



Statement before the Senate Committee on Health, Education
Labor and Pensions; Subcommittee on Children and Families

EpiPen Price Increases

How Regulatory Barriers Inhibit Pharmaceutical Competition

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Mr. Chairman, thank you for the opportunity to testify before the Committee:

The rising list price of drugs such as the lifesaving EpiPen autoinjector,¹ coupled to the increasing exposure that consumers have to these costs as a consequence of secular change in the design of insurance coverage, has appropriately focused increasing scrutiny on how drugs are priced. It's often argued that drugs are one of the last vestiges of market-based pricing in our highly regulated health care industry. By contrast, regulators in Washington set most prices for clinical services. It's true that drug makers have more pricing discretion than other sectors in health care, whether it's in comparison to hospitals, providers, or even medical device makers. But the market for drug products is hardly a utopia of free market pricing and vibrant competition. The drug market is subject to its own peculiar price setting and regulation. These rules undermine the competitive opportunities that could help inspire more choice and competition, and help lower costs.

Today I want to talk about three areas where I believe that regulation creates barriers to pharmaceutical competition. I will focus my remarks on how policymakers could remedy these market failures, enable more choice, and stimulate more price competition.

The first issue deals with the way that the Food and Drug Administration (FDA) regulates drugs. Here I focus on what I categorize as complex medicines. These are circumstances where the drugs have certain intricacy associated with their formulation or delivery. Developing cheaper, copy versions of these complex drugs, after legitimate patents have lapsed, are made especially difficult by shortcomings in regulatory policy.

The second area relates to existing price controls and mandatory rebates in programs such as Medicaid and 340B. These government rebate schemes put upward pressure on drug prices, by creating financial pressure to raise the list prices on drugs in order to provide fiscal room for accommodating the mandatory kickbacks. The problems associated with this system are longstanding and manifold. But these burdens are made more acute by a recent, sharp, and secular change in the structure of drug insurance coverage that has left more consumers exposed to the list price of drugs, before the rebates are applied.

Consumers who increasingly find themselves underinsured for drugs—even while more medical care shifts toward the use of higher-cost, specialty medicines—are not directly benefiting from the rebates that end up lowering the real, net price of the medicine. The health plan benefits from these rebates. They help offset premium costs. But the underinsured consumer can end up paying the full list price, not the post-rebate price.

In the case of EpiPen, a drug product that's used for the emergency treatment of certain allergic reactions, the invoice price for a two-pack EpiPen product in 2016 is currently about \$600. But these invoice or "list" prices do not account for any rebates and other

discounts. According to recently published data, the net price received by Mylan for each EpiPen 2-Pak was \$274.² This is the “net” or “real” price.

The remaining 54 percent of the list price was split among Pharmacy Benefit Managers (PBMs), insurers, wholesalers, and pharmacy retailers.

Toward addressing these challenges, our drug market would be more competitive if drug makers were able to offer—and purchasers able to demand—up-front discounts off the list price of drugs, rather than have to settle for back-ended rebates that aren’t available to consumers when they purchase a drug at the pharmacy counter. But legal precedents that Congress could address through legislation largely stand in the way of the ability of drug purchasers to demand discounts, and the feasibility of drug makers to offer them.

Third and finally, there are obstacles to the more competitive pricing of the sort of “single source” breakthrough medicines that are providing some of the most meaningful public health advances. These include branded drugs that provide substantial benefit and even outright cures for some forms of cancer and diseases such as Hepatitis C.

We need to allow innovative drugs that offer meaningful advances in medical care to be priced in a market system based on the benefit that they offer, and the cost of the capital required to underwrite the long and uncertain development path for creating these sorts of breakthroughs. We don’t want to undermine the model for investment and innovation that makes these advances possible and has given us the most vibrant market for the research and development of biotech and drug products in the world.

But at the same time, those who purchase these drugs should be able to demand prices that relate to the benefits that these products deliver and the circumstances for which they are prescribed. Right now, government rules regrettably prevent this sort of price discrimination based on indication and outcomes. Drug makers can’t offer prices based on measures of benefit or grounded in the purpose for which a drug is prescribed. And patients can’t demand these sorts of price concessions.

FDA Regulation Shortcomings Obstruct Copies of Complex Generics

Drugs such as EpiPen fall into a category of products that one might classify as complex generic medicines. It’s been noted that the active ingredient in the EpiPen is epinephrine, a very old drug. What makes the EpiPen unique is its delivery vehicle—an autoinjector that’s packaged in a convenient, pen-like device. The product’s key attribute is its ability to reliably deliver accurate doses of the essential medicine. This meaningful convenience

and the product's reliability allowed EpiPen to capture a substantial portion of the market for injected epinephrine, but it is not the only such product available.

The current market for these epinephrine products breaks down this way: Of the 4.2 million prescriptions for epinephrine products written in 2016, about 3.9 million were for combination products (i.e., autoinjectable devices containing the medicine, such as the EpiPen). According to IMS Health, Mylan represented about 3.8 million of these prescriptions. Impact Laboratories comprises the bulk of the remaining market share of autoinjectables. A third autoinjectable combination product, Auvi-Q marketed by Sanofi, was voluntarily recalled in 2015 due to malfunctions with the device.³

In addition to these autoinjectable products, a number of generic forms of epinephrine are available in ampule and vial form as well as packaged in a prefilled syringe. These products constitute a small number of prescriptions written for epinephrine in 2016. The top four vial manufacturers totaled about 217,000 prescriptions.

While the EpiPen's manufacturer, Mylan, maintains some important intellectual property around its autoinjector that the company believes differentiates its device, this should not—and has not—prevented other companies from developing their own pen-like devices for autoinjecting epinephrine. However, the way that FDA administers its generic drug regulatory process has left the agency tied in some policy knots when approving similar products as generic substitutes for EpiPen. At the same time, other regulations make it hard for competitors to EpiPen to get their products approved as new, branded alternatives to EpiPen through the new drug approval pathway. Policy shortcomings can leave potential competitors in a regulatory Catch-22.

One issue relates to the existing statute and FDA regulations that govern the approval of generic drugs, the Abbreviated New Drug Application (ANDA) process. FDA maintains that, if a patient has to be retrained to use a generic alternative to a branded product, then the alternative product cannot bear the same labeling as the drug it seeks to copy, and it cannot meet the burden of the ANDA process and be approved as a generic equivalent. The copy drug can't be considered the "same" and serve as a substitutable alternative.

This means that an alternative to a complex drug or a complex drug and device combination such as EpiPen would have to function in the exact same manner as EpiPen. To the extent that Mylan maintains some intellectual property around some of the functions of the EpiPen that correlate to some unique instructions on how to use the device, this can impede entry of generic competitors to EpiPen—even if most of the fundamental intellectual property (IP) on the drug and the device has lapsed.

At the same time, under FDA's existing rules it could be difficult for a competitor to EpiPen to seek approval under the longer and costlier new drug approval process as a branded alternative to EpiPen. Here is the Catch-22, of sorts, at play. A competitor might not be able to go through the ANDA route, but may not qualify as a new drug, either.

This could occur in an instance where a competitor to EpiPen might be filing for approval under a regulatory pathway referred to as 505B(2). The regulatory pathway is named for the section of FDA's statute that gives rise to this alternative approval process.

First, it would be unusual for FDA to approve a drug through the 505B(2) pathway and allow it to be therapeutically substitutable for another product (in this case EpiPen). So any EpiPen alternative approved under 505B(2) would not be a true generic alternative to EpiPen. Such an approval would, nonetheless, still create market competition that could help lower costs. But there is a second regulatory obstacle. In situations where a product is likely to be a therapeutic equivalent to a drug, FDA encourages (and could in some cases require) a drug developer to file as an ANDA. So there could be situations where FDA compels drug makers to file under the ANDA route, only to hit a policy obstacle in trying to copy the instructions for use in the EpiPen label without infringing some of EpiPen's IP around its autoinjector and its unique functions.

Such is the case with another epinephrine product, Adrenaclick.⁴ Like EpiPen, it is a formulation of epinephrine delivered through an autopen. Pharmacists cannot substitute it for EpiPen, despite the similarities. That's because while it's the same drug, Adrenaclick has a different autoinjector and, thus, bears a different set of instructions for using the device. It cannot be approved as a generic product that is substitutable for EpiPen.

These issues fall broadly into a category of challenges that relate to the approval of "complex generic drugs."⁵ While there is no official definition of "complex" generics, one can broadly define complex generics as generic drugs for which it is particularly difficult to establish therapeutic equivalence as defined in the Orange Book.

Some complex generics present significant challenges in establishing pharmaceutical equivalence due to problems related to physiochemical characterization. For some, a simple bioequivalence study is not enough to establish that the generic drug will have the same clinical and safety profile as the reference-listed drug that it seeks to copy.⁶

In soliciting a study from the Government Accountability Office, Congress defined complex generics as drugs that were not fully characterized because the active pharmaceutical ingredient has molecular diversity, because scientific analytic methodologies are unable to fully identify the molecular structures and physiochemical

properties of the active ingredient, and because the nature of the active ingredient is not understood well enough to identify the drug's mechanism of action that produces its therapeutic effect.⁷

Similarly, complex drugs have also been defined by authors as nonbiological products “where the active substance is not a homo-molecular structure, but consists of different (closely related and often nano-particulate) structures that cannot be isolated and fully quantitated, characterized and/or described by state of the art physicochemical analytical means and where the clinical meaning of the differences is not known.”⁸ In this regard, complex drugs can share characteristics with biologicals.

FDA has defined complex generics more broadly to include these circumstances, as well as situations such as EpiPen, where the complexity is related to the drug's delivery. This could include situations like EpiPen, where a drug is delivered through a complex device.

This might involve, for example, a drug that acts locally on tissue lining the gut (such as oral vancomycin) or an inhaled drug that acts directly on the lungs (like metered dose inhalers (MDIs) for the treatment of asthma and other lung diseases). Complex drugs might also be one that is delivered through a complicated delivery mechanism such as EpiPen or, to take another example, a drug delivered through a controlled-release patch.

FDA has faced perpetual policy challenges, in part of its own making, when it has tried to “genericize” a growing number of these complex drugs through its ANDA pathway. Because of the FDA's policy constraints, as well as its own scientific ambiguity when advancing regulatory principles for developing copies of complex drugs, sponsors often say that they feel like they are “shooting in the dark” when developing the product, preparing dossier for an effective FDA filing, or engaging in the back-and-forth between FDA and the company during the review.

For example, the agency delayed for years the approval of a generic alternative to long-acting heparin—long after the legitimate intellectual property on that medicine had lapsed.⁹ Similar delays challenged the approval of complex generic formulations, such as oral vancomycin, liposomal Doxorubicin HCl injection,¹⁰ and topical Acyclovir ointment.

In other cases, FDA made errors in how it approved generic alternatives to complex drugs like IV iron, requiring its decisions to be revisited. Or FDA established regulatory principles that were widely criticized and ultimately rescinded, such as when FDA tried to address the generic approval of certain eye drops that act topically on the eye. In the latter case, for products that act locally on tissue rather than acting systemically after

being absorbed into the blood, FDA can lack reliable, rigorous principles for demonstrating sameness in how two versions of a drug act on the target organ.

The problem is that the generic drug approval process was crafted at a time when most drugs were relatively simple, small molecule pills. The process for copying these drugs was relatively straightforward. The system for proving sameness largely turned on the ability to show that a copy of a drug can get into the blood at the same levels and in the same timeframe as the branded drug that it was seeking to emulate. It could then be postulated, based on these “bioequivalence” and “bioavailability” studies, that the generic drug would have the same therapeutic profile as the branded drug that it sought to copy.

This classical generic pathway was sufficient for many well-defined, small, low molecular weight drugs where the analytical testing fully characterized the product and showed pharmaceutical sameness to the reference-listed drug. Together with a proof of bioequivalence to the reference product, this information allowed for the submission of an abbreviated file (ANDA) with a waiver for efficacy and safety studies. FDA would nonetheless be able to declare that the copy was fully substitutable for the reference drug.

With complex generics, the ability to determine sameness based on bioequivalence and bioavailability is sometimes not as straightforward. That might be because the complex drugs act locally on an organ and therefore, the level of drug found in the blood is not an effective surrogate for surmising its therapeutic effect. Or the complex drug might be an intricate formulation, where the concentration of active ingredient found in the blood cannot be accurately measured. Or the drug might be like the EpiPen and involve a complex delivery system that requires instructions for use that cannot be precisely copied in labeling from one version of the product to the next.

As a consequence, I believe that Congress should consider legislation to modernize the generic drug framework to allow FDA greater discretion in the kinds of data it relies on for its generic approvals in this narrow category of complex drugs. This would require, for example, granting FDA the ability to ask for more than just bioequivalence and bioavailability data in making judgments around sameness. Or it might require Congress to grant FDA more discretion to make minor modifications in generic labeling to account for small variations between a branded drug and the proposed generic copy, for example, when instructions for use might be marginally different.

It’s noteworthy that generic industry stakeholders named the creation of a specialized review pathway for complex abbreviated new drug applications as a priority during user fee negotiations. The agency has also discussed with generic drug manufacturers the need for more clarity from FDA in this pre-ANDA space, according to meeting minutes.

These challenges with the complex drugs are compounded by the overall slowness and inefficiency of the generic drug approval process. As I recently noted in *The Wall Street Journal*,¹¹ the complexity and cost of completing even an average (less complex) generic drug application has also grown enormously. In 2003, when I began working at the FDA, we estimated that it cost less than \$1 million for a firm to file a generic drug application. A drug would have to earn about \$10 million in annual revenue before it would be subject to generic competition. Today, filing a generic application requires an average of about \$5 million and can cost as much as \$15 million. This means that a drug may not face brisk generic competition until it exceeds \$25 million in annual revenue.

As I previously noted, the key to the generic economic model is to keep entry prices low enough to attract multiple competitors. One study estimated the cost to consumers of generics to be 90 percent of the branded drug's price if there is only one generic entrant. But the price falls to 63 percent if there are five competitors and 40 percent when there are 10 competitors. Yet of the 1,328 branded drugs on the market, about 10 percent have seen patents and exclusivities expire, but face no generic competition.¹²

Some of these are the high-cost medicines that are the subject of political wrangling, drugs such as clomipramine (which saw a 1,818 percent price hike from 2013 to 2014); fluconazole (996 percent increase); and doxazosin (1,169 percent). Each of these drugs accounts for less than \$2 million in total Medicaid spending, meaning that very few people are using them. Given the high generic entry costs and the infrequent use of these drugs, it's often no longer economically viable for more than one firm to make them.

Owing to these economic challenges, infrequently used generics may now have only one competitor and cost as much as branded drugs. When the price of a drug rises, it becomes profitable and the target of new competition. The FDA recently committed to review new generic drug applications in a 15-month cycle, an improvement over a median of more than two years for applications submitted in 2013.¹³ For generics filed in 2009, the median review time exceeds three years. Yet generics launched in 2015 took about four years for the FDA to approve, since less than 2 percent of applications were approved on their first submission.¹⁴ FDA committed to improve first-cycle approvals, but it still rejects most applications before demanding resubmissions, delaying competition.¹⁵

Toward addressing these challenges, in addition to defining a new path for complex generic drugs, FDA should also prioritize files for these sorts of busted generic drug categories, especially where the generic targets an uncommon and serious ailment. Companies that pursue copies of these "discarded" generics could receive a voucher that

would allow them to get expedited review of another generic drug. The value of this voucher would give firms more incentive to market copies of low volume generics.

FDA must also scrap a draft rule it crafted to deliberately expose generic companies to rampant product liability suits—the so-called generic drug labeling rule.¹⁶ FDA also needs to tailor its oversight of manufacturing to the way that generics operate, usually by manufacturing dozens of different drugs on each production line and hundreds of different medicines in a single plant. Right now, FDA is trying to force generics into the much costlier way that branded firms operate their manufacturing plants, by requiring that generic product lines be dedicated to just one or two different drug products.

The regulatory delays are even more apparent with the complex drugs. Yet these complex medicines comprise a growing and important portion of our therapeutic armamentarium. The generic entry of some important copies of these medicines, once the legitimate intellectual property has lapsed on the branded alternatives, has sometimes been needlessly delayed. This saddles consumers with unnecessary costs that were never intended when the generic pathway was envisioned. These shortcomings largely stem from the absence of scientific tools for determining sameness in these settings, and the regulatory framework to efficiently approve these copies through FDA's ANDA pathway. Yet the agency insists on trying to force these drugs down the traditional generic drug approval process. It's time for Congress to define a more efficient pathway.

Price Controls Force Rebates at the Expense of Discounts

In the cost of medicines, another challenge facing consumers is the growing gap between the list price of drugs and the actual, net price paid by those who purchase the medicines on their behalf. In many cases the average net price is much lower than the list price. In fact, the average net price for drugs actually rose at a five-year low in 2015 and is rising in relative concert with overall health care inflation.¹⁷

But the list prices of drugs are rising much more sharply. The gap between these two prices—the list price and the real, net price actually paid by health plans—reflects rebates that drug makers eventually pay to health plans as a way to provide money off the sticker price of a medicine. This byzantine system is an unintended consequence of past policymaking. But its growing impact on consumers is unmistakable.

As more consumers find themselves on health plans that have adopted very high deductibles, that also use closed and narrow drug formularies that leave a growing number of important medicines completely uncovered, and that use fixed coinsurance rather than fixed co-pays as a way to distribute costs to consumers, these conditions mean

that the high list prices on drugs are the prices being paid by a growing number of consumers when they buy medicines at the pharmacy counter. Recent data from Kaiser that examined drug spending from 2004 to 2014 showed just how much these out-of-pocket costs have risen, far outpacing the costs paid by the health plans. Average payments toward deductibles more than tripled, rising 256 percent, and average payments toward coinsurance more than doubled, rising 107 percent. Over this time, average payments by health plans themselves increased only 58 percent.¹⁸

In the end, insurers may ultimately pay a price for a medicine that is half the “list” price paid up front by the consumer. And the consumer never receives the direct benefit of the rebate, which gets paid to the insurer. This is precisely the circumstance that occurred for many consumers who purchased EpiPen at or near its list price.

These challenges are not just a function of high deductibles, which leave consumers exposed to the list cost of their drugs up to the point that they reach their deductibles. They are also a function of the growing use of narrow and closed drug formularies. These are schemes where insurers agree to cover to a shrinking list of drugs. When the drugs don’t make it onto these narrow formulary lists, the closed structure of the formulary means that a drug is completely uncovered. Moreover, what consumers spend out of pocket doesn’t count against their deductible or out of pocket maximums.

Now that these insurance features have become a mainstay of plans sold in the Affordable Care Act and are being sanctioned—if not encouraged—by federal regulators as a way to accommodate the law’s other regulatory costs, these same insurance designs are being imported into employer-sponsored coverage and coverage sold outside the exchanges. The Kaiser Family Foundation says that a quarter of workers with employer sponsored insurance (ESI) must pay the full cost of drugs before their coverage kicks in, up from 17 percent in 2011.¹⁹

The problem is that our current system provides incentives for companies to push list prices higher, only to rebate the money later on the back end. Yet the rebates don’t benefit consumers equally and they don’t necessarily help offset the costs paid by those who need a particular drug. The rebates eventually make their way back to health plans to help offset the collective costs of premiums. But if a patient needs a particular drug, they will increasingly find that they are paying the full, negotiated price at the pharmacy counter. They never see the real “net” price, after the rebate is applied much later. The rebate is paid to the health plan, not the patient buying the drug.

Government policies help push the list prices higher, even as the net prices grow more slowly and in some cases even decline. For one thing, mandatory rebates required by

programs such as Medicaid and 340B create incentives to launch drugs with high list prices if companies know they will be required to provide a fixed rebate off those charges. The use of average sales price in Medicare provides similar incentives to launch with a high list price, so do market conditions that largely prevent companies from offering up-front discounts to health plans and instead force them to compete based on providing rebates.

Because companies can negotiate based only on providing rebates rather than discounts, they know that the list price will bear increasingly less relation to their real price.²⁰

This is another place where Congress can act to provide more market competition based on a system where purchasers can demand discounts up front, rather than back-ended rebates. Discounts would actually benefit consumers more evenly since consumers would have the opportunity to acquire drugs at the pharmacy at the discounted price.

It gets to the issue of why there is this artificial divide between the list and net price in the first place. Why, in other words, does the discounting in the drug space take the form of rebates paid to pharmacy benefit managers through a convoluted system on the back end of the transaction, rather than an up-front discount on the drugs?

It all stems from litigation in the late 1990s, brought by chain store pharmacies, that claimed that drug makers were colluding to discount to HMOs and not providing the same discounts to pharmacies, in violation of Sherman Antitrust Act. Drug makers contended that they did nothing wrong, and the discounts they made available to HMOs and providers were appropriate because these purchasers could move market share, while the pharmacies could not.²¹ The litigation, which comprised dozens of separate cases, was ultimately consolidated into a single class action. Drug makers eventually settled the suits. They agreed to offer the same price to all channel partners. In other words, discounts that they made available to HMOs would also be available to pharmacies.²²

To get around this outcome, the drug makers moved away from offering discounts and toward today's model of rebates. These rebates are based on complex formulas tied to some measure of units of a drug that are sold. The idea was that these rebates could be offered to everyone, including pharmacies. But the pharmacies would never be able to satisfy the burden of evidence to qualify for the rebates. Only the health plans could make the required representations related to how many units of a particular drug that it sold.

This raises an interesting question: Could Congress legislate to make it legal for drug makers to engage in price discrimination based on purchaser, offering discounts to one channel and not to another, so long as the drug makers were not conspiring to offer

similar discounts? The answer, probably, is yes. If drug makers could offer discounts, purchasers would start demanding them. A discount would potentially be far more equitable, transparent, and pro-competitive than a rebate—especially where the rebate does not flow evenly to all consumers. Increasingly, it's consumers who are underinsured or uninsured that are stuck paying the full list price at the pharmacy counter.

If the “rebate” came in the form of up-front discounts, rather than back-ended givebacks, more consumers who are underinsured would benefit from the negotiated “real” price.

We Should Allow Drugs to be Priced Based on Outcomes and Indications

Third and finally, we need to allow drugs to be priced based on how they are being prescribed and the outcomes that they deliver. Right now, regulation largely prevents the same medicine from being sold at different prices when it's being used in different settings. For example, a drug must largely be sold at the same price whether it is used in a high-value indication or used for which there might be less evidence of benefit. The same rules also largely prevent drugs from being priced based differently based on measuring the outcomes that they deliver to a group of patients. Regulations largely foreclose these kinds of arrangements, referred to collectively as value-based contracts.

Among other things, the Office of the Inspector General would probably view such indication-based discounts as an illegal inducement for doctors to prescribe more of a drug for a certain use. The FDA might interpret a contract tied to an indication or outcome that isn't precisely specified in the drug's FDA-approved label as a form of illegal, off-label promotion. In order to enable these arrangements, FDA would need to concede that commercial, contract-related communications constitute protected speech under the First Amendment and thus are not subject to the agency's active regulation.²³

The way that the Medicaid best price and average sales price (ASP) are calculated (two price schedules that are maintained by the Centers for Medicare and Medicaid Services (CMS) for the purpose of price setting) would also present an obstacle to these kinds of value-based contracts. Under these price schedules, when drug companies offer indication- or outcomes-based discounts, they would be penalized across all of the indications for which a drug is prescribed. The discounts offered in one indication-based contract would lower the cost paid by every plan that ties its price to the ASP and Medicaid best price. It would also mean that the benefit of these discounts would be available to health plans—through a lower overall Medicaid best price and ASP—even when the health plans don't enter into the same value-based contracts.

Congress could act to provide a safe harbor when companies pursue these value-based contracts, to make sure that sponsors don't face regulatory obstacles from FDA, CMS, or OIG when the contracts meet certain public health goals. This could provide another vehicle for purchaser to demand more discounts from drug makers, and more ways to tie these discounts to circumstances and outcomes that matter most for patients.

Conclusion

These policies will take on increasing importance as the nature of drug coverage changes. These changes in coverage are partly a consequence of the Affordable Care Act, which favored narrow provider networks and drug formularies as a way to accommodate the cost of other regulatory priorities. This has left more consumers underinsured for their drug purchases. The exchange-based plans also relied on constructs like closed drug formularies. These same insurance constructs—having been rendered politically acceptable under the ACA—are being imported into commercial insurance plans as well. The National Business Group on Health, in a 2016 survey, found that 50 percent of employers reported that they plan to use a closed formulary to help control costs.²⁴

The result is a sharp, secular change in the structure of drug coverage. More consumers are paying the list price for drugs, not the lower net price eventually paid by health plans, after rebates are applied. Congress can act to increase competition by enabling more drugs to reach the market, especially low-cost generic medicines. And enabling more health plans to negotiate discounts that can directly benefit consumers.

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