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Statement by Michael A. Carrier
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to Health Subcommittee of House Committee on Energy & Commerce
on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

I. Introduction

- A. Drug prices too high
  1. Brand drug companies abuse system by delaying generic entry
  2. Brands withhold samples needed by generics, pay generics not to enter market, and abuse regulatory system
- B. This conduct cannot be justified by patents or innovation
- C. Congress can address through legislation on samples, settlements, and regulatory fixes

II. My Background

- A. I have studied pharmaceutical antitrust law as co-author of leading IP/antitrust treatise; author of more than 115 articles (60 on pharmaceutical antitrust law); author of "amicus" briefs on behalf of hundreds of professors; and one frequently cited in media (1500+ times) and courts (including Supreme Court)

III. Sample denials: CREATES Act and FAST Generics Act

- A. Generics need samples to reach market but brands have denied them
  1. FDA has received 150 inquiries from generics unable to obtain samples; costs $5+ billion/year
  2. FDA powerless: its "generics are safe" letters ineffective; agency not examine competition issues
  3. Sample denials violate legislative provision that brands not use REMS to "block or delay" generics
- B. Brands have abused Single Shared REMS program, applicable when brand, generic each have REMS
  1. Have slow-walked negotiations, sometimes for years (e.g., Suboxone, Xyrem)
     a) FDA acts "after substantial delay" and "ha[s] to try and try and try and try, and then finally . . . declare defeat and . . . go ahead and let the generics have their own system."[1]
- C. Antitrust law uncertain – even if should be violation for conduct making no economic sense, courts could accept brands' arguments based on safety, product liability, and lack of duty to deal with rivals
- D. Sample denials
  1. H.R. 965, Creating and Restoring Equal Access to Equivalent Samples Act (CREATES) of 2019, offers simple fix, allowing targeted lawsuits to obtain samples
  2. Requirement that generic obtain "covered product authorization" addresses safety concerns
  3. Unequivocal limitation of liability addresses liability concerns
  4. Remedies of attorneys' fees/costs and monetary amount sufficient for deterrence will stop abuse
  5. H.R. 985, Fair Access for Safe and Timely (FAST) Generics Act of 2019, would allow HHS Secretary to require access to samples as condition of approval/licensing
- E. Shared REMS
  1. Bottleneck relieved through CREATES Act's "different, comparable" REMS, FAST Generics' 120-day waiver
- F. Legislation offers simple fix to non-REMS restrictions like Martin Shkreli's 5000%-price-hiked Daraprim
  1. 62 years after approval and for no apparent reason, Turing restricted distribution system; official "would block [generic] purchase" and company "do[es] [its] best to avoid generic competition."[2]

IV. Pay-for-Delay Settlements: Open 180-day Bottleneck

- A. Brands paying generics to delay entering market costs consumers $3.5 billion a year
- B. Pay-for-delay settlements reveal perversion of Hatch-Waxman Act (HWA)
  1. 180-day exclusivity period twisted from incentive to invalidate patents to bottleneck blocking entry
     a) By paying first-filer, brand delays entry by all generics, as 180-day period begins when generic enters
     b) Toothless forfeiture provisions apply after years-delayed appellate court decision
     c) Later-filing generics do not challenge patent: not obtain exclusivity, may lack standing
- C. Solution: expand universe of parties eligible for 180-day exclusivity
  1. H.R. 1506, Fair and Immediate Release (FAIR) of Generic Drugs Act, expands "first applicants" to include:
     a) Generics obtaining judicial invalidity/noninfringement decision
        (1) More likely to lead to competition than challenge-blocking settlement

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[1] *See* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL LAW REVIEW 1, 41-47 (2017).

[2] *See* Michael A. Carrier, Nicole L. Levidow, & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECHNOLOGY LAW JOURNAL 1379, 1400 (2017).

b) Generics not sued for infringement
(1) Brands lack incentive to sue later filers (could invalidate patent); change allows earlier generic launch
2. 180-day incentive not needed: shared exclusivity not stop first-filing challenges by multiple generics, and presence of brands' own generics not reduce challenges even in small markets

D. Solution harnesses Congress's ability to directly address regulatory evasion
1. At oral argument in *FTC v. Actavis*, Justice Scalia stated that "Hatch-Waxman made a mistake" and Justice Kagan lamented the Act's "glitch . . . that the 180 days goes to the first filer" and that once the filer "is bought off, nobody else has the incentive" to challenge patents (Transcript, at 11, 35)

V. Pay-for-Delay Settlements: Illegality

A. H.R. 1499, Protecting Consumer Access to Generic Drugs Act of 2019, beneficial
B. Most important, creates framework of illegality applying when generic receives "anything of value" (including exclusive license) and delays "research . . ., development, manufacturing, marketing, or sales"
1. Illegality makes clear that pay-for-delay settlements anticompetitive and helps FTC prove cases in court
2. Parties allowed to settle cases based on patent, not payment
C. To prevent companies from treating antitrust liability as cost of doing business, FTC can recover penalty
D. H.R. 1499 would address errors like *AbbVie*, where brand provided generic with drug at price "well below what is customary" but court (despite recognizing deal's "large value") concluded it "was not a reverse payment."[3]
E. Two amendments to H.R. 1499 would make clear that courts cannot undermine landmark *FTC v. Actavis* decision:
1. Generic entry before end of patent term is not automatically procompetitive
a) Despite Supreme Court's overturning of scope-of-patent test, E.D. Pa. court in *AbbVie* and Administrative Law Judge in *Impax*[4] assumed pre-expiration entry procompetitive
2. Risk aversion is not a legitimate procompetitive justification
a) Third Circuit in *Wellbutrin*[5] relied on risk aversion (rejected by Supreme Court as defense) to dismiss argument that size of payment reflects patent weakness

VI. Orange Book Updating

A. Notice function
1. Generics, doctors, and consumers can learn critical information from Orange Book
2. H.R. 1503, Orange Book Transparency Act of 2019, useful in incorporating information on patent invalidity
3. Enhanced certainty from making clear that patents on drug delivery devices cannot be listed in Orange Book
B. Amendment to H.R. 1503 could prohibit listing of REMS patents in Orange Book[6]
1. Brand describes REMS in product label but generic must have same label (21 U.S.C. § 355(j)(4)(G))
2. Patents on REMS programs thus put generic between rock of FDA law ("Don't alter label!") and hard place of patent law ("Don't infringe patent!")
3. Not needed for innovation: Many REMS patents issued before *Alice* decision restricting patentable subject matter and not appear necessary to recover significant investment

VII. Purple Book Accessibility

A. Purple Book, applying to biologic products, not as useful as Orange Book
1. H.R. 1520, Purple Book Continuity Act of 2019, would make Purple Book searchable, enhancing usefulness
2. Helpful to consider types of biologic patents to be included in Purple Book

VIII. Conclusion

A. Drug prices too high; generic and biosimilar competition would lower them
B. Legislation on samples, settlements, and regulatory system would achieve goals without affecting patents or innovation

[3] *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015).

[4] *In the Matter of Impax Labs., Inc.*, Dkt. No. 9373, at 144, 146 (FTC ALJ Chappell May 18, 2018).

[5] *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017).

[6] *See* Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 BOSTON UNIVERSITY LAW REVIEW 1661 (2017).