Senator Collins' Q&A with Dr. Gottlieb
Appropriations Subcommittee
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COLLINS: Doctor, we have previously discussed the need for improved health care provider education with regard to the prescribing of opioids. Medicaid beneficiaries are prescribed pain relievers at a higher rate than those with other sources of insurance, and they also, not surprisingly given the higher rate, have a higher risk of overdose from prescription opioids, heroin, and fentanyl. What opportunities do you see for greater collaboration among the FDA, CMS, state Medicaid directors, medical societies, and other parties in order to address this problem of appropriate prescribing of opioids?

GOTTLIEB: I appreciate the question Senator, I'd also add DEA to that because there might be things we can do in conjunction with our partners at the Justice Department. As part of the steering committee we've set up, we're currently having discussions about what steps we can take to improve provider education, and maybe take a look at packaging as well, as a way to help make sure prescriptions more appropriately match the circumstances in which they're being written. I don't want to get to far ahead of that process other than to say that this is something that's at the top of the list of things that we're looking at right now, what additional steps we can do under our current authorities both through the risk management plans that we currently promulgate in conjunction with the approval of opioids and other narcotics, other scheduled drugs, as well as in partnership, potentially, with the DEA which obviously has authority to potentially look at certain requirements as part of the process for giving a DEA license to individual practitioners.

COLLINS: Thank you. As you know from our numerous discussions, the Senate Aging Committee last year undertook a major investigation examining the explosion in prices of off-patent prescription drugs for which there is no generic equivalent. In one case, a drug was purchased by a company that played absolutely no role in developing the medicine, and then raised its price by 5,000 percent overnight. And one of the problems that we found is that these companies warded off competition from generic companies by putting their drugs in Closed Distribution Systems or in specialty pharmacies. And the intent in doing so was to delay access or even block access to a sufficient quantity of the brand-name drug to do the bio-equivalency studies that the FDA requires. These abuses are serious and contribute to the cost increases that we're seeing. By one estimate in 2014, such abuses resulted in increased cost to consumers of $5.4 billion per year. I've had extensive conversations and hearings and privately with Dr. Janet Woodcock about this problem, and she has testified that FDA has done 150 referrals to the FTC to take a look at this anticompetitive process without any success, and she suggested that there needs to be a law change in order for the REM system not to be abused. I know that you've testified before the House Appropriations Subcommittee and noted your concern about this type of anticompetitive behavior. Should Congress revise the REMs law as suggested by Dr. Woodcock since there's only so much that FDA can do now about the problem?

GOTTLIEB: Well, I appreciate the question Senator. I know there's some legislation Congress is currently contemplating in this regard, and we'd be happy to provide technical assistance with that and I think we already have. I think there are things we can do in the scope of our current

authorities, through administrative action, to address this challenge. There's two different challenges here: one is the REMs, which is sometimes misused as a way to block the ability of generic companies to get access to the samples they need in order to develop a generic drug, it takes between 1,500 to 3,000 actual doses in order to develop a generic equivalent. The other issue is things embedded in the contracts with sometimes the distributer or the specialty pharma companies that make it hard for the distributers or pharmacy companies to sell the drugs to the generic companies when they try to purchase them at fair market value. So there are two different issues; some I think we can solve or address through the scope of FDA, and some might require us, if we want to try to address them administratively to partner with Medicare where there might be opportunities to do that. We can identify, to your point, the situations where we believe the generic companies aren't able to get the access to the doses and make referrals, we can't full address some of the commercial restrictions that prevent them from getting access to those doses but we could in partnership with other agencies.

COLLINS: Thank you.