

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

# Banned Devices; Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious Behavior; Proposed Rule

Docket No. FDA-2016-N-1111

Preliminary Regulatory Impact Analysis  
Initial Regulatory Flexibility Analysis  
Unfunded Mandates Reform Act Analysis

Economics Staff  
Office of Planning  
Office of Policy, Planning, Legislation and Analysis  
Office of the Commissioner

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## I. Introduction and Summary

FDA proposes to ban electrical stimulation devices (ESDs) for the purpose of treating self-injurious or aggressive behavior. This action would 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 \$438 to \$753. The present value of the incremental treatment costs over 10 years ranges from \$0.0 to \$60.1 million at a three percent discount rate, and from \$0.0 to \$51.4 million at a seven percent discount rate. Annualized costs range from \$0.0 million to \$6.8 million at a three percent discount rate and from \$0.0 million to \$6.8 million at a seven percent discount rate.<sup>1</sup> Non-quantified benefits of the proposed rule include a reduction in adverse events, such as the risk of burns, post-traumatic stress disorder, and other physical or psychological harms related to use of the device. Additionally, there would be transfer payments between \$11.5 million and \$15.0 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 1a of this document provides the Regulatory Information Service Center and Office of Information and Regulatory Affairs Combined Information System accounting information for this analysis.

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

Table 1a.--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	\$3.4 million	\$6.8 million	2015	7%	10 years	
		\$0.0 million	\$3.4 million	\$6.8 million	2015	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	\$11.5 million	\$13.3 million	\$15.0 million	2015	7%	10 years	
		\$11.5 million	\$13.3 million	\$15.0 million	2015	3%	10 years	
	From: Affected entity for current treatment			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							

## II. Analysis of Impacts

We have examined the impacts of the proposed 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 (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). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed 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 proposed rule would only affect one entity that is not classified as small, we propose to certify that the proposed rule would 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 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 \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

## A. Background

Some individuals with intellectual or developmental disabilities exhibit aggressive or self-injurious behavior (SIB), while other individuals that exhibit SIB or aggressive behavior do not have intellectual or developmental disabilities. Examples of self-injurious behavior include head-banging, hand-biting, excessive scratching or picking of the skin. In addition, some individuals engage in aggressive behaviors that endanger 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 with SIB and aggressive behavior. 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.

We propose to ban electrical stimulation devices (ESDs) for the purpose of treating SIB or aggressive behavior. ESDs allow observers to administer an electric shock to an individual engaging in SIB or aggressive behavior or engaging in a precursor to SIB or aggressive behavior. 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 aggressive behavior in the individual. The devices operate on the principle of aversive conditioning and are sometimes referred to as

“aversives.” Though similar devices may be used for other indications, we seek only to ban ESDs for the treatment of SIB or aggressive behavior.

### B. Need for the Rule

Individuals with SIB or aggressive behaviors may injure themselves and others. To protect the individual from injury caused by SIBs and to protect others from injury caused by aggressive behaviors, some form of intervention may be required. At one facility, ESDs are used on some individuals with self-injurious or aggressive behaviors who reportedly have not responded well to other 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.

We are proposing to ban these devices for treatment of aggressive or self-injurious behavior, because we have determined that these devices present unreasonable and substantial risks 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 IV of the Preamble contains a full discussion of

why labeling cannot correct or eliminate the unreasonable and substantial risk posed by this device.

Individuals with 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.<sup>2</sup> 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<sup>3</sup>. 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 can't 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. Affected Firm and Products

The proposed rule would affect one firm that manufactures and uses aversive conditioning devices for self-injurious or aggressive behavior. The ban is for electrical stimulation devices that deliver a noxious shock to cause a reduction or cessation in aggressive or self-injurious behavior. We request comment on any other entities or devices that may be affected by the proposed rule.

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<sup>2</sup> In 2011, the Massachusetts Department of Developmental Services (DDS) proposed regulations to prohibit the use of contingent skin shock on individuals other than those who have an existing court-approved treatment plan that includes the use of such devices as of September 1, 2011.

<sup>3</sup> 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.



#### D. Costs of the Proposed Rule

Some changes in expenditures for transitioning individuals to alternative therapy would 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 would incur costs to learn about the rule. Such costs would include time to read and interpret the rule. Based on current best practice to account for costs to read and understand the rule, we assume an average adult reading speed of 200 to 250 words per minute. The preamble is 28,898 words, which translates to around 1.9 to 2.4 hours per person to read the rule. In valuing this time, we use average wages from the Bureau of Labor Statistics' national industry-specific occupational employment and wage estimates (Ref. 1).<sup>4</sup> The average hourly wage rate ranges from \$40.49 to \$43.70 for management occupations (average of occupation codes 11-1000, 11-3031 and 11-9111), from \$24.96 to \$25.19 for healthcare occupations (occupation code 29-0000), and is \$48.33 for legal occupations (occupation code 23-0000).<sup>5</sup> The average wage for the three occupations ranges from \$37.93 to \$39.07. The lower-bound wage rates are for Residential Intellectual and Developmental Disability Facilities (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 would cost between \$438 and \$753 for three to four people from the affected entity to read the rule ( $=1.9*3*2*\$37.93$  and  $2.4*4*2*\$39.07$ ). We request comment on these costs.

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4 May 2014 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/>>

5 The BLS did not publish wage estimates for legal occupations within NAICS 623210 in 2014. We use instead the legal occupation wage reported in NAICS 623220.

## 2. *Impact on the affected entity*

The ban of aversive conditioning devices would require that the facility stop using the devices immediately upon publication of the proposed rule. A comment submitted by the affected entity in June 2015 reported that the device was court-approved for use in 61 individuals, with 47 currently using the device (Ref. 2). We use a range of 47 to 61 as the number of individuals affected by this proposed rule, which captures those currently using 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 treatment, including the reimbursement for the affected entity. In 2015, the reimbursement for the affected entity was \$245,700 per individual.<sup>6</sup> If affected individuals were to move to a different facility, between \$11.5 million and \$15.0 million in revenue from those individuals would be transferred to another entity providing alternative treatment ( $=47*\$245,713$  and  $=61*\$245,713$ ).

The incremental treatment costs of the proposed rule would equal the difference in the cost of treatment with the device and the cost of an alternative treatment. We looked at Massachusetts' reimbursement rates for other residential facilities that appear to serve similar individuals. Annual rates for 2015 for these facilities ranged from about \$242,000 to about \$358,000 per year. If individuals transfer to a cheaper facility, ongoing treatment costs could decrease slightly; if individuals transfer to the most expensive facility, the treatment costs could increase. For example, if all 61 individuals transferred to the most expensive facility reimbursed

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<sup>6</sup> Accessed October 7, 2015 from <http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/osd/special-education-pricing.html>. Massachusetts' reimbursement rates are listed as tuition rates and include the program cost for a student in a residential program including incidental medicine costs.

by Massachusetts that treats SIB or aggressive behaviors, incremental treatment costs would increase up to \$6.8 million per year ( $61 * (\$357,790 - \$245,713)$ ).<sup>7</sup>

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 the two thirds of its residents that do not use the device and to all residents when they first arrive at the facility. 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 would remain unchanged. However, we lack information about the cost to provide alternative treatment to the 47 individuals currently on the device. Providing alternative therapy is not necessarily more costly than the existing treatment at the affected facility: one study found that Dialectical Behavioral Therapy cost averages about \$179,500 per year in 2015 dollars, with the most expensive treatment costing \$195,900 per year (Ref. 3).<sup>8</sup> Nevertheless, the affected facility would likely incur some transition costs as they move residents to alternative treatments. These transition costs could include additional professional expertise, training for existing staff, the administration of additional drugs, and possibly the hiring of additional staff. We request detailed data and comment on the potential cost of transitioning residents for the affected entity.

### *3. Impact on Individuals*

For the 47 individuals currently using the device, costs to them would vary, depending on how quickly they adjust to an alternative treatment program and whether for the individual, the alternative treatment 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 would

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<sup>7</sup> This facility is located in New Hampshire.

<sup>8</sup> These costs range from \$482 to \$526 per day, or \$175,930 to \$191,990 per year, in 2013 dollars.

change due to rule-induced switches to other treatment programs. We request detailed comment and data on the possible effects of shifting to a different treatment program for individuals.

#### 4. *Other costs*

We request comment on additional costs we may have excluded from our analysis.

#### D. Cost to Government

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

#### E. Summary of the Quantified Costs of the Rule

The estimated one-time costs of the rule would range from \$438 to \$753; the annual incremental costs of the rule range from about \$0 per year to about \$6.8 million per year.<sup>9</sup> The annualized costs of the present value of total costs range from \$0.0 million to \$6.8 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 alternative treatments or moving to a different facility. Our primary estimate of the present value of the total incremental costs of the proposed rule over 10 years equals \$25.7 million with a 7 percent discount rate and \$30.0 million with a 3 percent discount rate. The

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<sup>9</sup> These estimates assume that, without the rule, the number of individuals who would have used the device would be constant over time.

primary estimate of annualized costs of the present value of total costs equal \$3.4 million at both a 3 percent and 7 percent discount rate.

#### F. Potential Benefits of the Proposed Rule

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

Individuals with SIB and aggressive behavior 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 treatment. 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 post-traumatic stress disorder. For other individuals using similar devices for other indications (e.g. smoking cessation therapy), individuals may be able to avoid these risks by discontinuing their treatment. Because the individuals with SIB or aggressive behavior can't give or withdraw consent for the use of the device, these individuals can't choose to avoid these risks. Because individuals often can't express their preferences about the device and are not the ones deciding whether to use it, we do not know what economic benefit removing the device would have for these individuals. We request comment on the potential economic benefits of the proposed rule.

In addition to the individuals currently using the device, society may benefit from banning the device because we have determined that ESDs present unreasonable and substantial risks 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. In this 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 to treat self-injurious and aggressive behavior 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 treatment. We do not know how much society values the ban of this device.

#### G. 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.

#### H. Alternatives Considered

The proposed rule, if finalized, would require that use of the device cease by the effective date. One alternative would be to extend the effective date or compliance date of the rule, and allow a more gradual removal of the device. Some of the members of the Advisory Committee suggested that a transition period of up to six months would be appropriate. Because an extended compliance period would delay incremental costs related to shifts in treatment, this alternative could reduce the costs of the proposed rule by a modest amount. However, as part of a longer compliance period, the affected entity may develop a transition plan, which would require additional resources and add to the costs of the proposed rule.

This alternative 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. Other individuals may be worse off with an extended compliance

period, as they may experience more adverse effects of the device than if the device was removed immediately. Thus, a longer transition would delay potential benefits, as individuals would be exposed to the risks of the device for a longer period. A delay in benefits would reduce the benefits of the proposed rule.

### I. Impact on Small Entities

The Regulatory Flexibility Act requires a Regulatory Flexibility Analysis (RFA) unless the Agency can certify that the proposed rule would have no significant impact on a substantial number of 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 proposed rule reported revenues of about \$64.5 million in 2013<sup>10</sup>, which exceeds the size threshold for small entities in this industry. Thus, we propose to certify that the rule would not have a significant economic impact on a substantial number of small entities.

### III. References

1. U.S. Bureau of Labor Statistics, “Occupational Employment Statistics: May 2014 National-Industry Specific Occupational Employment and Wage Estimates.” <http://www.bls.gov/oes/> November 2015.
2. Judge Rotenberg Center. Letter to FDA. June 19, 2015.
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, 2014, Table of Size Standards. <http://www.sba.gov/content/table-small-business-size-standards> January 2015.

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<sup>10</sup> The entity reported 2013 revenues on IRS Form 990.