DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids; Final Rule

Docket No. FDA-2021-N-0555

Regulatory Impact Analysis
Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This final rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the annualized cost over ten years is $0.009 M per firm, which is unlikely to represent more than three percent to five percent of the revenue of an affected manufacturer, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule will result in an expenditure in at least one year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This final rule will generate potential benefits in the form of cost savings for consumers with perceived mild to moderate hearing impairment who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of state regulations or because they do not shop online. We estimate consumer benefits of between $6 M (million) and $147 M per year based on fifth and ninety-fifth percentile Monte Carlo results with a mean of $63 M per year. Because this is an annual benefit, the annualized benefits are the same at 3 percent and 7 percent discount rates.

The final rule will also generate costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures (SOPs) in response to the rule. We estimate annualized cost of between $1 M and $2 M with a mean of $1 M per year at both 3 percent and 7 percent discount rates.

This final rule may also generate potential benefits and costs for consumers, if any, who currently buy hearings aids online, not bundled with professional services, but who find that the hearing aids meeting the OTC requirements, such as output limits, do not suit their purposes and thus need to move to prescription devices with professional input. The potential cost involves the need to buy the professional services required for the prescription to obtain a hearing aid they can currently obtain without such services, while the potential benefit involves the avoidance of health risks and issues the professional services are meant to address for consumers who require prescription hearing aids. We do not have sufficient information to quantify this potential

tradeoff. We also lack data to quantify costs to any consumers who may currently buy particular brands or models of hearing aids online, that are not bundled with professional services and do not meet the OTC requirements, who would reject alternative prescription or OTC hearing aids that may become available, including those sold online and in brick and mortar shops, and who prefer to wait for their preferred brand or model to either become available as a prescription hearing aid or be redesigned to meet OTC requirements and offered as an OTC device. Such consumers may face some delay in getting their preferred hearing aids.

Combining benefits and costs, we estimate annualized net benefits of between $5 M and $145 M per year based on the fifth and ninety-fifth Monte Carlo percentile results with a mean of $62 M per year at both 3 percent and 7 percent discount rate.

Table 1: Summary of Benefits, Costs and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$63	$6	$147	2020	7%	10 years	
		$63	$6	$147	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential increase in hearing aid and hearing technology use leading to associated health benefits, potential fostering of innovation in hearing aid technology. Potential increase in consumer utility, derived from reduced health risks, from inability to buy some existing hearing aids under existing conditions.						
Costs	Annualized Monetized $millions/year	$1	$1	$2	2020	7%	10 years	
		$1	$1	$2	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential loss of consumer utility from inability to buy existing						

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
		hearing aids under existing conditions, including consumers of online hearing aids that do not meet OTC requirements. Costs to manufacturers of hearing aids sold online that do not meet OTC requirements to render their products and sales methods consistent with the requirements of either OTC or prescription hearing aids.						
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth: Distributional effects are also possible that would favor general retailers and new manufacturers entering into the hearing aid market who do not have relations with current specialty retail suppliers and disfavor specialty retail suppliers and associated workers including hearing healthcare professionals, and established manufacturers with relations with those suppliers.							

II. Economic Analysis of Impacts

A. Comments on the Proposed Rule and Changes to the Proposed Rule

We received a small number of comments relating specifically to issues and our requests for information in the preliminary regulatory impact analysis (PRIA). We summarize the significant comments and provide responses in this section. We did not receive information that would require us to revise the analysis we presented in the PRIA. We also made a few changes, most of which were relatively minor changes from the proposed rule; however, we do not have sufficient information to adjust our estimates on the basis of those changes. We discuss those changes in this section after discussing the comments on the PRIA.

Comments on the Proposed Rule

(Comment 1) One comment suggested we failed to take proper account of the effects on all stakeholders in our assessment of social costs and that our estimate of social costs underestimated the true social costs.

(Response) The effects discussed in the comment, the loss of customers or revenue for existing firms, potential firm closures, and reduction in demand for certain job categories, are not social costs per se but distributional issues. They do not correspond to additional resources expended on any given activity because of new regulatory requirements relative to the baseline, but to a reallocation of productive resources. Such distributive issues may, of course, be very important for the firms and people involved, and they may justify governmental response. The comment is correct that those engaged in selling hearing aids under the current regulatory regime may see negative distributional effects, a reduction in profits, as a result of this rule. However, preserving the economic situation of current firms or categories of workers is not an accepted role for FDA. In this case, in the same way some firms and workers may be adversely affected by shifting patterns of demand following this rule, other firms and workers may be favorably affected. Therefore, we have not revised the discussion of social costs and distributional issues we presented in the PRIA.

(Comment 2) One comment said the information we used for the percentage of hearing aid owners with perceived mild to moderate hearing impairment of 60 percent was too low and gave information that suggested the correct value is between 80 and 85 percent.

(Response) The data we presented in the PRIA related to perceptions of hearing aid owners, while the data presented in the comment related to professional assessment in a clinical setting. Because OTC hearing aids are intended to compensate for perceived mild to moderate

hearing impairment, the perception of hearing aid owners is the relevant input for the analysis relating to hearing aid owners or prospective hearing aid owners trying OTC hearing aids.

(Comment 3) One comment argued the figure we used for the average cost of an economy-level hearing aid bundled with professional services purchased from a specialty retail outlet in 2014 of $1,657, or $1,849 in 2020 dollars, was too high, and the comment noted a reference suggesting two-thirds of hearing aid professional practices in 2014 offered devices starting at less than $800 with some starting at $500.

(Response) The information on the lowest cost models available at some specialty retail outlets does not contradict the information on the average cost of an economy-level hearing aid bundled with professional services purchased from a specialty retail outlet, which is the input we used in our analysis. We do not have any information to suggest that the cheaper hearing aids sold by a subset of professional practices in 2014 would meaningfully change the overall calculated mean cost of an economy-level hearing aid. In particular, we do not know how the availability of lower cost models translates to the average cost of models customers eventually buy under professional guidance at specialty retail outlets, the market share associated with the outlets that offer units at these prices, or the lowest cost units available at the remaining outlets.

(Comment 4) One comment suggested the rule may impact insurance coverage of hearing aids, which may affect affordability for some consumers.

(Response) We discussed the distributional issues relating to consumers paying out of pocket and participating in insurance plans along with other consumers in the PRIA and repeat the discussion in the material that follows. The rule does not prohibit insurance plans covering OTC hearing aids; however, if a loss of coverage were to occur, it could affect affordability for

some consumers, which may potentially be at least partially offset by reductions in premiums and the presumed generally lower cost of OTC hearing aids.

(Comment 5) One comment urged FDA to establish a mandatory return policy for OTC hearing aids because purchasers may find that their OTC hearing aids do not perform satisfactorily, or they may otherwise decide that the hearing aid is unsuitable, perhaps after consultation with a licensed person.

(Response) Mandating return policies would constrain manufacturer choice relating to return policies and thus could potentially affect the price for hearing aids that might otherwise be sold with lesser or no return policies. We have insufficient information on potential issues relating to consumers buying hearing aids who do not like or will not use, but cannot return, the hearing aids to evaluate constraining producer and consumer choice along that dimension and thus potentially affecting the price of OTC hearing aids. The preamble to the final rule discusses some legal and policy issues, distinct from these economic considerations, related to mandatory return policies.

Changes to the Proposed Rule

One of the relatively minor changes, in terms of economic effects, that we made in the final rule was to revise the output limits we originally proposed to lower output limits. The output limit for an OTC hearing aid is defined as the maximum acoustic output sound pressure level (SPL), with the prescribed acoustic coupler, when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on. We proposed an output limit of 115 dB SPL at any frequency, except for devices with input-controlled compression and user adjustable volume control, for which we proposed an output limit of 120 dB SPL at any frequency. In this final rule, the corresponding output limits are 111 dB SPL at any frequency, except for devices with

activated input-controlled compression, which have an output limit of 117 dB SPL at any frequency.

We did not analyze the proposed rule along the dimension of output limits. However, to the extent the lower output limits help intended users avoid any health issues associated with unnecessarily high output levels for mild to moderate hearing impairment, the lower output limits may encourage use of OTC hearing aids for the intended user population, which will tend to increase estimated benefits. We do not have sufficient information on the number of consumers with perceived mild to moderate hearing impairment who may want to try OTC hearing aids but really require output limits in the relevant ranges, or the number of consumers who currently buy hearing aids online, not bundled with professional services, and who require output limits in the relevant ranges, to revise our analysis of impacts.

We also considered the potential effect of the lower output limits relative to the proposed output limits with respect to manufacturers that currently sell hearing aids online that do not meet the OTC requirements. Such manufacturers have the choice of modifying their existing products to meet the OTC requirements, including the output limits. At a minimum, manufacturers would have to revise the labeling of their products to meet either the OTC or prescription hearing aid labeling requirements. Manufacturers may also need to revise their online sales process to continue selling the products online. The lower output limits relative to the proposed output limits may mean more products currently sold online would not meet the OTC requirements if manufacturers that would have modified their products to accommodate the proposed limits decide not to modify their products because of the lower final limits. However, we do not have sufficient information on the products involved to revise our quantitative analysis of impacts.

Another relatively minor change to the final rule is that we have revised the wording of the proposed labeling to make it more understandable for hearing aid users (non-experts). We have not revised our estimates of labeling costs because those costs pertain to the labeling in general and not to the particular words or phrasing used in the labeling. Making labeling easier to read for non-experts will generate information benefits for consumers considering OTC hearing aids and will likely increase benefits from consumers switching to OTC hearing aids, particularly over time, as correct understanding of the devices should increase satisfaction with their use. We do not have sufficient information to estimate behavioral changes such as increased uptake based on the differential effects of the revised labeling.

A final change is that the preamble to the final rule explains that FDA does not intend to enforce the requirement to submit a 510(k) and obtain 510(k) clearance where: a hearing aid is legally offered for sale prior to the effective date; the changes that require a new 510(k) are made on or before the compliance date and are made solely to satisfy the OTC Hearing Aid Controls; the changes do not adversely affect device safety or effectiveness; the device is otherwise in compliance with applicable requirements; and on or before the compliance date, the manufacturer documents the changes and its determination that the changes do not adversely affect device safety or effectiveness.

In general, the preamble to the proposed rule did not include an enforcement discretion policy with respect to the 510(k) requirements. In the current situation, not enforcing the 510(k) requirements under the specified conditions would represent a change from the baseline of our usual enforcement policies. The effect of not enforcing those requirements would be a reduction in the cost of introducing new OTC hearing aids under the conditions specified in the preamble to the final rule for cases in which the device modifications necessitate 510(k)s. We do not have

sufficient information to estimate the change in OTC product costs or availability based on the stated intent to not enforce the 510(k) requirements under the stated conditions.

B. Background

The current regulatory approach to hearing aids is based in part on the notion that consumers generally benefit from medical evaluation before they are sold hearing aids, though consumers who are age 18 or older may waive such evaluation. Further, the current regulatory approach presumes that consumers will generally benefit from professional fitting and counseling services upon and after purchase. Federal regulations allow, and all states currently have, state requirements governing the qualifications of those dispensing and fitting hearing aids, including in some cases bans or restrictions on online sales. For these and other reasons, most hearing aids are currently sold through brick and mortar specialty retail outlets. Purchasing hearing aids through specialty retail outlets may increase the price of hearing aids by bundling the devices with professional services thus complicating comparison shopping and price competition, which are further complicated by the fact most specialty retail outlets carry only a limited selection of brands and models with many outlets carrying only one. When consumers are unable to easily cross-compare devices with different features (e.g., acoustic performance, battery life, mobile operating system compatibility), it may impair the discovery function of determining what features they would like out of their device. Complications relating to comparison shopping may thus decrease consumers' satisfaction with their hearing aids. Current FDA regulations may also play a role in terms of concentration in the hearing aid industry in which six larger manufacturers produced about 98 percent of hearing aids in 2013, Ref. [1].

Increased industry concentration may be associated with increased opportunities for non-competitive pricing.

Hearing aids sold online are not subject to these effects and are currently available in most states. Generally similar sound amplification products known as personal sound amplification products (PSAPs) are also not subject to this effect and are also currently available in all states both online and in brick and mortar general retail outlets. PSAPs are intended to amplify sound in specific listening environments for non-hearing impaired consumers and are not intended to aid a person with or compensate for impaired hearing. Although PSAPs share some characteristics with hearing aids, they are not classified as hearing aids for regulatory purposes and are marketed differently from hearing aids, including with a different intended use.

While there is an online market for hearing aids that are not bundled with professional services, online sales are restricted in some states, and not all consumers are able or willing to purchase hearing aids online. Enabling the sale of hearing aids without bundled services in brick and mortar retail outlets will result in a new relatively low cost option to buy hearing aids (i.e., products regulated as medical devices). Thus, the size of the market for hearing aids, and the overall number of individuals who will benefit from access to hearing aid technology, will likely increase at least to some extent as a result of the rule.

C. Market Failure Requiring Federal Regulatory Action

The current regulatory approach in which states regulate the purchase of hearing aids and corresponding provision of services may be viewed as part of the overall government response to an ostensible market failure we addressed previously and have now reassessed. We have determined that some hearing aid technology can be made safe and effective under certain

conditions without professional evaluation or involvement. Therefore, we are defining and establishing requirements for a category of hearing aids that can be sold over the counter (OTC), and such requirements will preempt certain state regulations, such as those requiring that hearing aids be sold by licensed hearing aid dispensers.

To the extent current regulations facilitate concentration in the hearing aid industry by setting up conditions of sale amenable to any given state licensed hearing aid dispenser tending to dispense only a small number of brands, and in some cases only one brand, this rule may also address the market failure of "market power." OMB Circular A-4 defines "market power" as occurring when firms "reduce output below what would be offered in a competitive industry in order to obtain higher prices." It notes further, "They may exercise market power collectively or unilaterally. Government action can be a source of market power…" We do not have information suggesting manufacturers of hearing aids exhibit market power defined in this way, by reducing output below what would be available in a competitive market in order to charge higher prices for a given product, although we have determined government action encouraged conditions under which some consumers may buy more bundled services of hearing aid professionals and buy more advanced and higher priced hearing aids than they would otherwise; however, such market power is always a concern in any highly concentrated industry.

D. Purpose of the Rule

This rule defines and establishes requirements for a new regulatory category for OTC hearing aids, including new labeling requirements for OTC hearing aids, and makes corresponding changes to the existing regulatory framework, including defining hearing aids not

meeting the OTC requirements as prescription medical devices, and amending the existing labeling requirements that will apply to prescription hearing aids.

E. Baseline Conditions

Costs and benefits must be assessed relative to a baseline. In this analysis we use the existing state of affairs under the current regulatory regime as the baseline.

F. Benefits of the Rule

This rule defines and establishes requirements for a new regulatory category, OTC hearing aids, and defines any hearing aids not meeting the requirements for OTC hearing aids as prescription hearing aids. Defining a new category for regulatory purposes does not automatically or necessarily generate social benefits but does create the potential for benefits or costs to occur.

One potential benefit of this rule is that some consumers with perceived mild to moderate hearing impairment who buy hearing aids through brick and mortar specialty retail outlets under the baseline scenario may be able to obtain their hearing aids more cheaply and thus experience cost savings for two reasons: 1) the product will be available without the bundling with professional services generally included with hearing aids bought through brick and mortar specialty retail outlets from state licensed distributors, 2) the actual device hardware and software may become cheaper, particularly over time, due to a potential increase in price competition and reduction in barriers to entry, which may spur product innovation and

development. These cost savings may involve out of pocket expenditures for consumers who buy their own hearing aids, reductions in insurance premiums for all members of insurance plans that cover hearing aids, or potential reductions in taxes for all taxpayers given the reductions in Medicaid costs. For consumers obtaining hearing aids through insurance plans that cover hearing aids, the cost savings will accrue to those consumers, other consumers in those insurance plans, and those insurance companies through reduced costs for hearing aids. For consumers buying hearing aids not in insurance plans that cover hearing aids, the cost savings will accrue to the consumers buying the hearing aids. For consumers obtaining hearing aids through Medicaid, where that option is available, the cost savings will accrue to taxpayers funding the Medicaid program.

Another potential benefit of this rule that we anticipate is that the introduction of OTC hearing aids will expand access for consumers who have perceived mild to moderate hearing impairment yet do not currently use hearing aids and would not have begun using hearing aids under the former rules. OTC hearing aids will likely be less expensive than those sold as a bundle with professional services and will be sold in brick and mortar stores. It is likely that there are consumers who prefer to purchase hearing aids in brick and mortar stores, or who don't have access to the online market, but whose budgets do not allow them to afford the current bundled product even though they may place a high value on the benefits hearing aids would provide. These consumers also may not buy PSAPs because they are not labeled as hearing aids and do not meet FDA regulations on hearing aids because PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. The number of these consumers who currently lack hearing aids who will obtain them OTC will depend on the elasticity of demand relating to the price differential between models currently sold in specialty retail bundled with

professional services and the probably although not necessarily cheaper models with less advanced technical features sold unbundled with professional services of the sort currently available online. We do not have information on the relevant elasticity and therefore cannot estimate the number of consumers who would benefit from expanded access. An increase in the uptake of hearing aids specifically resulting from the OTC availability of hearing aids, if it were to occur, would generate various benefits including the potentially important but difficult-to-monetize benefit of inclusion of those with hearing impairment into family, social, economic, civic, and religious life, and the reduction of stigma around hearing aid use (such that hearing aids would become more akin to eyeglasses). More serious health consequences including dementia and emergency room visits may be associated with hearing impairment, albeit perhaps not necessarily at the level of perceived mild to moderate hearing impairment relevant to this rule, although one's response to perceived mild or moderate hearing impairment may have implications for one's response to later and more advanced hearing impairment.

Some consumers whose current hearing aids do not meet the technical requirements for OTC hearing aids and who choose to switch to OTC devices may lose some features of their existing hearing aids and thus experience negative benefits, albeit mitigated by a countervailing reduction in cost. For this reason, we cannot infer a net increase in consumer welfare relative to the baseline from current hearing aid users switching to OTC hearing aids because these consumers would not have the choice of maintaining their current hearing aids under current conditions. However, we can infer that if these consumers experience a net loss in welfare, any net loss must be smaller than the net loss that would result from continuing to use their current devices as prescription medical devices because otherwise they would not switch to the OTC devices.

Other benefits may ensue from the ability of consumers to easily compare OTC devices with different features (e.g., electroacoustic performance, battery life, mobile operating system compatibility). These benefits may include improvement in the discovery function of determining what features consumers would like out of their devices. Facilitating comparison shopping of hearing aids by offering an OTC option may thus increase consumers' satisfaction with their hearing aids in the long term.

The rule reduces the barriers to entry for producers into the brick and mortar retail segment of the hearing aid market. In addition to these potential new entrants, it is possible that expansions in market size resulting from hearing aids being available in brick and mortar general retail outlets (and corresponding marketing efforts) will create new incentives for firms to engage in technological innovation that enhances product quality or reduces the costs of production. Innovation in product features of hearing aids could increase the array of products offered to consumers and improve consumer welfare if the quality of the devices improves relative to prices. This innovation may take the form of entirely new entrants, but it also may incentivize existing PSAP providers to modify their products to meet standards and other requirements for hearing aids and/or incentivize existing online providers to reach additional customers in brick-and-mortar stores—any of which could increase consumers' options and ability to access devices of sufficient quality that will safely and effectively address perceived mild to moderate hearing impairment.

1. Consumer Cost Savings and Benefits to New Users

The closest existing analog to the OTC hearing aids are relatively low-cost hearing aids sold online bundled with minimal or no professional services. However, some states currently do not allow or heavily restrict online sales of hearing aids. The main source of potential negative costs or cost savings for this rule is that the sort of relatively inexpensive hearing aid currently sold online in most states will become available in all states, and also in brick and mortar general retail outlets, rather than online only. This may result in some people who currently buy hearing aids through specialty retail outlets bundled with professional services, or who would have bought such hearing aids even in the absence of this rule, switching to OTC hearing aids. It may also result in some people who do not currently buy hearing aids, and would not have begun buying hearing aids in the absence of this rule, buying OTC hearing aids. We suppose the share of the market of such devices will be along the lines of similar products sold online, after correcting for the unavailability or restricted status of online sales in some states, the potential inability or unwillingness of some consumers to buy such devices online, and other features that may distinguish online products and OTC devices sold in brick and mortar stores, such as potentially increased product visibility, opportunities for impulse buying, etc. As with similar products sold online, some consumers may prefer to work with a hearing professional when they first start using hearing aids, but once they gain familiarity with the product, may prefer to buy hearing aids not bundled with those services. However, we have insufficient information to determine the degree to which that market share will be generated by current users switching to OTC hearing aids or new users taking up OTC hearing aids. Because of the uncertainty associated with predicting the uptake of hearing aids and valuing benefits for new users, we discuss both possibilities separately then consider a mix of the two.

In 2008, the last year for which we were able to find data, about 4.7 percent of hearing aid sales involved relatively low-cost models bundled with little or no professional services purchased online. Ref. [2]. The data are old and such products may represent a greater share of the hearing aid market today. Our benefit estimates, based ultimately on the market share of such products, will be low to the extent this percentage has increased since 2008. However, the total upon which this percentage is based includes hearing aid sales in three states that do not currently allow online sales and may not have allowed online sales in 2008: Florida, New York, and West Virginia. If we use the general populations (as of 2008) of the states involved to correct for this effect, then the percentage of hearing aids sold online in states allowing such sales would be about 5.4 percent. If we apply a similar correction for the ten states that place non-trivial restrictions on online sales (California, Illinois, Kansas, Massachusetts, Missouri, Nevada, New Hampshire, Oregon, Texas, and Washington), then the percentage of hearing aids sold online in states that allow such sales with no or only trivial restrictions would be about 9.0 percent. However, the effects of regulatory restrictions that stop short of a ban are unclear and may vary from operating similarly to a ban to having little or no effect on online sales. If we use a uniform distribution and treat these regulations as approximating a ban at one endpoint and having no effect at the other endpoint, the mean of the estimated percentage of hearing aids sales composed of relatively low-cost models purchased online would be about 7.2 percent. This increase in the percentage of hearing aid sales composed of relatively low-cost models not bundled with professional services despite state laws restricting such products sold online is one element of the potential benefits generated by this rule.

Another element of the potential benefits generated by this rule is that the relatively low-cost hearing aids currently sold online may become available in brick and mortar general retail

outlets and hence to consumers who choose not to shop for hearing aids online. A nationally representative survey of adults from 2016 showed about 79 percent of Americans made an online purchase of any type. Ref. [3]. The data are a few years old and do not relate specifically to hearing aids or the population buying hearing aids for perceived mild to moderate hearing impairment. If we use the population that shopped online to correct for this effect, then the effective market share going to lower cost hearing aids of the sort currently sold online would increase further to about 9.1 percent. These adjustments, in total, represent an increase of 4.4 percentage points over the current rate of 4.7 percent.

Based on survey data from 2015, about 3.2 percent of the adult (18 years or older) population of the United States owned a hearing aid. This implies about 9.6 million adults owned hearing aids. However, about 3 percent of those who reported owning hearing aids reported not using them. This implies about 9.3 million adults reported both owning and using hearing aids in 2015. About 60 percent of hearing aid owners in 2009 reported having perceived mild or moderate hearing impairment. Ref. [4]This suggests about 5.8 million consumers currently own and use hearing aids to address perceived mild to moderate hearing impairment. In the 2015 survey data, about 74 percent of respondents reporting hearing loss reported hearing loss in both ears (bilateral hearing loss). This suggests about 4.3 million consumers with perceived mild to moderate hearing impairment who own and use hearing aids own two hearing aids each, and 1.5 million consumers with perceived mild to moderate hearing impairment who own and use hearing aids own one hearing aid each. Altogether, this suggests there are about 10 million hearing aids currently being used to treat perceived mild to moderate hearing impairment in the United States.

One hearing aid provider suggested the average lifespan of current hearing aids is about 4 to 6 years, which we represented using a uniform distribution running from 4 to 6 years with a mean of 5 years. Ref. [5]. This implies about 2 million existing hearing aids that are being used to treat perceived mild to moderate hearing impairment need to be replaced each year. In that case, a shift of 4.4 percentage points toward relatively low-cost OTC hearing aids sold in stores or online would represent about 88,210 hearing aids.

The cheapest hearing aid we found online at the time we wrote this analysis was $399 or $411 in 2020 dollars. The average cost of an economy-level hearing aid bundled with professional services purchased from a specialty retail outlet in 2014 was $1,657 or $1,849 in 2020 dollars. Ref. [6]. Given our assumption that OTC hearing aids are likely to be similar to relatively lower cost models current sold online, consumers most likely to switch to OTC hearing aids from hearing aids bought in specialty retail outlets are probably currently using economy-level hearing aids. If this price difference is similar to the future price difference between OTC hearing aids and economy-level hearing aids currently sold through specialty retail outlets, these data and assumptions suggest possible cost savings on the order of $1,438 per unit, which would amount to a total cost savings of about $127 million per year. The savings would be higher if prices of OTC hearing aids are pushed lower than comparable models currently sold online, perhaps due to the absence of restrictions on online sales in some states.

However, we do not know how much of this cost savings would represent a net increase in welfare for consumers because consumers moving from relatively higher-cost products sold in specialty retail outlets to relatively lower-cost products sold OTC would give up bundled professional services and may give up some product features as well and hence may experience negative non-monetary benefits. For some consumers who choose to switch to OTC hearing aids,

the net value of the cost savings may be only slightly higher than the associated decrease in non-monetary benefits from the loss of professional services and product features. Indeed, some consumers may elect to pay for professional services even though they choose to buy OTC hearing aids, thus negating a major element of the potential cost saving. For other consumers, the net value of the cost savings may be much higher than any associated decrease in non-monetary benefits because they do not value the foregone professional services or product features. Similarly, some consumers who switch from products sold in specialty retail outlets bundled with professional services may only value those services when they first decide to buy hearing aids, perhaps to confirm a need for hearing aids or the degree of hearing impairment, and later do not value professional services related to adjusting or using particular devices, replacing their current hearing aid at the end of its lifespan, keeping abreast of technological developments, or monitoring changes in their own hearing. To reflect this uncertainty, we use a uniform distribution running from 0 to represent a very small increase in welfare from the cost savings to the full value of the cost savings. The mean of that distribution is about $63 million per year.

Another possibility is that the market share of OTC hearing aids may involve only or significant numbers of new users who would not have bought hearing aids otherwise.

For new users, the associated benefit would be the net gain or utility from taking up hearing aids. Assuming the amount consumers would be willing to pay for hearing aids is based on their subjective assessment of the potential benefits to be gained from using hearing aids, including the positive utility from beneficial health effects and the negative utility or disutility from negative effects like inconvenience, stigma effects, and so on, we can infer the perceived net utility gains for consumers who will not buy a currently available economy-level hearing aid bundled with professional services purchased from a specialty retail outlet for $1,848, but who

would buy an OTC hearing aid at an estimated cost of $411, would be between $411 and $1,848, which under a uniform probability distribution gives a mean of $1,130. Assuming consumers have realistic expectations regarding product life and plan on replacing the device in 4 to 6 years with a mean of 5 years, the estimate of annual perceived net benefits including health benefits for new users of hearing aids would be between $0 and $288 with a mean of $144. If we apply this figure to the estimated number of new hearing aids required to generate the anticipated market share going to these devices we calculated in the context of potential cost savings for existing users, we obtain estimated annual benefits of between $0 and $27 M per year with a mean of $14 M per year. This is substantially below the estimate we obtained when we assumed generating the anticipated market share would involve only existing users switching to OTC devices. If the relevant market were generated by some combination of existing users switching to OTC hearing aids and new users, the mean estimate of benefits would lie in a range between $14 M per year and $63 M per year with a mean of those means of about $39 M per year.

However, there are alternative methods of valuing the health benefits of hearing aids for new users in particular that provide significantly different results and, in particular, the potential for much higher estimates of net benefits. See the appendix for one such approach. To the extent these methods are meant to be based on the subjective value of the benefits of hearing aids by prospective new users, they are difficult to reconcile with observed market behavior. However, there may be ways to reconcile the estimates using independent estimates of the disutility associated with hearing aids, both in terms of stigma effects and practical issues related to use and maintenance, and considering that perceived health benefits from the uptake of OTC hearing aids would be incremental from any benefits currently available through other amplification

technology such as PSAPs, although some consumers may not be familiar with PSAPs and may not use them considering that PSAPs are intended for non-hearing impaired consumers.

However, it should be noted the uptake of hearing aids is a complex issue and the effect of the introduction of OTC hearing aids on the overall use of hearing aids is unclear. In the United States, as in other countries, the prevalence of hearing aid use is significantly lower than the prevalence of hearing impairment. One study from 2012 estimated an overall utilization rate for hearing aids of about 14 percent. A study from 2011 found a strong relationship between hearing aid use and the severity of hearing impairment, with 3 percent of those with a mild impairment, 40 percent of those with a moderate impairment, and 77 percent of those with a severe impairment regularly wearing hearing aids. In that study, the severity of hearing impairment, college education, and leisure noise exposure were positively associated with hearing aid use, but race / ethnicity, age, sex, and income were not significantly associated with the use of a hearing aid. A study from 2014 found utilization rates of 4 percent of those with mild hearing impairment and 23 percent for those with moderate to severe hearing impairment. Another study from 2014 found individuals with the highest income were more likely to use hearing aids than individual with the lowest income; however, that study did not adjust for education. A study from 1998 found an overall utilization rate of 15 percent and a utilization rate of 33 percent for participants who reported significant communication problem and handicaps. Factors associated with hearing aid use in that study were severity of hearing impairment, age, education, performance on word recognition tests, and self-reported hearing impairment. Some potential reasons for low usage rates may be that some consumers with perceived mild to moderate hearing impairment don’t realize they have measurable hearing impairment, don’t

believe hearing aids would be beneficial for them, or don't believe the benefits would be worth the costs.

Because of the uncertainties associated with estimating uptake of hearing aids due solely to changes in price and availability, given concomitant changes in bundling with professional services as well as potential changes in product characteristics, we have based our benefits estimate on the assumption the primary factor in generating the estimated market share will be existing users of hearing aids switching to OTC devices in markets where they are currently unavailable.

G. Costs of the Rule

No one will be required to develop or offer for sale OTC hearing aids, and no one will be required to buy them. However, changing the status of some existing hearing aids to prescription medical devices may generate social costs relative to the baseline.

For manufacturers of hearing aids currently on the market, the least costly way to comply with the rule depends on whether the existing hearing aid meets the technical specifications, performance limits, and design requirements for OTC hearing aids. If so, the least costly option is likely to revise the product labeling to make it consistent with the OTC hearing aid labeling requirements and sell the device as an OTC hearing aid under the conditions for sale. If the device does not meet the technical specifications, performance limits, and design requirements for OTC hearing aids the least costly option may be to treat the device as a prescription medical device, revise the product labeling to make it consistent with the prescription hearing aid labeling requirements, and comply with state regulations relating to prescription medical devices. We

assume hearing aids currently sold online are the most likely to be consistent with OTC technical specifications, performance limits, and design requirements and require only a labeling change while hearing aids currently sold through specialty retail outlets will more likely convert to prescription medical devices. In either case manufacturers would also need to read and understand the rule and revise internal SOPs in response to the rule.

We expect changing the regulatory status of some hearing aids currently on the market may generate costs for some subset of consumers. Based on current practices relating to the sales of hearing aids, we expect consumers whose current hearing aids are bought online and not bundled with professional services but do not meet the technical requirements for OTC hearing aids, and who wish to either repurchase those devices as prescription medical devices or wait for that same product to be redesigned to meet OTC requirements and offered as an OTC hearing aid, will see additional costs. We anticipate that, in other cases, consumers will be able to follow current procedures for obtaining their hearing aids, moving from hearing aids currently bundled with professional services to prescription hearing aids similarly bundled with professional services, or use simpler and less costly procedures to obtain OTC hearing aids. Whether hearing aid users experience increases in product prices would depend on the relative effects of OTC product availability and acceptability, short- to medium-term interruptions in online product availability (until OTC or prescription specifications can be met) for particular brands or models of devices, and potentially additional state regulations and restrictions on prescription medical devices.

1. Relabeling

The rule will require all current hearing aids to be relabeled according to either the OTC or prescription hearing aid labeling requirements. About 105 firms manufacture air conduction hearing aids of the type that may be affected by this rule. Casual online research indicates one large manufacturer is currently offering 15 models, each of which would require new labeling. Smaller manufacturers may offer fewer models. If we estimate the number of products per manufacturer using a uniform distribution running from 1 to 15 with a mean of 8, we get a mean estimate of 840 products requiring relabeling. Based on a compliance date 240 days after publication of this final rule (an effective date of 30 days after publication plus a compliance period of 210 days after the effective date), our 2015 labeling cost model suggests a one-time mean cost estimate for relabeling of about $6 M. Ref. [7] We based our estimate of labeling change costs on the mean costs for a major label change plus the mean cost of an insert labeling change plus the cost for lost labeling inventory. We used the cost estimates for a major labeling change based on the description of a major label change in the model documentation. For printing process for the major label change and insert, we used a weighted average of the different printing methods listed based on the overall distribution of labels produced using the different methods in the model documentation. We estimated inventory loss using the model tab on inventory costs suggesting no loss of package inventory and ten percent loss of existing insert inventory.

2. Reading and Understanding the Rule

Any new regulation must be read and understood by those affected by that regulation. Using the same labor times and classifications we have used in previous analyses, we assume

this may require 5 hours of time for one each of the following three types of personnel: executive, lawyer, and marketing manager. The time estimate is based on an average reading speed of 200 to 250 words per minute and document length of approximately 32,000 words for a reading time of approximately 2.5 hours, plus a comparable time to consider material. Using recent BLS wage rates and doubling for employee benefits and overhead, we estimate this one-time cost at about $0.3 M. Ref. [8].

3. Revising Guidelines or Standard Operating Procedures

In addition to the activity required by this rule, manufacturers will need to revise internal guidelines or standard operating procedures (SOPs) to reflect those requirements. Using the same labor times and classifications we have used in previous analyses, we assume this may require 10 to 25 hours of time for one executive, 40 to 100 hours for one marketing manager, and 80 to 150 hours for one technical writer. These time estimates are based on estimates we used for the cost of revising standard operating procedures for an unrelated issue involving direct-to-consumer prescription drug advertisements, which were accepted without public comment in the analysis of that proposed rule and increased at the high end by 25 percent during the analysis of the corresponding final rule stage. These costs are meant to be rough estimates. We do not have sufficient information to fine tune the cost of revising guidelines or SOPs in particular cases. Using recent BLS wage rates, we estimate this one-time cost at $4 M. Ref. [8].

4. Costs Associated with State Regulation of Prescription Medical Devices

Currently, states regulate the personnel who may distribute hearing aids. We have no reason to suppose states will impose more onerous restrictions on hearing aids that will be prescription medical devices as a result of this final rule than are currently imposed on distribution of hearing aids. However, it is possible changes in state regulation of prescription hearing aids as well as potentially increased variation in state regulation of prescription hearing aids may increase the cost of hearing aids that convert to prescription medical devices. Although this rule will not cause the state actions that would generate these costs, it would generate the potential for such costs to occur.

5. Summary

We used Monte Carlo analysis to estimate annualized net costs of between $1 million and $2 million per year based on the fifth and ninety-fifth Monte Carlo percentile results with a mean of $1 million per year at both a discount rate of 3 percent and 7 percent.

Table 2 – Summary of Costs, Monte Carlo Run Means and Percentiles, Millions

	Mean	5% Percentile	95% Percentile
Costs in First Year Only			
Label Changes	$6	$1	$12
Revise SOPs	$4	$3	$5
Read Rule	$0.1	$0.1	$0.2
Total Costs			
Total Cost Year 1	$10	$5	$15
Total Cost Year 2 and After	$0	$0	$0
Annualized Costs			
Annualized Cost Over 10 years Infinity at 3 %	$1	$1	$2
Annualized Cost Over 10 years Infinity at 7 %	$1	$1	$2

H. Distributional Effects

The primary actors likely to gain from this rule are: brick and mortar general retail outlets that may begin selling OTC hearing aids; manufacturers who may supply OTC hearing aids to retail markets but may not have a network of affiliated specialty retail outlets, including new entrants to the hearing aid industry as well as current producers of PSAPs and online hearing aids; consumers with perceived mild or moderate hearing impairment in states that currently disallow or restrict online sales of hearing aids who currently use hearing aids or would have begun using hearing aids even in the absence of this rule but do not value the professional services typically bundled with hearing aids when purchased through specialty retail outlets or the features of hearing aids sold through specialty retail outlets; and consumers in any state who simply choose to not purchase such hearing aids online but would purchase the same sort of product in brick and mortar stores. Consumers most likely to fit into this category are lower income consumers who live in rural areas remote from specialty hearing aid retailers and general retailers selling related PSAPs, consumer with poor internet connectivity, and less educated consumers who have difficulty with online shopping where it is available. Thus, this rule will benefit communities that would conventionally be classified as disadvantaged, vulnerable, or marginalized communities.

The primary actors likely to lose from this rule are hearing health care professionals and specialists who currently dispense hearing aids through specialty retail outlets in states that currently disallow or restrict online sales of hearing aids who may lose some of their current customers to the OTC hearing aid market in the same way they may have previously lost

customers to online sales and PSAPs, and established hearing aid manufacturers that may lose some of their consumers to new entrants selling OTC devices in states that currently disallow or restrict online sales of hearing aids. Thus, this rule will not inappropriately burden communities that would conventionally be classified as disadvantaged, vulnerable, or marginalized communities. A possible exception would be that some people in communities that might conventionally be classified as disadvantaged, vulnerable, or marginalized who prefer buying hearing aids bundled with professional services sold in specialty retail may be made worse off when OTC products are introduced as competing products, for example, if they live in a remote small town and work with an audiologist who is currently able (but just barely) to stay in business and who finds it advantageous after the introduction of OTC hearing aids to move to a larger urban area. We do not have sufficient information to predict the severity of these distributive effects.

I. International Effects

Many hearing aid manufacturers, including five of the six large companies that currently dominate the world-wide market for hearing aids, are based outside the United States. These firms would accrue the relatively modest cost associated with relabeling existing hearing aids and may face increased competition from entrants into the OTC hearing aid market.

J. Uncertainty and Sensitivity Analysis

The primary source of uncertainty for both benefits and costs is the number of consumers switching to OTC hearing aids. We assumed modest changes in behavior based on current

consumption patterns relating to online hearing aid sales, the general shopping patterns relating to online versus brick and mortar outlets, as well as the general availability of PSAPs. However, it is possible OTC hearing aids may be or become substantially more attractive to consumers than hearing aids currently offered online and PSAPs, either because they vary in some relevant way such as product characteristics or cost or, in the case of hearing aids sold online, because simply appearing in brick and mortar general retail outlets makes them dramatically more visible or acceptable to consumers than comparable models sold online. If more consumers convert to OTC hearing aids than anticipated, more consumers will obtain the potential cost savings and fewer consumers will need to arrange additional visits to licensed providers and potentially pay more for hearing aids that convert to prescription medical devices.

An important source of uncertainty for cost savings is the eventual price of OTC hearing aids. Sound amplification technology can range in price from under one hundred dollars for some PSAPs to relatively low-cost hearing aids available online for several hundred dollars to relatively expensive hearing aids with many advanced features sold through specialty retail outlets for a few thousand dollars. We assume OTC hearing aids, at least initially, may have similar costs and features to hearing aids currently available online. However, if they are much simpler devices and priced even lower, perhaps with prices more similar to PSAPs, the potential cost savings for consumers who choose to use them would be greater than anticipated, although of course the change in product capabilities and characteristics and thus the potential decline in utility from switching to OTC hearing aids from current hearing aids may also be greater than anticipated.

Another important source of uncertainty for costs is the percentage of consumers with perceived mild to moderate hearing impairment who own and use hearing aids who would need

to make additional visits to licensed providers if they wish to obtain prescriptions for hearing aids that convert to prescription medical devices. We assumed those aged 70 and over would have no additional cost but those under age 70 would have a 0 to 100 percent probability of needing to make an additional visit to a licensed provider to obtain a prescription. If most of these consumers can obtain prescriptions for hearing aids without scheduling additional visits to licensed providers, the costs associated with existing devices converting to prescription medical devices would be lower than anticipated.

With respect to the discussion of potential new users, the main sources of uncertainty are the numbers of new users and the value of the hearing aids to new users. As with existing users, if OTC hearing aids represent a bigger departure from the current situation, including online hearing aids and PSAPs, then the number of new users may be higher than estimated.

K. Analysis of Regulatory Alternatives

1. Extend Compliance Date

An alternative to this final rule would be to issue it with an extended compliance date by delaying the effective date or extending the compliance period. Extending the compliance date of any rule requiring products to be relabeled or repackaged reduces costs by allowing firms additional time to dispose of existing labeling and package inventory. In this case the labeling costs are a relatively minor component of total costs. If we extend the compliance date from 240 days after publication to 365 days after publication, our labeling cost model suggests we could increase the percentages of required labeling changes coinciding with

regularly scheduled labeling changes from 2 percent to about 4 percent, although it would not change the estimated 10 percent of paper inserts or 0 percent of packaging lost. This would reduce the one-time labeling costs by about $0.1 M. However, it would also delay some consumer benefits by an additional four months, which based on estimated annual cost savings would imply a reduction in cost savings in the first year of about $16 M. A compliance date extension could also reduce costs to consumers who currently buy online hearing aids that do not meet OTC requirements, and who would rather wait for their preferred brand or model to be redesigned to meet OTC requirements than either obtain it by prescription or select an available OTC or prescription alternative.

2. Provide Fewer or Less Restrictive Specifications and Requirements for OTC Hearing Aids

Another alternative would be to revise the specifications and requirements for OTC hearing aids to further reduce the cost of those devices. For example, we could look at the specifications that may generate differences in costs relative to low-cost PSAPs and revise those with the intent of encouraging OTC devices more similar to PSAPs than existing hearings aids sold online. We do not have enough information on the likely effect on benefits and costs of revising these specifications and requirements to allow us to perform a thorough quantitative evaluation of these types of changes. However, as noted above (in the assessment of an option to extend the final rule's compliance date), there are products currently available online that exceed the final rule's maximum acoustic output limit; as such, different final specifications—such as the output limit originally proposed—would be associated with lower market-interruption costs.

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We certify that this rule will not have a significant economic impact on a substantial number of small entities. The estimated annualized cost over ten years is $0.009 M per firm, which is unlikely to represent more than three percent to five percent of the revenue of an affected manufacturer.

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