UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Office of Policy Planning Bureau of Economics

> Food and Drug Administration Dockets Management Staff (HFA-305) Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, Proposed Rule

The staff of the Federal Trade Commission

Office of Policy
Planning, Bureau of Economics, and Bureau of Competition

1 appreciate the
opportunity to respond to your request for comments on the Proposed Rule, RIN 091-Al21,
Establishing Over-the-Counter Hearings Aids, implementing pertinent provisions of the
FDA Reauthorization Act of 2017.2 We write to express our support for the proposed rule,
given the benefits to competition and health care consumers that the rule would likely
promote.

As noted in the

- x The increased availability and diversity of lower-priced bundles of hearing aidsand services for consumers for whom price or access to services is a barrier to acquisition and use of hearing aids.
- x The development and entry of remote and webbased ancillarytools for hearing aids.
- x Increased competition and innovation in legacy hearing aids, given a supply expansion for both lower-cost alternative hearing aids and new channels of distribution.

FTC \$aff notes, at the outset, that the central procompetitive provisions of the Proposed Rule are required by statute: establishment a regulatory category of OTC hearing aids,35 streamlining of regulations for hearing aids,6 and preemption of contrary state laws,37 We note, fo "y.z,y.öq aäBñÚal/r D"Cã,' 3Jn a''ë ± @ € p† '—‡ 4 " ™ p•'á ' P

Someportion of the average price may be due toactors other than the cost of the hearing aids themselves, such as inefficient channels of distribution diminished competition. For example, it has been reported that the U.S. Department of Veterans Affairs

• '" \ddagger — Š f • — TM 62 The surväyćevidence also suggests that a quarter location aid consumers never use a single followup appointment.63

3. Search and Information Costs:

An additional barrier to access for consumer are high information costs or search costs. PCAST, the National Academies, and workshop participants altertoa lack of transparency in hearing aids and hearing health care markers. Consumers have difficulty " $\ddagger \bullet \ddagger f$ " ... $\S \hookleftarrow \bullet$ " '" $\lnot \lor \bullet \lor \bullet$ '" $\lnot \lor \lor \bullet \lor \bullet$ '" $\lnot \lor \lor \bullet \lor \bullet$ '" $\lnot \lor \lor \lor \bullet \lor \bullet$ comparisons between various models and varied bundles of hearing aid and ancillary services, such as hearing aid adjustments by audiologists.

New channels of distribution may be especially helpful for the development and marketing of new low-cost safe and effective hearing aids, not least because relatively low priced products may appeal to new hearing aid consumers who cannot afford the buled of hearing aids and services that dominate traditional channels of distribution. In addition, such consumers may benefit from the provision of relatively lowcost follow-up services via internet or telephony, along the lines of the RTHIservices the Walready provides to its audiology patients?

A supply expansion comprising both extant devices made more widely availabled new devices may have wider competitive benefits still, as the presence of lowericed and more convenient alternatives could exert competitive pressure on legacy devices and established channels of distribution. Potential effects include lower prices for some legacy devices and increased availability of unbundled pricing (or more varied bundles). Without suggesting that any paticular product-plus-services bundle is optimal for all hearing aid consumers, where devices are established as safe and effective, competition within and across bundles and models of distribution may best meet the demands and budget constraints of varied health care consumers.

Streamlined and clarified regulations and more uniform national regulations should further serve to lower regulatory costs (and potential liability), expand supply, and, hence, to increase access. Along those lines, we natspecific aspect of the proposed regulatory simplification. Whereas most hearing aids are not, strictly speaking, prescription devices, extant regulations require that a prospective purchaser must either present to a dispenser (vendor) a signed statement medical evaluation from a physician or, in the alternative, waive the medical evaluation requirement by signing a formal

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28 Id. at § 709(b)(1).
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- ³¹ Id. f- yr { "No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of overe-counter hearing aids . . . through inperson transactions, by mail, or online, that is different from, in addition to, or otherwise ot $(\uparrow \ddagger \bullet \checkmark \dots f \ \ \ \ \) = (1 + 2) + (1 + 3) + (1 +$
- 32 Sectext accompanying notes 39 44, infra.
- 33 See, e.gFTC Workshop, Testimony of Frank Lin, p. 107; Testimony of Ian Windmill, p. 109.
- 34 PCAST 2015 supranote4, at 3.
- ³⁵ FDARA Section 709(b)(1-)(2).
- ³⁶ ld.
- ³⁷ Id. at Section 709(b)(4).
- ³⁸ ld.
- ³⁹ Frank R. Lin, et al.Hearing Loss Prevalence in the United State9ARCHIVESINTERNALMED. 171 (2011)Loss РТеогаК€ "Æ y(%

²⁹ Id. at § 709(b)(2).

³⁰ Id. at § 709(b)(2)(d).

<u>HEALTHHEARINGHEARBETTERSPOT</u>1 The 2016 National Academies Report observed that the average retail price of a pair of hearing aids in 2013 was \$4,700 (in 2013 dollars). NASEM, supra note at 11. Similarly,

⁵⁹ As contemplated in the Proposed Rule, medical care or other ancillary services may be recommended for some hearing heath indications; and they may be required for certain higherisk devices or other interventions, instead of the low-risk ClassI type technologies that would be available as OTC hearing aids.

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