UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

ANNABELLE GURWITCH, individually and on behalf of all others similarly situated,

Plaintiff,

Case No. 1:25-cv-00006-LJV

vs.

AMENDED CLASS ACTION COMPLAINT Jury Trial Demanded

SAVE ON SP LLC, EXPRESS SCRIPTS, INC., and ACCREDO HEALTH GROUP INC.,

Defendant.

TABLE OF CONTENTS

I.	Nature of Action	. 1
II.	Parties	. 7
III.	Jurisdiction and Venue	. 9
IV.	Class Action Allegations	. 9
V.	Factual Allegations	14
A	. The ACA provides important protections to American healthcare consumers.	15
	1. The ACA imposes an annual limit on patients' cost-sharing obligations.	15
	2. Any sums paid by or on behalf of patients towards covered health care, including prescriptions, counts towards patients' annual limits.	17
В	Specialty drugs place extraordinary cost burdens on the patients who need them	18
	1. Specialty medications can cost patients thousands of dollars a month.	18
	2. PBMs shift a larger share of specialty drug costs away from insurers and onto patients.	19
C	2. Patients who need expensive specialty medications depend on patient copay assistance to help manage their healthcare costs	21
D	2. SaveOnSP and its co-conspirators Express Scripts and Accredo divert patient copay assistance away from the patients that need it and to those patients' insurers.	22
	1. SaveOnSP claims to have found a loophole in the ACA that allows them to evade the ACA's patient-protective requirements.	23
	2. SaveOnSP and Express Scripts created the SaveOn Program to shift insurers' payment obligations onto patient copay assistance programs and patients themselves	24
	3. SaveOnSP and Accredo coerce targeted patients to sign up for SaveOnSP with the threat of financial ruination if they do not	27

i.	SaveOnSP, Express Scripts, and Accredo coerce patients into
	enrolling in the SaveOn Program and require them to enroll
	in patient copay assistance programs28
::	SaveOnSD Evanges Sovints, and Accords vetalists financially
11.	SaveOnSP, Express Scripts, and Accredo retaliate financially
	against targeted patients that refuse to sign up for the SaveOn
	Program
•••	
111.	The SaveOn Program's \$0 medication cost to patients is not
	a benefit: it is a sham
4 (SOCD F
	SaveOnSP, Express Scripts, and Accredo collect funds from
_	patient copay assistance programs even when targeted patients
•	re ineligible for that funding 35
i.	SaveOnSP, Express Scripts, and Accredo misrepresent
	targeted patients' copay obligations to patient copay
	assistance programs to extract excess funds
ii.	Most targeted patients are ineligible for patient copay
	assistance funds because they have been subjected to the
	SaveOn Program—but SaveOnSP, Express Scripts, and
	Accredo collect those funds anyway
iii.	Some patient copay assistance funds require participating
	patients to pay a small portion of a medication's cost—but
	SaveOnSP, Express Scripts, and Accredo evade these
	requirements38
iv.	SaveOnSP and Express Scripts offer to, and do, operate the
	SaveOn Program in circumstances in which they admit the
	Program is illegal
E. Sa	veOnSP, Express Scripts, and Accredo's scheme is very
lu	crative for them and for their insurer clients, but harms
ta	rgeted patients41
	The SaveOn Program foists additional healthcare costs on
]	oatients42
2.	Targeted patients cannot escape the financial harm caused by
1	he SaveOn Program46
3.	SaveOnSP, Express Scripts, and Accredo's scheme creates a
J	oenefit design that discriminates against certain patients47
	SaveOnSP, Express Scripts, and Accredo disproportionately
J	narm minorities and other marginalized groups48

5. SaveOnSP, Express Scripts, and Accredo have fraudulent concealed the harm to patients from the SaveOn Program	
VI. Impact on Interstate Commerce	51
VII. Causes of Action	51
VIII. DEMAND FOR JUDGMENT	60
IX. JURY DEMAND	60

Plaintiff Annabelle Gurwitch brings this action on behalf of itself individually and on behalf of a plaintiff class (the "Class"), pursuant to Rule 23 of the Federal Rules of Civil Procedure, consisting of all individuals or entities who were harmed by the conduct alleged herein (the "Class Period"). Plaintiff brings this action for injunctive relief under the Employee Retirement Income Security Act (ERISA) and treble damages under the Racketeer Influenced Corrupt Organizations Act against Save On SP LLC ("SaveOnSP"), Express Scripts, Inc. ("Express Scripts"), and Accredo Health Group Inc. ("Accredo") and demand a trial by jury.

I. Nature of Action

- 1. SaveOnSP offers what it calls a "non-essential health benefits" program, but in reality is a fraudulent enterprise that deprives patients of the benefits of patient copay assistance funding and increases patients' healthcare costs. It has teamed up with pharmacy benefit manager ("PBM") Express Scripts and Express Scripts' affiliated specialty pharmacy Accredo to purloin hundreds of millions, if not billions, of dollars in funding meant to help *patients* and diverted that money to instead benefit *plans* and enrich themselves. And in the process, the trio knowingly and intentionally ensures patients bear additional healthcare costs.
- 2. The scheme has five main elements. *First*, SaveOnSP, Express Scripts, and Accredo flout statutory constraints on copay costs for specialty medications. *Second*, SaveOnSP created a program, the SaveOn Program, that inflates patients' copays for those targeted medications to siphon all available funding out of patient copay assistance programs. *Third*, Defendants use the threat of prohibitively expensive copays to coerce patients into signing up for the SaveOn Program. *Fourth*, they divert the assistance meant for patients to benefit health plan sponsors instead, while keeping 25% of the purloined funds for themselves. And *fifth*, they force patients to shoulder additional healthcare expenses.

- 3. The patients that SaveOnSP, Express Scripts, and Accredo target are some of our country's most vulnerable. These targeted patients are managing serious health conditions like cancer; multiple sclerosis; and autoimmune disorders like Crohn's Disease, ulcerative colitis, and psoriatic arthritis. Their conditions are complex, and expensive to treat: the specialty medications needed to attack cancer, slow the progression of multiple sclerosis, or stave off the harms of autoimmune diseases carry a sticker price of tens, if not hundreds, of thousands of dollars per year. Insurers (including both insurance companies and employers that sponsor health plans for their employees) and their affiliated PBMs (like Express Scripts) negotiate steep discounts, called rebates, off of that price. But they do not share those savings with patients. That leaves the average patient on the hook for copays¹ that represent more than a quarter of the medications' list price—a sum that can reach several thousand dollars every month.
- 4. None but the wealthiest of patients could hope to shoulder these crushing healthcare costs. Even at a comparatively low cost of \$250, 70 percent of patients are forced to make the difficult decision to skip filling their life-sustaining, or even life-saving, medications. Patients who cannot afford to fill their prescriptions face worse health outcomes: unaffordable prescriptions can lead to a severe deterioration of their condition, relapses, permanent disability, or even death.
- 5. To help patients afford their essential specialty medications, many drug manufacturers offer (in addition to the rebates that benefit health plan sponsors and PBMs), assistance meant especially for patients, called patient copay assistance programs. These programs cover part or all the portion of a medication's price that insurers are not contractually bound to

2

¹ Except where otherwise noted, the term "copay" in this complaint is generally meant to encompass both a fixed amount paid by or on behalf of the patient at the point of sale as well as co-insurance, which is a percentage of the cost of the product paid by or on behalf of the patient at the point of sale.

cover. For patients with complex diseases treated by specialty medications, this relief is a lifeline—sometimes literally. With the help of patient copay assistance programs, patients can afford to protect their health while minimizing the risk of financial ruination from their healthcare expenses.

- 6. But health plan administrators and PBMs want deeper discounts for themselves, rather than their patients. So SaveOnSP, founded in 2015, devised a twisted legalistic—but not legal—argument to nullify the salutary effects of patient copay assistance on patients' health and financial wellbeing by inventing a non-existent loophole in the federal healthcare laws.
- 7. The Patient Protection and Affordable Care Act ("ACA") imposes several patient-protective limits on health plan sponsors' ability to avoid paying for healthcare. First, it imposes cost-sharing limitations: an upper limit on the total expense health plan sponsors and their affiliated PBMs can force patients to incur for their healthcare each year. Plans may impose healthcare costs on patients through several mechanisms. One is the deductible a patient must satisfy before the health plan sponsor is responsible for a single penny of healthcare coverage. Another is copay or coinsurance, or the portion of each medical intervention (from prescriptions to lab tests, doctor's office visits to hospital admissions) that patients are responsible for. As it is, the average deductible is nearly \$2,000 for employer-sponsored health plans and \$3,825 for insurance plans sold on the exchange, and while copays can vary based on the type of care, the average copay for specialty medications is 26% of the medicine's list price. Without guardrails, these costs could dwarf the benefit of health insurance. The ACA provides these guardrails: it caps the sum of these expenses by imposing an annual cost-sharing limit.
- 8. Second, the ACA prohibits insurers from evading this limit by ignoring payments made towards patients' annual cost-sharing limits. The statute defines cost-sharing to include all

deductibles, coinsurance, copays, or similar charges (among other expenses²) for covered services. This includes not only payments by a patient out of their own pocket, but also to payments made on behalf of the patient.

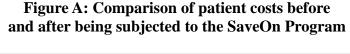
- 9. Yet SaveOnSP claims to be able to evade these patient-protective rules on insurers' behalf, and it designed a program—the SaveOn Program—claiming to do just that. It recruited Express Scripts to help market its scheme, and together, SaveOnSP and Express Scripts have deployed Accredo to help operationalize it.
- 10. The SaveOn Program declares some specialty medications "non-essential health benefits." The determination of which drugs the program targets as non-essential has nothing at all to do with how essential the drugs are. Some of the drugs are so essential that patients can die without them. Rather, SaveOnSP decides what medications are "non-essential health benefits" based on the amount of patient copay assistance available for those medications. That is because SaveOnSP, Express Scripts, and Accredo claim that copays and deductibles for non-essential health benefits do not count as cost-sharing, so those copays can be as high as they want—higher even than a patients' annual cost-sharing limits.
- 11. Under the SaveOn Program, SaveOnSP sets the copay for the targeted medications to a dollar value that ensures that each year, the Program extracts the full amount of patient copay assistance from a manufacturers' patient copay assistance program—an amount that almost always exceeds a patients' maximum cost-sharing obligation. But not one penny of that assistance benefits patients. Rather, Defendants give that assistance intended for patients instead to the health plan

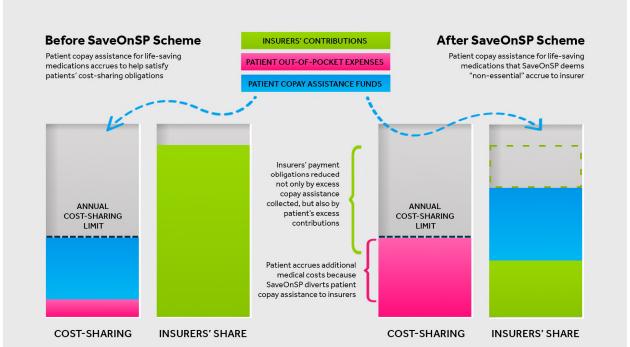
4

² To prevent insurers from evading the law by playing semantics, the law adds a catch-all to the definition of cost-sharing in a separately-numbered sub-paragraph, including in the definition any other expenditure required of an insured individual which is a qualified medical expense with respect to essential health benefits covered under the plan. 42 U.S.C. § 18022(c)(3)(ii).

sponsor, diminishing the sponsor's obligations to pay for patients' prescription drug needs. And they do so in violation of the terms of patient copay assistance programs—and sometimes, they admit, in violation of the law.

- 12. Express Scripts aggressively markets the SaveOn Program to health plan sponsors. Once a sponsor has agreed to join the program, SaveOnSP identifies targeted patients from the plan's membership rolls. SaveOnSP and Accredo then coerce targeted patients into enrolling in the Program: SaveOnSP threatens targeted patients that they will be responsible for paying the inflated copays out of pocket unless they enroll; and to make sure those patients get the message, Accredo falsely tells unenrolled targeted patients that their prescription claim has been rejected and withholds the patients' prescriptions until they enroll.
- 13. To induce targeted patients to enroll, the SaveOn Program promises patients that they will pay zero dollars for their specialty medications if they participate in the SaveOn Program. SaveOnSP, Express Scripts, and Accredo call this a "win" for patients. But in reality, it is not.
- None of the thousands of dollars in patient copay assistance collected ostensibly on behalf of targeted patients counts towards those patients' deductibles or annual cost-sharing limitations, so targeted patients are required to pay for other medical care instead. This might be laboratory testing or diagnostic imaging, doctors' visits, or other medical interventions. And because SaveOnSP, Express Scripts, and Accredo deprive them of the expense-mitigating benefits of patient copay assistance, targeted patients must shoulder all that expense themselves. Because of the SaveOn Program, targeted patients must pay thousands of dollars more per year than they would otherwise be required to pay if Defendants did not flout the ACA's rules.





- 15. Targeted patients are not just bystanders harmed by SaveOnSP, Express Scripts, and Accredo's conduct, they are also intended—thus, targeted—victims of the scheme. Express Scripts, when it markets the plan to health plan sponsors, admits as much: it boasts that its program not only diverts patient copay assistance to benefit the plan, but also forces patients to pay out of pocket for expenses that otherwise would have been obviated by the bogarted patient copay assistance.
- 16. The Court should enjoin Defendants from continuing to operate the SaveOn Program. SaveOnSP and Express Scripts' conduct violates provisions of the ACA incorporated by the Employee Retirement Income Security Act of 1974 (ERISA), which governs private employer-sponsored health plans. ERISA and the ACA prohibit plan administrators, like SaveOnSP and Express Scripts, from charging copay amounts beyond patients' cost-sharing limitation. But the

6

SaveOn Program does just that by imposing high copays and failing to count those copays toward patient's cost-sharing limit—even where the patient pays those copays out of pocket.

- 17. SaveOnSP, Express Scripts, and Accredo should also be required to make restitution for their intentional financial harm to targeted patients. The trio conducts the SaveOn Program as an illicit racketeering enterprise (the "SaveOnSP Copay Assistance Fraud Enterprise") in violation of RICO. Most, if not all, patient copay assistance programs' terms of service expressly require that the patient copay assistance be used solely to benefit the patient; many prohibit patients from collecting patient copay assistance if they are subject to a program like the SaveOn Program (some even mention SaveOnSP expressly in that prohibition); and for some types of health plans, it is illegal to collect patient copay assistance for patients before they have met their deductible. Yet SaveOnSP, Express Scripts, and Accredo mislead these programs into disbursing patient copay assistance for targeted patients that are ineligible under the patient copay assistance programs' terms or the law anyway. And they do so through a pervasive pattern of mail and wire fraud. In so doing, the Program causes financial harm to targeted patients.
- 18. Defendants' scheme violates ERISA; and their conduct violates RICO. They are causing real, and continuing, harm to targeted patients like Ms. Gurwitch and the Class. They should be enjoined from continuing to operate the SaveOn Program, and required to repay the patients they have harmed.

II. Parties

19. Plaintiff Annabelle Gurwitch is a citizen and resident of California. In 2020, Ms. Gurwitch was diagnosed with stage 4 lung cancer for which she was prescribed Tagrisso (osimertinib), a biologic and specialty medication. Tagrisso is an expensive medication. To help cancer patients afford their medication, Tagrisso's manufacturer, AstraZeneca, offers the AstraZeneca 360TM Program, which provides copay assistance to commercially insured patients

that have been prescribed Tagrisso. Ms. Gurwitch received patient copay assistance from the AstraZeneca 360TM since at least September 2020. Beginning in January 2022, Ms. Gurwitch participated in a Blue Cross Blue Shield health insurance plan sponsored by the Writers Guild of America. Ms. Gurwitch's plan participated in the SaveOn Program. As a result, beginning in January 2022, Ms. Gurwitch has been deprived of the benefit of the patient copay assistance that AstraZeneca 360TM offers and forced to incur excess healthcare expenses.

- 20. Defendant Save On SP LLC, a company organized under the laws of New York and headquartered at 40 la Riviere Drive, Buffalo, NY 14202, does business as SaveOnSP. SaveOnSP was founded in 2015. SaveOnSP advertises and administers a copay maximizer program called the SaveOn Program in partnership with pharmacy benefit manager Express Scripts, Inc. and Express Scripts' affiliated specialty pharmacy, Accredo.
- 21. Defendant Express Scripts, Inc. ("Express Scripts"), is a Delaware corporation with its principal place of business located at One Express Way, Saint Louis, Missouri 63121. It is a wholly-owned subsidiary of Express Scripts Holding Company, also a Delaware corporation with its principal place of business at the same address. Express Scripts controls the prescription drug benefits for approximately 100 million Americans.
- 22. Accredo Health Group Inc. is a Delaware corporation with its principal place of business located at 1640 Century Center Parkway, Suite 101, Memphis, Tennessee 38134. It operates Accredo Specialty Pharmacy ("Accredo"), which dispenses medications for patients with serious complex and chronic health conditions like cancer, hepatitis C, HIV, bleeding disorders, and multiple sclerosis.
- 23. Express Scripts and Accredo are both subsidiaries of Evernorth Health, Inc., a Delaware Corporation, which is, itself, a subsidiary of The Cigna Group, a Delaware Corporation

with its principal place of business located at 900 Cottage Grove Road, Bloomfield, Connecticut 06002.

III. Jurisdiction and Venue

- 24. This action arises under RICO, 18 U.S.C. § 1964(c), and ERISA, 29 U.S.C. § 1132(a)(3). Under RICO, Ms. Gurwitch seeks damages for her harms and for those suffered by members of the Class resulting from SaveOnSP's unlawful conduct. Under ERISA, she seeks injunctive relief for herself and for the class preventing SaveOnSP from continuing to harm patients. This Court thus has federal question subject matter jurisdiction under 28 U.S.C. § 1331 and 29 U.S.C. § 1132(e)(1).
- 25. SaveOnSP is headquartered in this district; is licensed to do business and does business in this District; and transacts its affairs and carries out interstate trade and commerce, in substantial part, in this District. Express Scripts and Accredo also does business within this district and conducts interstate trade and commerce, in substantial part, in this district. Venue is thus appropriate within this district under 18 U.S.C. § 1935 (RICO) and 29 U.S.C. § 1132(e)(2) (ERISA) as well as 28 U.S.C. § 1391(b) and (c) (general venue provisions).
- 26. The Defendants' activities, as described herein, were within the flow of, were intended to, and did have direct, substantial, and reasonably foreseeable effects on the interstate commerce of the United States.
- 27. No other forum would be more convenient for the parties and witnesses to litigate this case.

IV. Class Action Allegations

28. Ms. Gurwitch brings this action, under Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), as a representative of a class ("the Class") defined as:

All persons enrolled in a commercial healthcare plan that offers the SaveOn Program as a benefit who have been prescribed a drug selected for inclusion in the SaveOn Program and thereafter incurred a financial obligation for any health care expense in excess of what would have been paid in the absence of the SaveOn Program from November 13, 2017, to present, and continuing until the effects of Defendants' wrongful conduct ceases.

The Class includes all targeted patients who were coerced into signing up for the SaveOn Program, as well as all targeted patients who refused to sign up for the SaveOn Program, yet still bore additional cost-sharing obligations because their cost-sharing payments for their targeted medications did not count towards their annual limits. Excluded from this class are Defendants' officers, directors, management, employees, and agents, as well as the persons responsible for benefits administration at any health plan that joined the SaveOn Program.

29. Within this Class, and with respect specifically to the first cause of action below, there is a subclass (the "ERISA Subclass"), defined as:

All members of the Class enrolled in a non-grandfathered employersponsored healthcare plan subject to ERISA.

30. Members of the Class are so numerous that joinder is impracticable. There are many ways to categorize commercial health insurance: as explained in more detail below, one is by who bears the risk of the insurance. For some plans, called "self-funded plans," an employer, union, or other entity funds the insurance, and pays claims, directly from its own accounts. For other plans, called "fully insured plans," an employer, union, or other entity pays an insurance company to bear the risk for them. Express Scripts administers the prescription benefits for 1 in 3 Americans, or approximately 100 million people. Of those, 47% (or approximately 47 million individuals) receive their health insurance benefits through a fully insured plan (i.e., a Qualified Health Plan or a fully insured large group plan) and the other 53% (approximately 53 million) are members of a self-funded health plan.

- 31. For fully funded health plans, Express Scripts' parent company, The Cigna Group, carries the insurance risk; it is therefore reasonable to expect that Cigna exploits the SaveOn Program on all its fully insured plans to minimize its own costs. There is no publicly available information regarding how many self-funded plans have joined the SaveOn Program. However, assuming (conservatively) that self-funded plans accounting for only 10% of Express Scripts' self-funded covered lives participate, that would mean another 5.3 million patients receive their health benefits through a self-funded plan enrolled in SaveOnSP.
- 32. In total then, an estimated 52.3 million patients receive their benefits through health plans participating in the SaveOn Program. From SaveOnSP and Express Scripts marketing materials, it appears that approximately 1.4% of those 52.3 million patients are targeted patients. That would mean that the number of Class members exceeds 732,000.
- 33. The identity of Class members is readily ascertainable from information and records in Defendants' possession. Express Scripts administers the pharmacy benefit for all Class members, meaning that it has detailed records of the medications prescribed to its members; which patients were prescribed targeted medications; and the amount paid for those medications by patients, patient copay assistance programs, and Express Scripts (which Express Scripts then charges to the plan). Furthermore, SaveOnSP maintains detailed records of patients that it and its co-conspirators successfully coerced into signing up for the SaveOn Program, and Accredo maintains records of the patients for whom it collects patient copay assistance from manufacturer patient copay assistance programs. SaveOnSP and Express Scripts rely on this data to prepare detailed monthly invoicing reports for participating health plans from which they calculate their fees for administering the service.

- 34. Ms. Gurwitch's claims are typical of the claims of Class members. She and all Class members were damaged by the same wrongful conduct of Defendants—i.e., they will show that defendants imposed cost-sharing in violation of the ACA and ERISA, and the same unlawful SaveOnSP Copay Assistance Fraud Enterprise caused them to pay more out of pocket for their healthcare than they would have in the absence of SaveOnSP, Express Scripts, and Accredo's unlawful conduct.
- 35. Ms. Gurwitch's counsel has extensive experience in the prosecution of class action litigation, including ERISA and RICO class action litigations, with particular experience in class action litigation involving the healthcare industry. Counsel possesses the resources and expertise needed to vigorously litigate the case for the Class.
- 36. Ms. Gurwitch will fairly and adequately protect and represent the interests of Class members. Her interests and those of counsel fully align with, and are not antagonistic to, the interests of Class members. Ms. Gurwitch can and will carry out the duties incumbent on Class representatives to protect the interests of all Class members.
- 37. With respect to Ms. Gurwitch's damages claims on behalf of the Class, questions of law and fact common to the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.
 - 38. Questions of law and fact common to the Class include:
 - a. Whether covered prescription drugs constitute essential health benefits under the ACA;

- b. Whether payments made by patient copay assistance programs constitute costsharing payments within the meaning of the ACA;
- c. Whether all copays must count toward the annual cost-sharing limit;
- d. Whether the SaveOn Program violates the ACA;
- e. Whether Defendants agreed, explicitly or implicitly, to form the SaveOnSP Copay Assistance Fraud Enterprise;
- f. Whether the SaveOnSP Copay Assistance Fraud Enterprise constitutes an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4);
- g. Whether SaveOnSP conducted, or participated in the conduct of the SaveOnSP
 Copay Assistance Fraud Enterprise;
- h. Whether Express Scripts conducted, or participated in the conduct of the SaveOnSP
 Copay Assistance Fraud Enterprise;
- i. Whether Accredo conducted, or participated in the conduct of the SaveOnSP Copay
 Assistance Fraud Enterprise;
- j. Whether Defendants committed mail fraud in furtherance of the SaveOnSP Copay Assistance Fraud Enterprise;
- k. Whether Defendants committed wire fraud in furtherance of the SaveOnSP Copay Assistance Fraud Enterprise;
- Whether Defendants engaged in a pattern of racketeering activity in operating the SaveOnSP Copay Assistance Fraud Enterprise;
- m. Whether Defendants misrepresented to targeted patients the financial impact of the SaveOn Program on patients' cost-sharing expenses for healthcare;

- n. Whether Defendants caused misrepresentations to be made to patient copay assistance programs regarding targeted patients' eligibility to receive patient copay assistance funds;
- o. Whether Defendants proximately caused financial harm to targeted patients;
- p. Whether targeted patients were among the intended or foreseeable victims of Defendants' scheme to defraud; and
- q. The quantum of damages in the aggregate.
- 39. Class action treatment is the superior method for the fair and efficient adjudication of the controversy. Such treatment will permit many similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class action mechanism, including providing injured persons a method of obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in managing this class action.
- 40. The plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. Factual Allegations

41. The SaveOn Program—conceived of by SaveOnSP, marketed by Express Scripts, and operated by SaveOnSP, Express Scripts, and Accredo—flouts the patient-protective federal health insurance laws to seize copay assistance meant for patients. It has twin goals: to help health plans mitigate their payment obligations for specialty medications, and to ensure patients cannot access patient copay assistance. Through the Program, Defendants defy federal law; mislead copay assistance programs into benefitting health plans and enriching the trio, rather than helping

patients; and deprive patients of copay assistance, forcing patients to pay for healthcare expenses in excess of what the ACA allows.

A. The ACA provides important protections to American healthcare consumers.

- 42. The ACA is a comprehensive health care reform law that has increased health insurance coverage for millions of Americans. The ACA built on existing health insurance systems with changes to Medicare, Medicaid, and employer-sponsored coverage;³ and introduced regulated health insurance marketplaces for those without access to employer- or government-sponsored insurance.
- 43. Prior to its enactment in 2010, many Americans were uninsured or underinsured due to the unaffordability of health insurance and exclusions based on preexisting conditions. Those who did have health insurance often faced extremely high costs and coverage limits.
- 44. The ACA protects patients from prohibitively high health care costs and prevents insurers from denying coverage to patients just because those patients suffer from chronic medical conditions. The statute provides access to ten categories of essential health benefits. One of those categories is prescription medications. It established minimum standards of coverage for most private health insurance plans in the U.S., including employer-sponsored plans and plans sold on the individual and small group markets.

1. The ACA imposes an annual limit on patients' cost-sharing obligations.

45. Cost-sharing refers to the portion of costs for covered healthcare services for which the patient is responsible. The term "cost-sharing" is defined in the ACA itself:

The term "cost-sharing" includes—

³ As used herein, "employer-sponsored" coverage refers to both insurance plans sponsored by employers and those sponsored by unions or other bargaining units.

- (i) Deductibles, coinsurance, copayments, or similar charges; and
- (ii) Any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of title 26) with respect to essential health benefits covered under the plan.

Many plans incorporate all these types of cost-sharing, with the specifics depending on the service provided and whether or not the patient has met their annual deductible. Plans impose cost-sharing when a policyholder uses their medical or prescription drug benefits.

- 46. The ACA also expressly enumerates limited exceptions to the definition of cost-sharing:
 - Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.
- 47. Under the ACA, most health plans must have an annual cost-sharing limit. This limit is set by regulation and varies from year to year. For a single individual, it was set to \$8,150 in 2020; \$8,550 in 2021; \$8,700 in 2022; and \$9,100 in 2023. The limit for 2024 is \$9,450 and will be \$9,200 in 2025.
- 48. Cost-sharing limits are distinct from deductibles. A deductible is an amount that must be satisfied by or on behalf of a patient before the health plan will pay for most types of benefits. For example, in a plan with a \$2,000 deductible that generally covers medical services at 80%, the policyholder would need to contribute \$2,000 from sources other than its insurer before the plan will pay 80% of the cost of medical services. Until the deductible is met, the patient is generally responsible for 100% of the cost of their medical services and any other healthcare expenses; after the deductible is met, the patient is responsible for only 20% (a coinsurance amount).

49. Unlike a deductible, a cost-sharing limitation caps the overall cost-sharing responsibility for a policyholder in a given year. After that limit is reached, the plan pays 100% of covered, in-network services and the patient is responsible for \$0.

2. Any sums paid by or on behalf of patients towards covered health care, including prescriptions, counts towards patients' annual limits.

- 50. Individual and small group marketplace health plans are required to provide coverage for essential health benefits. These essential health benefits encompass 10 categories of healthcare services, including prescription medications. Thus, under the ACA, prescription medications are essential health benefits that individual and small group plans must cover. Plans that meet these minimum coverage requirements are generally called Qualified Health Plans.
- 51. Unlike individual and small-group health plans, the ACA does not require large-group health plans, including employer-sponsored plans in which a large employer carries the risk of the plan (called "self-funded plans"), to cover all ten categories of essential health benefits. However, almost all such plans do cover the essential health benefits, including prescription drugs, in order to ensure the employer's benefit offerings attract and retain employees.
- 52. Qualified Health Plans and non-grandfathered⁴ employer-sponsored plans are subject to the ACA's rules limiting expenses for enrollees. These plans must comply with the ACA's annual limitation on cost-sharing. Therefore, any cost-sharing imposed by a plan must count towards the plan's annual limits. The three federal agencies tasked with implementing the ACA—the Department of Health & Human Services (HHS), the Department of Labor, and the Department of the Treasury—have confirmed that non-grandfathered large group health plans,

17

⁴ A very small number of health plans have remained nearly completely unchanged since before March 23, 2010, when the ACA went into effect. These plans, known as "grandfathered" plans, are exempt from the ACA's rules.

including employer-sponsored plans, must have an annual cost-sharing limitation that caps a patient's responsibility for covered services.

53. Copays paid for prescription drugs must count toward a plan's annual cost-sharing limits, including manufacturer assistance paid on the patient's behalf for such drugs. Under the regulations currently in effect, insurers may only exclude manufacturer assistance from cost-sharing where there is a medically appropriate generic equivalent available.

B. Specialty drugs place extraordinary cost burdens on the patients who need them.

- 54. Despite these patient-protective provisions of the ACA, most commercial health plans still impose considerable costs on enrollees. These include a patient's premium (which averages to about \$117 a month for employer-sponsored coverage and \$477 per month for a plan on the health insurance marketplace), an annual deductible (on average, \$1,922 for employer-sponsored plans and \$3,825 for healthcare exchange plans) and, most often, co-insurance (a percentage of the cost of care) or copays, each time a patient uses their insurance benefit. So, even though patients' annual cost-sharing obligations for deductibles and copays are capped, the average American could still be on the hook for more than \$10,000 in medical expenses.
- 55. Most Americans cannot afford these costs: three quarters of U.S. adults worry about their ability to afford an unexpected medical bill; half say it is difficult to afford healthcare costs; and one in four report that they or a family member had problems paying for health care in the past year.

1. Specialty medications can cost patients thousands of dollars a month.

56. The affordability problem is particularly acute in the prescription drug context: more than 20% of adults have skipped or postponed filling a prescription because of costs; another 20% have resorted to over-the-counter alternatives; and about 10% say they have rationed medications due to costs. Patient copays, in particular, can place severe financial burdens on

patients. A recent study revealed that, if a patient's copay is equal to or greater than \$250, 70% of patients cannot afford to fill the prescription, forced to forego care that their physician has deemed essential. Even half that copay poses an insurmountable financial hurdle for more than half of Americans: 55% of patients cannot afford a \$125 copay.

57. Specialty drug prices well exceed patients' financial tolerances for prescription medications. In 2020, the average specialty medication carried a list price of \$84,442 a year (\$7,036 per month); and that price has increased faster than the rate of inflation each year since. Today, the average specialty medication can cost in excess of \$200,000 a year (\$16,667 per month). To shift more of the cost of these expensive medications onto patients, half of all employer-sponsored health plans impose steep costs for specialty medications: the average specialty medication coinsurance is 26%. An average patient on one of these specialty medications thus faces monthly payment obligations of \$1,829 (26% of \$84,442) or even \$4,333 (26% of \$16,667) to obtain a single prescription.

2. PBMs shift a larger share of specialty drug costs away from insurers and onto patients.

- 58. Health insurers outsource design and administration of prescription medications to middlemen—PBMs like Express Scripts. Despite evidence that high drug costs lead patients to forgo their prescriptions, and despite evidence that skipping prescribed medications leads to worse health outcomes, PBMs have enriched themselves and their health-plan partners at the expense of patients.
- 59. For example, PBMs negotiate steep rebates off the sticker price, or list price, of brand name prescription medications. These rebates can reach 50 percent or more of the medication's list price. PBMs share these rebates with health plans, but not patients. As a result, when a patient's prescription drug benefit requires them to pay a percentage of the drug cost, PBMs

calculate that percentage off the high list price, not the net price. To use an example: if a medication costs \$1,000, the PBM negotiated a \$500 rebate, and a patient must pay a 20% coinsurance for that medication, the patient will pay \$200 (i.e., 20% of the list price) and the PBM will pay \$300. So in reality, the patient that reasonably believes they are paying for 20% of a prescription is actually paying 40% of the medication's true cost.

- 60. PBMs also shift additional costs to patients by exploiting the PBMs' corporate structure. Today, most of the largest PBMs, including Express Scripts, are each part of large, vertically integrated corporate conglomerates that each include nearly every entity in the pharmaceutical supply chain. Express Scripts, for example, is a subsidiary of The Cigna Group, along with a health insurer (Cigna Healthcare); a specialty pharmacy (Accredo); a mail order pharmacy (Express Scripts Pharmacy); healthcare providers (like those in the Evernorth Care Group); and a drug manufacturer (Qualient Pharmaceuticals) that sells private-label medications.
- 61. PBMs steer patients needing specialty medications to their affiliated specialty pharmacies, requiring patients to fill all prescriptions for specialty medications at their affiliated pharmacies (in Express Scripts' case, Accredo). The FTC recently performed an analysis that showed that 55% of all prescriptions for specialty medications filled between 2017 and 2022 by patients whose pharmacy benefits are administered by large PBMs like Express Scripts were filled at those PBMs' affiliated pharmacies.
- 62. PBMs like Express Scripts use this mechanism to keep the high profits from specialty medications within their own corporate structure. While specialty drugs were initially understood to be drugs that require special handling or close monitoring, there is no regulatory or statutory definition of a "specialty drug." Nor are "specialty drugs" a distinct category of benefits under the ACA. A specialty drug is whatever a PBM says it is. So PBMs, including Express Scripts,

designate particularly expensive (and therefore lucrative) medications as specialty medications, and then require patients to fill their specialty prescriptions at their affiliated pharmacies. And because patients have no choice but to use PBMs' affiliated pharmacies, the specialty pharmacies like Accredo can charge higher costs for those specialty medications than other pharmacies would.

63. Through these and other mechanisms, PBMs and the corporate conglomerates of which they are a part reap behemoth profits. In 2023 alone, The Cigna Group generated \$195.3 billion in revenue (\$8.54 billion of which was pure profit). Nearly 79% of this revenue—\$153.5 billion—came from Cigna's Evernorth group, which is mainly comprised of Express Scripts and Accredo.

C. Patients who need expensive specialty medications depend on patient copay assistance to help manage their healthcare costs.

- 64. Given the expense of specialty medications and the tactics of PBMs like Express Scripts to shift those costs to patients, most patients cannot afford their cost-sharing obligations for specialty medications on their own.
- 65. To help patients surmount this financial hurdle, most pharmaceutical manufacturers of expensive brand-name medications offer patient copay assistance programs to help cover some or all a patient's cost-sharing obligation for expensive prescription medications. Patients enrolled in a manufacturers' copay assistance program typically receive a copay card, which they can then present to their pharmacy when filling their prescription.
- 66. Patient copay assistance programs typically offer to provide financial assistance equal to a patients' cost-sharing obligation for a specialty medication, up to a maximum amount per year. Sometimes, patient copay assistance programs will require a patient to pay a nominal amount, like \$5, before the program assists with the rest of the patients' expenses.

- 67. These patient copay assistance programs exist to benefit patients—to ensure that patients can afford the prescription medications deemed necessary to their health by their medical professionals. They help by defraying the high costs associated with specialty medications that patients would otherwise have to pay out of their own pocket. They are not meant to help health plans defray their costs.
- 68. AstraZeneca, for example, has tailored its AstraZeneca 360TM program to ensure that the funds are used for the benefit of the patient. Pharmaceutical manufacturer AbbVie provides patient copay assistance to patients prescribed Humira, a medication prescribed to treat some autoimmune disorders. The program is called Humira Complete®. In Humira Complete®'s terms and conditions, AbbVie has made clear: this program is intended solely for the benefit of the patient. Likewise, Johnson & Johnson, the manufacturer of Stelara, provides patient copay assistance for patients through its Stelara withMe® program. The Stelara withMe® program's terms and conditions state that the patient copay assistance is designed solely for the benefit of the patient.

D. SaveOnSP and its co-conspirators Express Scripts and Accredo divert patient copay assistance away from the patients that need it and to those patients' insurers.

69. As explained above, the ACA imposes limits on the amounts an insurer can require a patient to pay towards their healthcare expenses each year. Any covered healthcare expenses beyond those limits must be borne by the health plan sponsor. There are only narrow exceptions to this rule, as HHS has explained: (1) "monthly premiums"; (2) "[a]nything [a patient] spend[s] for services [your] plan does not cover"; (3) "[o]ut-of-network care and services"; and (4) "[c]osts above the allowed amount for a service that a provider may charge." Only two of these categories are relevant to prescription drug coverage: if a prescription drug is not covered by the plan or the

patient's pharmacy is out-of-network, the patient's payments for those drugs do not count towards their annual cost-sharing limits.

- 70. SaveOnSP, Express Scripts, and Accredo, however, have constructed a scheme premised on the notion that they can ignore the ACA's patient protections, misappropriate patient copay assistance to line the pockets of insurers and enrich themselves, while forcing patients to bear a larger portion of their medical costs than the law allows.
- 71. As explained above, Defendants' scheme has five main elements. *First*, they circumvent statutory constraints on the level of copay costs that patients must pay for specialty medications. *Second*, SaveOnSP inflates targeted patients' reported copay costs to maximize the amount of money that can be siphoned out of patient copay assistance programs. *Third*, SaveOnSP, Express Scripts, and Accredo use the threat of prohibitively expensive copays to coerce patients to enroll in the SaveOn Program and pharmaceutical manufacturers' patient copay assistance programs. *Fourth*, they leverage the SaveOn Program to collect assistance meant for patients, and instead provide it to health plan sponsors. And *fifth*, they force patients to incur additional healthcare expenses they otherwise would not have incurred in the absence of the SaveOn Program. Each facet of this scheme is explained in detail in the sections below.

1. SaveOnSP claims to have found a loophole in the ACA that allows them to evade the ACA's patient-protective requirements.

- 72. SaveOnSP claims that a loophole in the ACA allows health plan sponsors to shift costs that must, under federal law, be borne by a health plan to patients instead.
- 73. According to SaveOnSP, it can designate expensive specialty medications with generous patient copay assistance programs as "non-essential health benefits," regardless of how critical that medication is for a patient's health or even their very survival. Under SaveOnSP's

reading, a health plan may cover a drug, yet deem that drug "non-essential" so long as the plan otherwise covers the bare minimum number of other drugs as essential health benefits.

- 74. A health plan must cover at least the same number of prescription drugs in each category and class as a benchmark plan. The regulations, therefore, set minimum coverage standards. Each state sets its own benchmark plan, and CMS annually publishes a list of the number of drugs in each category and class that appear on that benchmark plan. Utah's benchmark requires coverage for the fewest medications. It would, therefore, permit SaveOnSP to designate the maximum number of medications as non-essential in support of its scheme.
- 75. According to SaveOnSP, any drugs in excess of Utah's benchmark plan can be covered, yet deemed "non-essential health benefits," and thus excluded from the patient-protective provisions of the ACA. This, SaveOnSP theorizes, means that any payments by or on behalf of patients for those medications need not be counted towards patients' cost-sharing limits. SaveOnSP's scheme takes this regulatory *minimum* on the classes of covered drugs and treats it as the *maximum* level of coverage a plan must offer.
- 76. This purported "loophole" is not a loophole at all, as it violates the express requirements of the ACA. The plain text of the ACA requires that all copayments for covered medications are subject to the cost-sharing limitation, regardless of whether those copayments are for services or goods that insurers, pharmacy benefits managers, or companies like SaveOnSP call "non-essential."
 - 2. SaveOnSP and Express Scripts created the SaveOn Program to shift insurers' payment obligations onto patient copay assistance programs and patients themselves.
- 77. Based on SaveOnSP's strained interpretation of the ACA and its regulations, SaveOnSP and Express Scripts created the SaveOn Program.

- 78. When marketing the program to insurers and employers, SaveOnSP and Express Scripts call the SaveOn Program a copay off-set savings program, which means (as they have explained) that they use the member copay as a mechanism to create savings for health benefit plans, not patients. They claim to have a unique means for exploiting patient copay assistance programs.
- 79. SaveOnSP analyzed the various states' benchmark plans to identify the plan that allows health plan sponsors to provide the least coverage to its members in terms of prescription benefits. That plan is Utah's.
- 80. SaveOnSP and Express Scripts instruct participating health plan sponsors to use Utah's benchmark plan, even though this violates HHS guidance that indicates insurers and benefit plans should select benchmark plans based on their primary place of business.
- 81. The SaveOn Program targets medications in twenty specific therapeutic categories. These categories include medications that treat serious, often life-threatening conditions like cancer; Hepatitis C; cystic fibrosis; multiple sclerosis; hemophilia; and inflammatory diseases like Crohn's Disease, psoriasis, and psoriatic arthritis. Treatments for these targeted conditions are complex, and the medications that constitute best practices for their treatment are often very expensive.
- 82. SaveOnSP selected the targeted therapeutic categories based on the costs of medications in those classes.
- 83. Once SaveOnSP identified the targeted therapeutic categories of medications, SaveOnSP identified the medications within those categories with the most generous patient copay assistance programs and carved them out of participating health plans' standard benefit design. SaveOnSP has identified more than 270 medications to target.

- 84. SaveOnSP claims that none of these targeted medications qualify as essential health benefits for participating plans. Defendants contend that this maneuver allowed them to accomplish two things.
- 85. First, it removed any limit on how high SaveOnSP could set patients' cost-sharing obligations for the targeted medications. This allows SaveOnSP to fully leverage the patient copay assistance dollars to offset health plan sponsors' pharmacy benefit coverage obligations. When SaveOnSP administers the SaveOn Program, it creates a set drug list with a corresponding copay schedule: the copays are set to match the amount of annual funding offered by the drug manufacturer's patient copay assistance program.
- 86. To set that copay, SaveOnSP ascertains the total amount of patient copay assistance funding that is available for a targeted specialty medication annually and divides it by the number of prescriptions fills expected over the year. So, for example, if a targeted medication is typically taken daily with prescriptions filled monthly, SaveOnSP would divide the total amount of manufacturer patient copay assistance available over the course of the year by twelve.
- 87. In explaining the SaveOn Program to a potential client, Express Scripts' SaveOn Program leader used the example of an average prescription for Hepatitis C. Hepatitis C cures exist, but they are extraordinarily expensive—with a list price nearing \$100,000 for an 8-week course of treatment. To help patients bear their portion of this cost, the average amount of patient copay assistance available for these treatments is \$6,600 per fill. So for an average hepatitis C drug, SaveOnSP would literally set the patient copay to \$6,600 per fill.
- 88. Second, by designating the targeted medications as non-essential health benefits, the SaveOn Program shifts additional medical costs for services other than that medication onto patients. This is because SaveOnSP, Express Scripts, and Accredo assert that payments by patient

copay assistance programs for essential health benefits count towards patients' annual cost-sharing limit, but payments made for non-essential health benefits do not.

- 89. Ordinarily, many patients who must take expensive specialty medications to treat complex and life-threatening conditions are able to satisfy their deductible, and even their entire annual cost-sharing limit, using funds provided by patient copay assistance programs rather than paying out of their own pocket. But the SaveOn Program prevents a patient from satisfying any part of their cost-sharing obligations through funds provided by patient copay assistance programs. As a result, a targeted patient who would normally satisfy all or part of their cost-sharing obligations through patient copay assistance funding must instead pay for additional medical care for which, absent the SaveOn Program, their health plan would be obligated to cover.
- 90. The SaveOn Program thus has two goals: to enrich plans, Express Scripts, and SaveOnSP with excessive patient copay assistance payments meant to benefit patients, not plans; and to allow plans to shift additional healthcare costs onto patients.
 - 3. SaveOnSP and Accredo coerce targeted patients to sign up for SaveOnSP with the threat of financial ruination if they do not.
- 91. On or about November 13, 2017, SaveOnSP and Express Scripts entered into a Master Program Agreement pursuant to which, on information and belief, Express Scripts agreed to market the SaveOn Program to its health-plan sponsor clients, to require prescriptions for any targeted medications to be filled only at its specialty pharmacy Accredo, and to deploy Accredo to help further the scheme; and SaveOnSP agreed to administer the Program for interested health plan sponsors.
- 92. SaveOnSP and Express Scripts aggressively market the SaveOn Program to health plan sponsors. Sometimes, Express Scripts deploys its own representatives to convince sponsors

to sign on to the program; other times, they deputize benefits administrators like Rx Benefits, Inc. to do it for them.

- 93. After convincing a health plan sponsor to sign up, Express Scripts (or sometimes Rx Benefits) executes a Joinder Agreement with that sponsor, under which the sponsor becomes a party to the Master Program Agreement.
 - i. SaveOnSP, Express Scripts, and Accredo coerce patients into enrolling in the SaveOn Program and require them to enroll in patient copay assistance programs.
- 94. It is SaveOnSP's job to convince targeted patients to enroll in the SaveOn Program and to help patients enroll in the relevant patient copay assistance program—often by walking them through the steps—so that SaveOnSP, Express Scripts, and Accredo can secure the patient copay assistance dollars for participating health plans.
- 95. Under the Master Program Agreement (as confirmed in the Joinder Agreements), Express Scripts provides participating health plans' claims data to SaveOnSP, including historical co-pay credit information or plan documentation design information for the purposes of enabling SaveOnSP to implement the SaveOn Program for the participating health plan sponsor. SaveOnSP uses that information to identify patients who rely on the targeted medications for purposes of enrolling them, and then conducts an aggressive campaign to enroll patients.
- 96. Beginning 60 days before the SaveOn Program is scheduled to go live for a participating plan sponsor, SaveOnSP sends a letter to targeted patients, and quickly follows up on the letter with three personal phone calls to each targeted patient to try to enroll them in the Program.
- 97. In these phone calls and letters, SaveOnSP representatives instruct patients about the SaveOn Program, explain that it is a "benefit" offered by their plan, guide them through the

steps they need to complete to obtain manufacturer assistance, and answer questions about the program.

- 98. The letters sent are co-branded, meaning they carry the logos of both SaveOnSP and the participating plan sponsor, or sometimes SaveOnSP and the targeted patients' PBM, Express Scripts.
- 99. Thirty days before the SaveOn Program is scheduled to go live, SaveOnSP sends another co-branded letter and commences another round of phone calls to try to contact targeted patients and get them enrolled in the Program. Through these two rounds of letters and calling campaigns, SaveOnSP enrolls 55 to 65 percent of a health plan's targeted patients.
- 100. To convince the remaining 35 to 45 percent of targeted patients into signing up, SaveOnSP relies on help from Express Scripts and Accredo.
- 101. When a targeted, but unenrolled, patient tries to fill a prescription for a targeted specialty medication through Accredo, Express Scripts' claims processing software rejects the patient's prescription claim. This rejection prompts Accredo to connect the patient with a SaveOnSP representative.
- 102. Once Accredo connects the targeted patient with SaveOnSP, SaveOnSP tries again to enroll the patient in the SaveOn Program. Once a targeted patient capitulates, SaveOnSP assists that patient in enrolling in the patient copay assistance program associated with their prescription medication. Many of the patient copay assistance programs allow patients to enroll online: SaveOnSP assists targeted patients in filling out the patient copay assistance program enrollment form—either by filling out the form for them, or by instructing patients on how to fill them out. Other programs require a patient to enroll by phone: for those programs, SaveOnSP instructs patients how to respond to the questions that they are being asked as part of that over-the-phone

enrollment. SaveOnSP then forwards patients' copay assistance program enrollment information to Accredo and informs the pharmacy that it can process the patient's prescription claim.

- 103. In the meantime, Express Scripts refuses to process, and Accredo refuses to fill, targeted patients' prescriptions—which SaveOnSP refers to as a pharmacy pause. The only way a targeted patient can bypass this pharmacy pause is by enrolling in the SaveOn Program and allowing SaveOnSP, Express Scripts, and Accredo to divert patient copay assistance from that targeted patient to their plan sponsor. Until then, Express Scripts will not allow a targeted patient's prescription claim to move forward until it obtains confirmation that the patient has enrolled in a patient copay assistance program. And without Express Scripts' permission, Accredo will not advance any further in the process of filling the targeted patient's prescription.
- 104. Targeted patients often report being prevented access to life-saving drugs unless they signed up for the SaveOn Program. "I [got] a call from Accredo last night," one targeted patient wrote in a forum for narcolepsy patients: "They had a notation indicating I must be enrolled with SaveonSp [sic] before they're allowed to ship me Lumryz." A targeted patient with psoriatic arthritis reported: "[M]y Otezla is being held hostage by Accredo until I talk to . . . SavOnSP [sic]." "My insurance suddenly mandated that I use Saveon last year otherwise they refused to refill my Enbrel," wrote a targeted patient with rheumatoid arthritis. Another targeted patient echoed this experience, commenting "Last year my insurance . . . blocked my Enbrel mid-prescription . . . until I signed up with Saveon." And a targeted patient with eczema reported that Express Scripts would not approve a prior authorization request for their medications unless they first signed up for SaveOnSP.
- 105. By withholding access to medications unless and until a targeted patient acquiesced to enrolling in the SaveOn Program—a process that could take some time because the time it takes

to enroll in patient copay assistance programs depends on the manufacturer's requirements for participation—SaveOnSP, Express Scripts, and Accredo jeopardize patients' health. Many medications, including for example Otezla and Enbrel discussed above, should not be suddenly discontinued. Suddenly stopping a biologic (because, for example, the pharmacy refuses to refill it) can cause symptoms to recur even in patients in remission. And worse, stopping immunosuppressants cold turkey may cause a rebound phenomenon because when a patient's immune system is repressed, taking away the medication can cause even more severe symptoms to develop.

- 106. SaveOnSP, Express Scripts, and Accredo also deprive plan participants and beneficiaries of the ability to challenge the SaveOn Program as illegal or a violation of their benefit plan's terms.
- 107. Under ERISA, Express Scripts' rejection of a pharmacy claim, which is triggered when a patient has not enrolled in the SaveOn Program, is an "adverse benefit determination" because it is the failure to pay a claim for benefits. Similarly, the "pharmacy pause" is also an adverse benefit determination because it amounts to a failure to provide or make payment for a prescription drug benefit. But Express Scripts and SaveOnSP do not treat the claim rejection or "pharmacy pause" as an adverse benefit determination.
- 108. ERISA plans, and administrators of those plans, are required to provide a notice of the determination to the plan participant or beneficiary in accordance with ERISA's claims procedure regulations. Those regulations have specific timing, manner, and content requirements for all notifications of adverse benefit determinations. The notice must explain the specific reason for the denial, reference the specific plan provisions on which the determination is based, describe

any information necessary for the claimant to remedy the claim denial, and describe the plan participant or beneficiary's appeal rights.

- 109. On information and belief, Express Scripts and SaveOnSP do not provide any formal notification of the pharmacy claim denial. While the denial will prompt a representative from SaveOnSP to speak to the patient and coerce them into signing up for the program, the denial does not generate the standard adverse benefit determination notice that Express Scripts would provide for other types of pharmacy claim denials.
- 110. Because the patient never receives a notice of the denial, they cannot challenge the denial through their plan's internal appeal procedures.
 - ii. SaveOnSP, Express Scripts, and Accredo retaliate financially against targeted patients that refuse to sign up for the SaveOn Program.
- 111. A targeted patient might decline to sign up for the SaveOn Program despite being bombarded by phone calls and letters from SaveOnSP, despite being told their prescription claim has been rejected, and despite Accredo putting them in touch with SaveOnSP sales representatives. SaveOnSP and Express Scripts designed the SaveOn Program to punish those patients.
- 112. SaveOnSP, Express Scripts, and Accredo set up the SaveOn Program to capitalize on funding from patient copay assistance programs, so they have inflated targeted patients' copays to bill the patient copay assistance program. For patients who enroll, SaveOnSP and Express Scripts pay the inflated copay (or cause the plan to pay the copay) after raiding the patient assistance program. If a patient does not enroll in the SaveOn Program, SaveOnSP, Express Scripts, and Accredo charge the patient that same inflated copay.
- 113. And because SaveOnSP has designated the drug a non-essential health benefit, the payment of the inflated copay is not applicable to the targeted patient's annual cost-sharing limit.

- 114. Returning to the example of a \$6,600 copay for Hepatitis C drugs that Express Scripts representatives have used to tout the SaveOn Program to its health plan sponsor clients, a targeted patient who declines to enroll in the SaveOn Program would be required to pay \$6,600 out of pocket each time they filled a prescription of their Hepatitis C medication. And none of that would count towards satisfying their deductible or meeting their annual cost-sharing limits.
- 115. SaveOnSP and Express Scripts deliberately designed the SaveOn Program to create these harsh and coercive consequences for targeted patients who do not acquiesce to their health plan taking their patient copay assistance funding. And they depend on this to ensure that the SaveOn Program scheme works. If targeted patients could just say no and opt out—which would deprive SaveOnSP, Express Scripts, and Accredo of the opportunity to divert patient copay assistance to themselves and the health plan sponsor—it would defeat the SaveOn Program's purpose of creating savings for the plan.

iii. The SaveOn Program's \$0 medication cost to patients is not a benefit: it is a sham.

- 116. To convince targeted patients to enroll in the SaveOn Program, SaveOnSP, Express Scripts, and Accredo tell targeted patients that, if they enroll in the Program, they will enjoy a \$0 copay for their qualifying specialty medications. But the \$0 copay offer is a sham. Not only does the SaveOn Program and its "\$0 copay" offer provide no benefit to targeted patients, it leaves them worse off than they were before for two reasons.
- 117. *First*, the \$0 copay offer is a sham because it does not help targeted patients save money on their specialty medications. Most, if not all, targeted patients *already* received their specialty medications for no cost out-of-pocket before being subjected to the SaveOn Program. Patient copay assistance programs have—for years prior to the founding of SaveOnSP—provided financial assistance to cover patients' cost-sharing obligations. The SaveOnSP Program does not

offer any new benefit to targeted patients; instead, it offers new barriers to targeted patients' ability to afford their healthcare. The only benefit is to SaveOnSP, Express Scripts, Accredo, and their plan partners: the SaveOn Program diverts patient copay assistance funds to enrich plans and Defendants.

- 118. Second, the SaveOn Program is not designed to help patients and is instead designed to conceal Defendants' scheme. The Program's \$0 feature is not benevolence. It is self-preservation—a means of protecting their scheme from detection. SaveOnSP, Express Scripts, and Accredo ensure that a targeted patient never faces a surprise bill for their specialty medication because, they reason, there is not much for targeted patients to complain about when they get their specialty drug for free. And without surprise bills, there is less likelihood a targeted patient will uncover their scheme.
- 119. In the past, health insurers and PBMs have tried other types of programs to divert patient copay assistance funds for their own benefits. One was known as a copay accumulator adjustment program which collected the maximum amount of patient copay assistance at the beginning of the year and excluded it from the patient's annual cost-sharing limits. Once the patient copay assistance funding dried up, patients were surprised to discover that none of the patient copay assistance funds collected counted toward their cost-sharing obligations. Suddenly, late into their plan year, unsuspecting patients faced steep and unanticipated medical costs. This led to outcry from patients and healthcare advocates. The reaction was quick and severe: 23 states have banned insurers within their regulatory authority from deploying accumulator adjustment programs; another 17 have similar legislation pending.
- 120. So insurers and PBMs switched tactics, introducing what became known as a copay maximizer. Copay maximizers accomplish the same thing as copay accumulators, except they

spread the collection of patient copay assistance out over the course of the year, so patients do not face the surprise bills that led to outcry against accumulators.

- 121. The SaveOn Program is little more than a maximizer program in fancy dress. It bears many of the hallmarks of maximizer programs—maximizing copay assistance program payments without any benefit to targeted patients, resulting in increased healthcare costs to those patients—but wraps the scheme in the guise of a legalistic (but not legal) argument about how the patients' life-saving medications are "non-essential."
- Accredo operate—the SaveOn Program to avoid patient backlash that could frustrate their scheme. By touting a \$0 cost to targeted patients who enroll, the trio seems to hope, patients will not complain, and the Program can persevere where other programs have faltered. The \$0 cost to patients is, therefore, not benevolence, but an effort to conceal the Program's harm to patients.
 - 4. SaveOnSP, Express Scripts, and Accredo collect funds from patient copay assistance programs even when targeted patients are ineligible for that funding.
- 123. The lynchpin of the SaveOn Program is a scheme to deceive patient copay assistance programs into paying SaveOnSP's artificially inflated copays for targeted patients. The Program does not work—it has no purpose—unless SaveOnSP, Express Scripts, and Accredo can collect excessive patient copay assistance funds meant to benefit *patients* and divert them to benefit the *plan* and enrich administrators like SaveOnSP, Express Scripts, and Accredo.
- assistance programs about patients' eligibility for patient copay assistance in at least four ways. *First*, they mislead these programs into believing targeted patients are responsible for paying astronomically high copays for their specialty medications when the patient is actually responsible for \$0. *Second*, they force patients to sign up for patient copay assistance programs for which they

are ineligible as a result of their enrollment in the SaveOn Program. *Third*, they evade some patient copay assistance programs' requirement that a patient bear a small amount of copay obligation out of pocket. And *fourth*, they offer to, and do, operate the SaveOn Program for health plan sponsors whose plan designs render it illegal to collect patient copay assistance. Each of these tactics, which help ensure that the SaveOn Program can function as intended, is discussed below.

- i. SaveOnSP, Express Scripts, and Accredo misrepresent targeted patients' copay obligations to patient copay assistance programs to extract excess funds.
- 125. As described above, SaveOnSP sets patients' copays to a precise dollar value intended to collect the maximum available amount of patient copay assistance available from patient copay assistance programs each year. When a targeted patient that has enrolled in the SaveOn Program submits a prescription for a targeted medication to Accredo, Accredo represents to the patient copay assistance program that the targeted patient is responsible for that inflated copay.
- 126. Yet SaveOnSP, Express Scripts, and Accredo tell targeted patients something else. They caution patients that they may see high copays if they check their prescription online through their health plan, but assure patients that their actual responsibility will be \$0. And, for targeted patients that enroll in the SaveOn Program, their copay obligation is paid by SaveOnSP and Express Scripts, so they are ultimately responsible for \$0.
- 127. SaveOnSP, Express Scripts, and Accredo intend to induce the patient copay assistance program to pay an inflated copay in reliance on Accredo's representation to the patient copay assistance program that a targeted patient faces hundreds, if not thousands, of dollars in copay obligations (when, under the terms of the SaveOn Program, SaveOnSP, Express Scripts, and/or the plan covers the patient's copay obligations, regardless of whether it is covered by patient assistance).

- ii. Most targeted patients are ineligible for patient copay assistance funds because they have been subjected to the SaveOn Program—but SaveOnSP, Express Scripts, and Accredo collect those funds anyway.
- 128. Many patient copay assistance programs have noticed the effects of the SaveOn Program, and have changed their terms of service to ensure that only patients benefit. Most, if not all, patient copay assistance programs' terms of service make clear that the program is intended solely to benefit the patient, not the health plan or PBM.
- 129. Targeted patients forced to enroll in the SaveOn Program are ineligible for patient copay assistance under many programs, or else are eligible only for curtailed assistance. Most patient copay assistance programs expressly say so in their terms of service. AstraZeneca's terms and conditions for the AstraZeneca 360TM Program, for example, state:

Some prescription drug plans have established programs referred to as 'co-pay maximizer' or 'co-pay accumulator' programs. Co-pay maximizer and co-pay accumulator programs are ones in which the amount of the patient's out-of-pocket costs is adjusted to reflect the availability of support offered by a co-pay support program. Patients enrolled in co-pay maximizer or co-pay accumulator programs may receive varied program benefits to ensure the program funds are used for the benefit of the patient.

130. AbbVie tells patients they are ineligible for the Humira Complete program if their health plan implements either an accumulator adjustment or co-pay maximizer program, since such programs are inconsistent with AbbVie's intent that its program is solely for the patient's benefit. Eli Lilly & Company, the maker of Taltz, states that a patient is not eligible for and prohibited from using the Taltz Savings Card Program if the patient's health plan operates a program in which coverage, reimbursement, or patient out of pocket costs for a product in some way vary based on the availability of a manufacturer co-pay program. And Johnson & Johnson excludes from its Stelara withMe program any patients whose health plan partners with SaveOnSP in particular.

- 131. Yet SaveOnSP, Express Scripts, and Accredo nevertheless force targeted patients to sign up for these patient copay assistance programs. Part of the purpose of SaveOnSP's outreach to targeted patients after a health plan signs up for the SaveOn Program is to walk patients through the sign up process for these programs. Upon information and belief, SaveOnSP leads targeted patients to unwittingly mislead the patient copay assistance program into allowing ineligible members to enroll.
- 132. And it works. One manufacturer has reported that the SaveOn Program has caused it to pay more than \$100 million more in patient copay assistance than it otherwise would have.
 - iii. Some patient copay assistance funds require participating patients to pay a small portion of a medication's cost—but SaveOnSP, Express Scripts, and Accredo evade these requirements.
- obligation. Many, in fact, require patients to cover a nominal amount—often between \$5 and \$50—of the copay out of their own pocket. Under the terms of such programs, the patient must pay that amount; and any patient on a health plan with a plan design that claims to eliminate the patient's costs is not eligible to receive patient copay assistance. Patient copay assistance programs implement these rules for a simple, commonsense reason: to ensure that patient copay assistance benefits only those patients who must pay for their medications.
- 134. Yet SaveOnSP, Express Scripts, and Accredo interfere with this safeguard, and conceal their meddling from patient copay assistance programs.
- amount out of pocket, SaveOnSP, Express Scripts, and Accredo have devised what they refer to as a "tertiary biller" scheme. The primary biller is the participating health plan, which covers the cost of the medication in excess of SaveOnSP's inflated copay; the secondary biller is the patient copay assistance program, which would pay most of the copay. A tertiary biller, rather than the patient,

pays the portion that patient copay assistance programs require patients to pay. That tertiary biller is really SaveOnSP behind the scenes.

- assistance program requires a patient to pay. Take the hypothetical example of a specialty medication with a monthly cost of a medication is \$10,000 for which a patient copay assistance program offers up to \$12,000 annually (\$1,000 a month) in assistance, so long as the patient pays \$5 per month. Under those circumstances, SaveOnSP would set its inflated copay at \$1,000; the patient copay assistance program would pay \$995, and expect that the remaining \$5 would be the patient's responsibility. But instead, SaveOnSP, acting as a tertiary biller, would pay the \$5, and then invoice that \$5 cost back to the health plan sponsor.
- 137. The SaveOn Program's tertiary biller scheme allows SaveOnSP, Express Scripts, and Accredo to violate the terms of patient copay assistance programs and evade requirements designed to ensure that the patient copay assistance program funding goes to a patient that has a financial obligation to pay for a portion of their medications.
 - iv. SaveOnSP and Express Scripts offer to, and do, operate the SaveOn Program in circumstances in which they admit the Program is illegal.
- 138. High-deductible health plans ("HDHPs") with qualifying health savings accounts ("HSAs") have, as their name suggests, a high deductible. These HSA-eligible HDHPs plans predated the ACA, and allowed plan sponsors to reduce their costs by increasing patients' costs. To assist patients in bearing these increased costs, to choose HDHPs despite the increased deductibles, the Tax Code allows enrollees to establish an HSA that can be used for any qualifying health expenses and is funded by pre-tax dollars.
- 139. To qualify as an HSA-eligible HDHP, the plan must require that enrollees satisfy the full amount of their deductible before the plan provides benefits (other than coverage for

preventative care) to that patient. A HDHP plan loses qualified HSA eligibility if enrollees receive healthcare services at no cost to the member before the deductible is met.

- 140. Under this rule, sometimes referred to as a ban on first-dollar coverage, any patient on an HSA-eligible HDHP cannot legally be enrolled in the SaveOn Program because under the Program, they receive healthcare services at no cost to them before their deductible is met.
- 141. SaveOnSP, Express Scripts, and Accredo acknowledge that, in such plans, before patients can receive any additional paid benefit from the plan, they must fully satisfy their deductible out of their own pocket. They admit that patient copay assistance is not ACA compliant in such plans. And they acknowledge that there is legal risk in implementing the SaveOn Program for HSA-eligible HDHPs.
- 142. Yet SaveOnSP, Express Scripts, and Accredo are willing to, and do, administer the SaveOn Program for HSA-eligible HDHPs. When marketing the SaveOn Program to potential clients, Express Scripts often tells plans how much money they can make from the Program if they do include these plans that it is illegal to include, before showing plans how much less they would make if they did not.
- 143. SaveOnSP, Express Scripts, and Accredo justify knowingly violating the Tax Code's HSA provisions because, they acknowledge, there is no requirement that patients confirm that they have met their deductible before the SaveOn Program extracts patient copay assistance in their name, and because there is no governing body monitoring compliance with the first dollar policy. So SaveOnSP, Express Scripts, and Accredo are willing to operate the SaveOn Program in what they acknowledge is a legal gray area, leaving it to clients to determine whether to include their high-deductible health plans with qualifying HSAs in the SaveOn Program.

E. SaveOnSP, Express Scripts, and Accredo's scheme is very lucrative for them and for their insurer clients, but harms targeted patients.

- 144. SaveOnSP, Express Scripts, and Accredo profit from the SaveOn Program.
- 145. For operating the SaveOn Program on behalf of participating health plan sponsors, Express Scripts and SaveOnSP collect a commission equaling 25% of the amount of patient copay assistance funds SaveOnSP, Express Scripts, and Accredo collect from patient copay assistance programs. Express Scripts invoices participating plans for that commission on its ordinary administrative invoices.
- 146. SaveOnSP and Express Scripts create detailed reports in order to calculate their earnings. Express Scripts provides SaveOnSP with historical claims data to establish the average copay targeted patients paid for their specialty prescriptions before the SaveOn Program was implemented. Express Scripts also provides SaveOnSP with claims data for targeted patients once they are enrolled, showing how much patient copay assistance program funding was collected for each targeted patients' prescriptions. SaveOnSP analyzes those claims files and builds detailed monthly reports.
- SaveOnSP's reports detail each prescription drug claim administered through SaveOnSP, showing a complete flow of the money. This includes the total cost of the medication; the copay SaveOnSP, Express Scripts, and Accredo charged the patient copay assistance program; and any amounts due that SaveOnSP paid as a tertiary biller to mislead the patient assistance programs, as described above. SaveOnSP uses this information to calculate the total amount the health plan sponsor saved—that is, the total amount of benefit of patient copay assistance diverted to the plan—which it uses to calculate a plan's gross savings and, from that, SaveOnSP and Express Scripts' 25% fee.

- 148. Based on these monthly reports prepared by SaveOnSP, Express Scripts invoices health plan sponsors for the fee each month; and SaveOnSP and Express Scripts provide a high-level summary report each quarter.
- 149. The SaveOn Program is very lucrative for SaveOnSP, Express Scripts, Accredo, and their health-plan clients. In a presentation to one health plan with 43,000 members and just 612 targeted patients, SaveOnSP and Express Scripts calculated that the plan could expect net savings of \$4.9 million, after deducting their fee. That means that for just those 612 targeted patients, SaveOnSP and Express Scripts collect \$1.6 million in fees annually. Taking into account the 100 million lives Express Scripts covers SaveOnSP, Express Scripts, and Accredo stand to make billions of dollars in SaveOn Program fees per year.
- 150. But recall that the billions of dollars of diverted patient copay assistance funding is only half of the SaveOn Program's objective. The Program is also designed to force targeted patients to shoulder an excessive amount of their healthcare costs. Those excess healthcare costs constitute a direct financial harm to targeted plaintiffs.

1. The SaveOn Program foists additional healthcare costs on patients.

- 151. Under the SaveOn Program, targeted patients are not charged anything out of pocket for the targeted medications. SaveOnSP, Express Scripts, and Accredo call this a win for patients, and tells patients that the SaveOn Program is designed to help them save money on their specialty medications. This is a lie.
- 152. For employer-sponsored healthcare, the average deductible for employer-sponsored healthcare is \$1,922; and the average cost-sharing limit is \$4,346 (for individual plans purchased on states' ACA marketplaces, these numbers are slightly higher).
- 153. Most relatively healthy patients are lucky: absent an extraordinary emergency medical condition or injury, they never need to shoulder healthcare expenses high enough to reach

their annual cost-sharing limits. But patients with chronic, expensive, lifelong conditions routinely satisfy their deductible, and even hit their annual cost-sharing limits with their first couple of medication shipments each year.

- 154. As noted above, patients who need specialty medications face monthly costs well into the thousands of dollars. For patients on expensive specialty medications, therefore, patient copay assistance funding is essential to help defray their high healthcare expenses and ensure they can obtain the treatment they need. Few patients can afford thousands of dollars each month in prescription-drug cost sharing obligations: patient copay assistance can help to lower or eliminate those costs. Patients enrolled in patient copay assistance programs for specialty medications often strategically schedule medical care so as to not need routine office visits, lab tests, or other treatment during the first quarter of the year. For patients that can satisfy their deductible with their first few prescription drug copayments each year, this enables them to delay medical care expenses until they have satisfied their deductible and their plan must cover some of their cost. For the unfortunate patients whose first few prescription claims exceed their annual cost-sharing limitations, this strategic scheduling can help them avoid excess medical expenses.
- 155. The SaveOn Program harms targeted patients because it deprives them of this cost management strategy. In fact, it is designed to. Because SaveOnSP designates targeted patients' medications as non-essential health benefits and excludes those payments from calculating whether the patient has met their cost-sharing limitation, none of the patient copay assistance program funding collected in the patients' names benefit the patients. It does not count towards satisfying their deductible, and it does not count towards reaching their annual cost-sharing limits.
- 156. Therefore, targeted patients who are subjected to the SaveOn Program are forced to cover healthcare expenses that would otherwise be covered—or at least mitigated—by patient

copay assistance program funding. So while targeted patients' up-front costs for targeted medications is zero, in many cases, the lack of progression towards their deductible or annual cost-sharing limits means they experience more cost in the end.

- one with a \$1,922 deductible, a \$4,346 cost-sharing limit, and a 26% coinsurance obligation for specialty medications—that is prescribed a specialty medication (Drug X) with an average \$84,442 annual list price for which their insurer and affiliated PBM enjoys a \$34,000 rebate, and for which the manufacturer offers up to \$24,000 in patient copay assistance funding. That patient would face a \$7,037 copay for their very first prescription of the medication in January—more than satisfying their \$1,922 deductible. For the portion of the \$7,037 cost in excess of that deductible, the patient would be responsible for 26%, or \$1,330, bringing their total obligation in January to \$3,252. In February, they would hit their annual cost-sharing limitation with an additional coinsurance payment of \$1,094. If that patient were enrolled in the manufacturer's patient copay assistance program, the assistance program would pay \$4,346—\$3,252 in January and \$1,094 in February—and the insurer would be responsible for covering the remaining \$46,096. After that, the patient would have no further healthcare expense obligations.
- 158. The calculus changes dramatically once a patient's health plan sponsor has joined the SaveOn Program. Under the Program, SaveOnSP would designate Drug X a non-essential health benefit and set the patients' monthly copay to \$2,000 per month. Over the course of the year, the SaveOn Program would siphon \$24,000 from the patient copay assistance program, and the plan would be responsible for only \$26,442. But none of the \$24,000 the Program collected would count toward the patient's deductible or annual cost-sharing limit. So even after the manufacturer pays \$24,000 in the patients' name, the patient would still be responsible for covering

\$4,346 in medical expenses. Therefore, this hypothetical patient would suffer \$4,346 in financial harm from the SaveOn Program, as demonstrated in the below table:

Table 1: Itemization of Healthcare Expenses With and Without SaveOn Program

	Without SaveOnSP	With SaveOnSP
Drug X Annual List Price	\$84,442	
Rebate to Plan	\$34,000	
Available Copay Assistance	\$24,000	
Patient Deductible	\$1,922	
Patient Annual Cost-Sharing Limit	\$4,346	
Expected Plan Net Cost	\$46,096	
Plan-Set Copay Obligation	26%, or \$1,094 ⁵	\$2,000
Patient Copay Assistance Collected	\$4,346	\$24,000
Payment to SaveOnSP	\$0	\$4,913.50
Plan Net Cost ⁶	\$46,096	\$26,442
Total Payments on Behalf of Patient	\$4,346	\$24,000
Patient Payments Applied to Cost-Sharing Limits	\$4,346	\$0
Remaining Patient Contribution	\$0	\$4,346

159. Patients with a higher-than-average deductible or cost-sharing limitation face more significant financial harm. And patients who decline to enroll in the SaveOn Program face even more than that: they would be responsible not only for paying for other medical care up to the \$4,346 cost sharing limit, but also for 30% of the list price of Drug X, or \$25,332.60.

 $^{^5}$ One the patient in this hypothetical had satisfied their \$1,922 deductible, their monthly obligation for Drug X would be 26% of the monthly cost of the drug (\$7,032), or \$1,094. In this hypothetical, the patient would reach their annual cost-sharing limitation in February.

⁶ List price less rebate and patient contribution.

2. Targeted patients cannot escape the financial harm caused by the SaveOn Program.

- 160. Once a patient has been targeted by the SaveOn Program—and regardless of whether they sign up for it—they cannot avoid the financial harm of the program.
- 161. SaveOnSP designates a targeted drug as a non-essential health benefit for all targeted patients, regardless of whether the patients enroll in the SaveOn Program. A targeted medication remains a non-essential health benefit even for a targeted patient that does not enroll in the Program. That means that even if a patient does not enroll in the SaveOn Program, and shoulders the inflated copay out of pocket, those payments—\$24,000 in payments, in the hypothetical above—would not count towards satisfying the patient's cost-sharing obligations: they would still have to pay for \$4,346 in other healthcare expenses, on top of that \$24,000.
- 162. So targeted patients are harmed, regardless of their acquiescence to the SaveOn Program. Once their health plan sponsor has joined the Program, they have only four options:
 - a. Sign up for the SaveOn Program to avoid paying thousands of dollars in copays created by the Program, unwittingly verify to the manufacturer that they are eligible for assistance when they are, in fact, not, and be forced to cover additional medical expenses up to the annual cost-sharing limit;
 - Refuse to sign up for the Program, sign up for patient assistance on their own to cover the thousands of dollars of copays, but be forced to cover additional medical expenses up to the annual cost-sharing limit;
 - c. Refuse to sign up for the Program, pay thousands of dollars of copays for the specialty medication, and *still* be forced to cover additional medical expenses up to the annual cost-sharing limit; or

- d. Decide to forgo their physician-prescribed, necessary medical treatment, and be forced to cover cost-sharing additional (and, in light of the fact they're not taking a necessary medication, enhanced) medical expenses up to the annual cost-sharing limit.
- 163. In light of this dynamic—the hopeless position that the SaveOn Program puts targeted patients in—many patients feel they have no other choice but to enroll in the Program.

3. SaveOnSP, Express Scripts, and Accredo's scheme creates a benefit design that discriminates against certain patients.

- 164. The ACA prohibits health insurers from discriminating against patients on the basis of race, color, national origin, sex, sexual orientation, gender identity, age, or disability. HHS's regulations implementing this prohibition prohibits health plan sponsors from "impos[ing] additional cost sharing or other limitations or restrictions on coverage" or having "benefit designs that discriminate on the basis of . . . disability . . . in health insurance coverage or other health-related coverage." The SaveOn Program violates the statute and these regulatory provisions.
- 165. Medications targeted by SaveOnSP, Express Scripts, and Accredo in the SaveOn Program are those used to treat conditions that constitute disabilities. This includes, for example, cancer, multiple sclerosis, and cystic fibrosis.
- 166. Cancer is considered a disability under the Americans with Disabilities Act. So is multiple sclerosis. And cystic fibrosis.
- 167. The SaveOn Program constitutes a benefit design that treats patients differently on the basis of their disability: the Program deprives patients with certain disabilities of access to patient copay assistance for their medications; and it imposes additional cost-sharing obligations on patients with disabilities.

168. The exclusion of targeted medications from a targeted patient's benefit plan based only on utilization and cost, not on efficacy or necessity, discriminates against patients with disabilities that happen to be treated by higher-cost medications. SaveOnSP, Express Scripts, and Accredo, therefore, violate the ACA's prohibitions on discrimination.

4. SaveOnSP, Express Scripts, and Accredo disproportionately harm minorities and other marginalized groups.

- 169. In addition to discriminating against targeted patients on the basis of their disabilities, SaveOnSP, Express Scripts, and Accredo's scheme may disproportionately harm minorities and other marginalized groups.
- assistance programs at similar rates, the potential for a patient to be subjected to a copay adjustment program, like SaveOnSP, which takes away that assistance, is much higher among non-White patients vs. White patients. The study's authors quantified that disparity: non-Whites are 27% more likely to be exposed to programs like the SaveOn Program than Whites.

5. SaveOnSP, Express Scripts, and Accredo have fraudulently concealed the harm to patients from the SaveOn Program.

- 171. SaveOnSP, Express Scripts, and Accredo have affirmatively and fraudulently concealed their patient copay assistance fraud by various means and methods since at least 2015. Ms. Gurwitch and the Class, therefore had neither actual nor constructive knowledge of the facts giving rise to their claim for relief. Neither Ms. Gurwitch nor the class discovered, nor could they have discovered through the exercise of reasonable diligence, the existence of SaveOnSP, Express Scripts, and Accredo's fraudulent scheme to increase their cost-sharing obligations in or before 2021.
- 172. SaveOnSP, Express Scripts, and Accredo actively conceal the harm caused to patients by the SaveOn Program. When SaveOnSP representatives reach out to targeted patients,

they do not accurately disclose their role in the patients' pharmacy benefits: they identify SaveOnSP as "your specialty pharmacy's specialty pharmacy"; leading patients to believe that the SaveOnSP Program is a legitimate part of the prescription drug supply chain, when it is not.

- 173. Defendants also market the program to patients as a "cost-saving healthcare solution" that helps patients. They tout that targeted patients will pay zero dollars for their targeted specialty medications and thus save money on those prescriptions. But they do not disclose that this leads, dollar for dollar, to increased cost-sharing obligations for other healthcare expenses. This omission makes SaveOnSP, Express Scripts, and Accredo's statements about the SaveOn Program materially misleading.
- 174. These materially misleading statements concealed the harm to targeted patients, and did not reveal facts sufficient to put Ms. Gurwitch or the Class on inquiry notice. While targeted patients may have noticed that their cost-sharing expenses increased after their health plan partnered with the SaveOn Program, healthcare expenses have increased every year. So this alone is not sufficient to put a reasonable person on notice that targeted patients' healthcare expenses increased *because of*, rather than just *after*, their health plan joined the SaveOn Program. An ordinary person acting reasonably diligently would not have had the time, resources, or specialized training to uncover the misconduct that Ms. Gurwitch, through counsel highly experienced in racketeering fraud class action litigation, allege herein.
- patients by SaveOnSP, Express Scripts, and Accredo's fraudulent scheme before, at best, May 4, 2022, when Johnson & Johnson, a drug manufacturer with a patient copay assistance program that has been raided by the SaveOn Program, sued SaveOnSP. However, even with that lawsuit, and the media attention it garnered, an ordinary person acting reasonably diligently, would not have

had reason to suspect that SaveOnSP conspired with Express Scripts and Accredo to operationalize the fraudulent scheme.

- 176. Ms. Gurwitch and the Class exercised reasonable diligence at all times since SaveOnSP was founded in 2017. They could not have discovered SaveOnSP, Express Scripts, and Accredo's misconduct sooner by exercising reasonable diligence because of Defendants' deceptive and secretive actions to conceal their misconduct.
- 177. Since discovering the possibility that SaveOnSP, Express Scripts, and Accredo's fraudulent misconduct harmed not just patient copay assistance programs but also targeted patients, Ms. Gurwitch has diligently examined Defendants' behavior regarding increasing patients cost-sharing obligations, their coordination regarding the same, their joint purpose to harm targeted patients, and the effects of such conduct through publicly available sources, such as Defendants' public statements and media coverage. Once this investigation revealed a basis for filing this claim, Ms. Gurwitch promptly did so.
- 178. SaveOnSP, Express Scripts, and Accredo's fraudulent concealment of their wrongful misconduct has tolled and suspended the running of the statute of limitations concerning the claims and rights of action of Ms. Gurwitch and the Class arising from the conspiracy, including all parts of the class period earlier in time than the four years immediately preceding the date this action was filed.
- 179. SaveOnSP, Express Scripts, and Accredo's misconduct has also resulted in a continuing violation against Ms. Gurwitch and the Class. These continuing violations have tolled and suspended the running of the statute of limitations concerning their claims and rights of action arising from the conspiracy, including all parts of the class period earlier in time than the four years immediately preceding the date this action was filed.

VI. Impact on Interstate Commerce

- 180. SaveOnSP, Express Scripts, and Accredo's efforts to divert patient copay assistance have substantially affected interstate commerce.
- 181. At all material times, SaveOnSP, Express Scripts, and Accredo marketed, promoted, and administered the SaveOn Program in a continuous and uninterrupted flow of commerce across state lines and throughout the United States.
- 182. At all material times, SaveOnSP, Express Scripts, and Accredo transmitted funds, contracts, invoices, information, and other forms of business communications across state and national lines and throughout the United States.
- 183. In furtherance of the scheme, Accredo intentionally hindered the dispensing and shipment of essential medications through the U.S. mail and interstate carriers to coerce targeted patients to sign up for the SaveOn Program and to punish those that did not.
- 184. In furtherance of their scheme, SaveOnSP, Express Scripts, and Accredo employed the U.S. mail, interstate carriers, and the interstate wire lines.

VII. Causes of Action

COUNT I: VIOLATIONS OF ERISA, 29 U.S.C. § 1132(a)(3) By the ERISA Subclass against Defendants Express Scripts and SaveOnSP

- 185. Ms. Gurwitch repeats and incorporates by reference all preceding paragraphs and allegations.
- 186. At all relevant times, Defendants Express Scripts and SaveOnSP acted as fiduciaries of the ERISA plans they administer under 29 U.S.C. § 1001(21)(A), including, but not limited to, the following fiduciary acts:
 - a. By denying pharmacy claims for prescriptions subject to the SaveOn Program when patients attempt to fill those prescriptions without enrolling in the Program;

- b. By failing to recognize copay amounts paid by patients for prescriptions subject to the SaveOn Program as counting toward the patient's annual cost-sharing balances;
- c. By contacting participants and beneficiaries by letter and by phone to instruct them to sign up for SaveOnSP;
- d. By paying, or causing plans to pay, inflated copays for participants and beneficiaries in the SaveOn Program, but charging those inflated amounts to those who do not sign up; and
- e. By paying, or causing plans to pay, a portion of the cost-sharing drug manufacturers require patients to make to be eligible for manufacturer patient copay assistance.
- 187. As fiduciaries, Defendants Express Scripts and SaveOnSP are required to discharge their duties in the interests of participants and beneficiaries and in accordance with ERISA.
- 188. When enrolling plan participants and beneficiaries in SaveOnSP's Program and operating the SaveOn Program, Defendants Express Scripts and SaveOnSP have violated numerous provisions of ERISA, including, but not limited to, as follows:
 - a. Failing to count prescription drug copays toward the plan participant or beneficiary's annual cost-sharing limitation balance, in violation of 42 U.S.C.
 § 300gg-6(b), as incorporated in ERISA at 29 U.S.C. 1185d(a)(1);
 - Issuing claim wrongful pharmacy claim denials without proper notice to the patient,
 depriving plan participants and beneficiaries of their appeal rights, in violation of
 U.S.C. § 1133 and its associated regulations;
 - c. Instructing plan participants and beneficiaries on how to obtain patient assistance from drug manufacturers by, in part, misrepresenting or omitting material facts and

- causing patients to make misrepresentations to drug manufacturers, in violation of their duty of loyalty under 29 U.S.C. § 1104(a)(1);
- d. Failing to perform their duties in the best interests of plan participants and beneficiaries and instead operating the SaveOnSP scheme to benefit themselves, in violation of 29 U.S.C. § 1104(a)(1).
- 189. By violating numerous provisions of ERISA, Defendants Express Scripts and SaveOnSP also violate their obligation to execute their duties consistent with ERISA, in violation of 29 U.S.C. § 1104(a)(1)(D).
- 190. By failing to notify Ms. Gurwitch and similarly situated members of the Class of the adverse benefit determination that occurred when a targeted patient's claim was rejected, Defendants Express Scripts and SaveOnSP deprived Ms. Gurwitch and similarly situated Class members of the ability to appeal those determinations. Therefore, to the extent any internal claims procedures apply to Ms. Gurwitch and the Class's claim, those procedures are deemed exhausted.
- 191. As a result of these breaches of fiduciary duty and violations of ERISA, Ms. Gurwitch and the Class are entitled to equitable relief in the form of an injunction prohibiting Defendants Express Scripts and SaveOnSP from operating the SaveOn Program.
- 192. In addition, Ms. Gurwitch and the Class are entitled to attorneys' fees, costs, and litigation expenses under 29 U.S.C. § 1132(g).

COUNT II: VIOLATION OF THE RACKETEER INFLUENCED CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(c) By the Class against All Defendants

- 193. Ms. Gurwitch repeats and incorporates by reference all preceding paragraphs and allegations.
 - 194. Defendant SaveOnSP is a "person" within the meaning of 18 U.S.C. § 1961(3).

- 195. Defendant Express Scripts is a "person" within the meaning of 18 U.S.C. § 1961(3).
- 196. Defendant Accredo is a "person" within the meaning of 18 U.S.C. § 1961(3).
- 197. The SaveOn Program constitutes an association-in-fact enterprise, the SaveOnSP Copay Assistance Fraud Enterprise, within the meaning of 18 U.S.C. § 1961(4), consisting of: (i) SaveOnSP, including its employees and agents; (ii) Express Scripts, including its employees and agents; and (iii) Accredo, including its employees and agents.
- 198. The defendant "persons" are each distinct from the SaveOnSP Copay Assistance Fraud Enterprise.
- 199. The SaveOnSP Copay Assistance Fraud Enterprise fits within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" that created and maintained systematic links for a common purpose: to profit from minimizing health plan sponsors' obligations to pay for specialty medications and other healthcare costs by diverting patient copay assistance funds and forcing patients to bear additional healthcare expenses as a result.
- 200. SaveOnSP conducts or participates in the conduct of the affairs of the SaveOnSP Copay Assistance Fraud Enterprise. SaveOnSP conceived of the Program, developing and promoting a plan to exploit a perceived loophole in the ACA and its regulations. It analyzed states' benchmark healthcare programs to identify the program (Utah's) that was most permissive of the scheme, therapeutic categories of medications in that benchmark plan to identify medical conditions that are treated by expensive medications, and manufacturers' patient copay assistance programs for medications in those classes to identify lucrative programs worth exploiting. SaveOnSP recruited Express Scripts to help operationalize the Program, and entered into the Master Program Agreement with Express Scripts. It set inflated copays for targeted medications. It created and maintains a "SaveOnSP drug list" for participating health plans. It identifies targeted

patients from participating health plans' prescription claims data and engages in a letter-writing and phone-call campaign to convince targeted patients to enroll in the SaveOn Program. SaveOnSP coerces patients to enroll in the SaveOn Program and relevant patient copay assistance programs, and often assisted patients in enrolling in patient copay assistance programs. It administered the SaveOn Program as it applied to enrolled targeted patients. And it prepared detailed reports of the patient copay assistance collected in the name of, but not for the benefit of, targeted patients, the "savings" to participating health plans, and the fraudulently reduced net cost to the plans, which it then transmitted to Express Scripts via the wires.

- 201. Express Scripts conducted or participated in the conduct of the affairs of the SaveOnSP Copay Assistance Fraud Enterprise. It entered into the Master Program Agreement with SaveOnSP. It marketed the SaveOn Program to its health plan sponsor clients, entering into joinder agreements with participating health plans sponsors. It provided detailed prescription claims data from participating health plans to SaveOnSP for the purpose of identifying targeted patients. It transmitted instructions to Accredo to reject prescription drug claims from patients that had not yet enrolled in the SaveOn Program. Express Scripts provided, via the wires, detailed claims data regarding targeted patients' claims after the patients enrolled in the SaveOn Program to SaveOnSP to aid SaveOnSP in preparing reports to be sent to participating health plans. And it received from Accredo excessive copayments collected from patient copay assistance programs and disbursed it to participating health plans, then billed participating health plans for its services, and collected a fee equal to 25% of the patient copay assistance collected from those health plans on behalf of SaveOnSP.
- 202. Accredo conducted or participated in the conduct of the affairs of the SaveOnSP Copay Assistance Fraud Enterprise. Accredo falsely told targeted patients that their prescription

drug claims had been rejected and connected those patients with SaveOnSP representatives in aid of efforts to coerce them into signing up for the SaveOn Program. And in the meantime, it withheld targeted patients' life-saving specialty medications. Accredo transmitted prescription drug claim information, including the artificially inflated copays set by SaveOnSP to patient copay assistance programs; collected those inflated copays; and transmitted it via the wires to Express Scripts to be apportioned between SaveOnSP, Express Scripts, and participating health plans.

- 203. SaveOnSP, Express Scripts, and Accredo may want to claim that they have not conducted or participated in the conduct of the SaveOnSP Copay Assistance Fraud Enterprise because health plans, and not them, are responsible for the design and implementation of the Program. But that is not true. Express Scripts, on behalf of SaveOnSP, Accredo, and itself, has admitted:
 - a. "[W]e're using the member copay as a mechanism to create savings for the plan at the point of sales";
 - b. "[W]e're targeting" specific therapy classes and applicable drugs so that "we can effectively carve out and administer a different benefit design";
 - c. "[W]e can carve [a number of drugs] out and create a different benefit design where we designate these drugs as non-essential";
 - d. "[T]here's no maximum as to how high we can set the member responsibility";
 - e. "We would literally set the patient copay to \$6,600 and you would save that amount on every fill";
 - f. "[W]hat we're doing is we're creating savings for the plan and we're keeping the patient responsibility at zero but we're just not going to allow [patient copay assistance funding] to hit their max out of pocket";

- g. "[W]e're maximizing plan cost savings;"
- h. "[W]e're not disrupting the rest of the benefit design";
- i. "So whenever we administer this program, we will have a set drug list with a corresponding copay schedule";
- j. "[W]e have a targeted drug list that we can share with you."

The "we" referred to means SaveOnSP, Express Scripts, and Accredo. It does not include the plans, as Express Scripts makes clear in its sales pitches. It emphasizes in conversations with health plan sponsors that "we're getting such significant savings for you all." Express Scripts also makes clear that the SaveOn Program is SaveOnSP, Express Scripts, and Accredo's benefit design, not the health plans, describing how "we administrate our program"

- 204. SaveOnSP, Express Scripts, and Accredo conducted and participated in the conduct of the affairs of the SaveOnSP Copay Assistance Fraud Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5). This pattern includes hundreds, if not thousands, of instances of mail fraud in violation of 18 U.S.C. § 1341; hundreds, if not thousands, of instances of wire fraud in violation of 18 U.S.C. § 1343; and travel in interstate and foreign commerce in aid of a racketeering enterprise in violation of 18 U.S.C. § 1952, as described above.
- 205. The SaveOnSP Copay Assistance Fraud Enterprise engaged in and affected interstate commerce because, *inter alia*, it altered and affected the means by which health insurance plans sold in interstate commerce; exploited patient copay assistance programs that provided aid to patients in all 50 states; altered targeted patients' cost of (and delayed access to) specialty medications shipped by Accredo in interstate commerce.

- 206. The scheme devised by SaveOnSP, Express Scripts, and Accredo and operationalized through the SaveOnSP Copay Assistance Fraud Enterprise amounted to a common course of conduct intended to (a) deceive patient copay assistance programs into disbursing excessive patient copay assistance, often to targeted patients who (by virtue of being subject to the SaveOn Program) were not eligible to receive those funds; then (b) divert patient copay assistance to benefit their health plans clients rather than patients; such that (c) targeted patients were deprived of the ability to offset some of their healthcare costs with patient copay assistance funds; and, as a result, (d) forcing patients to bear additional healthcare costs.
- 207. All of SaveOnSP, Express Scripts, and Accredo's racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and has similar results affecting similar victims, including Ms. Gurwitch.
- 208. The pattern of racketeering activity alleged herein and the SaveOnSP Copay Assistance Fraud Enterprise are separate and distinct from each other. SaveOnSP, Express Scripts, and Accredo engaged in the pattern of racketeering activity alleged herein for the purposes of conducting the affairs of the SaveOnSP Copay Assistance Fraud Enterprise.
- 209. As a result of SaveOnSP, Express Scripts, and Accredo's fraudulent activities, targeted patients like Ms. Gurwitch were forced to incur healthcare expenses that they would not have had to incur but for the SaveOn Program, resulting in increased healthcare costs for Ms. Gurwitch and all members of the Class.
- 210. Ms. Gurwitch and others similarly situated have been injured in their business and property by reason of SaveOnSP, Express Scripts, and Accredo's fraudulent scheme and the success of the SaveOnSP Copay Assistance Fraud Enterprise. She and other members of the Class have paid hundreds of millions, if not billions, more in healthcare expenses than they would have

in the absence of the fraudulent course of conduct underlying the SaveOnSP Copay Assistance Fraud Enterprise.

- 211. SaveOnSP, Express Scripts, and Accredo's racketeering activity is the direct and proximate cause of Ms. Gurwitch's and the Class's injuries.
- 212. Ms. Gurwitch's injuries were caused by SaveOnSP, Express Scripts, and Accredo's racketeering activity. By conducting the SaveOnSP Copay Assistance Fraud Enterprise through a pattern of racketeering activity, SaveOnSP, Express Scripts, and Accredo directly caused patients to pay more for their healthcare needs. But for SaveOnSP, Express Scripts, and Accredo's unlawful conduct, targeted patients like Ms. Gurwitch and members of the Class would have been able to apply patient copay assistance funds to their deductible and annual cost-sharing limits, thus avoiding excess health care expenses.
- 213. Ms. Gurwitch's injuries and those of the Class were directly caused by SaveOnSP, Express Scripts, and Accredo's racketeering activity. The SaveOnSP Copay Assistance Fraud Enterprise caused two categories of harm: (i) harm to patient copay assistance programs in the form of excessive disbursements from the programs; and (ii) harm to patients that are deprived of the opportunity to avail themselves of the patient copay assistance programs' funding and thus forced to incur additional healthcare expenses out of pocket.
- 214. This second category of harm was experienced directly by targeted patients like Ms. Gurwitch and members of the Class, and there is no other individual or entity more directly harmed. Therefore, there is no other plaintiff or class of plaintiffs better situated to seek a remedy for the economic harms of SaveOnSP, Express Scripts, and Accredo's fraudulent scheme.
- 215. By virtue of these violations of 18 U.S.C. § 1962(c), and pursuant to 18 U.S.C. § 1964(c), SaveOnSP, Express Scripts, and Accredo are jointly and severally liable to Ms. Gurwitch

and the Class for three times the damages they have sustained, plus the cost of this suit, including reasonable attorneys' fees.

216. This cause of action is not dependent upon, or subsidiary to, Count I, in that Defendants' conduct violates RICO regardless of whether their conduct is also in violation of ERISA.

VIII. DEMAND FOR JUDGMENT

WHEREFORE, Ms. Gurwitch, on behalf of herself and the Class, respectfully requests that the Court:

- A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare Ms. Gurwitch as representative of the Class;
- B. Enter a judgment that Defendants are jointly and severally liable in favor of Ms. Gurwitch and the Class;
- C. Permanently enjoin Defendants from operating the SaveOn Program;
- D. Award the Class treble damages in an amount to be determined at trial, plus interest in accordance with the law; and
- E. Award such further and additional relief as is necessary to correct for the effects of Defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

IX. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Ms. Gurwitch, on behalf of herself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: January 8, 2025 Respectfully Submitted,

/s/ Marco Cercone

Marco Cercone, Esq.

RUPP PFALZGRAF LLC

1600 Liberty Building

424 Main Street

Buffalo, NY 14202

Telephone: (716) 854-3400 Facsimile: (716) 332-0336 cercone@rupppfalzgraf.com

Stephen J. Teti

Kristie A. LaSalle (pro hac vice forthcoming)

Lockridge Grindal Nauen PLLP

265 Franklin Street, Suite 1702

Boston, MA 02110

Phone: (617) 535-3763

sjteti@locklaw.com

kalasalle@locklaw.com

Brian D. Clark (pro hac vice forthcoming)

David W. Asp (pro hac vice forthcoming)

Derek C. Waller (pro hac vice forthcoming)

Kira Q. Le (pro hac vice forthcoming)

Lockridge Grindal Nauen PLLP

100 Washington Ave S, Suite 2200

Minneapolis, MN 55401

Phone: (612) 339-6900

bdclark@locklaw.com

dwasp@locklaw.com

dcwaller@locklaw.com

kqle@locklaw.com

Counsel for Plaintiff and the Proposed Class