340B: THE SHOULDER OF FRANKENSTEIN'S MONSTER

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ABSTRACT

Like other components of our healthcare system, the 340B program has rapidly grown and evolved with the changing healthcare landscape, and questions not sufficiently addressed by the statute creating it have arisen. One such question, the focus of this Article, is whether hospitals participating in the program may use contract pharmacy arrangements (and if so, how many) and still be eligible for 340B drug discounts. The answer to this question profoundly impacts the income stream of hospitals that serve low-income populations because it affects hospitals' very ability to participate in the 340B program, which in turn affects the ability of vulnerable populations to access affordable prescriptions and healthcare services. This Article is the first to articulate the limits of courts in resolving this question due to the statute's ambiguity.

This Article also argues that Congress, rather than courts, is the best body to resolve the dispute. Much like shooting the shoulder of Frankenstein's monster, shotgun litigation is a poor solution when clarity is needed across the 340B program. And legislative reform provides an effective means of addressing existing bipartisan policy goals of lowering prescription drug costs and spending due to the program's impact, particularly for the un- or under-insured.

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I. Introduction

Congress and the Biden administration have been working to address increasing prescription drug costs, particularly among vulnerable populations like the un- or under-insured.[1] While this has become a hot policy topic on both sides of the aisle leading to recent legislation to improve drug prices for Medicare beneficiaries,[2] Congress has yet to take up the second-largest drug pricing program measured by total drug reimbursement—the 340B program—in its reform efforts, though the program has recently taken the interest of members on both sides of the aisle.[3]

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[1] *See, e.g.*, Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818; Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong. (2021); HHS Press Office, *Biden Administration Announces Savings on 43 Prescription Drugs as Part of Cost-Saving Measures Under President Biden's Inflation Reduction Act*, U.S. Dep't Health & Hum. Servs. (June 9, 2023), https://www.hhs.gov/about/news/2023/06/09/biden-administration-announces-savings-43-prescription-drugs-part-cost-saving-measures-president-bidens-inflation-reduction-act.html [https://perma.cc/K4YB-4X7A].

[2] *See* Inflation Reduction Act of 2022; *see also* Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes & Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ [https://perma.cc/763L-6FAA].

[3] Victoria Bailey, *Lawmakers Seeking Stakeholder Input to Improve 340B Drug Pricing Program*, Revcycle Intel. (June 20, 2023), https://revcycleintelligence.com/news/lawmakers-seeking-stakeholder-input-to-improve-340b-drug-pricing-program [https://perma.cc/PY33-RYSZ]; *see also Spanberger Leads Bipartisan 181-Member Effort Pressing Administration to Prevent Damaging Prescription Drug Price Hikes, Preserve Discounts for Virginia's Hospitals & Rural Healthcare Providers*, Congresswoman Abigail Spanberger (July 18, 2022), https://spanberger.house.gov/posts/spanberger-leads-bipartisan-181-member-effort-pressing-administration-to-prevent-damaging-prescription-drug-price-hikes-preserve-discounts-for-virginias-hospitals-rural-healthcare-provider [https://perma.cc/FS34-YW3X].

The 340B program was intended to ensure that vulnerable populations have access to affordable prescription drugs by requiring drug manufacturers participating in the program to offer drug discounts to "covered entities."[4] Among other types of healthcare facilities and clinics, "covered entities" include certain safety net and critical access hospitals, which provide essential healthcare services to those in need.[5] Some of these hospitals have their own in-house pharmacies and order the discounted drugs directly through them. Others contract with third-party pharmacies, and these "contract pharmacies" act as the hospitals' "agents" in handling the hospitals' 340B drug orders. Hospitals may pass the drug discounts they receive through the 340B program to low-income patients directly or use their profits from the discounted drugs to subsidize needed but belly-up healthcare services in marginalized communities.[6]

Measured by total sales of 340B discounted drugs, the 340B program is at least a $38 billion program, though its exact financial impact on participating hospitals and entities is unknown.[7] And importantly, because the program regulates "covered entities" rather than targeting certain programs such as Medicare Part D, legislative changes for the 340B program could impact drug prices for patients who have all types of insurance—government or private—or no health insurance at all.[8] Given the 340B program's impact, this Article notes the importance of addressing existing gaps in the 340B statute as well as policy concerns about the program in legislative efforts to decrease prescription drug costs among low-income populations. Not only would reform of the 340B program present an efficient means to address these policy concerns, but it would provide Congress with an opportunity to address a critical gap in the statute creating the 340B program, which is the focus of this Article—the issue of whether, and how many, contract pharmacy arrangements are allowed.

Of the various gaps in the 340B statute, the answer to this question most profoundly impacts the income stream of critical, safety net hospitals because it affects hospitals' very ability to participate in the program. This in turn affects the ability of vulnerable populations to access affordable prescriptions.

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[4] *See* 42 U.S.C. § 256b.

[5] *Id.* § 256b(a)(4)(L)(i) ("A . . . hospital . . . that—(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter"). This Article focuses on eligible hospitals under the 340B program and uses "hospital" and "covered entity" interchangeably.

[6] *See infra* Part V.

[7] Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2020 Update*, BERKELEY RSCH. GRP. (June 30, 2022), https://www.thinkbrg.com/insights/publications/measuring-relative-size-340b-program-2020-update/ [https://perma.cc/XV97-CZ8P].

[8] *See* 42 U.S.C. § 256b.

This Article asserts that Congress must address this question via legislative reform. First, this Article is the first to explore the limits of the judiciary's ability to resolve this question due to the statute's ambiguity. Second, due to the judiciary's limitation, this Article will demonstrate that if Congress does not intervene, the practical result will be that drug manufacturers will continue to impose restrictions on contract pharmacy arrangements. Finally, aside from the limitations of courts in addressing this issue, this Article asserts that reform of the 340B program could effectively be used to accomplish Congress's bipartisan goal of lowering prescription drug costs, particularly among vulnerable populations.

II. Overview of the 340B Program

The 340B program was created in 1992 as part of the Veterans Health Care Act, which was designed to improve healthcare services and access among veterans.[9] The 340B program was intended to assist covered entities that serve vulnerable or low-income populations in accessing affordable prescriptions.[10]

Drug manufacturers must participate in the 340B program for their drugs to be covered by Medicaid.[11] Participating manufacturers cannot charge covered entities more than the applicable ceiling price for eligible drugs if they also make these drugs available to other purchasers at the wholesale acquisition cost, which is the price a manufacturer typically charges a wholesaler.[12] This results in potential drug cost savings for low-income patients when covered entities pass their savings directly on to these patients.[13] And the program provides an additional revenue stream for hospitals who serve these patients, as hospitals continue to be reimbursed for the drugs at the non-discounted rate by insurers.[14]

But the financial benefit to hospitals is not unfettered. First, the 340B statute prohibits duplicate discounts. In other words, if the covered entity has already received a rebate via the Medicaid program, it cannot get a

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[9] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71.

[10] *See Fact Sheet: The 340B Drug Pricing Program*, Am. Hosp. Ass'n (March 2023), https://www.aha.org/fact-sheets/fact-sheet-340b-drug-pricing-program [https://perma.cc/7QXH-5AJH].

[11] *Medicaid Drug Rebate Program (MDRP)*, Medicaid.gov, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html [https://perma.cc/PC2U-3MMW] (last updated Aug. 11, 2022).

[12] *See* 42 U.S.C. § 256b(a)(1). This discount is set by HHS and is calculated according to the average price paid by wholesalers to drug manufactures or off the best available price.

[13] *See infra* Part V.

[14] *See id.*

duplicate discount under the 340B program.[15] Second, the 340B statute prohibits diversion: only "patients" of covered entities can receive discounted drugs.[16]

The 340B program is managed by the Health Resources and Services Administration ("HRSA") within the Department of Health and Human Services ("HHS").[17] The 340B statute does not grant HHS general rulemaking authority.[18] Rather, HHS has enumerated responsibilities—to enter agreements with drug manufacturers wishing to participate in the 340B program,[19] to monitor and prevent overcharges by drug manufacturers,[20] to create a database to monitor and prevent duplicate discounts or rebates by covered entities,[21] to establish the 340B prime vendor program,[22] and to monitor and prevent diversion by covered entities.[23] HHS may impose civil monetary penalties on both covered entities and drug manufacturers if they violate the statute.[24] Finally,

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[15] 42 U.S.C. § 256b(a)(5)(A)(i) ("A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act."). To prevent duplicate discounts, HHS created the Medicaid Exclusion File ("MEF") for covered entities taking the "carve in" approach, in which covered entities must register and keep up-to-date its entity and billing information used to bill manufacturers under the 340B program and Medicaid. *See 340B Medicaid Exclusion File*, Health Res. & Servs. Admin., https://www.hrsa.gov/opa/updates/2015-october [https://perma.cc/A7PF-UKDX] (last reviewed Apr. 2017).

[16] 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). This is the only mention of the term "patient" in the 340B statute, and HHS has restricted its interpretation of who constitutes a patient over time. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156, 55157–58 (Oct. 24, 1996) (currently recognized guidance); *cf.* 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300, 52306–07 (Aug. 28, 2015) ("an individual will be considered a patient . . . if all of the following conditions are met . . . ."). There has been a fight between covered entities and HHS on this definition, as it impacts when covered entities can receive discounted prices when a patient receives care from professionals that have contractual arrangements with the covered entity. *See* Genesis Healthcare, Inc. v. Becerra, 39 F.4th 253, 262–63 (4th Cir. 2022) (finding that there is standing to determine whether HRSA's finding of diversion for a covered entity due to its definition of "patient" violated the APA).

[17] For simplicity, this Article refers to the Department of Health and Human Services as "HHS."

[18] *See* Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 703 (3d Cir. 2023).

[19] *See* 42 U.S.C. § 256b(a)(1).

[20] *See id.* § 256b(d)(1).

[21] *See id.* § 256b(a)(5)(A)(ii).

[22] *Id.* § 256b(a)(8). HHS has contracted with Apexus to serve as the prime vendor tasked with negotiating additional drug discounts on top of 340B discounts with participating manufacturers while maintaining compliance with the 340B statute. *See The PVP Supports the 340B Drug Pricing Program*, 340B Prime Vendor Program, https://www.340bpvp.com/about-340b-and-pvp [https://perma.cc/2ESE-TDRB].

[23] 42 U.S.C. § 256b(d)(2)(A).

[24] *Id.* § 256b(d)(1)(B)(vi).

HHS has been tasked with developing an alternate dispute resolution process to address overcharge claims between manufacturers and covered entities.[25]

The 340B statute also provides some level of monitoring authority to drug manufacturers to ensure that covered entities remain compliant. Both HHS and drug manufacturers, "acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits," may audit a covered entity's records to identify impermissible duplicate discounts or diversions.[26] Before auditing a covered entity, a manufacturer must first attempt to resolve the issue in good faith. It must also submit an "audit work plan" to HRSA and follow the Manufacturer Audit Guidelines.[27]

But like other components of our healthcare system, the 340B program has rapidly grown and evolved with the changing healthcare landscape.[28] As a result, multiple questions not sufficiently addressed by the statute have arisen.[29] One such question, which is the focus of this Article, is whether hospitals participating in the 340B program may use contract pharmacy arrangements (and if so how many) and still be eligible for 340B drug discounts.

III. Dispute Over Contract Pharmacy Arrangements

Not all hospitals have their own in-house pharmacies. Some contract with third-party pharmacies. Contract pharmacies act as the hospitals' "agents" in handling the hospitals' 340B drug orders. Other hospitals may have a combination of in-house and contract pharmacies to widen their geographic reach.[30] The only problem is that the 340B statute does not speak to whether drug

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[25] *See id.* § 256b(d)(3).

[26] *Id.* § 256b(a)(5)(C).

[27] *See* Manufacturer Audit Guidelines and Dispute Resolution Process 0905–ZA–19, 61 Fed. Reg. 65406, 65409–10 (Dec. 12, 1996).

[28] *See, e.g.*, Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. P, tit. I, subtit. C, § 121, 136 Stat. 49, 792–93 (temporarily expanding covered entity eligibility during COVID-19); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII, subtit. B, § 7101, 124 Stat. 119, 821–23 (2010) (expanding which facilities qualify as covered entities).

[29] One such issue is how discounts provided under the 340B statute should impact covered entities' reimbursement rate under Medicare for these drugs. *See, e.g.*, Am. Hosp. Ass'n v. Becerra, 142 S. Ct. 1896, 1903–06 (2022) (holding unanimously that HHS may not vary its Medicare reimbursement rates only for 340B hospitals because HHS failed to conduct a survey of the hospitals' acquisition costs as required by the Medicare Prescription Drug, Improvement, and Modernization Act and remanding to the lower courts to determine the appropriate remedy); *see also* Am. Hosp. Ass'n v. Becerra, No. 18-2084 (RC), 2023 WL 143337, at *2–*6 (D.D.C. Jan. 10, 2023) (addressing remedy for the underpayments to covered entities). Another is who is considered a "patient" under the 340B program, which impacts whether the covered entity is eligible for the drug discount. *See* Genesis Healthcare, Inc. v. Becerra, 39 F.4th 253, 256 (4th Cir. 2022).

[30] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996); *Fact Sheet: 340B Drug Pricing Program Contract Pharmacy Arrangements*, Am. Hosp. Ass'n (Apr. 2023), https://www.aha.org/fact-sheets/2020-10-06-fact-sheet-340b-drug-pricing-program-contract-pharmacy-arrangements [https://perma.cc/GE5G-CBTN].

manufacturers must offer 340B drug discounts to covered entities using contract pharmacy arrangements, or whether they are only required to offer discounted prices to hospitals' in-house pharmacies. In fact, contract pharmacy arrangements are not defined or addressed in the 340B statute at all.

HHS and covered entities claim that the 340B statute requires manufacturers to recognize and offer discount drug prices to an unlimited number of contract pharmacy arrangements. Many hospitals cannot afford in-house pharmacy arrangements, so these entities argue that allowing contract pharmacy arrangements better fulfills the program's purposes of stretching federal resources and helping the under- and un-insured access affordable prescriptions.[31]

Drug manufacturers have pushed back on the proliferation of contract pharmacy arrangements, citing concerns of an increase in diversion and duplicate discounts. To limit the use of these arrangements, manufacturers have unilaterally imposed distribution restrictions on covered entities, including requiring covered entities to provide patients' data on prescriptions ordered under the 340B program and limiting the number of contract pharmacies with which covered entities may contract.[32] Because these restrictions have cost hospitals millions in lost revenue,[33] HHS has gotten involved, and litigation has ensued. This Part will explore HHS's shifting stance on contract pharmacy arrangements since the enactment of 340B statute, the actions the agency has taken against manufacturers imposing restrictions on contract pharmacy arrangements, and lawsuits brought by drug manufacturers against HHS in response.

A. Development of Contract Pharmacy Arrangements

Absent from the original 340B statute or subsequent amendments is any mention of a contract pharmacy arrangement, so it was not clear at the inception of the 340B program whether such arrangements were permissible. But, at the outset of the 340B program, often due to limited resources and cost, less than five percent of hospitals had in-house pharmacy arrangements, particularly critical access and safety net hospitals.[34] In an effort to increase program

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[31] *See* U.S. Dep't of Health & Hum. Servs., Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf [https://perma.cc/UM8N-UH7U]; Notice Regarding Section 602, 61 Fed. Reg. at 43550.

[32] *See* Nat'l Ass'n of Cmty. Health Ctrs., 340B Manufacturer Restriction on Contract Pharmacies Chart 1–14 (2023), https://www.nachc.org/wp-content/uploads/2022/05/NACHC-340B-Manufacturer-Restrictions-Chart.pdf [https://perma.cc/ZUX5-8Z6T] (last updated Oct. 4, 2023).

[33] Rebecca Pifer, *Hospitals, PBMs Say Drugmaker Restrictions on 340B Discounts Stifling Finances*, HealthcareDive (May 5, 2022), healthcaredive.com/news/hospitals-pbms-drugmaker-restrictions-340b-discounts/623277/ [https://perma.cc/XT83-9Y7A].

[34] *See* Notice Regarding Section 602, 61 Fed. Reg. at 43550 ("During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500) . . . .").

participation, HHS first addressed contract pharmacy arrangements in 1996, when it issued non-binding guidance allowing hospitals that did not have their own in-house pharmacies to contract with a single third-party pharmacy to dispense discounted drugs under the program to eligible patients on the hospital's behalf.[35]

After additional projects testing multiple contract pharmacy arrangements,[36] in 2010, HHS issued additional guidance allowing hospitals to use a seemingly unlimited number of contract pharmacy arrangements, even if the hospitals had their own in-house pharmacies as well, causing this distribution arrangement to dramatically increase in popularity among covered entities.[37] As a result, between 2010 and 2020, contract pharmacy arrangements increased by 4,228% from 2,321 to 100,451 contract pharmacy arrangements.[38]

While HHS conducts periodic audits of covered entities to ensure they are not receiving duplicate discounts,[39] it is largely up to covered entities to set up a system to ensure they do not receive duplicate discounts.[40] And, as participation in the 340B program continues to skyrocket—driven by these third-party arrangements that add another level of auditing complexity—manufacturers contend there is not adequate monitoring to police duplicate discounts.[41] Citing concerns related to the vast increase of these arrangements and concerns that these arrangements do not adequately prevent duplicate discounts, over the past few years, drug manufacturers began unilaterally placing restrictions on allowing unlimited contract pharmacy arrangements.[42]

In response to manufacturers' distribution restrictions,[43] HHS released its (since-removed) Advisory Opinion 20-06 ("Advisory Opinion") asserting that the 340B statute requires drug manufacturers to offer 340B drug discounts to an unlimited number of contract pharmacies.[44] HHS pulled this Advisory

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[35] *Id.* at 43549–56.

[36] *See* Aaron Vandervelde, Kevin Erb & Lauren Hurley, Berkeley Rsch. Grp., For-Profit Pharmacy Participation in the 340B Program 3 (2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf [https://perma.cc/3FV4-Z7AW].

[37] *See* Notice Regarding 340B Drug Pricing Program, 75 Fed. Reg. 10272, 10272–73 (Mar. 5, 2010).

[38] Vandervelde et al., *supra* note 36, at 4.

[39] *See* 42 U.S.C. § 256b(a)(5)(C).

[40] *See* Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, USC Schaeffer (Oct. 14, 2023), https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/ [https://perma.cc/GHM5-EKSA].

[41] *See id.*

[42] *See* Dep't of Health & Hum. Servs., Off. of Inspector Gen., Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 2 (2014); Nat'l Ass'n of Cmty. Health Ctrs., *supra* note 32.

[43] *See* Nat'l Ass'n of Cmty. Health Ctrs., *supra* note 32.

[44] *See* U.S. Dep't of Health & Hum. Servs., Advisory Opinion 20-06, *supra* note 31. HHS relies on the "purchased by" provision in its Advisory Opinion, whereas it also asserts in violation letters that the "shall offer" provision unambiguously requires manufacturers to deliver to an

Opinion after litigation ensued, saying it wanted to "avoid[] confusion and unnecessary litigation."[45]

Around the same time, HHS sent multiple violation letters to drug manufacturers claiming the manufacturers' restrictions violated the 340B statute and ordering them to reimburse covered entities for overcharges or face civil monetary penalties.[46] In other words, the violation letters imposed the same interpretation that HHS expressed in its original Advisory Opinion.[47]

B. Litigation Challenging Contract Pharmacy Arrangements

Drug manufacturers challenged these actions in multiple forums.[48] AstraZeneca sued HHS in the District of Delaware.[49] Sanofi-Aventis and Novo Nordisk sued HHS in the District of New Jersey.[50] Eli Lilly sued HHS in the Southern District of Indiana.[51] And Novartis Pharmaceuticals and United Therapeutics sued the agency in the District Court for the District of Columbia.[52]

The Third Circuit is the only appellate court to weigh in thus far. In its review of two contrary district court decisions, the Third Circuit held that HHS's violation letters and Advisory Opinion violated the Administrative Procedure Act ("APA"), favoring the District of Delaware's resolution.[53] The District of Delaware had found that HHS's actions violated the APA because the 340B statute did not "compel any particular outcome with respect to

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unlimited number of contract pharmacy arrangements. For analytical completeness, this Article will wrestle with all arguments presented by HHS despite its voluntary removal of the Advisory Opinion, and it will refer to the violation letters and Advisory Opinion collectively as HHS's challenged actions and interpretation.

[45] Ian Lopez, *HHS Pulls Policy on Drug Discounts for Contract Pharmacies*, Bloomberg L. (June 21, 2021), https://news.bloomberglaw.com/health-law-and-business/hhs-pulls-policy-on-drug-discounts-for-contract-pharmacies [https://perma.cc/ZQT2-NBXN].

[46] *See HRSA Issues Follow-Up Letters to Drug Manufacturers in Violation of 340B Statute,* AAMC (Sept. 24, 2021), https://www.aamc.org/advocacy-policy/washington-highlights/hrsa-issues-follow-letters-drug-manufacturers-violation-340b-statute [https://perma.cc/T88K-KTSU].

[47] *See id.*

[48] When litigation ensued in the District of Delaware, the court found that the Advisory Opinion constituted a final agency action. AstraZeneca Pharms. LP v. Becerra, 543 F. Supp. 3d 47, 57 (D. Del. 2021). While HHS rescinded its Advisory Opinion, the Third Circuit found that the manufacturer's challenge to the Advisory Opinion was not moot because the court could still "enjoin HHS from reverting to the Advisory Opinion's interpretation of Section 340B." Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 703 (3d Cir. 2023).

[49] *AstraZeneca Pharms.*, 543 F. Supp. 3d at 50.

[50] Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs., 570 F. Supp. 3d 129, 146 (D.N.J. 2021).

[51] Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs., No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *1 (S.D. Ind. Oct. 29, 2021).

[52] Novartis Pharms. Corp. v. Espinosa, No. 21-cv-1479, 2021 WL 5161783, at *1 (D.D.C. Nov. 5, 2021); United Therapeutics Corp. v. Espinosa, No. 21-cv-1686, 2021 WL 5161783, at *1 (D.D.C. Nov. 5, 2021).

[53] Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 702–06 (3d Cir. 2023).

covered entities' use of [contract] pharmacies."[54] But the District of New Jersey had found that while the text of the 340B statute was ambiguous, the statutory purpose, legislative history, post-enactment history, and overall statutory scheme supported HHS's interpretation that the 340B statute required contract pharmacy arrangements.[55] Similar cases are on appeal in the Seventh Circuit[56] and D.C. Circuit.[57]

IV. Courts cannot resolve the dispute over contract pharmacy arrangements

Federal courts are, of course, limited in their ability to resolve disputes, deciding only cases and controversies arising under the Constitution or statutes.[58] Because of this limitation, courts may not unilaterally weigh policy issues[59] or provide relief that extends beyond their authority.[60] While courts can certainly interpret statutes using traditional tools of interpretation,[61] this Part will first demonstrate why applying these tools to the 340B statute will not resolve the dispute due to the statute's ambiguity, the competing policy concerns involved, and HHS's lack of authority to resolve this dispute via rulemaking. This Part will also articulate the practical implications resulting from the courts' limited ability to resolve this issue.

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[54] *AstraZeneca Pharms.*, 543 F. Supp. 3d at 59.

[55] *Sanofi-Aventis*, 570 F. Supp. 3d at 192–202. But the court remanded to HHS the question of how many contract pharmacy arrangements are consistent with the 340B statute. *Id.* at 203–04.

[56] *Eli Lilly*, 2021 WL 5039566, *appeal docketed*, No. 21-3128 (7th Cir. Nov. 15, 2021). In the decision below, the Southern District of Indiana held that HHS's actions were arbitrary and capricious because, before issuing violation letters against manufacturers for not recognizing multiple contract pharmacy arrangements, HHS previously stated its 1996 and 2010 positions on contract pharmacies were "non-binding" but did not explain its changed policy. *Eli Lilly*, 2021 WL 5039566, at *25.

[57] *Novartis Pharms.*, 2021 WL 5161783, *appeal docketed*, No. 21-5299 (D.C. Cir. Dec. 30, 2021). The District Court set aside the agency's guidance because the "plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities." *Novartis Pharms.*, 2021 WL 5161783, at *9 (emphasis in original). However, the court declined the drug manufacturers' request to "declare that their policies [restricting contract pharmacy arrangements] are permissible under Section 340B." *Id.*

[58] *See* U.S. Const. art. III, § 2, cl. 1.

[59] *See, e.g.*, Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 382 (2023) ("In a functioning democracy, policy choices like these usually belong to the people and their elected representatives.").

[60] *See* Pool v. City of Houston, 978 F.3d 307, 309 (5th Cir. 2020) (citing Jonathan F. Mitchell, *The Writ-of-Erasure Fallacy*, 104 Va. L. Rev. 933, 936 (2018)).

[61] That said, scholars and judges debate the appropriate theory for statutory interpretation. *See, e.g.*, Tara Leigh Grove, *Which Textualism?*, 134 Harv. L. Rev. 265, 307 (2020) ("Scholars have long engaged with the battle between textualism and purposivism. Although this debate is important, it has overshadowed another important division: that between formalistic and flexible textualism.").

A. Courts are unable to resolve this dispute because the 340B statute does not indicate whether Congress contemplated contract pharmacy arrangements.

A review of the various textual and structural arguments presented across the three jurisdictions reveals that the issue of whether manufacturers must recognize multiple contract pharmacy arrangements is best resolved by Congress.[62] First, courts cannot look to HHS's interpretation as it is not entitled to deference. Second, the text of the 340B statute does not address contract pharmacy arrangements. Third, the statutory scheme of the Veterans Health Care Act of 1992 does not indicate whether Congress intended to recognize multiple contract pharmacy arrangements in the 340B program. Fourth, while the purpose of the 340B statute favors the recognition of a single contract pharmacy arrangement, due to competing policy concerns, it is unclear whether the statute's purpose is also furthered by recognizing multiple contract pharmacy arrangements. Finally, for this same reason, the legislative and post-enactment history does not indicate how Congress would weigh policy concerns like preventing duplicate discounts with the recognition of contract pharmacy arrangements.

1. HHS's interpretation is not entitled to deference.

Aside from ongoing uncertainly regarding *Chevron*'s survival,[63] HHS's interpretation that the 340B statute requires drug manufacturers to recognize multiple contract pharmacy arrangements is not entitled to deference. HHS has limited authority under the 340B statute that does not extend to the 340B distribution arrangements at issue here.[64] Because of this and the 340B statute's ambiguity, the courts that have considered this issue thus far have uniformly

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[62] Whether this issue also invokes the major questions doctrine, a claim that the District of New Jersey quickly dismissed, is beyond the scope of this Article, as its application supports the same conclusion that Congress must resolve this dispute but is not commonly applied. *See* Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs., 570 F. Supp. 3d 129, 200–01 (D.N.J. 2021); *cf.* Nathan Richardson, *Keeping Big Cases from Making Bad Law: The Resurgent "Major Questions" Doctrine*, 49 Conn. L. Rev. 355, 392–93 (2016) (Some arguments in favor of the major questions doctrine "are based on the proposition that legislatures should decide major questions or, at least, that agencies should not.").

[63] *See* Loper Bright Enters., Inc. v. Raimondo, No. 22-451, 143 S. Ct. 2429, 2023 WL 3158352 (2023) (mem.) (granting certiorari to consider whether *Chevron* should be overruled). For a discussion on how the *Chevron* doctrine has been applied (or avoided) by the Supreme Court for HHS's action in setting Medicare reimbursement rates for 340B hospitals in *American Hospital Association v. Becerra*, see Leading Case, American Hospital Ass'n v. Becerra, 136 Harv. L. Rev. 480, 483 (2022).

[64] *See* Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs., 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Within section 340B, Congress specifically authorized rulemaking in three places . . . ."); Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs., 138 F. Supp. 3d 31, 39 (D.D.C. 2015) ("[E]ven though this Court concluded that HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute.").

held that HHS's interpretation is not entitled to *Chevron* deference.[65] And, as the courts uniformly held, nor is *Skidmore* "deference" applicable given the 340B statute does not define or mention contract pharmacies.[66]

2. The 340B statute does not address contract pharmacy arrangements.

In its Advisory Opinion, HHS relied on two provisions of the 340B statute to support its interpretation that the statute requires drug manufacturers to honor multiple contract pharmacy arrangements. First, the "purchased by" provision requires the Secretary of HHS to enter agreements with manufacturers of covered drugs under the statute, capping the prices of these drugs.[67] Second, the "shall offer" provision directs that a drug manufacturer "shall . . . offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[68]

HHS interpreted the "shall offer" provision to require manufacturers to offer the discounts to covered entities using multiple contract pharmacy arrangements, interpreting "shall" as a command and reasoning that covered entities still receive the benefit of the discounted drugs even if they are purchased

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[65] Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 703 (3d Cir. 2023); Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs., No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *16 (S.D. Ind. Oct. 29, 2021); Novartis Pharms. Corp. v. Espinosa, No. 21-cv-1479, 2021 WL 5161783, at *5 (D.D.C. Nov. 5, 2021); *cf.* United States v. Mead Corp., 533 U.S. 218, 236–37 (2001) ("[T]he range of statutory variation has led the Court to recognize more than one variety of judicial deference . . . .").

[66] *Sanofi Aventis*, 58 F.4th at 703; *Eli Lilly*, 2021 WL 5039566, at *20 n.15 ("Having used the tools of statutory interpretation to arrive at what we believe is the appropriate and correct interpretation of the 340B statute, we need not discuss whether the agency's interpretation is entitled to *Skidmore* deference . . . ."); *Novartis Pharms.*, 2021 WL 5161783, at *5–*8; *cf.* Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) ("The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.").

[67] *See* 42 U.S.C. § 256b(a)(1) ("The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price'), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.").

[68] *Id.* This latter provision was added by Congress in 2010 via the Affordable Care Act when Congress expanded the covered entities eligible to participate in the 340B program. Patient Protection and Affordable Care Act, 124 Stat. at 827.

through a third-party contract pharmacy arrangement.[69] And it interpreted the "purchased by" provision to require manufacturers to offer discounts to covered entities using multiple contract pharmacy arrangements because a contract pharmacy merely acts as the covered entity's agent.[70] In other words, HHS reasoned the covered entity is still purchasing the discounted drugs, so the fact that it does so through a third-party arrangement is irrelevant.[71] But the text of the 340B statute is silent as to whether multiple contract pharmacy arrangements are required.

Neither of these statutory provisions discuss details of drug distribution or mention contract pharmacies; the language of the statute only discusses the relationship among covered entities and manufacturers.[72] So the statute simply does not address whether manufacturers must treat contract pharmacy arrangements the same as they do in-house pharmacy arrangements, allowing covered entities to receive discounted drug prices even on drugs ordered through multiple contract pharmacy arrangements.[73]

For example, the "shall offer" provision discusses manufacturers' obligation not to discriminate between offering covered drugs to covered entities under the 340B program if it makes that same drug available to other purchasers.[74] "Offer" means "[t]he act or an instance of presenting something for acceptance."[75] Of course, manufacturers could "offer" discounted drugs to covered entities through contract pharmacy arrangements, as articulated by HHS.[76] But, on the other hand, manufacturers are still arguably offering discounted drugs to covered entities even with their restrictions, as there is at least one distribution method by which covered entities can purchase discounted drugs under the 340B program—in-house pharmacy arrangements.[77]

Nor does the "purchased by" provision offer additional clarity. The "purchased by" provision directs HHS to enter an agreement with manufacturers to cap prices for covered drugs. The distribution arrangement between covered entities and manufacturers is not addressed by this provision.[78] In finding the statute ambiguous, the Third Circuit observed that the "purchased by" provision "imposes only a price term for drug sales to covered entities, leaving all

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[69] *See* U.S. Dep't of Health & Hum. Servs., Advisory Opinion 20-06, *supra* note 31.

[70] *Id.* ("The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant.").

[71] *See id.*

[72] *See* 42 U.S.C. § 256b(a)(1).

[73] *See id.*

[74] *See id.*

[75] *Offer*, Black's Law Dictionary (11th ed. 2019); *see also* Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 703 (3d Cir. 2023) (quoting *Offer*, Black's Law Dictionary (11th ed. 2019)) ("'Offer' means 'to present[ ] something for acceptance.' Even if drug makers limit where they will deliver drugs, they still present the drugs for covered entities' acceptance." (citation omitted)).

[76] *See* U.S. Dep't of Health & Hum. Servs., Advisory Opinion 20-06, *supra* note 31.

[77] *See* Nat'l Ass'n of Cmty. Health Ctrs., *supra* note 32.

[78] *See* 42 U.S.C. § 256b(a)(1).

other terms [such as what drug distribution arrangements manufacturers must recognize] blank."[79] "[W]hen Congress's words run out, covered entities may not pick up the pen."[80] Distribution arrangements not addressed in the statute's text therefore cannot be unambiguously mandated.

However, declining to put words in the mouth of Congress when none are there should go both ways.[81] The Third Circuit asserted that "Congress's use of the singular 'covered entity' in the 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies."[82] But just because the statute does not mention third-party transactions does not mean that Congress intended to *prohibit* such transactions, or to give manufacturers the power to restrict such transactions, especially when the statutory purpose is arguably furthered by recognizing contract pharmacy arrangements.[83] The Third Circuit therefore should have resisted the urge to gap-fill by speculating that Congress contemplated only direct transactions.

The 340B statute does not mention distribution details—whether Congress intended for a covered entity to receive the discounted drugs themselves or whether third-party distribution arrangements are permissible. Because the 340B statute is silent as to drug distribution arrangements, it is ambiguous.[84]

3. It remains ambiguous whether Congress intended to recognize contract pharmacy arrangements in the 340B program when interpreting the 340B statute in relation to the overall statutory scheme.

While something akin to a contract pharmacy arrangement is referenced in a neighboring statute, it is still unclear whether Congress intended for manufacturers to recognize multiple contract pharmacy arrangements in the 340B program given the differences in the two statutes.

"A statutory 'provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . .'"[85] While some structural clues may lean in favor of an interpretation that Congress did not intend to require the recognition of multiple contract pharmacy arrangements, a

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[79] *Sanofi Aventis*, 58 F.4th at 704.

[80] *Id.*

[81] *See, e.g.*, United States v. Shimer, 367 U.S. 374, 381–82 (1961) (considering the limits of a court's scope of review when there are conflicting policy choices).

[82] *Sanofi Aventis*, 58 F.4th at 704.

[83] *See infra* Part IV.A.4.

[84] "When a statute does not include even a single reference to the pertinent word (e.g., 'pharmacy'), it is highly unlikely (if not impossible) that the statute conveys a single, clear, unambiguous directive with respect to that word." AstraZeneca Pharms. LP v. Becerra, 543 F. Supp. 3d 47, 59 (D. Del. 2021); *see also* Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs., 570 F. Supp. 3d 129, 193 (D.N.J. 2021) (quoting *AstraZeneca Pharms.*, 543 F. Supp. 3d at 59).

[85] Util. Air Regul. Grp. v. EPA, 573 U.S. 302, 321 (2014) (quoting United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd., 484 U.S. 365, 371 (1988)).

holistic review of the statutory scheme indicates that the 340B statute remains ambiguous as to legislative intent.

The Third Circuit reasoned that Congress could have written third-party distribution arrangements in the statute, as evidenced by its inclusion of a similar type of distribution arrangement in a separate statute in the Act by which the government could obtain discounted drug pricing, but Congress chose not to do so for the 340B statute.[86] "'[N]egative implications raised by disparate provisions are strongest' in those instances in which the relevant statutory provisions were 'considered simultaneously when the language raising the implication was inserted.'"[87] Here, the 340B statute's "statutory neighbor" in the Veterans Health Care Act of 1992, which "started on the very page of the Act where Section 340B ended,"[88] provides discounted drugs to certain federal agencies.[89] Much like the 340B statute, this neighboring provision directs the HHS Secretary to enter agreements with drug manufacturers to offer the discounted drug prices.[90] But unlike the 340B statute, Congress offered more clarity on the distribution arrangement, noting that agencies could obtain the drugs via "depot contracting systems."[91] Thus, the statutory scheme suggests that perhaps Congress's silence on drug distribution in the 340B statute means it did not intend to allow a third-party distribution arrangement under the 340B statute as it did for its neighbor.

At the same time, there is an important distinction between the 340B statute and its neighbor. "As the word 'generally' indicates, this rule is not absolute. Context counts, and it is sometimes difficult to read much into the absence of a word that is present elsewhere in a statute."[92] Because the neighboring provision concerns discounted drug purchases by federal agencies, presumably it would be more common for these government entities to rely on third-party drug distribution arrangements. The 340B statute, on the other hand, concerns a broader range of both public and privately owned

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[86] *Sanofi Aventis*, 58 F.4th at 704–05; *cf.* Badgerow v. Walters, 596 U.S. 1, 11 (2022) ("[W]hen Congress includes particular language in one section of a statute but omits it in another section of the same Act, we generally take the choice to be deliberate." (internal quotation omitted)).

[87] Gomez-Perez v. Potter, 553 U.S. 474, 486 (2008) (quoting Lindh v. Murphy, 521 U.S. 320, 330 (1997)).

[88] *Sanofi Aventis*, 58 F.4th at 704.

[89] *See* 38 U.S.C. § 8126.

[90] *See id.* § 8126(a).

[91] *Id.* § 8126(a)(2). "The term 'depot' means a centralized commodity management system through which covered drugs proceed by an agency of the Federal Government are . . . received, stored, and delivered through . . . a commercial entity operating under contract with such agency; or . . . delivered directly from the commercial source to the entity using such covered drugs." *Id.* § 8126(h)(3).

[92] Bartenwerfer v. Buckley, 598 U.S. 69, 78 (2023); *see also* King v. Burwell, 576 U.S. 473, 493 n.3 (2015) (quoting Util. Air Regul. Grp. v. EPA, 573 U.S. 302, 320 (2014) ("'[T]he presumption of consistent usage readily yields to context,' and a statutory term may mean different things in different places. That is particularly true when . . . 'the Act is far from a *chef d'oeuvre* of legislative draftsmanship." (internal citation omitted))).

entities—including some governmental entities as well as covered hospitals and clinics.[93] Some of these entities may be more likely to use in-house pharmacies; some may rely on third-party arrangements; and still others may use some combination of the two. And in recognizing these differences and not wanting to limit a covered entity's distribution arrangement options, perhaps Congress intentionally failed to mention the distribution arrangement in the 340B statute.

In other words, there is enough difference in the context of these statutes to raise doubt that Congress omitted language regarding contract pharmacy arrangements in the 340B statute because it intended to prohibit such arrangements.[94] In fact, had Congress wished to prohibit or limit contract pharmacy arrangements under the 340B statute, it could have just as easily written such a limitation in the statute. Therefore, in interpreting the statutory scheme, it remains ambiguous as to whether Congress intended to require manufacturers to recognize contract pharmacy arrangements in the 340B program.

4. While recognizing contract pharmacy arrangements furthers the statutory purpose, it is not clear how Congress would have weighed competing policy concerns.

Even if the purpose of the 340B statute is furthered by recognizing contract pharmacy arrangements, there are competing policy concerns such that it is not clear how many contract pharmacy arrangements Congress intended to permit.[95]

The primary purposes of the 340B statute are to (1) "enable[] covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" and (2) ensure the un- and under-insured can access affordable prescriptions.[96] Contract pharmacy arrangements allow covered entities to avoid the startup and operating costs of in-house pharmacies, instead leveraging existing pharmacy infrastructure within their community to increase financial and geographic

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[93] *See* 42 U.S.C. § 256b.

[94] *See* Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs., 570 F. Supp. 3d 129, 200 (D.N.J. 2021) ("Sections 340B and 8126(h)(3) appear to have sufficiently different contexts and purposes to warrant different meanings, despite their shared enactment history."); *cf.* City of Columbus v. Ours Garage & Wrecker Serv., Inc., 536 U.S. 424, 435–36 (2002) (The "presumption that the presence of a phrase in one provision and its absence in another reveals Congress's design[] grows weaker with each difference in the formulation of the provisions under inspection.").

[95] If the text of a statute remains ambiguous, "the doubt would be resolved by a consideration of the purpose and history of the act . . . ." Prussian v. United States, 282 U.S. 675, 678 (1931); *cf.* Bostock v. Clayton Cnty., 140 S. Ct. 1731, 1749–50 (2020) ("[W]hile legislative history can never defeat unambiguous statutory text, historical sources can be useful for a different purpose . . . .").

[96] *See 340B Drug Pricing Program*, Health Res. & Servs. Admin., https://www.hrsa.gov/opa [https://perma.cc/87AW-RZXU] (last reviewed Oct. 2023).

access, particularly among vulnerable populations.[97] Access not only concerns financial accessibility, but also the geographical accessibility of healthcare services. Contract pharmacy arrangements allow covered entities to offer the discounted drugs across multiple pharmacies that are closer to the rural or low-income populations they serve.[98]

The Third Circuit acknowledged that because "few covered entities had in-house pharmacies" when the 340B statute was passed, "Congress might have expected that a covered entity without its own in-house pharmacy could instead use one contract pharmacy."[99] But the court then shied away from wrestling with the statutory purposes further, other than refuting that Congress allowing a single contract pharmacy arrangement "is a far cry from the government's current position that covered entities may use an unlimited number of contract pharmacies."[100]

It seems unlikely that Congress would seek to address its policy concerns by drafting legislation that would only impact less than five percent of entities covered by the legislation.[101] Perhaps recognizing this, lower courts that have considered the contract pharmacy question have determined that recognizing contract pharmacy arrangements allows the 340B program to reach more vulnerable populations.[102] But even accepting that Congress intended to allow contract pharmacy arrangements in the 340B statute, as such a reading best supports Congress's statutory purpose, the question becomes how many contract pharmacies Congress intended to allow due to the competing congressional concerns in the 340B statute.

While Congress wanted to ensure vulnerable populations had greater access to affordable prescriptions, it was also concerned about preventing covered entities from receiving duplicate discounts.[103] And it was HHS's expansion from recognizing one contract pharmacy arrangement to recognizing unlimited contract pharmacy arrangements that caused manufacturers to

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[97] *See Fact Sheet: 340B Drug Pricing Program Contract Pharmacy Arrangements*, *supra* note 30; *see also infra* Part V.

[98] *See Fact Sheet: 340B Drug Pricing Program Contract Pharmacy Arrangements*, *supra* note 30.

[99] Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 706 (3d Cir. 2023).

[100] *Id.*

[101] *See* Notice Regarding Section 602, 61 Fed. Reg. at 43550.

[102] As the District of New Jersey recognized, "[a]bsent contract pharmacy arrangements, § 340B may be 'a dead letter in' many of its applications 'from the very moment of its enactment,' given the number of covered entities which cannot afford to create or maintain in-house pharmacies." Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs., 570 F. Supp. 3d 129, 197 (D.N.J. 2021) (quoting United States v. Hayes, 555 U.S. 415, 427 (2009)). And the Southern District of Indiana determined that "[t]he fairest and most reasonable interpretation of the 340B statute would not authorize drug manufacturers to impose unilateral restrictions on the distribution of the drugs that 'would frustrate Congress' manifest purpose' in enacting the statute." Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs., No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *19 (S.D. Ind. Oct. 29, 2021) (quoting *Hayes*, 555 U.S. at 426–27).

[103] *See* 42 U.S.C. § 256b(a)(5)(A)(i).

become concerned about the associated increase in risk of duplicate discounts and drug diversion.[104] So even if the statutory purpose is furthered by interpreting the 340B statute to require manufacturers to recognize contract pharmacy arrangements, it is still not clear how Congress would have balanced its competing policy concern of preventing duplicate discounts and whether it would have limited a covered entity's use of contract pharmacy arrangements. "[T]here may be a point at which the number of contract pharmacy arrangements ceases to advance Program goals, such as making drugs as cheap as possible for underinsured communities, undermines Congress' other statutory priorities, such as preventing fraud and abuse, or squares better with the needs and characteristics of certain covered entities over others."[105] As the next Part further explores, only Congress can clarify these competing policy questions.[106]

5. The legislative history also does not indicate how Congress would have weighted competing policy concerns.

To the extent a court even looks to legislative history as an indicator of legislative intent,[107] the same problem that arose when looking to statutory purpose arises here.

One draft of the 340B statute specified a dispensing mechanism, permitting both in-house and contract pharmacy arrangements, but the final statute lacked this specification.[108] The Third Circuit asserts that this omission could be because Congress intended to prohibit any contract pharmacy arrangement. Otherwise, specifying an on-site pharmacy dispensing mechanism would be superfluous.[109] It is hard to read this drafting history as the Third Circuit suggests because, had Congress intended to prohibit contract pharmacy arrangements, it was capable of including language that did so more directly.[110] Indeed, one lower court reached the opposite result when considering legislative history.[111] Regardless of what one gleans from a review of legislative history, however, it again does not provide any insight as to whether Congress

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[104] *See* Mulligan, *supra* note 40.

[105] *Sanofi-Aventis*, 570 F. Supp. 3d at 205.

[106] "Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." Rodriguez v. United States, 480 U.S. 522, 526 (1987) (emphasis in original).

[107] *See* Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2364 (2019) (considering how courts approach legislative history as an interpretive tool).

[108] *See* S. Rep. No. 102-259, at 2 (1992) (". . . and dispensed by, or under a contract entered into for on-site pharmacies services with . . .").

[109] *See* Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 705 (3d Cir. 2023).

[110] Congress "does not, one might say, hide elephants in mouseholes." Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 468 (2001).

[111] *See* Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs., 570 F. Supp. 3d 129, 195 (D.N.J. 2021).

would have placed a limit on contract pharmacy arrangements had it expressly considered them due to the competing policy concerns of preventing duplicate discounts and drug diversion.

Nor does the 340B statute's post-enactment history offer additional clarity. Congress expanded 340B in 2003 and 2010.[112] One might argue that Congress's failure to expressly prohibit contract pharmacy arrangements in these expansions after hospitals had been utilizing this distribution indicates its intent to allow such arrangements.[113] However, "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one."[114] And, regardless, the same thorn returns—whether Congress would have limited the number of contract pharmacy arrangements due to its competing concern of preventing duplicate discounts and drug diversion. Until 2010, HHS only allowed one such arrangement under its guidance,[115] so Congress did not have an opportunity to consider the effects of multiple contract pharmacy arrangements on drug diversion and duplicate discounts at the time it passed amendments to the 340B statute. A single contract pharmacy arrangement is a far cry from the current prolific use of this distribution arrangement among hospitals, and only Congress can weigh and decide these competing policy concerns.

Traditional tools of statutory interpretation thus leave stakeholders with a dissatisfying result for this multi-billion-dollar question. The 340B statute does not support HHS's interpretation that Congress intended to require drug manufacturers to offer discounts to covered entities using contract pharmacy arrangements. But neither does the statute support the manufacturers' interpretation that the statute does not recognize contract pharmacy arrangements. Due to HHS's lack of general rulemaking authority as well as the limited role of the judiciary, this is a gap that only Congress can fill.[116]

B. If Congress does not get involved, this piecemeal litigation will undermine the purpose of the 340B statute.

A second dissatisfying result stems from the courts' limited ability to resolve this issue. Because these lawsuits involved challenges to HHS's actions

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[112] *See generally* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-And-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 26–31 (2019) (surveying major congressional reforms).

[113] *See Sanofi-Aventis*, 570 F. Supp. 3d at 195.

[114] United States v. Price, 361 U.S. 304, 332 (1960).

[115] *See* Notice Regarding Section 602, 61 Fed. Reg. at 43549.

[116] *See supra* Part IV.A. State legislatures could also potentially pass legislation to resolve this ambiguity. *See* Ark. Code Ann. §§ 23-92-601–06 (2023); La. Stat. Ann. §§ 40:2881–86 (2023); H.B. 6669, 2023 Leg., Jan. Sess. (Conn. 2023). However, state legislative action is vulnerable to constitutional challenges by drug manufacturers and, of course, leads to inconsistent approaches across jurisdictions. *See* Pharm. Rsch. & Mfrs. of Am. v. McClain, 645 F. Supp. 3d 890, 897–98 (E.D. Ark. 2022), *appeal docketed*, No. 22-3675 (8th Cir. Dec. 30, 2022).

under the APA which were not supported by the 340B statute,[117] unless HHS determines another statutory provision supports its interpretation that manufacturers must recognize an unlimited number of contract pharmacy arrangements, it cannot prohibit manufacturers from imposing conditions on these arrangements.[118] So even if courts expressly declined to adopt manufacturers' interpretation that the 340B statute prohibits covered entities from using contract pharmacy arrangements,[119] because manufacturers are not prohibited from restricting these arrangements unilaterally, it leads to the same result. Many covered entities will be forced to limit the reach of their 340B program or spend considerable resources to create and operate their own in-house pharmacies.[120] And due to the prolific use of contract pharmacy arrangements, these practical realities will undoubtedly impact vulnerable populations' ability to access prescriptions through the program.[121]

As explored in the next Part, not only do the limits of the courts support the need for Congress to resolve the ambiguity surrounding contract pharmacy arrangements, but the 340B program also provides Congress with an effective means to address both criticisms that the program has faced as well as further legislative efforts to lower prescription drug costs, particularly among vulnerable populations.

V. Congressional Action is Required to Address Broader Healthcare Policy Concerns

The 340B program as a whole highlights broader healthcare policy issues, including critical access hospitals' decreasing ability to generate

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[117] *See supra* Parts III.B–IV.A. For example, because HHS failed to acknowledge that its interpretation that the statute requires the recognition of multiple contract pharmacy arrangements constituted a change in its position from its 1996 guidance, which only allowed hospitals to have one contract pharmacy arrangement, its actions stemming from its interpretation that manufacturers must recognize an unlimited number of contract pharmacy arrangements were arguably arbitrary and capricious. *See* FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009) ("[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position. An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books."). Review under the arbitrary and capricious standard is "not toothless" but has "serious bite": agencies must reasonably consider relevant issues and reasonably explain their decisions. Data Mktg. P'ship, LP v. U.S. Dep't of Lab., 45 F.4th 846, 855–56 (5th Cir. 2022) (internal quotations omitted).

[118] Novartis Pharms. Corp. v. Espinosa, No. 21-cv-1479, 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021) ("The plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities. . . . Nor do they *permit* all conditions.").

[119] *See, e.g.*, *id.*

[120] *See supra* Part II.

[121] *See id.*

profit,[122] as well as the rising costs of prescriptions.[123] So in addition to judicial limitations in resolving the contract pharmacy arrangement dispute, this Part explores Congress's potential policy interests in 340B reform. First, 340B reform would provide an opportunity for Congress to weigh and resolve competing policy concerns within the 340B program. Second, due to its reach, the 340B program offers a viable opportunity for Congress to accomplish its policy efforts to decrease prescription drug costs and improve access to prescription drugs among vulnerable populations.[124]

Congressional action is needed to weigh and resolve competing policy concerns within the 340B program.[125] One such concern is whether the program should recognize an unlimited number of contract pharmacy arrangements to ensure it reaches the most vulnerable populations possible, or whether such arrangements should be limited, or other regulations should be put in place, to prevent competing concerns of duplicate discounts and drug diversion.[126] Should drug manufacturers continue refusing to provide discounted

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[122] *See* Ron Southwick, *Hospitals Losing Billions in 2022, More Than Half Could Have Negative Margins*, CHIEF HEALTHCARE EXEC. (Sept. 16, 2022), https://www.chiefhealthcareexecutive.com/view/hospitals-losing-billions-in-2022-more-than-half-could-have-negative-margins [https://perma.cc/NKW2-CZJB].

[123] *See* Juliette Cubanski, Tricia Neuman, Meredith Freed & Anthony Damico, *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?*, KFF (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/ [https://perma.cc/GN8U-TJXJ] ("In 2020, 1.4 million Medicare Part D enrollees without low-income subsidies had annual out-of-pocket drug spending of $2,000 or more, including 1.3 million enrollees who had spending above the catastrophic coverage threshold (which equaled roughly $2,700 in out-of-pocket costs that year for brand-name drugs alone).").

[124] Proposing specific legislative initiatives is beyond the scope of this Article. For specific legislative approaches for reducing prescription drug prices more broadly, see Fisher, *supra* note 112, at 66 (calling on Congress to increase HHS's rulemaking authority under the 340B statute); Ryan Knox, Note, *More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States*, 18 YALE J. HEALTH POL'Y, L. & ETHICS 191, 226–34 (2019) (arguing against indication-specific pricing in favor of other value-based pricing to control prescription drug spending and increase prescription drug access for low-income patients); Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303, 356–76 (2020) (arguing for increased drug price transparency and decreased market concentration of major drug manufacturers to control prescription drug spending).

[125] *See supra* Part IV.

[126] *See, e.g.*, Richard P. Church & Victoria K. Hamscho, *Contract Pharmacy Restrictions, Legal Challenges, and Congressional Action: What to Expect from the 340B Drug Pricing Program*, 23 J. HEALTH CARE COMPLIANCE, Jan.–Feb. 2021, at 45, 77 ("Accordingly, most likely, it will be necessary for Congress to intervene if contract pharmacy arrangements are to be sustained. Drug manufacturers' contract pharmacy actions have attracted the attention of a number of policymakers in both the House and Senate, which have written to HHS and the pharmaceutical industry on this matter. It is possible, however, that Congress and President Joe Biden's administration may be hesitant to take action due to the pending litigation in federal court. Even if Congress works on a legislative fix to these actions, it would likely include overarching program authority for HRSA to better regulate all 340B Program stakeholders as well as program transparency requirements for participating providers. As such, any legislative fix should be closely watched by covered entities and will likely come with new compliance requirements for covered entities as well as manufacturers in the years ahead.").

prices for contract pharmacy arrangements, "urban hospitals estimate their median loss from the restrictions at $2.2 million a year . . . A tenth of them expect their losses to exceed $21 million a year."[127] And given that more than eighty percent of rural hospitals that serve vulnerable populations use contract pharmacy arrangements, this issue affects the survival of safety net and critical access hospitals as well as vulnerable populations' ability to access health care services and affordable prescription drugs.[128] As policymakers, Congress is better suited at addressing this issue, as it is not limited to interpreting a statute that did not have contract pharmacy arrangements in mind. Rather, Congress has the option of addressing all policy concerns in its reform efforts, such as by permitting unlimited contract pharmacy arrangements but putting additional safeguards in place to prevent duplicate discounts and diversion.

But a broader policy concern surrounds whether the existing 340B program is doing enough to ensure vulnerable populations have access to affordable prescriptions and services, specifically regarding how hospitals use savings or profits generated through the program. Proponents of the 340B program claim that the program is essential for the survival of critical access and safety net hospitals that serve vulnerable populations.[129] So while these hospitals could pass drug discounts directly on patients, even for those that do not, they may use the cost savings or profits generated from the discounted drugs (as hospitals may pay discounted prices for the drugs but get reimbursed the full amount by insurers) to provide needed, but margin-draining healthcare services to vulnerable communities.[130] According to a GAO report on the 340B statute's effectiveness:

> [A]ll covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Entities generating 340B program revenue that exceeded drug-related costs were also able to serve more patients and to provide additional services.[131]

Others criticize the lack of transparency and the lack of regulation surrounding how covered entities must use the cost savings and profits generated from the 340B program.[132] And, due to a lack of reporting requirements, it

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[127] Pifer, *supra* note 33.

[128] *See Fact Sheet: 340B Drug Pricing Program Contract Pharmacy Arrangements*, *supra* note 30.

[129] *See id.*

[130] *See id.*

[131] U.S. Gov't Accountability Off., GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (2011), https://www.gao.gov/products/gao-11-836 [https://perma.cc/X479-NUN5].

[132] *See* Feldman, *supra* note 124, at 352 ("[340B] hospitals receive [drug] rebates even for those patients who have private insurance. Private plans generally reimburse for those drugs at rates even higher than Medicare, further increasing the spread. In theory, the amounts are intended to help those hospitals in their work for low-income or vulnerable patients, but the law does not require any showing that the funds are actually used in that manner. Some government

is difficult for researchers to determine the direct impact of the program on vulnerable populations.[133] Thus, in addition to clarifying gaps that exist in the 340B statute which have a direct impact on the costs that patients incur for healthcare services and drugs, 340B reform would provide an opportunity for Congress to weigh and resolve these competing policy concerns and to require greater transparency.

The reach of the 340B program also demonstrates the potential impact of 340B reform in congressional efforts to reduce drug prices for Americans.[134] First, the 340B program is the second-largest drug pricing program measured by total drug reimbursement[135] and almost one-third of hospitals in the United States participate in the 340B program despite all its uncertainties.[136] Second, because the 340B program provides indirect benefits to patients, in that the covered entity receives the discount,[137] reform efforts to the 340B program could impact vulnerable populations' ability to access discounted prescription drugs regardless of whether they have private insurance, insurance from a government program, or no insurance at all.

In other words, Congress must decide whether the program should be reformed to pass drug savings more directly on to patients, or whether allowing hospitals to decide how to use their revenue cushion accomplishes the program's purpose in other, more indirect ways. But no matter whether Congress opts for regulations that more directly pass the savings of the program on to patients, or for greater transparency and restrictions on how hospitals decide to use those savings for other services that benefit vulnerable populations, the 340B reform effort offers an effective opportunity for Congress to accomplish its policy efforts to decrease prescription drug costs and improve access to prescription drugs among vulnerable populations.

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sources and commenters have questioned whether the spread simply increases hospitals' bottom lines and market shares. . . . Whenever spread exists, the economics create incentives for rising prices and agreements that entrench large drug companies and disfavor lower-cost or newer entrants.").

[133] *See, e.g.*, Fisher, *supra* note 112, at 72; John Michael O'Brien, *After 30 Years of 340B, It's Time for Data and an Honest Conversation*, STAT (Oct. 26, 2022), https://www.statnews.com/2022/10/26/after-30-years-of-340b-time-for-data-honest-conversation/ [https://perma.cc/XH62-PW7X] ("The law neither prevents health systems from making a profit when a patient or their insurance company pays the full cost of penny-priced drugs, nor does it put any strings on what they actually do with the extra money. . . . The challenge to [researching the effectiveness of the 340B program] is the 340B program lacks even the simplest of transparency requirements. The federally funded health clinics, nonprofit hospitals, contract pharmacies, and third-party administrators that are part of the 340B pipeline don't disclose how many patients receive 340B drugs and whether or not they received the 340B discount, leaving researchers to come up with inventive methods to peer into this box of mysteries.").

[134] *See, e.g.*, Inflation Reduction Act of 2022.

[135] *See* Blalock, *supra* note 7, at 7.

[136] U.S. Gov't Accountability Off., *supra* note 131, at 20.

[137] *See* 42 U.S.C. § 256b(a)(1).

VI. Conclusion

Due to ambiguity in the 340B statute, courts are ill-suited to resolve the question of whether manufacturers must offer discounted drug prices to hospitals who use contract pharmacy arrangements, the answer to which profoundly impacts the revenue of critical access hospitals that serve vulnerable populations. And piecemeal litigation and existing healthcare programs that fail to meaningfully address broader policy concerns only add to the inefficiencies in our healthcare system. The time has come for Congress to face this monster head on. Reform of 340B provides an opportunity for much needed statutory gap-filling. And as the second-largest drug pricing program, and the largest affecting patients with various forms of health insurance or no insurance at all, 340B reform also provides an opportunity for Congress to meaningfully address its broader healthcare policy concerns, including improving access to affordable prescription medications for vulnerable populations.