission of Claims Data and objected to Lilly's arbitrary 45-day deadline. SH explained that claim numbers are assigned by payors after claims are submitted, that payors often permit claims to be submitted months after an encounter, and that Lilly's demand may violate patient-privacy laws. SH warned that refusal to offer 340B pricing on that basis would constitute a knowing and intentional overcharge and violation of state law, subjecting Lilly to civil monetary and other penalties, and stated that SH expected Lilly not to terminate pricing on the stated timeline.

105. Without adequate assurance that Claims Data will not be re-identified, and without the other information requested, Plaintiffs could not meaningfully evaluate Lilly's "offer" or vet

the Policy's HIPAA-specific and general Claims Data use and security concerns.

106. Lilly's failure to respond to Plaintiffs' reasonable requests for information confirms the unfair and deceptive nature of Lilly's Policy and its implementation. Lilly knows that the Terms required by the Policy are unconscionable and that Plaintiffs have refused to comply with them. And Lilly knew that cutting off Plaintiffs' access to the 340B Ceiling Price upon their refusal would reduce the amount of 340B-discounted drugs Lilly was required to deliver and result in an economic windfall for Lilly.

LILLY CUT OFF PLAINTIFFS' ACCESS TO 340B DISCOUNTS

107. Lilly exploited its superior market power and leveraged the 340B Program to force Plaintiffs into the untenable choice described above: surrender valuable Claims Data without compensation and assume compliance risk and burdens, or forgo vital 340B savings and pay higher prices for Lilly's drugs—depleting resources to continue serving their underserved populations.

108. Plaintiffs refused to submit Claims Data to Lilly.

109. Since on or about June 18, 2026, and July 2, 2026, respectively, Lilly has deprived BWH and MGH of access to the 340B Ceiling Price.

110. Since on or about June 18, 2026, Lilly has deprived UMass Memorial of access to the 340B Ceiling Price.

111. Since on or about October 21, 2026, Lilly has deprived SH and Harrington of access to the 340B Ceiling Price.

112. Annualized, loss of 340B discounts for MGH, BWH, and SH will result in tens of millions of dollars in lost 340B savings and added drug expense while Lilly continues to enjoy access to the extensive Medicare and Medicaid markets.

113. By way of example, MGH overpaid by approximately $2,478 for a single package of Lilly's cancer drug Cyramza, and BWH overpaid by approximately $200 for a single package

of Lilly's Alzheimer's infusion drug Kisunla.

114. Since on or about June 18, 2026, UMass Memorial has been forced to purchase covered outpatient drugs from Lilly at costs significantly above the Ceiling Price, facing annualized overpayments of at least $20 million.

115. Since October 21, 2026, SH and Harrington have been forced to purchase Lilly's covered outpatient drugs far above the 340B Ceiling Price, depleting resources otherwise available to support patient care and community services.

116. On June 25, 2026, and July 6, 2026, respectively, BWH and MGH submitted notices of overcharge to HRSA reporting that Lilly had cut off their access to statutorily required 340B discounts.

117. On June 22, 2026, UMass Memorial submitted a notice of overcharge to HRSA reporting that Lilly had cut off UMass Memorial's access to statutorily required 340B discounts.

118. On October 23, 2026, SH submitted a notice of overcharge to HRSA reporting that Lilly had cut off its access to statutorily required 340B discounts.

119. On October 27, 2026, Harrington submitted a notice of overcharge to HRSA reporting that Lilly had cut off its access to statutorily required 340B discounts.

120. Plaintiffs seek relief from this Court under the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A. Plaintiffs do not seek to use Chapter 93A to evade HRSA's authority.

121. While HRSA may adjudicate overcharging disputes, it lacks authority to provide relief regarding Lilly's coercive Policy, its unconscionable Terms, data-use rights, privacy and cybersecurity risk-shifting, selective enforcement, and retaliatory market-power conduct. HRSA cannot award Chapter 93A-based injunctive relief, damages, treble damages, attorneys' fees, or

restitution for unfair trade practices harming Plaintiffs and the citizens of Massachusetts.

122. The 340B Program and Lilly's overcharging provide factual context, but the unfair and deceptive conduct alleged here includes separate coercive acts that HRSA's administrative process does not remedy: Lilly's extra-statutory Claims Data demand, use of non-negotiable Terms, threatened and actual retaliation, selective enforcement, and imposing extraction of valuable, legally protected information as the price of statutory access.

LILLY'S CONDUCT IS UNCONSCIONABLE, UNFAIR, AND DECEPTIVE

123. The 340B Program exists to assist nonprofit entities like Plaintiffs that provide significant amounts of free and subsidized care, services, and medicines, and help their vulnerable patients access healthcare. As a condition of participating in and realizing substantial profits from the Medicare and Medicaid programs, Lilly voluntarily promised to extend the 340B Ceiling Price to Covered Entities in exchange for access to the enormous patient population covered by those programs.

124. Through its unprecedented self-help measures, Lilly still has access to Medicare and Medicaid patients, including patients served by Plaintiffs, but no longer offers Plaintiffs the required 340B Ceiling Price. Lilly reaps the benefits of the 340B Program without paying any of the costs.

125. Lilly, with a market capitalization of over one trillion dollars, is extracting additional profits to which it is not entitled at the expense of nonprofit hospitals and their most vulnerable patients. Lilly's patents provide it with significant market power in several pharmaceutical markets, and Lilly is the single source or monopoly supplier of numerous critical medicines for which there is significant consumer demand and no generic or biosimilar equivalents. The absence of competitive alternatives, presence of high demand, and Lilly's

intellectual property rights provide it with significant pricing power and the ability to make a "take it or leave it" offer.

126. Plaintiffs cannot decline to do business with Lilly and still fulfill their obligations to their patients and communities, and Lilly knows this.

127. By denying Plaintiffs access to required 340B discounts, Lilly has knowingly and willfully reduced access to 340B savings and raised the price of its products to Plaintiffs, abusing its market power to deprive nonprofit hospitals of resources to expand healthcare access and improve health outcomes. Lilly's conduct was carried out entirely and intentionally to protect and increase its already extraordinary profits to the detriment of Massachusetts residents and their healthcare systems.

128. Lilly has represented that it will provide 340B drugs at the Ceiling Price while simultaneously implementing the Policy to circumvent its 340B obligations. Lilly knew that its conduct would hurt, rather than improve, healthcare in underserved Massachusetts communities.

129. Lilly is applying its Policy in an arbitrary, capricious, and unfair manner by enforcing it against some Covered Entities but not others and on different timelines, singling out Plaintiffs while choosing not to cut off 340B pricing for similarly situated Covered Entities that are also not in compliance with the Policy.

130. There are no procompetitive benefits to Lilly's conduct. A wealth transfer from nonprofit hospitals to the largest pharmaceutical company in the world does not benefit competition or consumers.

131. Lilly ceased honoring the 340B Ceiling Price for Plaintiffs around the same time the Medicare GLP-1 Bridge program went live, a program expected to significantly increase demand for drugs that Lilly manufactures. The timing suggests that Lilly's Policy is driven by a

profit motivation to force Plaintiffs to pay full price for these high-demand drugs, rather than the pretextual justifications Lilly has offered.

132. In short, Lilly's conduct is unconscionable, unfair, and deceptive because Lilly uses its substantial market power to force nonprofit hospitals either to surrender protected, commercially valuable Claims Data on Terms that strip them of control and shift all risk to them, or to forgo vital 340B savings and pay unlawfully inflated prices for Lilly's drugs. Either path jeopardizes Plaintiffs' missions and the 340B Program's objective of stretching scarce resources to serve underserved patients. The result is increased healthcare costs for Massachusetts citizens and increased risk for the healthcare providers who serve them.

PLAINTIFFS WILL BE IRREPARABLY HARMED WITHOUT AN INJUNCTION

133. Absent an injunction, Plaintiffs will be irreparably harmed as a direct result of Lilly's coercive conduct. Harms to Plaintiffs go beyond obvious monetary damages and cannot be adequately remedied through a later damages award.

134. Plaintiffs' expenditures for Lilly's products total millions of dollars annually, comprising a significant portion of their overall drug spend. Plaintiffs have no choice but to be Lilly's customers to serve their patient populations consistent with their nonprofit missions. Lilly's drugs are in some instances the only drugs or one of only a few drugs in a therapeutic category covered by a patient's health plan, whether commercial or government. Zepbound and Foundayo are key examples.

135. Lilly's conduct is particularly harmful because the Policy applies to all of Lilly's covered outpatient drugs, many of which treat cancer and other chronic conditions, and Plaintiffs must continue purchasing Lilly's drugs to serve their patients. Lilly's refusal to provide the 340B Ceiling Price does not merely create a compensable pricing dispute; it forces Plaintiffs to subsidize Lilly's unlawful condition while continuing to care for patients who depend on Lilly's

medications. Plaintiffs cannot refuse necessary patient care as leverage against Lilly.

136. Consistent with Congress's purpose in establishing the 340B Program, Plaintiffs reinvest 340B savings to expand healthcare access and improve services for medically underserved, uninsured, and underinsured patients. Plaintiffs use 340B savings to support specialized treatment, subsidize services reimbursed below cost (such as addiction treatment), and expand access to essential services for uninsured and underinsured patients. Every dollar Lilly wrongfully diverts from Plaintiffs is unavailable to support these patient care programs.

137. In fiscal year 2025 alone, UMass Memorial provided $413 million in uncompensated care, over 18,000 no-cost prescriptions, and $92 million in absorbed Medicaid losses. Approximately 65 percent of UMass Memorial's patients are Medicaid, Medicare, or self-pay. UMass Memorial provides more care to underserved patients than any other provider in Central Massachusetts and accounts for more than 70 percent of Medicaid inpatient care in the region.

138. UMass Memorial's 340B savings support programs that provide free prescription medications to uninsured patients, connect underinsured patients with copay assistance programs, and help patients obtain and remain on medically necessary therapies. These programs include the Ronald McDonald Care Mobile (providing free healthcare and dental services to medically underserved populations in ten low-income neighborhoods through more than 4,500 annual visits at 28 public schools), the Road to Care Mobile Addiction Team (which in 2023 provided 3,699 clinical encounters for individuals experiencing behavioral health and substance use disorders), medical respite beds for individuals experiencing homelessness, and the Child Protection Program.

139. In fiscal year 2025, approximately 70.7 percent of Harrington's patients were covered by Medicare or Medicaid or were self-pay. That same year, Harrington provided

approximately $21.1 million in uncompensated care, including approximately $3.7 million in free care, $10.8 million in Medicaid shortfall, and $6.6 million in implicit price concessions/bad debt. Harrington's 340B savings help sustain a broad continuum of behavioral-health and substance-use-disorder services, including two inpatient behavioral-health units, an Addictions Immediate Care Unit providing an urgent-care model for substance-use treatment, Psychiatric Emergency Services, a partial hospitalization program, outpatient behavioral-health services, and pediatric psychiatric services including transcranial magnetic stimulation. Harrington also operates a medical oncology and infusion center that provides local access to cancer treatment and supports community programs addressing chronic disease education, health fairs, food and clothing insecurity, and other needs of underserved patients. Every dollar Harrington is forced to spend because Lilly denies the 340B Ceiling Price is a dollar no longer available to support these safety-net services.

140. MGH, BWH, and SH in fiscal year 2025 alone provided over $800 million in charity care and health-related services, including $151 million in net charity care through the Massachusetts Health Safety Net program, $122 million in subsidies for five community health centers in underserved communities in the greater Boston area, $21 million in free care at employed physician practices, $42 million in community health improvement services, and $486 million in unreimbursed services to Medicaid patients. Using 340B savings, MGH, BWH, and SH provide community-based health centers and mobile community care vans for reducing hypertension and cardiometabolic disease, increasing cancer screenings, initiating substance use disorder treatment, improving maternal health, promoting heart health programs, and operating mobile markets to address food insecurity. In fiscal year 2025, these clinical community programs provided health care services to more than 7,000 patients across diverse and underserved

communities in the greater Boston area.

141. To date, Plaintiffs have attempted to protect patients from the immediate consequences of Lilly's actions by absorbing these costs rather than reducing patient access to Lilly medications and other 340B-supported services. That approach is not sustainable indefinitely. Continued losses will require difficult decisions regarding where limited resources can be deployed, including delaying planned investments in patient care, limiting program expansion, reducing financial support for existing services, or scaling back access initiatives that depend upon 340B savings.

142. Lilly's refusal to offer the 340B Ceiling Price in retaliation for Plaintiffs' refusal to comply with the Policy could cause Plaintiffs' days-cash-on-hand to drop low enough to risk violating bond covenants (in the case of UMass Memorial) or cause a downgrade in Plaintiffs' respective bond ratings, with consequences including mandatory consultant call-in, increased borrowing costs, decreased access to capital, and potential facility closures.

143. By denying Plaintiffs access to the 340B Ceiling Price, Lilly interferes with Plaintiffs' ability to fulfill their missions and serve their communities. The elimination of 340B savings for Lilly's covered outpatient drugs directly impairs Plaintiffs' ability to provide comprehensive care to underserved and uninsured patients.

144. Reduced 340B savings impair Plaintiffs' ability to provide financial assistance for essential medications, bridge therapy while insurance coverage is obtained, and furnish medications at reduced or no cost when patients otherwise would be unable to afford treatment. The resulting reduction in medication access is likely to increase medication nonadherence, disease progression, avoidable emergency department utilization, preventable hospitalizations, and poorer clinical outcomes among Plaintiffs' most vulnerable patient populations. Once patient care

programs are scaled back, the clinical continuity, staff expertise, patient outcomes, and community relationships lost in the interim cannot be restored by an end-of-case monetary award.

145. Lilly has used its market power and leveraged the 340B Program to gain an unfair advantage and coerce Plaintiffs into an unlawful choice: surrender valuable, legally protected Claims Data for no compensation and assume all attendant risk, or lose the 340B discounts to which Plaintiffs are lawfully entitled and need to serve their communities and underserved patients. That coercive choice, where Lilly stands to gain and Plaintiffs stand to lose under either scenario, is itself an unfair and deceptive act under Chapter 93A. Lilly is not offering Plaintiffs a commercial alternative in a competitive market, nor is it merely asking Plaintiffs to resolve a technical statutory dispute through HRSA. Plaintiffs cannot simply walk away from Lilly's drugs without impairing their ability to treat patients whose physicians prescribe those drugs and whose health plans cover them.

146. Reinstating 340B discounts at the end of this case would not undo the harm Plaintiffs are suffering now. Plaintiffs' losses grow every day Lilly withholds the Ceiling Price, and nothing in the 340B statute or HRSA's framework would clearly require Lilly to repay the overcharges with interest or otherwise compensate Plaintiffs for the time value of money. That loss is substantial given the gap between WAC and the 340B Ceiling Price on Lilly's high-cost products, and any award of pre-judgment interest is discretionary and not guaranteed. In addition, a significant portion of Plaintiffs' losses can never be recouped through rebilling because claims generally cannot be rebilled more than one year after the date of service. Since Plaintiffs do not expect a final resolution within that window, Plaintiffs must bill the higher acquisition costs where acquisition cost reporting is required. Even for claims that might otherwise be eligible, rebilling across multiple payors, systems, and third-party administrators is highly complex and error-prone,

so some damages are inherently incapable of being fully remedied after the fact.

147. Nor can end-of-case damages adequately remedy the ongoing loss of 340B savings. Plaintiffs use 340B savings to support uncompensated care, medication access, behavioral health, oncology, pharmacy, community health, and other essential services for medically underserved, uninsured, and underinsured patients. Plaintiffs rely on statutorily mandated 340B pricing to support these essential programs that would otherwise be difficult or impossible to sustain. Lilly's continued refusal to provide 340B pricing will increasingly force Plaintiffs to reduce services to the very patient populations the 340B Program is intended to serve and protect. Ongoing disruption threatens Plaintiffs' financial stability for providing community benefits and uncompensated care, undermining access to care for underserved communities in Massachusetts. The resulting reduction in access, continuity of care, and patient trust cannot be fully restored through a later damages award.

148. Lilly's Policy thus inflicts irreparable harm in both directions. If Plaintiffs refuse to surrender the Claims Data, they lose statutory discounts and critical resources intended to support safety-net care. If they capitulate, they permanently lose control over valuable Claims Data and assume ongoing privacy, cybersecurity, regulatory, and reputational risks that cannot be fully measured or undone.

149. Once Claims Data is disclosed, the disclosure is immediate and practically irreversible. Plaintiffs cannot retrieve every copy, fully control downstream use, ensure that recipients will not combine the Claims Data with other information in ways that create re-identification risk, or quantify the resulting loss of control over protected health information and commercially valuable Claims Data. Plaintiffs also cannot undo the governance consequences of having established a recurring Claims Data-transfer process to a manufacturer-selected platform

under non-negotiable Terms. The resulting harms include loss of control over Claims Data, increased exposure to privacy and data-security incidents, regulatory enforcement risk, civil or criminal penalties, impairment of patient trust, reputational injury, and uncompensated loss of a commercially valuable information asset.

150. The data-related harm is unquantifiable. The Claims Data Lilly demands is both legally protected and commercially valuable. As alleged in paragraphs 74 through 79, producing it would require Plaintiffs to build, staff, and continually maintain custom data workflows outside their ordinary patient-care, reimbursement, and pharmacy purchasing systems—a burden that is especially acute for medical-benefit claims. Disclosure could expose Plaintiffs to regulatory scrutiny, civil claims, breach-response obligations, cybersecurity and privacy-monitoring costs, reputational injury, and loss of patient trust if Lilly's or Second Sight's handling of the Claims Data proves unlawful or insecure. Those risks are amplified by Lilly's non-negotiable Terms, which shift substantial privacy and security risk to Plaintiffs while limiting the aggregate direct liability of Second Sight and its affiliates to $100.

151. Injunctive relief is necessary to prevent Lilly from continuing to leverage its market power to force Plaintiffs into an unlawful and unfair choice. No later award of damages can restore confidentiality once Claims Data is disclosed, ensure against downstream re-identification or misuse, unwind recurring manufacturer-directed data-transfer workflows, recapture the full value of derivative analyses created from Plaintiffs' Claims Data, repair loss of patient trust, or restore patient-care services and access disrupted while Lilly withholds access to the 340B discounts Plaintiffs are entitled to receive.

152. The requested injunction is prohibitory and in substance restores the pre-Policy status quo by preventing Lilly from continuing to enforce the challenged Policy and from

withholding access to 340B discounts based on Plaintiffs' refusal to accept Lilly's extra-statutory data condition. It would not require the Court to supervise 340B pricing calculations or create a new commercial relationship between the parties.

COUNT I

VIOLATION OF MASSACHUSETTS GENERAL LAWS CHAPTER 93A

153. Plaintiffs repeat and reallege all preceding paragraphs as if fully set forth herein.

154. Mass. Gen. Laws ch. 93A, § 2(a), provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

155. Lilly is a "person" within the meaning of Mass. Gen. Laws ch. 93A, § 1(a).

156. Lilly is engaged in "trade" and "commerce" within the meaning of Mass. Gen. Laws ch. 93A, § 1(b), by manufacturing, marketing, distributing, and selling prescription pharmaceutical products to Covered Entities, wholesalers, pharmacies, and other purchasers including Plaintiffs, in Massachusetts.

157. Lilly's conduct giving rise to this action occurred and is occurring primarily and substantially within Massachusetts, including Lilly's communications to Plaintiffs and its unlawful refusal to offer the 340B Ceiling Price to Plaintiffs.

158. While Lilly's actions arise against the backdrop of the 340B Program, Plaintiffs' claims are not private claims to enforce the 340B statute. They challenge conduct that Massachusetts independently prohibits: unfair methods of competition, unfair trade practices, deceptive leverage, unconscionable Terms, and coercive market-power conduct.

159. As a condition of participation in Medicare and Medicaid, Lilly is required to extend the 340B Ceiling Price to Covered Entities like Plaintiffs in exchange for access to an enormous population of patients covered by government-funded programs. Through self-help,

Lilly still has access to that market of patients, but it is no longer offering Plaintiffs the requisite 340B discounts. In so doing, Lilly has contradicted its public representations to the market, bypassed the statutory and regulatory framework governing 340B pricing and audits, and justified its conduct through pretext, all in service of its goal to deny Plaintiffs and other safety-net hospitals the resources they rely on to serve the underprivileged populations the 340B Program is intended to serve. Such conduct is immoral, unethical, oppressive, and unscrupulous, and therefore independently unfair and deceptive under Chapter 93A.

160. Lilly's anticipated assertion that Plaintiffs must proceed only through HRSA or ADR underscores the unfairness of Lilly's conduct. Lilly did not wait for HRSA, seek reasonable-cause audit approval, or pursue ADR before cutting off Plaintiffs' 340B discounts. Instead, Lilly used private leverage in the marketplace to impose immediate consequences on Plaintiffs while invoking HRSA exclusivity only as a defense to judicial review of its own self-help.

161. Lilly has engaged in unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade and commerce in Massachusetts, including, without limitation:

- Exploiting its monopoly and market power to withhold access to 340B discounts and injure consumers;
- Unilaterally imposing unlawful conditions on Plaintiffs' access to the 340B Ceiling Price in contravention of 42 U.S.C. § 256b and HRSA guidance;
- Circumventing the statutory and regulatory audit framework set forth in 42 U.S.C. § 256b(a)(5)(C) and 61 Fed. Reg. 65,406 by subjecting Plaintiffs to permanent and unregulated scrutiny of every 340B-eligible claim, without reasonable cause, without HRSA approval, and without the procedural protections Congress and HRSA prescribed through the Guidelines;
- Representing to Plaintiffs that Lilly is "committed to compliance with the 340B statute" while under a court order declaring that it has no power to impose unilateral conditions on Covered Entities;
- Leveraging Lilly's dominant market position and the fact that its drugs not only appear on Medicare, Medicaid, and commercial plan formularies, but also are in

scope for the lucrative Medicare GLP-1 Bridge program, thereby making Plaintiffs a captive purchaser with no alternative supplier to extract valuable and confidential Claims Data and impose conditions to which Plaintiffs would not otherwise agree;

- Terminating Plaintiffs' access to the 340B Ceiling Price in retaliation for Plaintiffs' refusal to comply with Lilly's unlawful Policy;

- Charging Plaintiffs WAC for drugs which Plaintiffs would otherwise be entitled to purchase at the 340B Ceiling Price or a negotiated GPO price;

- Requiring Plaintiffs to disclose Claims Data that may be re-identifiable, without providing Plaintiffs with a sufficient legal basis or adequate HIPAA-related assurances; and

- Forcing Plaintiffs to surrender protected and commercially valuable Claims Data on non-negotiable Terms that permit broad use, downstream disclosure, and potential monetization while shifting privacy and security risk to Plaintiffs.

162. Lilly has knowingly and willfully exploited its market power, Plaintiffs' status as captive purchasers, and leveraged the 340B Program to impose unlawful terms on Plaintiff hospitals that it knows are dependent upon 340B discount pricing to serve low-income, uninsured, and rural patients across Massachusetts. Lilly did so knowing that Plaintiffs could not simply refuse to purchase Lilly's products without impairing their ability to continue to provide services to their most vulnerable patients, the very patients the 340B Program is intended to serve. Lilly's conduct is not a good-faith resort to HRSA's administrative processes; it is coercive, private self-help designed to extract money, Claims Data, or both before any neutral process can occur.

163. As a direct and proximate result of Lilly's unfair methods of competition and unfair and deceptive acts and practices, Plaintiffs have suffered and continue to suffer substantial injury, including lost 340B savings that would otherwise be reinvested in patient care.

164. Both Plaintiffs and Massachusetts consumers are harmed by Lilly's profit-motivated conduct that goes far beyond the bounds of acceptable business conduct and common decency.

165. Lilly's violations are willful and knowing, entitling Plaintiffs to an award of not less than double, and up to treble, damages, together with interest, costs, and reasonable attorneys' fees.

COUNT II

UNJUST ENRICHMENT

166. Plaintiffs repeat and reallege all preceding paragraphs as if fully set forth herein.

167. Lilly obtains a substantial monetary benefit from its participation in the Medicare and Medicaid programs and, as a condition of that participation, is required to comply with the 340B Program.

168. Despite this, Lilly has imposed unlawful conditions on access to 340B discounts and is now withholding access to the 340B Ceiling Price *and* the GPO price and selling drugs to Plaintiffs at WAC.

169. By forgoing vital 340B savings and purchasing Lilly's drugs at higher prices, Plaintiffs conferred a financial benefit on Lilly under duress and without meaningful choice, as Plaintiffs cannot substitute Lilly's drugs with those of another manufacturer for many of their patients who rely on drugs manufactured exclusively by Lilly or whose insurance plans cover only Lilly's products in certain therapeutic categories.

170. Under these circumstances, it would be inequitable and unconscionable to allow Lilly to retain the profits it derived from Plaintiffs' purchases of covered outpatient drugs.

171. Through its Policy, Lilly also seeks to extract valuable and legally protected Claims Data from Plaintiffs that Lilly and its vendor retain broad rights to use for purposes extending beyond Duplicate Discount review, through unconscionable Terms that shift all risk to Plaintiffs while capping Second Sight's aggregate liability at $100. The benefit Lilly seeks includes access to raw claims information and the ability to combine, analyze, derive, and potentially

commercialize insights from that information in ways Plaintiffs cannot monitor or undo once disclosure occurs.

172. Equity should not permit Lilly to retain either unlawfully inflated drug revenues or the separate, uncompensated value of Plaintiffs' Claims Data extracted through coercive self-help.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendant Eli Lilly and Company, and grant the following relief:

A. Preliminary and Permanent Injunctive Relief enjoining Defendant, its officers, agents, employees, and all persons acting at the direction of Defendant, from:

i. Enforcing the Policy and the Terms against Plaintiffs;

ii. Continuing to deny, restrict, or otherwise interfere with Plaintiffs' access to the 340B Ceiling Price for covered outpatient drugs;

iii. Imposing Claims Data submission requirements or other conditions on Plaintiffs' access to the 340B Ceiling Price that are not required by 42 U.S.C. § 256b, including those in Defendant's Policy;

iv. Denying, restricting, prohibiting, or otherwise interfering with the acquisition and delivery of its drugs to Plaintiffs, whether administered or dispensed by Plaintiffs or dispensed on behalf of Plaintiffs by a contract pharmacy, except as such restrictions are required by law; and

v. Interfering with the ability of Plaintiffs to dispense drugs to eligible patients, whether administered or dispensed by Plaintiffs or dispensed on behalf of Plaintiffs by a contract pharmacy;

B. Preliminary and Permanent Injunctive Relief preventing Defendant from

conditioning Plaintiffs' access to covered outpatient drugs at or below the applicable 340B Ceiling Price on Plaintiffs' acceptance of the unlawful conditions described herein, including those set forth in the Policy;

C. Compensatory Damages in an amount to be proven at trial, including but not limited to the amounts Plaintiffs have paid to Defendant above the applicable 340B Ceiling Price, lost 340B savings, and other consequential damages;

D. Multiple Damages under Mass. Gen. Laws ch. 93A, § 11, in an amount not less than two times and up to three times the actual damages sustained by Plaintiffs, based on Defendant's willful and knowing violations;

E. Restitution and Disgorgement of all benefits unjustly retained by Defendant, including the difference between the prices Plaintiffs have paid for Defendant's drugs and the applicable 340B Ceiling Prices;

F. Attorneys' Fees and Costs pursuant to Mass. Gen. Laws ch. 93A, § 11, and any other applicable law;

G. Pre-Judgment and Post-Judgment Interest at the maximum rate permitted by law; and

H. Such Other and Further Relief as this Court deems just, equitable, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all claims and issues so triable.

Dated: October 27, 2026

Respectfully submitted,

THE GENERAL HOSPITAL CORPORATION D/B/A MASSACHUSETTS GENERAL HOSPITAL, THE BRIGHAM AND WOMEN'S HOSPITAL, INC., NORTH SHORE MEDICAL CENTER, INC. D/B/A SALEM HOSPITAL, UMASS MEMORIAL MEDICAL CENTER, INC., and UMASS MEMORIAL HEALTH – HARRINGTON HOSPITAL, INC.,

By their attorneys,

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