Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	
	)	
Standards for Hearing-Aid Compatible Handsets	)	WT Docket No. 20-3
	)	
	)	
	)	
Information Collection Being Reviewed by the Federal Communications Commission	)	OMB 3060–0999

COMMENTS OF THE CENTER FOR REGULATORY EFFECTIVENESS

Jim Tozzi
Center for Regulatory Effectiveness
1601 Connective Avenue, NW, Suite 501
Washington, DC 20009
tozzi@thecre.com

July 5, 2021

TABLE OF CONTENTS

BACKGROUND

A. Personal Sound Amplification Products Which Advertise Their Compliance with FCC Compatibility Requirements Should Be Required to Provide Advertising and Promotional Materials to the FCC 5

B. PSAPS are Acceptable for Amplifying Sounds from Distance Sources but not for Treating Malfunctions of the Ear 7

C. The Answer: Utilizing Reporting Requirements—Not Regulations 8

D. The FCC is a Cornucopia of Information for the FDA 11

E. Taking Steps That Permit the Public Sector to Assist in Compliance 12

F. The Ask 13

CONCLUSIONS 15

SUMMARY

The Center for Regulatory Effectiveness (CRE) applauds the work of the FCC to provide access by users of hearing aids to wireless handsets. The action taken by the FCC in conjunction with the oncoming creation of a new class of hearing aids, Over the Counter Hearing Aids (OTC HAs), will result in a substantial rejuvenation of the market for hearing aids.

The resultant market will not only present an increased range of choice for consumers but could also lead to their confusion if they are not provided succinct information from which to base their decisions. The most significant source of confusion is the difference between a hearing aid and a PSAP, a personal sound amplification product.

The Federal Trade Commission has been most vigilant in assuming a prominent role in promoting the health of our citizenry by taking the needed steps to ensure PSAPs are used as intended, as so described by the U.S. Food and Drug Administration. The FDA states that hearing aids and PSAPs differ "in that only hearing aids are intended to make up for impaired hearing…". Choosing a PSAP as a substitute for a hearing aid can lead to more damage to your hearing."[1] To this end, in recent litigation, the FTC settled a suit against a party who overstated the merits of a sound amplifier and stated that it was suspending a judgment of $47 million given the defendants agreement to "an order that will require them to have human clinical testing to support future representations."

The FCC has the statutory authority to impose reporting and recordkeeping requirements on the PSAPS. Consequently CRE recommends that the pending Information Collection Request be modified to require the PSAPS who claim in their advertisements that their devices are

[1] U.S. Food and Drug Administration, Center for Devices and Radiological Health, *Guidance for Industry and Food and Drug Administration Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products* (Feb. 25, 2009).

compatible with a particular handset submit the attendant marketing brochures and related material to the FCC and post it on their website. This recommendation is commensurate with the existing program of the FCC to assign IDs to those PSAPs meeting the aforementioned requirements and obviates the need for the FCC to take any additional action beyond making the aforementioned submissions available to the public on its website.

We are now going to demonstrate the need for making the reporting requirements recommended by the Center for Regulatory Effectiveness applicable to PSAPS and to be so mandated in the forthcoming actions of the FCC and OMB in the collective discharge of their responsibilities under the Paperwork Reduction Act. The following is a quote from a manufacturer of a PSAP:

Syncs with Smarthphones

" Like most other Bluetooth headsets, our products let you take phone calls directly through the device and stream music or audio from your phone to the device".

The underlying principles set forth in the FCC Compatibility program imparts value to PSAPS; the relationship will become even more striking should the FCC decide to include PSAPS in its benchmarking program. In return those PSAPS who capitalize on this program should be directed to take the necessary steps to allow the public to make the informed decisions needed to protect their health, namely making their marketing and promotional material easily accessible to the public for peer review by posting it on their website and also furnishing a copy to the FCC. To this end, section D of this submission highlights the prominent role that the FCC can play in assisting the FDA comply with a statutory mandate regarding PSAPS. CRE has developed an Interactive Public Docket dedicated to the conditions necessary for a science-based compatibility between hearing aids and PSAPS titled Enhancing Hearing Through Smart Regulation.

Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	
	)	
Standards for Hearing-Aid Compatible Handsets	)	WT Docket No. 20-3
	)	
	)	
	)	
Information Collection Being Reviewed	)	
by the Federal Communications Commission	)	OMB 3060–0999

COMMENTS OF THE CENTER FOR REGULATORY EFFECTIVENESS

The Center for Regulatory Effectiveness (CRE) hereby comments on the Federal Communications Commission's (FCC) Information Collection Request to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.

BACKGROUND

A. Personal Sound Amplification Products Which Advertise Their Compliance with FCC Compatibility Requirements Should Be Required to Provide Advertising and Promotional Materials to the FCC

In 2016, the FCC asked the public to present their views on the place Personal Sound Amplification Products (PSAPS) might play in addressing the compatibility of PSAPS with wireless handsets.

The FCC stated that:

*"*As interested parties prepare a report on the achievability of a 100 percent hearing aid compatibility deployment benchmark, we expect that they will consider alternative hearing aid compatibility technologies, along with emerging technologies and devices designed to assist in modifying or amplifying sound for individuals with hearing loss, such as **personal sound amplification (PSA) products."**

Five years later, in 2021, justifiably, the FCC did not include PSAPS in the technologies to be included in the technologies to be used for compatibility deployment. The absence of PSAPS from the 2021 FCC Report and Order does not suggest that the FCC is not aware of the public policy implications of the technology. The misuse of PSAPS as a mechanism for addressing hearing loss leads to threat to public health; in a nutshell, PSAPS are to be used for issues dealing with hearing quaint sounds at a distance but not for issues dealing with the basic functioning of the ear. It is for this reason that PSAPS have been under the watchful eye of other regulators; for example, FDA concluded:

"However, PSAPs are subject to applicable provisions of the Radiation Control for Health and Safety Act of 1968, under which FDA regulates electronic products that emit sonic vibrations, such as sound amplification equipment. (See also 21 CFR 1000.15.) Manufacturers of PSAPs must report defects and adverse events and take other measures described in 21 CFR Part 1003. Manufacturers of PSAPs must also comply with the requirements to repurchase, repair, or replace electronic products required under 21 CFR Part 1004." In addition, the FCC has implemented an ID system for certain PSAPs which is discussed in detail in Section C below.

In summary those PSAPS which orchestrate benefits from the objectives of the FCC compatibility program should no longer be excused from its reporting requirements as explained in detail in section E below.

B. PSAPS Are Acceptable for Amplifying Sounds from Distance Sources but not for Treating Malfunctions of the Ear

There are critically important differences between hearing aids and PSAPS As highlighted by the FDA:

A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. A PSAP is a wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities.[2]

Importantly, "while some of the technology and function of hearing aids and PSAPs may be similar, the intended use of each article determines whether it is a [medical] device or an electronic product."[3] In essence, hearing aids are medical devices tightly regulated by the FDA, whereas PSAPs are consumer electronics that have largely remained unregulated.

The FDA has made it clear that the intended use of a PSAP, which may be based on advertising, labeling, and promotional materials, will determine whether the consumer product should instead be classified as a medical device and thus subject to the regulatory requirements applicable to hearing aids. PSAPS that promote, either directly or indirectly, their being products for use by hearing impaired consumers cause the product to become a medical device and thus subject to regulation as a hearing aid by the FDA. However, despite this clear guidance by the FDA, many PSAP manufacturers continue to represent their products as intended to help with hearing loss. In some instances a close reading might even suggest that the manufacturers are classifying

[2] U.S. Food and Drug Administration, Center for Devices and Radiological Health, *Guidance for Industry and Food and Drug Administration Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products* (Feb. 25, 2009).
[3] *Id.*

their product as "hearing aids."[4]

C. The Answer: Utilizing Reporting Requirements—Not Regulations

The challenge being addressed herein is to determine the best way to provide the consumer with relevant information when making a decision as to purchase a hearing aid or a PSAP. Regulation should be the method of last resort not the method of initial consideration.

Therefore, the thrust of this recommendation is to simply assemble the information presently collected by the FCC in a number of different venues into one easily accessible website which is available to the public.

First, this proceeding, which is titled "*Standards for Hearing-Aid Compatible Handsets*," is the ideal proceeding to address the objectives discussed herein. We arrive at this conclusion because of the substantial reporting requirements set forth in "i" of the final rule. More specifically, reporting requirements are governed by Information Collection Requests (ICRs), which are ultimately decided upon by OMB. Each of these ICR's are accompanied by a Supporting Statement which describes the attendant reporting and recordkeeping requirements associated with the ICR.

CRE has reviewed some of the predecessor ICR's for programs which are nearly identical to the one under development at the current time. Here is a key statement in a predecessor ICR which provides the information needed to oversee PSAPs without regulating them:

"To assist the Commission in monitoring the implementation of the new requirements and to provide information to the public, the Report and Order also required manufacturers and service providers to continue to file annual reports on the status of their compliance with these requirements, and required manufacturers and service providers that maintain public websites to

[4] Each reader should consult this advertisement and arrive at their own conclusion.

publish up-to-date information on those websites regarding their hearing aid-compatible handset models". The annual reports required in the Order contained different and additional information than in previous versions of this information collection and, for the first time, were required to be submitted by manufacturers and service providers using electronic FCC Form 655. The reporting and third-party disclosure requirements for the aforementioned Report and Order were approved by OMB on June 5, 2009 under OMB Control Number 3060-0999. Authority: Hearing Aid Compatibility Act of 1988 (HAC Act).

The thrust of the strategy set forth herein duplicates the aforementioned reporting requirements because it is based upon the substantial amount of information presently reported to the FCC. More specifically as directed in the FCC final rule of May 4, 2021, titled *Standards for Hearing Aid-Compatible Handsets* the agency has opined:

(1) "Presently…handset manufactures must file a …forum showing compliance with these provisions by July 15 each year….The Commission uses these certifications and reports as the primary method of ensuring that handset manufacturers and service providers are complying with the Commission's hearing aid compatibility rules."

(2) The FCC places a premium on having up-to- date information on certification; it states "Section 20.19(i)(1) requires that each certification and report must be up-to-date as of The last day of the calendar month preceding the due date of each certification or report."

(3) Manufacturers shall submit Form 635 reports on their compliance with the requirements of this section by July 31 of each year.

Content of manufacturer reports

Reports filed by manufactures must include:

(1) Handset models tested, since the most recent report for compliance with the applicable hearing aid compatibility technical ratings, if applicable;

(2) Compliant handset models offered to service providers since the most recent report, identifying each marketing model name/numbers(s) and FCC ID number;

(3) For each compliant model, the air interface(s) and frequency band(s) over which it operates, the hearing aid compatibility ratings for each frequency band and air interface under the ANSI standard (if applicable), the ANSI standard version used, and the months in which the model was available to service providers since the most recent report;

(4) Non-compliant models offered to service providers since the most recent report, identifying each model by marketing model name/number(s) and FCC ID number;

(5) For each non-compliant model, the air interfaces(s) over which it operates and the months in which the model was available to service providers since the most recent report.

(6) Total numbers of compliant and non-compliant models offered to service providers for each air interface as of the time of the report.

(7) Any instance, as of the date of the report or since the most recent report, in which multiple compliant or non-compliant devices were marketed under separate model name/numbers but constitute a single model for purposes of the hearing aid compatibility rules, identifying each device by marketing model name/number and FCC ID number.

(8) Status of product labeling

(9) Outreach Efforts

(10) Provide a link to the manufacturer's website, if available

The essence of the strategy outlined herein is for those PSAPS which reap a benefit from advertising that they are compatible with a particular handset then such advertisements and related statements regarding their ability to address a particular hearing problem should be available for public scrutiny by posting their claims on a readily accessible website and providing a copy to the FCC.

D. The FCC is a Cornucopia of Information for the FDA

"Generally, owners or operators of establishments that are involved in the production and distribution of medical devices intended for use in the U.S. are required to register annually with the FDA. This process is known as establishment registration (Title 21 CFR Part 807)"

Hearing aids are medical devices, and, therefore, they have to register. PSAPS are not considered to be medical devices and therefore there is no need to register. However, the Paperwork Reduction Act promotes the interagency sharing of data collected by federal agencies covered by the Act. The Office of Personnel Management states that the Paperwork Reduction Act intended, among other things, to "ensure the greatest possible public benefit from and maximize the utility of

information created, collected, maintained, used, shared and disseminated by or for the Federal Government" and to "improve the quality and use of Federal information to strengthen decision-making, accountability, and openness in Government and society."

One thrust of this proposal is to use data collected by the FCC for the betterment of the American public through its subsequent use by the FDA. In particular, this initiative is aimed at facilitating the implementation of a statutory directive which the FDA must implement shortly after the FDA proposes a final rule on the implementation of the Over-the-Counter Hearing Aids Act which states:

(c) New Guidance Issued--Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update and finalize the draft guidance of the Department of Health and Human Services entitled ``Regulatory Requirements for Hearing Aid Devices and ***Personal Sound Amplification Products''****, issued on November 7, 2013.*

Such updated and finalized guidance shall clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a device in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and which products meet the definition of a ***personal sound amplification product****, as set forth in such guidance.*

Given the extremely stringent deadlines for the FDA, as described above, coupled with the fact that the FCC has a well-established system for collecting information from devices which assist consumers interested in sound devices, CRE recommends that the FCC issue a directive requiring the manufacturers of PSAPS who claim in their advertisements that their devices are compatible with a particular handset provide the totality of the copies of their advertising and promotional

material to the FCC. Such an action would be in accord with the requirements in the Paperwork Reduction Act which directs federal agencies to share in the responsibility for collecting data. And finally, of particular importance, is the fact that the FCC should collect the aforementioned data before a decision is made to incorporate PSAPS into its benchmark for compatibility.

E. Taking Steps That Permit the Public Sector to Assist in Compliance

Both the FCC and the FDA have a range of responsibilities that dwarf their available resources. Consequently mechanisms need to be implemented which will allow the public sector to assist in promoting compliance with the aforementioned disclosures. One such mechanism is set forth in the Interactive Public Docket developed by the Center for Regulatory Effectiveness and made available for use by the public. More specifically, see this Interactive Public Docket, developed for the sole purpose of providing the public a *modus operandi* for assisting in the enforcement of directives issued by both the FCC and the FDA regarding hearing aids and PSAPS and so posted on this website. It is envisioned that a similar mechanism will be employed to address the concerns expressed herein.

The above considerations were delineated in considerable detail in a previous publication in which CRE concluded:

"The introduction of OTC hearing aids could result in the emergence of novice manufacturers located throughout the world who will attempt to enter the US market. The key to designing and implementing a smart regulatory program is to recognize immediately that FDA, acting alone, will not have sufficient resources to ensure that all new products meet relevant safety standards. Manufacturers, working with affected consumers, must be involved in the enforcement on a continuing basis".

The implementation of the recommendations in the following section will make the public sector a crucial player in ensuring compliance with the OTC Hearing Aid legislation.

F. The Ask

It is not CRE's intention to regulate PSAPS. Instead, as stated above, it is CRE's intention that the FCC issue a directive requiring those manufacturers of PASPS who claim in their advertisements that their devices are compatible with a particular handset provide an extremely small subset of the information presently disclosed by other claimants to the FCC. It is recommended that the aforementioned PSAPS report the following information to the FCC:

(1) Company Name
(2) Brand Name
(3) Street Address
(4) City
(5) State
(6) ZIP Code
(7) Contact Phone
(8) Contact Email
(9) Website Address

The aforementioned data elements need to be augmented by the last three on the list currently in effect, as set forth in Section (C) which are contained in the FCC rule and associated Report and Order.

(10) Status of product labeling

(11) Outreach Efforts (including promotional materials and related health claims)

(12) Provide a link to all of the above on the manufacturer's website

FTC Forum 655 is the instrument used to collect the aforementioned information which results in the certification of handset manufacturers compliance with the compatibility requirements of the FCC.

CRE is only requesting that PSAPS furnish 12 data elements. Data elements (1) through (9) are minimal, or even trivial, in term of the burden they impose. Data elements (10) through

(12) are ensconced in the regulatory landscape and have been refined over a number of years.

CONCLUSIONS

It is recommended that those manufacturers of PSAPS who claim in their advertisements that their devices are compatible with a particular handset, provide advertising and promotional material to the FCC and also supply the information defined in items (1) through (12) described above, subject however to the *de minimis* exemption so described in the final rule. The recommendations set forth herein are needed because PSAPS could gain a competitive advantage based upon either an unsubstantiated claim of compatibility or the suggestion that they are equivalent to a hearing aid.

The data obtained by implementing the aforementioned recommendations will be of particular value to the FDA which has a very stringent deadline, so detailed in the OTC Hearing Aid Act, to report on how PSAPS should be addressed under the said Act The Act reads:

New Guidance Issued--Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update and finalize the draft guidance of the Department of Health and Human Services entitled ``Regulatory Requirements for Hearing Aid Devices and ***Personal Sound Amplification Products****'', issued on November 7, 2013. Such updated and finalized guidance shall clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a device in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and which products meet the definition of a* ***personal sound amplification product,*** *as set forth in such guidance*.