DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Banned Devices; Electrical Stimulation Devices For Self-Injurious and Aggressive Behavior; Final Rule

Docket No. FDA-2016-N-1111

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 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). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is not a 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 final rule would only affect one entity that is not classified as small, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "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 $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or

exceeds this amount.

B. Summary of Costs and Benefits

Under this final rule we are banning electrical stimulation devices (ESDs) for self-injurious (SIB) or aggressive behavior (AB). This action will impose costs on the affected entity to read and understand the rule, as well as to provide affected individuals with alternative treatments. Although uncertain, other treatments or care at other facilities may cost more. The costs for the one affected entity to read and understand the rule range from around $1,200 to $5,200. The present value of the incremental switching costs over 10 years ranges from $0 to $44 million, with a primary estimate of $22 million at a three percent discount rate, and from $0 to $38 million, with a primary estimate of $18.8 million at a seven percent discount rate. Annualized costs range from $0 million to $5.0 million, with a primary estimate of $2.5 million at a three percent discount rate, and from $0 million to $5.0 million, with a primary estimate of $2.5 million at a seven percent discount rate.[1] Non-quantified benefits of the final rule include a reduction in adverse events, such as the risk of pain, posttraumatic stress disorder (PTSD), and other physical or psychological harms related to use of the device. Additionally, there will be transfer payments between $14 million and $15 million annually either within the affected entity to treat the same individuals using alternative treatments, or between entities if affected individuals transfer to alternate facilities for treatment.

Table 1 of this document provides the Regulatory Information Service Center and Office of Information and Regulatory Affairs Combined Information System accounting information for this analysis.

[1] The lower-bound cost estimates only include administrative costs to read and understand the rule with no incremental costs for alternative treatments.

Table 1. Economic Data: Costs and Benefits Statement

Category		Low Estimate	Primary Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year							
	Annualized Quantified							
	Qualitative							Reduction in physical and psychological adverse events related to use of the device
Costs	Annualized Monetized $millions/year	$0.0 million	$2.5 million	$5.0 million	2018	7%	10 years	
		$0.0 million	$2.5 million	$5.0 million	2018	3%	10 years	
	Annualized Quantified							
	Qualitative							Transition costs to the affected entity and individuals for transitioning to alternative treatments
Transfers	Federal Annualized Monetized $millions/year							
		From:			To:			
	Other Annualized Monetized $millions/year	$13.8 million	$14.2 million	$14.6 million	2018	7%	10 years	
		$13.8 million	$14.2 million	$14.6 million	2018	3%	10 years	
		From: Affected entity for current use of device			To: Affected entity for other treatments or to other facilities that treat aggressive or self-injurious behavior			
Effects	State, Local or Tribal Government: State expenditures may rise or fall if individuals move across state boundaries. Small Business: No effect Wages: No effect Growth: No effect							

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite horizon. We do not estimate any cost-savings due to

this final rule. With a 7 percent discount rate, the primary estimated annualized net costs equal $2.6 million in 2016 dollars over an infinite horizon.

Table 2. EO 13771 Summary Table (in $ Millions 2016 dollars, over infinite time horizon)

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	$36.7	$0.0	$73.4	$82.5	$0.0	$165.0
Present Value of Cost Savings	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Present Value of Net Costs	$36.7	$0	$73.4	$82.5	$0	$165.0
Annualized Costs	$2.6	$0.0	$5.1	$2.5	$0.0	$4.9
Annualized Cost Savings	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Annualized Net Costs	$2.6	$0	$5.1	$2.5	$0	$4.9

C. Comments on the Preliminary RIA and Our Responses

Although we received many comments on the proposed rule, only one addressed our preliminary regulatory impact analysis. We discuss that specific comment below. As such, we have retained the basic cost methodolody for this final regulatory impact analysis, while adjusting for cost increases due to general inflation.

(Comment 1) One commenter stated that we did not consider certain serious impacts on individuals who would be forced to transition off of the device due to this rule. For example, the commenter stated that individuals may experience irreparable harm and substantial, significant and permanent injuries.

(Response 1) We acknowledge that costs to individuals may vary depending on how well individuals transition to alternative treatments. The commenter did not provide any additional information to revise our original discussion.

D. Summary of Changes

This analysis has been revised to reflect new wages and updated costs for the use of the device and alternative therapies. The final rule includes a compliance date of 180 days after

publication in the *Federal Register* for those devices currently in use and subject to a physician-directed transition plan. The compliance date for all other devices is 30 days after publication in the *Federal Register*. An extended compliance date was considered as an alternative in the proposed regulatory impact analysis, so this final analysis now considers the proposed rule as the alternative.

II. Final Regulatory Impact Analysis

A. Background

Some individuals with intellectual or developmental disabilities exhibit SIB or AB, while other individuals who exhibit SIB or AB do not have intellectual or developmental disabilities. Examples of SIB include head-banging, hand-biting, excessive scratching or picking of the skin. In addition, some individuals engage in AB that endangers their families or caregivers. As discussed in the preamble, by conservative estimates, counting only individuals who have intellectual and developmental disabilities (and not all people who exhibit self-injurious or aggressive behavior), at least 330,000 people in the United States exhibit those behaviors. The most extreme cases of serious self-injurious behavior afflict an estimated 25,000 or more individuals in the United States.

A number of pharmacological and behavioral treatments exist for individuals who manifest SIB and AB. Behavioral treatment strategies may employ positive approaches (to reward appropriate behavior) and negative approaches (to discourage inappropriate behavior). Physical measures and protective equipment may also be used to reduce the immediate threat of injury.

This final rule will ban electrical stimulation devices (ESDs) for SIB or AB. ESDs allow observers to administer an electric shock to an individual engaging in SIB or AB or engaging in

a precursor to SIB or AB. The device is intended to interrupt the behavior and condition the individual not to engage in that behavior, with the eventual goal of ending SIB and AB in the individual. The devices operate on the principle of aversive conditioning and are sometimes referred to as "aversives." Though similar products may be used for other purposes, we seek only to ban ESDs for SIB or AB.

B. Market Failure Requiring Federal Regulatory Action

Individuals with SIB or AB may injure themselves and others. To protect the individual from injury caused by SIBs and to protect others from injury caused by AB, some form of intervention may be required. At one facility, ESDs are used on some individuals with SIB or AB who reportedly have not responded well to treatments. These devices are attached to the individual's body. When the individual engages in self-injurious or aggressive behavior, an observer using a remote monitor or an automated mechanism attached to the device will trigger the device, delivering an electric shock to the skin in an attempt to condition the individual to reduce or stop their self-injurious or aggressive behaviors. Some individuals and their families have reported success in reducing these behaviors through the use of aversive conditioning devices. Many individuals prescribed the device, however, may have difficulty communicating about their experience with it and may lack the ability to consent to its use.

Under this final rule, we are banning these devices for SIB or AB, because we have determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling. Experiences with these devices vary between individuals and within individuals over time. Labeling cannot adequately define how providers could overcome this variability in individual experience, especially when many of these individuals have difficulty communicating information about their physical or

psychological state. Section V.F. of the Preamble contains a full discussion of why labeling cannot correct or eliminate the unreasonable and substantial risk posed by this device.

Individuals who receive shocks from the device do not generally make decisions about their own medical treatment. Instead, decisions about treatment are made by agents of the individual, including guardians and caregivers. From an economic perspective, this may result in a principal-agent problem. A principal-agent problem results from asymmetric information, where one individual (the principal) has information that other individuals (agents) do not have.[2] In this case, guardians and the affected facility may be agents, while the individual experiencing the shock from the device is the principal. The agents do not experience the effects of the device, and many individuals may not be able to communicate effectively about their experience with the device. Though agents can quantify the success of the device in reducing unwanted behavior, they cannot easily observe the adverse effects of the device on the individual, and the individual may not be able to communicate effectively about their experience. Agents may therefore recommend or approve the use or continued use of the device even when the individual would not have consented to its use.

C. Baseline Conditions

This final rule will affect one firm that manufactures and uses aversive conditioning devices for self-injurious or aggressive behavior. A comment submitted by the affected entity in July 2016 reported that the device was court-approved for use in 54 individuals, with 51 currently subject to the device (Ref. 2). We use a range of 51 to 54 as the number of individuals affected by this final rule, which captures those currently subject to the device and those at the

[2] The potential market failure due to the principal-agent problem does not depend on the intentions of the agent(s). We do not doubt the intentions of parents or guardians when faced with these most difficult decisions.

facility who could potentially use the device under court approval.

The ban is only for electrical stimulation devices that deliver a noxious shock to cause a reduction or cessation in aggressive or self-injurious behavior.

D. Costs of the Final Rule

Some changes in expenditures for transitioning individuals to alternative therapy will be costs and others will be transfers. We specify in this section which expenditures are likely to be transferred to other entities.

1. Administrative costs

The affected entity will incur costs to learn about the rule. These costs include time to read and interpret the rule. Based on the effort from the one affected entity to read and respond to the proposed rule, we estimate that several employees at the affected facility will each spend between 5 hours and 15 hours reviewing the final rule. In valuing this time, we use average wages from the Bureau of Labor Statistics (BLS) national industry-specific occupational employment and wage estimates (Ref. 1).[3] The average hourly wage rate ranges from $44.91 to $51.29 for management occupations (average of occupation codes 11-1000, 11-3031 and 11-9111), from $25.83 to $27.80 for healthcare occupations (occupation code 29-0000), and is $50.66 for legal occupations (occupation code 23-0000).[4] The average wage for the three occupations ranges from $40.47 for NAICS 623210 to $43.25 for NAICS 623220. The lower-bound wage rates are for Residential Intellectual and Developmental Disability Facilities

[3] May 2018 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 623210 – Residential Intellectual and Developmental Disability Facilities and NAICS 623220 – Residential Mental Health and Substance Abuse Facilities <http://www.bls.gov/oes/>

[4] The BLS did not publish wage estimates for legal occupations within NAICS 623210 or NAICS 623220 in 2018. We use instead the legal occupation wage reported in NAICS 623000.

(NAICS 623210) and the upper-bound wage rates are for Residential Mental Health and Substance Abuse Facilities (NAICS 623220). We double these wage estimates to account for benefits and overhead. It will cost between $1,214 and $5,190 for three to four people from the affected entity to read and understand the rule (=5*3*2*$40.47 and 15*4*2*$43.25).

2. Impact on the affected entity

The ban of electrical stimulation devices for self-injurious and aggressive behavior will require that the facility stop using the devices at the effective date of the final rule except for those devices currently in use and subject to a physician-directed transition plan, for which the facility will have until 180 days after publication of the final rule. A comment submitted by the affected entity in July 2016 reported that the device was court-approved for use in 54 individuals, with 51 currently subject to the device (Ref. 2). We use a range of 51 to 54 as the number of individuals affected by this final rule, which captures those currently subject to the device and those at the facility who could potentially use the device under court-approval. These individuals could either move to a different facility where the device is not used or transition to an alternative therapy at the affected facility. Massachusetts publishes its annual reimbursement for residential facilities, including the reimbursement for the affected entity. For fiscal year 2020 the reimbursement for the affected entity is around $270,550 per individual.[5] If affected individuals were to move to a different facility, between $13.8 million and $14.6 million in revenue from those individuals would be transferred to another entity providing alternative care (=51*$270,556 and =54*$270,556).

[5] Accessed July 24, 2019 from https://www.mass.gov/service-details/special-education-tuition-pricing-details. Massachusetts' reimbursement rates are listed as tuition rates and include the program cost for a student in a residential program including incidental medicine costs.

The incremental switching costs of the final rule will equal the difference in the cost of using the device and the cost of alternative care. We looked at Massachusetts' reimbursement rates for other residential facilities that appear to serve similar individuals. Annual rates for fiscal year 2020 for these facilities ranged from about $224,800 to about $363,300 per year. If individuals transfer to a cheaper facility, ongoing associated costs could decrease slightly; if individuals transfer to the most expensive facility, the costs could increase. For example, if all 54 individuals transferred to the most expensive facility reimbursed by Massachusetts that treats SIB or aggressive behaviors, incremental treatment costs will increase up to $5.0 million per year (54*($363,273 - $2670,556)).[6]

The affected entity could also keep individuals at its own facility and move them to alternative therapy. This entity has experience delivering alternative services to all residents, two thirds of whom do not use the device. Based on the information from the State of Massachusetts, we anticipate that the reimbursement received by the affected entity for each individual who stays at the facility will remain unchanged. However, we lack information about the cost to provide alternative care to the 51 individuals currently subject to the device. Providing alternative therapy is not necessarily more costly than the existing option at the affected facility: one study found that Dialectical Behavioral Therapy cost averages about $190,900 per year in 2018 dollars, with the most expensive treatment costing around $208,300 per year (Ref. 3).[7]

Nevertheless, the affected facility will likely incur some transition costs as they move residents to alternative care. These transition costs could include additional professional expertise, training for existing staff, the administration of additional drugs, and possibly the

[6] This facility is located in New Hampshire.
[7] These costs range from $482 to $526 per day, or $175,930 to $191,990 per year, in 2013 dollars. We update to 2018 dollars using the GDP deflator.

hiring of additional staff.

The compliance period of 180 days for those devices currently in use and subject to a physician-directed transition plan may reduce some of the incremental costs of this rule by a modest amount. Creating physician-directed transition plans may require additional resources.

3. Impact on Individuals

For the 51 individuals currently subject to the device, costs to them will vary, depending on how quickly they adjust to an alternative care program and whether for the individual, the alternative care program provides equivalent outcomes to the device. If, for example, self-injurious behavior changes with an alternative therapy, an individual may incur some cost for the alternative treatment. For these individuals, it is impossible to say how much their utility will change due to rule-induced switches to other care programs.

4. Cost to Government

Many of the individuals have the cost of care paid by their state or local government. Although uncertain, the ban of this device could affect the expenditure of governments that pay for the care of the affected individuals. If the cost of treating each individual without the device is higher than the cost of using the device on each individual, government expenditures could rise and if the cost of treating each individual without the device is lower than the cost of using the device on each individual, government expenditures could fall.

5. Summary of the Quantified Costs of the Rule

The estimated one-time costs of the rule range from around $1,200 to $5,200; the annual

incremental costs of the rule range from about $0 per year to about $5.0 million per year.[8] The annualized costs of the present value of total costs range from $0.0 million to $5.0 million at both a 3 percent and 7 percent discount rate. The lower bound cost estimate assumes that there are costs to the affected entity to read and understand the rule, but no change in the costs for changing to alternatives or moving to a different facility. Our primary estimate of the present value of the total incremental costs of the final rule over 10 years equals $18.8 million with a 7 percent discount rate and $22.0 million with a 3 percent discount rate. The primary estimate of annualized costs over 10 years is $2.5 million at both a 3 percent and 7 percent discount rate.

E. Potential Benefits of the Final Rule

The potential benefits of the final rule are unquantified and include possible benefits to individuals and to society.

Individuals who manifest SIB or AB are a vulnerable population. Often, individuals with these conditions are nonverbal and may not be able to communicate effectively to their caregivers about how they experience either their conditions or the use of the device. In addition to any adverse physical effects of the ESD, such as burns, individuals may experience cumulative psychological effects from the ongoing use of ESDs that result in posttraumatic stress disorder. For other individuals using similar devices for other indications (e.g., smoking cessation), individuals may be able to avoid these risks by discontinuing the use of those products. Because the individuals with SIB or aggressive behavior cannot give or withdraw consent for the use of the device, these individuals cannot choose to avoid these risks. Because individuals often cannot express their preferences about the device and are not the ones deciding

[8] These estimates assume that, without the rule, the number of individuals who would have been subject to the device would be constant over time.

whether to use it, we do not know what economic benefit removing the device will have for these individuals.

In addition to the individuals currently subject to the device, society may benefit from banning the device because we have determined that ESDs for self-injurious and aggressive behavior present an unreasonable and substantial risk of illness or injury for this indication. We do not currently foresee that society has an interest in banning this device for other indications in which individuals can give or withdraw consent for its use. For example, individuals can consent to use a similar device for the purpose of smoking cessation. In that case, there is no principal-agent problem because individuals can stop use of the device if they experience adverse effects. However, society does have an interest in protecting vulnerable populations from harm. That is, society has an interest in solving this principal-agent problem for the use of this device for SIB or AB in individuals (principals) who do not consent to use of this device, which poses unreasonable and substantial risks, and do not decide whether to discontinue use. We do not know how much society values the ban of this device.

F. Uncertainty

It is uncertain how individuals, the affected entity, and payers may react to the ban. We do not know how easily the affected entity can shift individuals away from using the device, or how quickly individuals will transition to alternative therapies. We do not know what alternative therapies the affected entity may choose to administer. We do not know whether individuals will stay at the affected facility or move to a different facility.

G. Analysis of Regulatory Alternatives to the Final Rule

This final rule will require that the use of the device cease by the effective date or, for devices currently in use and subject to a physician-directed transition plan, by 180 days after

publication of the final rule. One alternative would be to keep the effective date of 30 days in the proposed rule and not allow for an extended compliance date. This alternative would move up incremental costs related to shifts in treatment and could increase the costs of the final rule by a modest amount. However, the affected entity would not have to develop transition plans for specific individuals, which would reduce some of the costs of the final rule.

This alternative may make some individuals worse off if they would experience more self-injurious or aggressive behavior with an abrupt change in behavioral modification plans than they would experience with an extended compliance period. Other individuals may benefit, as they may experience more adverse effects of the device with a longer transition period than if the device was removed immediately. Thus, a shorter transition would move up potential benefits, as individuals would be exposed to the risks of the device for a shorter period.

Alternatively, we could extend the effective date or compliance date beyond the dates in the final rule. This would have opposite effect of shortening the effective date or compliance date that we discussed above. A more extended compliance date would delay incremental costs related to shifts in treatment. However, as part of a longer compliance period, the affected entity may develop a longer or more complex transition plan, which would require additional resources and add to the costs of the final rule. A longer compliance period may benefit individuals who would experience more self-injurious or aggressive behavior with an abrupt change in treatment than they would experience with an extended compliance period. (Note that comments on the proposed rule indicate to FDA that a 180-day transition would not be abrupt.) Other individuals may be worse off with an extended compliance period, as they may experience more adverse effects of the device. Thus, a longer transition period would delay potential benefits, as individuals would be exposed to the risks of the device for a longer period.

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. The small business cutoff from the Small Business Administration is $15 million for NAICS 623210 – Residential Intellectual and Developmental Disability Facilities or NAICS 623220 – Residential Mental Health and Substance Abuse Facilities (Ref. 4). The entity affected by the final rule reported revenues of about $72.1 million in 2017,[9] which exceeds the size threshold for small entities in this industry. Thus, we certify that the rule will not have a significant economic impact on a substantial number of small entities.

IV. References

1. U.S. Bureau of Labor Statistics, "Occupational Employment Statistics: May 2018 National-Industry Specific Occupational Employment and Wage Estimates." <http://www.bls.gov/oes/> May 2019.

2. JRC, Inc., public docket comment (attachment 11), FDA-2016-N-1111 (1k0-8reg-jdp8). Received July 25, 2016.

3. Brown, J.F., M.Z. Brown and P. DiBiasio. 2013. "Treating Individuals with Intellectual Disabilities and Challenging Behaviors with Adapted Dialectical Behavior Therapy." Journal of Mental Health Research in Intellectual Disabilities 6: 280-303.

4. U.S. Small Business Administration, 2017, Table of Size Standards. <http://www.sba.gov/content/table-small-business-size-standards> January 2018.

[9] The entity reported 2017 revenues on IRS Form 990. (Accessed July 24, 2019)