



Drivers of Health Costs in the U.S. Part II

Understanding the Pharmacy Benefit
Manager's Role

About

The Alliance for the Adoption of Innovations in Medicine (Aimed Alliance)

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Introduction



As members of the health care industry point the finger over whom to hold accountable for the high cost of health care in the U.S., drug manufacturers and insurers are often front and center. However, pharmacy benefit managers (“PBMs”), referred to by some as “healthcare’s shadowy middlemen,”¹ have largely flown under the radar while enjoying a lack of transparency and meaningful regulatory oversight.

PBMs are organizations that health plan sponsors contract with to administer prescription drug plans. They serve as intermediaries between the plan sponsor, drug manufacturers, and pharmacies. PBMs’ traditional functions have included negotiating discounts and rebates with drug manufacturers, developing formularies for pharmacy benefit plans, contracting with pharmacies, and processing and paying prescription claims.² PBMs argue that they drive down drug prices through negotiations, rebates, and formulary design. Others view PBMs as taking advantage of their strategic position as intermediaries between health insurers and other parties in the health system, while reaping significant profits at the expense of plan enrollees.³

PBMs Contributing to the Rising Cost of Health Care

The PBM market is highly concentrated, characterized by minimal competition and a lack of regulatory oversight. As a result, an environment exists “in which PBMs reign free to engage in anticompetitive, deceptive, and fraudulent conduct” that harms consumers.⁴ Large PBMs have been accused of engaging in several anticompetitive practices, including leveraging their own retail pharmacies, driving independent pharmacies out of business, and pushing consumers to high-price prescription drugs.⁵ The three largest PBMs—CVS Caremark, UnitedHealthcare’s OptumRx, and Express Scripts—control an estimated 80 to 85 percent of the market.⁶

A. Anticompetitive Practices Stifle Competition and Drive Prices Higher

Large PBMs have been accused of engaging in several profit-maximizing, anticompetitive behaviors. For example, some PBMs have allegedly diverted plan beneficiaries away from third-party pharmacies and toward the PBMs’ own specialty or mail-order pharmacies to fill and refill prescriptions. For example, in *Park Imrmat Drug Corp. v. Express Scripts*, the plaintiff, a small mail-order pharmacy, alleged that Express Scripts and CVS Caremark conspired in an illegal scheme to prevent competition and to put independent mail-order pharmacies out of business.⁷ The plaintiff argued that the PBM sought to audit competitor pharmacies in an abusive way, terminate contracts with mail-order pharmacies, and reimburse pharmacies for drugs at lower than the PBM’s acquisition costs.⁸

In August 2016, several pharmacies filed a class action lawsuit alleging that Express Scripts secretly used patients’



prescription data to divert clients from the independent pharmacies it contracted with to bolster its mail-order pharmacy business.⁹ According to the suit, the PBM used the data to determine when patients were eligible for refills, and then used its mail-order pharmacy to fill the prescriptions without first obtaining patients’ consent, while keeping the insurance payments in the process.¹⁰ The plaintiffs alleged that the PBM used the data to identify the patients with the most expensive prescriptions, and that the PBM prohibited the plaintiff-pharmacies from refilling prescriptions for those patients, thereby ensuring that revenues from those refills went to Express Scripts.¹¹ It is estimated that the lawsuit class could include as many as 50,000 pharmacies.¹²

Similarly, in March 2016, Grasso Enterprises filed an amended complaint alleging an “ongoing and multi-faceted conspiracy” between Express Scripts, CVS Caremark, OptumRx, and Prime Therapeutics LLC to boycott jointly compounding pharmacies, and to eliminate them from the market.¹³ A district court denied the PBMs’ motion to dismiss the complaint.¹⁴ In yet another example, *Prime Aid Pharmacy Corp. v. Express Scripts*, a small New Jersey pharmacy sued Express Scripts in January 2017 for allegedly implementing a fraudulent scheme and engaging in anticompetitive behavior—including terminating contracts with pharmacies that compete with its own pharmacy.¹⁵ This case is ongoing.

B. Rebates Increase Profits and Are Not Passed on as Savings to Consumers or Insurers

One major revenue source for PBMs comes from negotiated rebates from drug manufacturers. However, PBMs do not disclose the rebates they receive from manufacturers, and it is, therefore, unclear what percentage they keep for themselves.¹⁶ It has been estimated that PBMs generated a combined \$130 billion in rebates from 2012 to 2016.¹⁷

In theory, PBMs act on behalf of plan sponsors; yet, they keep rebate agreements with manufacturers secret from



the plan.¹⁸ In March 2016, Anthem, the nation's largest insurer, filed a \$15 billion-dollar lawsuit against Express Scripts, alleging that the PBM breached its contract with the insurer by setting higher than competitive prices for prescription drug benefits, causing the insurer to overpay billions of dollars.¹⁹ Through the discovery process, Anthem plan enrollees were able to see just how much the PBM and insurer were pocketing in rebates rather than passing on to enrollees. As a result, in May 2016, plan enrollees filed their own class action, claiming that they were overcharged based on the inflated prices imposed on Anthem by Express Scripts.²⁰ Similarly, in June 2016, certain Anthem plan enrollees filed a separate class action against both Express Scripts and Anthem. They alleged that Express Scripts breached its fiduciary duty to plan members by charging the members above competitive prices for prescriptions. They further alleged that Anthem breached its fiduciary duties to members by entering into a contract that allowed the PBM to overcharge for prescriptions and failed to adequately monitor the PBM.²¹

The rebate system creates a conflict of interest for PBMs. PBMs negotiate lower medication prices with drug manufacturers in the form of rebates in exchange for listing the medications on the PBMs' formularies.²² In theory, PBMs are supposed to pass the rebates on to insurers,



which then can pass discounts on to plan enrollees. PBMs, however, often keep a portion of the rebates as profit, which they reclassify as “administrative fees,” rather than passing them on as savings—a concept referred to as “pass-through pricing.”²³ Moreover, the rebate system incentivizes PBMs to promote high-price drugs to increase the profit they receive from rebates, a practice referred to as “rebate pumping,” instead of focusing on improving patient care and lowering prices.²⁴

PBMs also have engaged in “clawback” schemes, in which a medication’s retail cash price—the amount paid by a person without insurance—is less than the amount the person with insurance is required to pay at the pharmacy counter (i.e., the negotiated price between the pharmacy and plan provider).²⁵ In other words, a medication is cheaper for individuals who do not have insurance than

for those who do have it. For example, the individual without health insurance may pay \$5 at the pharmacy for a medication, while a covered plan participant may pay a \$20 co-payment for the same medication.²⁶ The PBM “claws back” the \$15 difference.²⁷ In cases in which the clawback amount exceeds the total price of the medication, the insurance plan provides no benefit to the covered plan participant.²⁸ Moreover, many of the PBMs that engage in



clawback schemes also have gag clauses in their contracts with pharmacists that prohibit the pharmacists from telling patients about insurance overcharges and less expensive measures to obtain their medication.²⁹

Since October 4, 2016, at least 16 lawsuits have been filed against PBMs and insurers, including Optum Rx, alleging clawback schemes kept hidden from plan enrollees.³⁰ Legal claims include defrauding patients through racketeering, breach of contract, and violations of federal insurance laws.³¹ Plan enrollees have alleged that they were forced to pay hidden fees in the form of these clawbacks.³² In a class action complaint filed against UnitedHealth Group, its subsidiaries, and Optum Rx, the plaintiffs alleged that “[t]he result [of the clawback scheme], in many instances, is that insurance plans [and PBMs] pay nothing towards the cost of covered individuals’ prescriptions, charge consumers an additional fee above and beyond the cost of their medications every time they fill a prescription, and leave patients financially worse-off than if they had no insurance at all.”³³

While rebates and clawback schemes lead to increased profits for PBMs, they also increase costs for plan sponsors and plan enrollees. PBMs essentially get paid twice by charging health plans an administrative fee and then also keeping a portion of the rebates. The cost savings from rebates are not available to be passed on to consumers, as intended. When PBMs engage in clawback schemes, consumers are essentially charged hidden fees.³⁴

C. Formulary Exclusions Result in Loss of Access to Treatment

In August 2017, Express Scripts released its formulary exclusion list for 2018, announcing all the medications that it would no longer cover.³⁵ It added 64 medications to its list, for a total of 159 drugs excluded.³⁶ CVS Caremark added 17 new products to its 2018 formulary exclusion list.³⁷ A May 2016 report by Tufts University examining the growth of exclusionary lists found that the total number of excluded medications by CVS and Express Scripts grew by approximately 65 percent between 2014 and 2016.³⁸ The report also suggested that drug manufacturers' rebates to PBMs influence PBM drug exclusion decisions.³⁹

Exclusion lists provide a mechanism for PBMs to negotiate better drug prices for consumers and health plans. However, as exclusionary lists have grown, the transparency of their development has not. Such lists are typically devised behind closed doors. In the case of Express Scripts, the names of the board of physicians and the one pharmacist who annually decide which prescription drugs will be excluded from coverage for the upcoming year are not made public.⁴⁰ Other PBMs use a similar practice as Express Scripts, relying on "the recommendations of unidentified experts"⁴¹ to determine which medications will be not be covered. While PBMs say the secrecy shields the process from the influence of lobbyists, critics say the process of choosing excluded drugs should be more transparent.⁴²

In addition, as new drugs become available, or the PBM negotiates more advantageous deals with other drug manufacturers, a PBM may update its formulary by removing a current medication. As a result, PBMs can make restrictive changes to their formularies after the plan year has begun. When a PBM drops a medication from its formulary, or places it on a higher tier, plan enrollees are often required to pay higher out-of-pocket prices.⁴³ Stable patients' current medication may become unaffordable, forcing them to switch to the PBM's new preferred drug, which may not be identical to their current medication. This forced change may be done without the prescriber's knowledge.



Formulary changes that result in forced switching of medications could violate certain laws, including state unfair and deceptive trade practices acts. For example, in 2008, attorneys general from 28 states and the District of Columbia sued Caremark for allegedly encouraging prescribers to switch patients from originally prescribed medications to other drugs in violation of the state consumer protection acts, using the justification that it would save the patients and health plans money.⁴⁴ However, the plaintiffs claimed that the PBM neither adequately informed prescribers of how patients would actually be impacted, nor informed the prescribers or patients that the PBM would be retaining cost savings rather than passing them to the health plan.⁴⁵ The parties settled the case for \$41 million, allocating \$38.5 million to the states, and \$2.5 million to patients who incurred expenses related to the switches.⁴⁶

D. Spread Pricing and Lowering Generic Drug Reimbursements to Pharmacies

PBMs often use "spread pricing," whereby PBMs negotiate separate contracts with pharmacies and plan sponsors to increase revenue. This practice drives up costs for insurers and consumers. In spread pricing, a PBM will reimburse a pharmacy at one rate for dispensing a medication, but charge a plan sponsor a higher rate for the same medication.⁴⁷ The PBM pockets the difference, or the "spread," between the two rates.⁴⁸ The spread price—up to \$200 for a single prescription drug⁴⁹—is charged on top of any agreed-upon maintenance fee between the insurer and PBM.

According to a 2013 report, Meridian Health Systems calculated the spread charged by Express Scripts, which was the PBM of Meridian's employee health plan. Meridian, a nonprofit owning and operating several hospitals, determined that Express Scripts paid Meridian's outpatient pharmacies \$26.91 for a generic amoxicillin prescription. Meridian cross-referenced this figure with data showing that the PBM charged the plan \$92.53 for the same prescription filled at an outside pharmacy—a



spread of over \$65 on a single generic prescription.⁵⁰ In another instance, Meridian discovered a spread of over \$26 for a prescription of the antibiotic azithromycin.⁵¹ While Meridian hired Express Scripts in hopes of reducing the system's spending on drugs for its employees,⁵² Meridian's prescription benefits costs increased by \$1.3 million in the first year of its contract with Express Scripts.⁵³

Independent and community pharmacies can also fall victim to PBM spread pricing. PBMs can alter their "maximum allowable cost" (MAC) list for generic drugs to those below the pharmacy costs, thereby forcing pharmacists to take a financial loss to serve their customers.⁵⁴ A MAC list includes an upper limit or maximum amount that a plan or PBM will pay for generic drugs and for brand drugs that have generic versions available.⁵⁵ Generic drugs' average wholesale prices (AWP) (i.e., the average price at which medications are purchased from the wholesaler) often vary. MAC prices can be used to reconcile the differences between an inflated AWP and the price the pharmacy actually pays.⁵⁶ Ideally, based on the MAC price, pharmacies will receive a reasonable markup on each medication, thereby incentivizing the pharmacy to promote generic medications, which are typically less costly than brand medications.⁵⁷

However, PBMs do not use standardized criteria for including a medication on a MAC list or for calculating the maximum price.⁵⁸ Additionally, PBMs are not required to disclose to pharmacies how much PBMs will pay the pharmacies for medications, and MAC payments for the same generic medications can vary significantly among pharmacies.⁵⁹ Based on this lack of transparency, PBMs have used their MAC lists to make a profit by pocketing the spread between the varying MAC prices pharmacies pay for generic medications.

E. PBM Auditing Practices of Contracting Pharmacies

Lack of transparency is a common thread among PBM profit-maximizing schemes; yet, PBMs can conduct unfair audits of the pharmacies with which they contract. Some PBMs claim that their increasingly rigorous pharmacy

audits are aimed at rooting out overpayments.⁶⁰ As the result of one audit, Express Scripts charged a pharmacy \$40,000 because the wrong initials appeared on certain paperwork.⁶¹ These unfair audit practices have led some pharmacies to sue PBMs. For example, in *HM Compounding Services, Inc. v. Express Scripts*, a court held that the plaintiff compounding pharmacy sufficiently pleaded on a motion to dismiss that the PBM conspired to drive the plaintiff and other independent pharmacies out of business through unfair auditing practices.⁶² The case is still ongoing.⁶³

Keeping PBMs Honest: Regulatory and Legislative Approaches

A. Regulatory Oversight and Transparency

In the face of mounting evidence, it is reasonable to conclude that PBMs' business practices contribute to the rising cost of health care for consumers, while enabling PBMs to increase their profits. Since PBMs are largely unregulated at both the federal and state levels, expensive litigation is one of the only courses of action to take against them.⁶⁴ While state departments of insurance have the authority and mechanisms in place to investigate and to take action in response to consumer complaints against health plans, their authority does not extend to PBMs in most states.⁶⁵ Attorneys general do have authority over PBMs, but their authority is limited to consumer protection laws and unfair and deceptive trade practices statutes.⁶⁶ Therefore, explicit regulatory oversight is required, such as requiring PBMs to be licensed and registered.⁶⁷

Several states have demonstrated a commitment to reining in PBMs by introducing or enacting laws and promulgating regulations. For example, in 2013, Oregon enacted a law providing the Department of Consumer and Business Services (DCBS) authority to oversee PBMs. The law required PBMs to register with DCBS.⁶⁸ However, the law's registration requirements and fee were minimal, and there was no verification process to ensure compliance.⁶⁹ To improve oversight, Oregon passed House Bill 2388 in May 2017 to grant DCBS the authority to deny, revoke, or suspend a PBM registration for specific conduct, including dishonesty, fraud, or gross negligence. A PBM refusing to allow an audit or produce requested information to DCBS could face similar consequences if the DCBA determines that the PBM made such a refusal to protect dishonest

or fraudulent activity. If Oregon's PBM law proves to be effective at deterring dishonest PBM behaviors, it can serve as a model for legislation in other states.

Other states, such as Rhode Island, California, and Nevada, have followed suit. Rhode Island passed a law that classifies PBMs as third-party administrators and requires them to file annual reports. California AB 315, which passed the California Assembly in June 2017 but is currently inactive, would have required PBMs to register to do business with any pharmacy licensed in the state.⁷⁰ It also would have required PBMs to provide transparency regarding pricing, and to reveal any relationships they may have with mail-order or specialty pharmacies and drug manufacturers that could result in a conflict of interest.⁷¹ To further prevent these types of conflicts of interest, Nevada put forth a bill in 2017 that would prohibit PBMs from owning the pharmacies they use to dispense medications.⁷² Vermont passed a law stating that health insurers may include a provision in their contracts with PBMs requiring timely access to financial and utilization information.⁷³

In addition to statutory reform at the state level, federal reform is also needed to provide adequate oversight. Federal laws regulating health insurance plans include the Employee Retirement Income Security Act (ERISA), the Health Insurance Portability and Accountability Act (HIPAA), the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA), and the Patient Protection and Affordable Care Act ("ACA"). Yet, PBMs are not subject to the same type of industry-wide federal regulation as commercial health insurers, and instead are regulated at best through a "patchwork of regulation at the state level."⁷⁴

The 115th U.S. Congress has introduced the Creating Transparency to Have Drug Rebates Unlocked Act of 2017 (C-THRU Act), which would require public disclosure of the rebate totals that drug manufacturers provide to PBMs, and of the rebate proportion passed on to health plans and ultimately consumers.⁷⁵ To benefit consumers and employers, the PBM aggregated information would be available for review and comparison on the U.S.



Department of Health and Human Services website. After two years of public reporting, the legislation would also require that a minimum percentage of the PBMs' rebates and discounts be passed to health plans.⁷⁶ The proposed legislation would also require greater transparency around PBM spread pricing.

Many states have also begun to introduce drug price transparency bills that require drug manufacturers to disclose information about the factors that contribute to drug prices.⁷⁷ Such bills must include transparency among all parties along the medication supply chain, including insurers and PBMs, to hold all parties accountable for rising prices. States can look to the C-THRU Act as an example of the type of transparency needed for PBMs.

In addition to legislation and regulations, health plans can hold PBMs accountable by contracting with PBMs to preclude secretive behavior and require affirmative transparency. Insurers can require PBMs to disclose any rebates received from pharmaceutical companies. If PBMs breach these contract provisions, insurers can bring suit and any anticompetitive behavior will be brought to light in a public forum. If larger PBMs are unwilling to implement such clauses in their contracts, insurers could work with smaller PBMs that may be more flexible.



B. Mail Order Anti-Competitive Practices

States have enacted laws to prevent anti-competitive PBM practices, including those through which PBMs have priced out other pharmacies in favor of their own mail order pharmacies. In April 2017, North Dakota passed a law that requires PBMs with ownership interests in mail order pharmacies to agree to fair competition, prohibits self-dealing, and requires a firewall between the mail order pharmacy and administrative functions. Also in 2017, Georgia introduced legislation that would prohibit PBMs from forcing consumers to use the PBMs' own pharmacies, including mail order pharmacies.⁷⁸ States such as Connecticut, New York, and Pennsylvania have passed similar laws prohibiting PBMs from requiring consumers to use their mail order pharmacies.⁷⁹ Moreover, as Anthem did with Express Scripts, insurers can include clauses in their contracts prohibiting PBMs from setting higher than competitive prices for prescription drug benefits and then hold PBMs accountable if they violate the provision.



of Health and Human Services the total amount of all rebates that the PBM negotiated with drug manufacturers during the prior year, the total amount of those rebates that the PBM retained, and the total amount of rebates that were negotiated for medications purchased for use by Medicare, Medicaid, and other public payer beneficiaries, as well as for private payer plan beneficiaries.⁸⁴

C. Clawbacks and Rebates

To prevent gag clauses in contracts between pharmacies and PBMs, Georgia introduced a set of bills in 2017 that would ensure that pharmacists can communicate openly with patients about prescription prices and drug alternatives.⁸⁰ Connecticut passed a similar law in 2017 making clawbacks and pharmacy gag clauses illegal. Louisiana, Georgia, Maine, and North Dakota also passed anti-clawback laws.⁸¹

To create more transparency around rebates, California introduced a bill this year that would require PBMs to disclose to their clients data on drug costs, rebates, and fees earned.⁸² PBMs would have to report on a monthly basis the aggregate amount of rebates and utilization discounts received by the PBM for each therapeutic class of medications.⁸³ Likewise, Nevada passed a law in June 2017 that requires PBMs to report to Nevada's Department

D. Negative Formulary Changes

Other states have enacted or introduced legislation that prohibits negative mid-cycle formulary changes or forced medication switches. For example, Texas passed a law in 2011 that prohibits health plans from making negative changes to their formularies after the plan year has begun.⁸⁵ Instead, changes can only occur when a plan year renews and with 60 days' advance written notice to the state insurance regulators, plan sponsors, and enrollees.⁸⁶ Prohibited mid-year changes include removing a drug from the formulary; imposing a new prior authorization or step therapy requirement for a medication; adding or altering a quantity limit for a medication; or moving a drug to a higher formulary tier unless a generic alternative is available.⁸⁷ States such as Louisiana, Nevada, and New Mexico have enacted similar laws.⁸⁸ However, most of these laws apply to health plans rather than to PBMs directly. Therefore, PBMs can and do make changes to their formularies throughout the year. While the PBMs



recommend these changes to health plans, plans are not required to implement such changes. With the enactment of these laws, health plans should either contract with PBMs to prevent midcycle formulary changes or decline to implement such changes when PBMs recommend them.

In 2000, Connecticut enacted a law that addresses forced medication switching. It allows individual and group health insurance plans to make formulary changes after the plan year has begun. However, it prohibits plans from denying coverage of a medication removed from a formulary if (1) the plan beneficiary was on the medication to treat a chronic condition and the medication had been covered before it was removed; and (2) the plan beneficiary's prescriber submits a letter to the insurer stating that the drug is medically necessary and explaining why it is more medically necessary than other drugs on the formulary.⁸⁹ This law does not address moving a medication to a higher cost-sharing tier or other changes, aside from dropping the medication from the formulary, that would result in higher out-of-pocket costs. As a result, Connecticut introduced legislation this year that would have strengthened the current law by prohibiting plans from removing any drugs from the formulary or reclassifying them to a higher tier after the plan year began.⁹⁰ The bill did not pass.

Other states, including Colorado, Florida, Illinois, Massachusetts, Maryland, New Mexico, New York, Tennessee, Texas, and Washington State, also introduced but did not pass legislation in 2017 aimed at prohibiting health plans from forcing plan enrollees to switch their medications due to a formulary change.⁹¹ These laws could be expanded to include PBMs or could result in insurers pushing back against PBMs that suggest midcycle formulary changes.

E. MAC Pricing

Some states have enacted or introduced legislation that restricts how PBMs set and utilize MAC lists, and allows pharmacies to dispute PBM reimbursement rates. Texas Senate Bill 1106, signed into law in June 2013, regulates the kinds of drugs that can be placed on a PBM's MAC list and specifies the information that must be given to pharmacies when they are entering into or renewing PBM contracts. The Texas law also includes an appeals process for pharmacies to contest reimbursement rates provided by a PBM.⁹² Also in 2013, the Oregon legislature passed House Bill 2123, which requires PBMs to disclose to pharmacies the sources used to determine MAC pricing at the start of each contract and prohibits PBMs from including dispensing fees in MAC calculations.⁹³

In 2014, Washington state enacted a law placing restrictions on the use of MAC pricing.⁹⁴ The law requires PBMs to make available to each network pharmacy at the beginning of the term contract, and upon renewal of a contract, the sources utilized to determine the PBM's MAC

pricing. Additionally, the law prohibits PBMs from including dispensing fees in the calculation of a MAC. Likewise, in 2015, Arkansas responded to the manipulation of MAC pricing lists by enacting legislation. The law requires PBMs to reimburse pharmacies at the rate that the pharmacies paid wholesalers for generic medications. The law also requires PBMs to update their MAC lists within a week of a significant increase in pharmacies' costs of buying the drugs from most wholesalers.⁹⁵ Although an association of PBMs challenged the Arkansas law, a court upheld the law in March 2017.⁹⁶

F. Auditing of Pharmacies

States have also begun enacting laws addressing PBMs' auditing practices. Between 2011 and 2016, at least 30 states enacted fair and uniform pharmacy audit laws.⁹⁷ For example, in Pennsylvania, pharmacies must be given at least 14 days' notice of an audit, and an audit may not cover a period of more than 24 months or include more than 250 new prescriptions. Furthermore, the auditor cannot include dispensing fees in its calculation of overpayments; cannot subject pharmacies to a charge-back or recoupment for a computer, clerical, bookkeeping, typographical, or scrivener's error, unless the error resulted in an overpayment; must provide the pharmacy with a preliminary and final report of the audit; and must allow the pharmacy to appeal a final audit.⁹⁸

Georgia also passed a law granting the Commissioner of Insurance enforcement authority over the Pharmacy Audit Bill of Rights, including the authority to impose fines.⁹⁹

Conclusion



PBMs have an enormous impact on U.S. health care. The power of the three largest PBMs allows them to exert considerable influence on the health care market, yet their industry remains largely unregulated. Policymakers must gain a deeper understanding of PBMs' current practices and their impacts on the cost and quality of health care in the U.S., and they must take action.

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