TESTIMONY OF
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Before the

UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY & COMMERCE SUBCOMMITTEE ON HEALTH

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Chairwoman Eshoo, Ranking Member Dr. Burgess, and distinguished members of the Energy & Commerce Subcommittee on Health, I want to thank you for the invitation to appear before you today to discuss competition to lower drug prices in the United States.

My name is Lou Kennedy and I am the CEO of Nephron Pharmaceuticals Corporation ("Nephron"), proudly headquartered in West Columbia, South Carolina. Nephron employs 1000 people and is a leading manufacturer of sterile generic medications and the compounding of drugs on the FDA shortage list for US hospitals and surgery centers. High-quality and affordable products for patients is the company focus.

Nephron believes drug patents should be controlled by a patent approval system that reasonably rewards innovation, but also incentivizes appropriate patent challenges, particularly for Orange-book listed patents. A fair playing field would ensure erroneously granted patents are not used to prevent generic competition and maintain monopoly drug prices to the detriment of American consumers.

The Trump administration has published the "American Patients First" policy position which if implemented, would encourage drug competition, and reduce drug prices in the United States. The "American Patients First" policy statement notes the negative impact of "parking" the 180-day exclusivity awarded to eligible "first-to-file" abbreviated new drug applications or "ANDAs". Parking, is the practice of delaying the introduction of a first-to-file ANDA by entering into a delayed entry settlement agreement between the ANDA filer and the original patent holder, this is commonly known as a "pay-to-delay" settlement.

Nephron applauds this policy position because of the immediate pricing reductions of second and follow-on suppliers of a generic drug. Pricing data commonly demonstrates drug costs for a single medication, will drop approximately 80% when the fourth competitor enters the market. Parking along with Paragraph IV patent challenges, and REMS program abuses, add significant delays to generic competition, thereby maintaining higher monopoly drug prices.

Nephron shares the goal of the Committee and the Administration of addressing the problem of purposeful parking that delays generic competition from tentatively-approved, subsequently-submitted ANDAs. However, while Nephron shares the goal of H.R. 938 ("Blocking Low-Cost Operations and Competition while Keeping Incentives for New Generics Act of 2019" or the "BLOCKING ACT of 2019") we are concerned as currently drafted, the legislation would undermine the value of the 180-day exclusivity period. This recent draft would prematurely terminate or reduce the first-to-file ANDA 180-day exclusivity period, by providing an overly-broad additional exclusivity "trigger" that can result in forfeiture of the award. This outcome would not be in the best interests of patients and taxpayers, as it would weaken the 180-day exclusivity incentive for generic manufacturers to drive challenges of brand patents.

The 180-day exclusivity period is important to allow the first-filer to bring its product to market at the earliest possible time. We are also concerned that this well-intentioned legislation fails to address pay-to-delay settlements between a first-to-file generic company and its brand counterpart, which is the main source of delays for generic competition.

Nephron believes that pay-to-delay agreements allow weak, unchallenged patents to remain in place, and serve as barriers to block subsequent generic drug manufacturers from obtaining final approval. The current framework provides no incentive for subsequent applicants to challenge blocking patents that are left untested in pay-to-delay settlements. Even if a subsequent applicant is successful in challenging all of the blocking patents, it cannot enter the market until a first applicant launches, allowing the 180-day exclusivity to expire. Delaying the start of a 180-day exclusivity period, results in higher prices for a drug.

The FAIR Generics Act, HR 1506, would achieve the needed broader fix of the parking problem by allowing subsequent applicants that win their patent challenges to share the 180-day exclusivity award with the first generic to file an application challenging a brand patent(s). As such, Nephron urges Congress to take action to fix the broader parking problem, not just a narrow subset of the problem, by enacting legislation along the lines of the FAIR Generics Act. We would welcome the opportunity to work with the Committee to strengthen and refine the legislation, which would enable a comprehensive solution to the parking problem. The Trump Administration, the Committee, and Nephron are all in agreeance of the need to lower drug costs for the American public.

Nephron supports pending bills related to ANDAs and the 180-day exclusivity—some which are directly related to H.R. 938, and others that are necessary to remove stumbling blocks for ANDAs being filed. The "Protecting Consumer Access to Generic Drugs Act of 2019" aims to prevent pay-to-delay settlements between first applicants and brand companies, by adding the clause "exchange of anything of value" to current laws which prevents money from being exchanged for delayed marketing under a parked 180-day exclusivity situation. Nephron believes it is important for there to be agreement options, other than money, for first applicants to settle with brand companies. If there is any agreement between the patent holder and the first-to-file, there should always be options to incentivize for subsequent applicants, which would challenge Orange Book patents as just discussed.

Nephron recognizes this brand gamesmanship is still a problem when generic and biosimilar companies attempt to obtain samples for branded products with restricted distribution, or join in FDA-mandated Risk Evaluation and Mitigation Strategies known as "REMS" with Elements To Assure Safe Use, "ETASU". ETASU REMS include measures such as patient testing, special physician training or certifications, and restricted distribution, the latter which has been exploited to prevent or delay generic market entry. FDA requires shared REMS only for ETASU REMS. ETASU REMS products enjoy extended monopolies, because branded companies have blocked samples and shared REMS entry using unfounded concerns for patient safety with generic products as a block for access to reference samples necessary for product development, testing, and approval. Nephron therefore supports the CREATES ACT (H.R. 965) and FAST Generics Act (H.R. 985), because both promote accessibility of reference product samples, particularly when they are marketed under restricted distribution. In addition, the bills would facilitate the development of shared ETASU REMS.

Nephron believes drug patent work should be carried out by appropriate patent attornies, but does lend general support to two bills aimed at generating and publishing additional product information helpful to the development of generic and biosimilar medicines, the Orange Book Transparency Act of 2019 ("Orange Book Act") and the Purpose Book Continuity Act of 2019 ("Purple Book Act"). The Orange Book Act would, among other things, require additional yet pertinent exclusivity information to be added to the Orange Book, along with including additional patent information, including the status of post-grant proceedings and litigations. The Purple Book Act would require listing certain asserted patent information and bioequivalence information, which would aid in the selection and development of biosimilar products. Keep in mind these compendiums are great aids, but patent search work reveals the ultimate information.

Nephron thanks the Committee for the opportunity to comment on these bills affecting generic and biosimilar product development and looks forward to working with the Committee to refine any of the bills that move forward for full House or Senate votes.