

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 895

[Docket No. FDA-2016-N-1111]

Banned Devices; Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to ban electrical stimulation devices used to treat aggressive or self-injurious behavior. FDA has determined that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. FDA is proposing to include in this ban both new devices and devices already in distribution and use.

DATES: Submit either electronic or written comments on the proposed rule by May 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-1111 for "Proposal to Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the

electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Proposed Rule

FDA is proposing to ban electrical stimulation devices (ESDs) used for self-injurious or aggressive behavior. ESDs are devices that apply a noxious electrical stimulus to a person's skin upon the occurrence of a target behavior in an attempt to condition the individual over time to reduce or cease the behavior. Self-injurious behaviors (SIB) and aggressive behaviors (AB) frequently manifest in the same individual, and people with intellectual or developmental disabilities exhibit these behaviors at disproportionately high rates. Notably, many such people have difficulty communicating and cannot make their own treatment decisions because of such disabilities, meaning many people who exhibit SIB or AB are among a vulnerable population. SIB commonly include: Head-banging, hand-biting, excessive scratching, and picking of the skin. However, SIB can be more extreme and result in bleeding, protruding, and broken bones; blindness from eye-gouging or poking; other permanent tissue damage; or injuries from swallowing dangerous objects or substances. AB involve repeated physical assaults and can be a danger to the individual, others, or property. In our proposed rule, like much of the scientific literature, we discuss SIB and AB in tandem.

ESDs are intended to reduce SIB and AB according to the principle of aversive conditioning. Aversive conditioning pairs a noxious stimulus with a target behavior such that the individual begins to associate the noxious stimulus with the behavior, with the intended result being that the individual ceases engaging in the behavior and, over time, becomes conditioned not to manifest the target behavior. A noxious stimulus is one that is uncomfortable or painful; the noxious stimulus delivered by an ESD is an

electric shock to the skin. Some ESDs are intended for other purposes, such as smoking cessation; however, the proposed ban includes only those devices intended to reduce or eliminate SIB or AB. ESDs are not used in electroconvulsive therapy, sometimes called electroshock therapy or ECT, which is unrelated to this proposed rulemaking.

The effects of the shock are both psychological (including suffering) and physical (including pain), each having a complex relationship with the electrical parameters of the shock. As a result, the subjective experience of the person receiving the shock can be difficult to predict. Physical reactions roughly correlate with the peak current of the shock delivered by the ESD. However, various other factors such as sweat, electrode placement, recent history of shocks, and body chemistry can physically affect the sensation. As a result, the intensity or pain of a particular set of shock parameters can vary greatly from patient to patient and from shock to shock. Possible adverse psychological reactions are even more loosely correlated with shock intensity in that the shock need not exceed certain physical thresholds. Rather, the shock need only be subjectively stressful enough to cause trauma or suffering. Trauma becomes more likely, for example, when the recipient does not have control over the shock or has developed a fear of future shocks, neither of which is an electrical parameter of the shock.

Whenever FDA finds, on the basis of all available data and information, that a device presents substantial deception or an unreasonable and substantial risk of illness or injury, and that such deception or risk cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, FDA may initiate a proceeding to ban the device. In making such a finding, FDA weighs the benefits against the risks posed by the device and considers the risks relative to the state of the art. With respect to ESDs for SIB and AB, FDA has weighed these factors based on consideration of information from a variety of sources, including the scientific literature, opinions from experts (including an advisory panel meeting), information from and actions of State agencies, information from the affected manufacturer, information from patients and their family members, and information from other stakeholders.

FDA has determined that ESDs for SIB or AB present a number of psychological and physical risks: Depression, fear, escape and avoidance behaviors, panic, aggression,

substitution of other behaviors (*e.g.*, freezing and catatonic sit-down), worsening of underlying symptoms (*e.g.*, increased frequency or bursts of self-injury), pain, burns, tissue damage, and errant shocks from device misapplication or failure. Based on literature for implantable cardioverter defibrillators, FDA has determined that ESDs present the risks of posttraumatic stress or acute stress disorders, shock stress reaction, and learned helplessness. That literature provides additional support for the risks of depression, anxiety, fear, and pain. Experts in the field of behavioral science, State agencies that regulate the use of ESDs, the sole current manufacturer and user of ESDs, and individuals who were subject to ESDs corroborate most of these findings, and they attest to additional risks.

Our search of the scientific literature revealed a number of studies showing that ESDs result in the immediate interruption of the target behavior upon shock, and some of the literature also suggested varying degrees of durable conditioning. However, the studies in the literature suffer from serious limitations, including weak study design, small size, and adherence to outdated standards for study conduct and reporting. The conclusions of several of the studies are undermined by study-specific methodological limitations, lack of peer review, and author conflicts of interest. There is also evidence that the shocks are completely ineffectual for certain individuals.

FDA weighed the benefits against the risks. FDA recognizes that ESDs can cause the immediate interruption of self-injurious or aggressive behavior, but the evidence is otherwise inconclusive and does not establish that ESDs improve the underlying disability or successfully condition individuals to achieve durable long-term reduction of SIB or AB. The short-term effect of behavior interruption is outweighed by the numerous short- and long-term risks. For many individuals who exhibit SIB or AB, these risks are magnified by their inability to adequately communicate the harms they experience to their health care providers. Even if immediate cessation is achieved, without durable conditioning the target behavior will recur over time and necessitate ongoing shocks to cause immediate cessation, magnifying the risks. For some patients, the shocks are wholly ineffective and can lead to progressively stronger shocks with the same result. Thus the degree to which the risks outweigh the benefits increases over time.

When considering the reasonableness of the risk of illness or injury posed by a device in a banning proceeding, FDA also considers the state of the art. Notably, the use of aversive conditioning in general, and ESDs in particular, has been on the decline for decades; only one facility in the United States still uses ESDs for SIB and AB. This decline is due in part to scientific advances that have yielded new insights into the organic causes and external (environmental or social) triggers of SIB and AB, allowing the field to move beyond intrusive punishment techniques such as aversive conditioning with ESDs. Moreover, punishment techniques (which include the use of ESDs) are highly context-sensitive, so the same technique may lose effectiveness simply by changing rooms or providers. The evolution of the state of the art responded to this limitation by emphasizing skills acquisition and individual choice. The evolution is also due in part to the ethical concerns tied to the risks posed by devices such as ESDs, especially regarding the application of pain to a vulnerable patient population.

In light of scientific advances, out of concern for ethical treatment, and in an attempt to create generalizable interventions that work in community settings, behavioral scientists have developed safer, successful treatments. The development of the functional behavioral assessment, a formalized tool to analyze and determine triggering conditions, has allowed providers to formulate and implement plans based on positive techniques. As a result, multi-element positive interventions (*e.g.*, paradigms such as positive behavior support or dialectical behavioral therapy) have become state-of-the-art treatments for SIB and AB. Such interventions achieve success through environmental modification and an emphasis on teaching appropriate skills. Behavioral intervention providers may also recommend pharmacotherapy (the use of medications) as an adjunct or supplemental method of treatment. Positive-only approaches are generally successful even for challenging SIB and AB, in both clinical and community settings. The scientific community has long since recognized that addressing the underlying causes of SIB or AB, rather than suppressing it with painful shocks, not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits.

Based on all available data and information, FDA has determined that the risk of illness or injury posed by ESDs for SIB and AB is substantial and

unreasonable and that labeling or a change in labeling cannot correct or eliminate the unreasonable and substantial risk of illness or injury. The purpose of this proposed rule is to seek comments on these determinations as well as seek comments on FDA's proposal to ban ESDs used for SIB or AB and comments on any other associated issues.

Legal Authority

The FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device presents substantial deception or an unreasonable and substantial risk of illness or injury. A banned device is adulterated except to the extent it is being studied pursuant to an investigational device exemption. This proposed rule is also issued under the authority to issue regulations for the efficient enforcement of the FD&C Act.

In determining whether a deception or risk of illness or injury is "substantial," FDA will consider whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing. Although FDA's device banning regulations do not define "unreasonable risk," FDA previously explained that, with respect to "unreasonable risk," we will conduct a

careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users. The state of the art with respect to this proposed rule is the state of current technical and scientific knowledge and medical practice with regard to the treatment of patients exhibiting self-injurious and aggressive behavior.

Thus, in determining whether a device presents an "unreasonable and substantial risk of illness or injury," FDA analyzes the risks and the benefits the device poses to individuals, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice. Actual proof of illness or injury is not required; FDA need only find that a device presents the requisite degree of risk on the basis of all available data and information.

Whenever FDA finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury, and that such deception or risk cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, FDA may initiate a proceeding to ban the device.

Summary of the Major Provisions of the Proposed Rule

If this proposed rule is finalized as proposed, the ban would include devices that apply a noxious electrical

stimulus to a person's skin to reduce or cease aggressive or self-injurious behavior. The proposed ban would apply to devices already in commercial distribution and devices already sold to the ultimate user, as well as devices sold or commercially distributed in the future. A banned device is an adulterated device, subject to enforcement action. The ban may not, however, prevent further study of such devices pursuant to an investigational device exemption.

Costs and Benefits of the Proposed Rule

FDA is proposing to ban ESDs for the purpose of treating self-injurious or aggressive behavior. Because we lack sufficient information to quantify the benefits, we include a qualitative description of some potential benefits of the proposed rule. We expect that the rule would directly affect only one entity. In addition to the incremental costs this entity would incur to comply with the requirements of the proposed rule, there would be potential transfer payments of between \$11.5 million and \$15 million annually either within the affected entity or between entities. The present value of total costs over 10 years ranges from \$0 million to \$60.1 million at a 3 percent discount rate, and ranges from \$0 million to \$51.4 million at a 7 percent discount rate. Annualized costs range from \$0 million to \$6.8 million at a 3 percent discount rate and range from \$0 million to \$6.8 million at a 7 percent discount rate.

TABLE OF ABBREVIATIONS AND ACRONYMS

Abbreviation or acronym	What it means
AB	Aggressive Behavior.
ABA	Applied Behavior Analysis.
AE	Adverse Event.
DBT	Dialectical Behavioral Therapy.
DDS	(Massachusetts) Department of Developmental Services.
DEEC	(Massachusetts) Department of Early Education and Care.
EA	Environmental Assessment.
ESD	Electrical Stimulation Device.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FONSI	Finding of No Significant Impact.
GED	Graduated Electronic Decelerator.
ICD	Implantable Cardioverter Defibrillator.
JRC	Judge Rotenberg Educational Center, Inc.
NASDDDS	National Association of State Directors of Developmental Disability Services.
NYSED	New York State Education Department.
PBS	Positive Behavioral Support.
PTSD	Post-traumatic Stress Disorder.
SIB	Self-Injurious Behavior.
SIBIS	Self-Injurious Behavior Inhibiting System.

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I. Background

A. Introduction

Electrical stimulation devices (ESDs) for self-injurious behavior (SIB) or aggressive behavior (AB) are devices that apply a noxious electrical stimulus (a shock) to a person's skin to reduce or cease such behaviors. Although FDA cleared a few of these devices more than 20 years ago, due to scientific advances and ethical concerns tied to the risks of ESDs, state-of-the-art medical practice has evolved away from their use and toward various positive behavioral treatments, sometimes combined with pharmacological treatments. Only one facility in the United States has manufactured these devices or used them on individuals in recent years. As a result of this evolution in treatment over the past several decades, the available data and information on the risks and benefits of ESDs are limited.

Although the available data and information show that some individuals subject to ESDs exhibit an immediate reduction or cessation of the targeted behavior, the available evidence has not established a durable long-term conditioning effect or an overall-favorable benefit-risk profile for ESDs for SIB and AB. No randomized, controlled clinical trials have been conducted, and the studies that have been conducted are generally small and suffer from various limitations, including the use of concomitant treatments over long periods that make it difficult to determine the cause of any behavioral changes. The medical literature shows that ESDs present risks of a number of psychological harms including depression, posttraumatic stress disorder (PTSD), anxiety, fear, panic, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness (becoming unable or unwilling to respond in any way to the ESD); and the devices present the physical risks of pain, skin burns, and tissue damage.

Because the medical literature likely underreports adverse events (AEs), risks identified through other sources, such as from experts in the field, State

agencies that regulate ESD use, and records from the only firm that has recently manufactured and is currently using ESDs for SIB and AB demand closer consideration. As discussed in section II.A, these sources further support the risks reported in the literature and indicate that ESDs have been associated with additional risks such as suicidality, chronic stress, acute stress disorder, neuropathy, withdrawal, nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and injuries from falling. In contrast to the state of the art for the treatment of SIB and AB, the risks of ESDs are unreasonable.

As discussed later in this document, FDA has determined that ESDs present a substantial and unreasonable risk of illness or injury and that the risks cannot be corrected or eliminated by labeling. Thus, FDA has decided to ban these devices under section 516 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360f). The proposed rule applies to devices already in distribution and use, as well as to future sales of these devices.

B. What are SIB and AB, and how do they affect patients?

SIB and AB are among the most striking and devastating conditions associated with intellectual and developmental disabilities (Ref. 1). Individuals with such disabilities may exhibit destructive behavior that falls within two major categories, self-injury and aggression toward others or property. The most common forms of self-injury include head-banging, hand-biting, excessive scratching, and picking of the skin. The most extreme cases of persons with serious self-injurious behavior afflict an estimated 25,000 or more individuals in the United States (Ref. 2). These more extreme behaviors usually involve repeated, self-inflicted, non-accidental injuries producing, for example: (1) Bleeding, protruding, and broken bones; (2) eye gouging or poking leading to blindness; (3) other permanent tissue damage; and (4) swallowing dangerous substances or objects. (For a more detailed technical discussion, see Ref. 3.)

Persons who exhibit SIB also frequently demonstrate aggression, the other major category of destructive behavior. Aggressive behaviors encompass a wide range of behaviors, which are generally defined by conduct that, due to its intensity or frequency, presents an imminent danger to the person who demonstrates it, to other people, or to property (see, e.g., Ref. 4

for a discussion of aggression in autistic children). Aggressive behaviors that involve repeated physical assaults are dangerous particularly for caregivers and family. Beyond the potential for obvious physical injury, SIB and AB can be very distressing for parents and caregivers (Ref. 5), severely limit the patient's participation in community activities, and lead to placement of the patient in a more restrictive living environment (Ref. 6). Accordingly, intervention is necessary for the safety of the individual engaging in the aggressive behavior, for those against whom the aggression is directed, and for the protection of property.

The majority of published studies on SIB include aggression either as part of the description of the clinical spectrum of the behavior or as an inclusion criterion for the clinical study. Accordingly, this proposed rule addresses self-injury and aggression in tandem as SIB and AB. Destructive behavior in both major categories—aggression and self-injury—are often present in individuals with intellectual or developmental disabilities. Examples of those disabilities include, but are not limited to: Autism spectrum disorder, Cornelia de Lange syndrome, Down syndrome, Fragile X syndrome, hereditary sensory neuropathy, Lesch-Nyhan syndrome, Rett syndrome, and Tourette syndrome. Those disabilities may also include visual impairment, severe intellectual impairment, and a variety of cognitive and psychiatric disorders.

Estimates of the prevalence of SIB in individuals with intellectual or developmental disabilities range from 2.6 percent to 40 percent (Ref. 7), or 2 to 23 percent in community samples (Ref. 8). More recently, one analysis found a prevalence of SIB in a clinical population of children with developmental disabilities at 32 percent, suggesting that the actual prevalence may be at the high end of earlier estimates (Ref. 9). Estimates of the prevalence of AB in individuals with intellectual or developmental disabilities range as high as 52 percent, though 10 percent is more commonly reported (Ref. 8). Thus, by conservative estimates, counting only individuals who have intellectual or developmental disabilities (and not all people who manifest SIB or AB), at least 330,000 people in the United States manifest SIB, AB, or both; less conservative estimates are much higher (see Refs. 3 and 8).¹

¹ An estimated 1 to 3 percent of individuals in the United States have an intellectual or developmental

C. What are ESDs and how do they affect SIB and AB?

As stated, ESDs apply a noxious electrical stimulus (a shock) to a person's skin upon the occurrence of a target behavior in an attempt to reduce or cease the behavior. As such, ESDs are a type of aversive conditioning device ("aversive"). ESDs apply shocks to the skin. ESDs are not used in ECT, sometimes called electroshock therapy, which is unrelated to this rulemaking. The electrical shock from an ESD is intended to interrupt the undesirable behavior and result in its quick cessation. Repeatedly pairing the shock with the unwanted behavior is intended to cause individuals to associate the two and thereby induce them to decrease the frequency of the behavior or stop it altogether. In order to achieve the intended results, the shock must be applied during the behavior (for cessation and decrease) or immediately afterward (for decrease). ESDs are intended to affect behavior in two ways: By interrupting the target behavior as an immediate response to the stimulus and, over time, through a conditioned reduction in the target behavior.

The main components of ESDs are an electrical stimulus generation module, electrodes, and a trigger switch. Either a remote monitor module or an automatic mechanism can trigger the electric shock to the individual. Typically, the patient carries the stimulus generation module, which applies an electrical current (the shock) to the individual's skin via electrodes. When a remote monitor is used, an observer determines when to apply an electrical shock to the patient and triggers a shock from a specific stimulus generation module via a radiofrequency signal. Alternatively, a sensor can detect certain unwanted behaviors and automatically activate the generation module. For example, an accelerometer attached to the head could detect head-banging and, when the behavior is severe enough, trigger an electrical shock.

Although several factors specific to the patient affect shock perception, the key device output characteristics that most affect shock perception include: Electric current, voltage, skin resistance (or load), pulse width, shock duration, output frequency and waveform,

electrode characteristics (e.g., size, location, design, or material), and the number and frequency of shocks delivered. For the purposes of this proposed rule, a stronger shock is one for which at least one of those parameters is adjusted to increase the intensity or sensation.

Electric current, measured in milliamperes (mA) for ESDs, is the primary variable for determining the effects of an electric shock that passes through the body. To determine the current output of a device designed to deliver a constant voltage, the voltage is divided by the electric resistance, measured in ohms (Ω), the relationship described by Ohm's Law. A lower resistance for a given voltage results in higher current; the skin's conducting resistance can vary between 1 k Ω and 100 k Ω (Refs. 10 and 11). Sweat and blood are excellent conductors and therefore lower the conducting resistance, which increases the current and the intensity of the stimulus.

The sensory nerves respond to the current as a function of its strength and duration. A stronger current will elicit a response with a shorter pulse width, and a weaker current will need a longer pulse width to elicit the same response. The pulse width (or pulse duration) is the length of time a pulse of current is applied to the skin, measured in milliseconds for ESDs. Longer pulse durations have been shown to increase the intensity or unpleasantness of the sensation in healthy subjects (Refs. 12–14).

The characteristics of the electrodes that deliver the shock to the skin also affect the perception of the shock. The amount of current delivered per unit area of an electrode is referred to as the current density. A higher current density has been found to correspond with a more intense or unpleasant feeling (Refs. 15 and 16). One study has shown that smaller electrodes deliver painful shocks that are described as sharp, cutting, or lacerating. Larger electrodes for the same current are associated with pain that was pinching, pressing, or gnawing (Ref. 16). A related measure, power density, is found by multiplying the current and the voltage and relating the product to surface area; it is expressed as watts per unit area. Both current and power densities correlate with the risk of burns; a higher current or power density increases the risk. The risk of burns also increases when the current itself is direct current; all FDA-cleared ESDs utilize alternating current (AC) rather than direct current (DC).

Electrodes additionally affect pain sensation in that placement on locations

with a higher density of sensory nerves will result in more pain. For that reason, the hands, feet, genitals, underarms, torso, neck, and face will be particularly sensitive to shocks. Repeated shocks to the same location will also alter the perception, increasing intensity or pain (Refs. 17–19). The exact mechanism behind this change is unclear, but one hypothesis holds that the changing sensation may result from changes in the skin's electrical resistance (Ref. 19). Others have hypothesized that repeated stimulation depletes endorphins, which are chemicals that affect pain sensation (Ref. 17).

Finally, with regard to key device output parameters, some authors have attempted to relate physiological responses, sensations and muscle contraction for example, to electric current (e.g., Refs. 10, 11, and 20). The Judge Rotenberg Educational Center, Inc. (JRC), the only entity of which FDA is aware that has recently manufactured ESDs and that currently uses ESDs, has submitted a similar comparison (Ref. 21). However, comparisons based solely upon the electric current oversimplify the relationship because they do not account for other key parameters, nor do they account for intersubject variability in perception. (See, for example, Refs. 11, 17, 18, and 22–25). Such comparisons also do not account for the recipient's psychological state (Refs. 18, 22, and 23), which can affect the response to shocks. Furthermore, the relationships between current and response as reported by these authors (Refs. 10, 11, and 20) are more relevant in a setting where a body part comes into direct contact with a 60-Hz AC electrical source (e.g., a current from a wall outlet), with the current passing through the chest. In contrast, ESDs provide localized stimulation to the skin through an electrode interface. Thus, although the amount of current may suggest a type of response (e.g., tingling, pain, or involuntary muscle contraction), predictions based on such thresholds are subject to considerable uncertainty.

These key device output parameters affect the experience of the shock primarily in terms of physiological responses (see Ref. 3 for a more technical discussion). As explained in more detail in section II.A.1, a stimulus need not be physically intense to trigger an adverse psychological reaction. Thus, although lower peak current or shorter pulse duration corresponds with lower physical intensity, neither necessarily corresponds with a less-adverse psychological response. Table 1 summarizes the device output characteristics of ESDs for SIB or AB

disability (Ref. 8). Given a U.S. population of 330 million, at least 3.3 million people would have such a disability; 10 percent of 3.3 million is 330,000, and 2 percent of 3.3 million is 66,000. If there is no overlap, the total would be 396,000 people. These numbers are based on the lowest bounds reported in Ref. 8. Using the same source and method, the highest bound would yield an estimate of about 7.4 million people.

that have been cleared by FDA or are currently in use. Note that FDA has

cleared 510(k)s for ESDs for SIB or AB from other manufacturers besides JRC.

TABLE 1—DEVICE OUTPUT CHARACTERISTICS

Device name	Average current	Max current	Max voltage	Pulse width	Shock duration	Frequency	Power density
Whistle Stop ¹	10 mA at 20 kΩ	200 V	1–2 ms	0.5–12 s	10 Hz	0.02 W/cm. ²
SIBIS	3.5 mA at 20 kΩ	10 mA	200 V	6.2 ms	0.1–0.2 s	80 Hz	0.16 W/cm. ²
GED, GED–3A ²	12 mA at 5 kΩ	29.4 mA at 5 kΩ	150 V	3.125 ms	2 s	80 Hz	1.01 W/cm. ²
GED–4 ²	42 mA at 5 kΩ	90 mA	3.125 ms	2 s	80 Hz

¹ The 510(k) did not include enough information for FDA to determine the average current of the device (as indicated by blank field).

² The GED–3A and GED–4 have not been cleared or approved by FDA, and we do not have information about all device characteristics (as indicated by blank fields).

Again, individual patient variability makes comparison across devices—and even individual shock applications—difficult. Some people are generally highly sensitive to current, experiencing involuntary muscle contraction from static electric shocks. On the other end of the spectrum, some individuals can draw a large static electric spark and hardly perceive it, much less experience a muscle spasm. Studies of subjects without intellectual or developmental disabilities have demonstrated a large range of intersubject variability for equally applied shocks. For example, one study found that the range of pain thresholds was 3.9 to 11.6 mA (Ref. 11), while another found the range was 0.45 to 2.4 mA (Ref. 25). Such articles often did not include key output characteristics, such as pulse width and frequency or electrode size and placement, further confounding attempts to compare or apply the findings. In light of variability and methodological limitations underlying the reported current-response relationships, physiological responses, including pain perception, are difficult to predict accurately, especially based solely on the current.

D. How has FDA regulated ESDs in the past?

In 1979, FDA classified aversive conditioning devices as class II (see § 882.5235 (21 CFR 882.5235)), which was consistent with the recommendation of the Neurological Device Classification Panel of the Medical Device Advisory Committee in 1978. Such devices may or may not use electric shocks to administer a “noxious stimulus to a patient to modify undesirable behavioral characteristics” (§ 882.5235). Thus, ESDs intended to treat SIB and AB are within the aversive conditioning device classification regulation. The proposed rule for classifying aversives, including ESDs, focused on the risks of: (1) Worsened psychological conditions, (2) errant

electric shocks, and (3) the harmful or lethal nature of excess electric current or its inappropriate application (43 FR 55705, November 28, 1978). At the time, FDA and the panelists believed that performance standards could adequately assure the safety and effectiveness of aversives. We received no comments from the public on the proposed rule, and we issued the final rule classifying aversives as proposed at § 882.5235 (44 FR 51726 at 51765, September 4, 1979).

FDA has cleared four devices for the treatment of SIB as substantially equivalent to the ones initially placed into class II, 510(k) notification numbers and clearance dates in parentheses:

- Stimulator Sonic Control, “Whistle Stop” (K760166; July 20, 1976);
- Self-Injurious Behavior Inhibiting System, “SIBIS” (K853178; February 28, 1986);
- SIBIS Remote Actuator (K871158; May 29, 1987); and
- Graduated Electronic Decelerator, “GED” (K911820; December 5, 1994).

A prescription is required for each, meaning that Federal law restricts the sale of these aversives to professionals licensed according to State requirements or those acting pursuant to a licensed professionals orders (see 21 CFR 801.109).

As part of the evaluation of the premarket notifications, *i.e.*, the 510(k) submissions, FDA reviewed the average current (the amount of electricity) and power density of the shocks (the wattage applied to a given area of skin), among other things. Average current and power density are important parameters in determining the likelihood and severity of a potential physical injury from a shock. The cleared ESDs include warnings never to place electrodes on the head or chest, or in such a way that current would flow through the chest because this could cause ventricular fibrillation (a dangerous irregularity in the heartbeat).

We are aware of only one manufacturer, JRC, that has recently

manufactured ESDs and that currently uses ESDs, including devices that we have not previously cleared. JRC uses these devices because it is also a residential facility, and its employees apply the devices to individuals there. In 2000, FDA incorrectly notified JRC that it qualified for exemption from registration and 510(k) requirements under 21 CFR 807.65(d). Once FDA recognized its error, FDA sent JRC an Untitled Letter on May 23, 2011, and a Warning Letter on December 6, 2012, for violations related to the lack of FDA clearance or approval for the modified GED devices.²

FDA now has a better understanding of the risks and benefits presented by these devices than it did 36 years ago when these devices were classified, and, as discussed later in sections II.A and II.B, the state of the art for the treatment of SIB and AB has progressed significantly over that time period. As a result, FDA now believes that the risk of illness or injury from the use of ESDs for the treatment of SIB and AB is unreasonable and substantial.

E. Scope of the Ban

The ban would apply to devices that apply a noxious electrical stimulus to a person’s skin to reduce or stop aggressive or self-injurious behavior. (See section I.B for a discussion of the relevant behaviors; see also Ref. 3 for a more technical discussion of the scientific literature regarding these behaviors.) To FDA’s knowledge, the only such devices that are currently in use are two models of the GED device (the GED–3A and GED–4), neither of which has been cleared or approved by the Agency.

The ban would not apply to ESDs used to create aversions to other conditions or habits, such as smoking. Although other ESDs have parallels in

² The Warning Letter is available on the Internet at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm331291.htm>.

treatment strategy and method, those devices address very different conditions in very different patient populations. Smoking-cessation devices differ with respect to whether patients have control over the shocks—and what level of control they have—as well as how the electric shock affects the target behavior and underlying conditions. These differing types of ESDs thus present different benefit-risk profiles.

Importantly, individuals who manifest SIB or AB typically have additional vulnerabilities that relate directly to the risks of the treatment method. For example, individuals with intellectual or developmental disabilities who manifest SIB or AB, and who have difficulty communicating pain or other harms that may be caused by ESDs would bear a higher risk of injury from the shock than smokers who choose to use an ESD to help quit smoking. Those smokers, if without intellectual or developmental disabilities, can immediately communicate pain to the device's controller or remove the device themselves. They can communicate symptoms of other harms that may be caused by ESDs, such as PTSD, to their health care provider, which may lead to discontinuation of the device's use. Communication challenges in patients who suffer from SIB and AB are discussed in the literature, were raised by the advisory panel, and are reviewed in more detail in section II.A.

F. Legal Authority

Section 516 of the FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device “presents substantial deception or an unreasonable and substantial risk of illness or injury” (21 U.S.C. 360f(a)(1)). A banned device is adulterated under section 501(g) of the FD&C Act (21 U.S.C. 351(g)), except to the extent it is being studied pursuant to an investigational device exemption under section 520(g) of the FD&C Act (21 U.S.C. 360j(g)). This proposed rule is also issued under the authority of section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which provides authority to issue regulations for the efficient enforcement of the FD&C Act.

In determining whether a deception or risk of illness or injury is “substantial,” FDA will consider whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued

marketing (see § 895.21(a)(1) (21 CFR 895.21(a)(1))). Although FDA's device banning regulations do not define “unreasonable risk,” in the preamble to the final rule promulgating 21 CFR part 895, FDA explained that, with respect to “unreasonable risk,” it “will conduct a careful analysis of risks associated with the use of the device relative to the state of the art and the potential hazard to patients and users” (44 FR 29214 at 29215, May 18, 1979; Ref. 25a). The state of the art with respect to this proposed rule is the state of current technical and scientific knowledge and medical practice with regard to the treatment of patients exhibiting self-injurious and aggressive behavior.

Thus, in determining whether a device presents an “unreasonable and substantial risk of illness or injury,” FDA analyzes the risks and the benefits the device poses to individuals, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice. Actual proof of illness or injury is not required; FDA need only find that a device presents the requisite degree of risk on the basis of all available data and information (H. Rep. 94–853 at 19; 44 FR 28214 at 29215).

Whenever FDA finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury, and that such deception or risk cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, FDA may initiate a proceeding to ban the device (see § 895.20). If FDA determines that the risk can be corrected through labeling, FDA will notify the responsible person of the required labeling or change in labeling necessary to eliminate or correct such risk (see § 895.25).

Section 895.21(d) requires this proposed rule to briefly summarize:

- The Agency's findings regarding substantial deception or an unreasonable and substantial risk of illness or injury;
- the reasons why FDA initiated the proceeding;
- the evaluation of the data and information FDA obtained under provisions (other than section 516) of the FD&C Act, as well as information submitted by the device manufacturer, distributor, or importer, or any other interested party;
- the consultation with the classification panel;
- the determination that labeling, or a change in labeling, cannot correct or eliminate the deception or risk;

- the determination of whether, and the reasons why, the ban should apply to devices already in commercial distribution, sold to ultimate users, or both; and

- any other data and information that FDA believes are pertinent to the proceeding.

We have grouped some of these together within broader categories and addressed them in the following order:

- Evaluation of data and information regarding ESDs, including data and information FDA obtained under provisions other than section 516 of the FD&C Act, information submitted by the device manufacturer and other interested parties, the consultation with the classification panel, and other data and information that FDA believes are pertinent to the proceeding, with respect to risks, benefits, and the state of the art;

- the reasons FDA initiated the proceeding and FDA's determination that ESDs for SIB and AB present an unreasonable and substantial risk of illness or injury (FDA has not made a finding regarding substantial deception);

- FDA's determination that labeling, or a change in labeling, cannot correct or eliminate the risk; and

- FDA's determination that the ban applies to devices already in commercial distribution and sold to ultimate users, and the reasons for this determination.

II. Evaluation of Data and Information Regarding ESDs

In considering whether to ban ESDs, FDA first conducted an extensive, systematic literature review to assess the benefits and risks associated with ESDs as well as the state of the art of treatment of patients exhibiting SIB and AB. In the literature review, as explained earlier, SIB and AB were considered in tandem, and these conditions presented in individuals with intellectual and developmental disabilities, such as autism spectrum disorder, Down syndrome, Tourette syndrome, as well as other cognitive or psychiatric disorders and severe intellectual impairment (including a broad range of intellectual measures). The studies encompassed both children and adults. (For more technical details, see Ref. 3.)

FDA next convened a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee (“the Panel”) on April 24, 2014 (“the Panel Meeting”), in an open public forum, to discuss issues related to FDA's consideration of a ban on ESDs for SIB and AB (see 79 FR 17155, March 27, 2014; Ref. 26). Although FDA is not

required to hold a panel meeting before banning a device, FDA decided to do so in the interest of gathering as much data and information as possible, from experts in relevant medical fields as well as all interested stakeholders, before proposing this significant regulatory action. Eighteen panelists with expertise in both pediatric and adult patients represented the following biomedical specialties: Psychology, psychiatry, neurology, neurosurgery, bioethics, and statistics, as well as representatives for patients, industry, and consumers (Ref. 27). FDA provided a presentation that described the banning standard, the regulatory history of aversive conditioning devices, alternative treatments, and a summary of the benefits and risks of ESDs, including a comprehensive, systematic literature review based on the information available at that time (Refs. 3 and 28). After the Panel Meeting, we reviewed all 294 comments from 281 unique commenters submitted to the public docket created for the Panel Meeting (Docket No. FDA-2014-N-0238).

FDA considered all available data and information from a wide variety of sources, including from the categories listed in this document. In weighing each piece of evidence, FDA took into account its quality, such as the level of scientific rigor supporting it, the objectivity of its source, its recency, and any limitations that might weaken its value. Thus, for example, we generally gave much more weight to the results of a study reported in a peer-reviewed journal than we did to non-peer-reviewed papers.

- *The scientific literature.* FDA considered published scientific sources to understand SIB and AB as well as the risks and benefits of ESDs and the state of the art for the treatment of challenging behaviors. However, several limitations influenced the conclusions drawn from the literature, including the likely underreporting of AEs, reporting biases, and various methodological weaknesses.

- *Information and opinions from experts,* including those expressed by the panelists at the Panel Meeting, as well as those expressed in individual expert reports obtained by FDA from Drs. Tristram Smith, Gary LaVigna, and Fredda Brown. Each of these experts has experience in the field of behavioral psychology, particularly with individuals who manifest SIB or AB. Drs. LaVigna and Brown have expertise regarding the state of the art for treatment of SIB and AB and the development of positive behavioral treatment plans for patients, including

for transition away from ESDs and other aversive strategies. FDA obtained reports from these experts to supplement our understanding of the risks and benefits of ESDs and the state of the art for the treatment of SIB and AB.

- *Information from State agencies and State actions on ESDs.* FDA has considered information regarding the use of ESDs for SIB and AB from agencies in Massachusetts and New York. These agencies possess substantial information on ESDs for SIB and AB because the overwhelming majority of patients—nearly 75 percent—on whom ESDs are used are from these two States. According to information provided by JRC in its comments, 60 of the 82 individuals enrolled at JRC as of April 2014 on whom GED devices were used are from these two States. FDA also considered a comment from the Executive Director of the National Association of State Directors of Developmental Disabilities Services (NASDDDS), which was supportive of a ban, and various State legal actions related to the use of ESDs for SIB and AB.

- *Information from the affected manufacturer/residential facility.* In addition to presenting information at the Panel Meeting and responding to questions from Panel members, JRC has made several submissions to the Panel Meeting docket, as has a former JRC clinician.

- *Information from patients and their family members.* Three individuals formerly on ESDs at JRC and family members of four such individuals currently at JRC spoke against a ban at the Panel Meeting. Two associations of family members of such individuals submitted comments opposing a ban (one of the comments included 32 letters from family members). Two individuals formerly on ESDs at JRC spoke in favor of a ban at the Panel Meeting, and one other individual submitted a comment in favor of a ban. In 2013 and 2014, FDA clinicians interviewed three individuals formerly on ESDs at JRC by phone (one of whom spoke in favor of a ban at the Panel Meeting).

- *Information from other stakeholders,* including other government entities, disability rights groups, and members of the public. In addition to NASDDDS and a JRC parents group, referenced earlier, 15 other organizations concerned with the treatment and the rights of individuals with disabilities spoke at the Panel Meeting, all of which supported a ban. Twenty-two disability rights organizations submitted written

comments to the Panel Meeting docket, one of which was signed by 23 disability rights groups. Nine of these organizations were among the 15 represented at the Panel Meeting. All of these comments support the ban. FDA also received a comment from the U.S. Department of Justice Civil Rights Division supportive of a ban, and we considered information from the National Council on Disability, the National Institutes of Health, and the United Nations Special Rapporteur on Torture.

A. Risks of Illness or Injury Posed by ESDs

1. Scientific Literature

FDA conducted an extensive, systematic review of the medical literature for harms, *i.e.*, AEs, associated with ESDs to understand specific risks and dangers that ESDs present to individuals' health. As previously discussed, the focus of the analysis in considering a ban is on risks and does not require proof of actual harm, but evidence of actual harms helps inform the analysis. One prospective case-control study and one retrospective chart review of 60 patients reported AEs (Refs. 29 and 30, respectively). Additionally, 26 case reports or series encompassing 66 subjects included an assessment of AE occurrences. Ten other case reports or series did not assess AEs, and 6 articles, encompassing 11 subjects in total, noted that the researchers did not observe AEs in their subject population. (See table 4 in Ref. 3 for a summary of articles reviewed for adverse events.) We identified the following AEs in the literature.

- a. Psychological risks.* The risks of psychological harm are less tightly linked to the electrical parameters of an ESD shock than are physical risks (section I.C discussed shock parameters and how they relate to the physical response). For example, when the recipient does not have control over the shocks and has previously received multiple such shocks, psychological trauma such as an anxiety or panic reaction can result even when the strength is relatively modest (Ref. 31). In this example, the shock does not necessarily need to be stronger to increase the risk of psychological trauma; it need only recur. Similarly, the shock need not be painful; it need only be psychologically stressful.

Further, a series of less traumatic events can cause the development of stress disorders such as PTSD. The underlying trauma need not be a single, discrete event, although a single trauma can lead to PTSD (Ref. 32; see also Ref.

31, discussing research on stressors prior to the 2013 update of the *Diagnostics and Statistical Manual of Mental Disorders*). Shocks that may be tolerable on their own could, in series, amount to a traumatic experience leading to a stress disorder. (See Ref. 33 discussing impaired cue-reversal independent of level of trauma.) In turn, such disorders can leave an individual susceptible to future traumas such as anxiety reactions that can be triggered by a relatively weak stimulus. For example, a provider reaching for an ESD remote control can trigger an anxiety response in individuals wearing ESDs, even without a shock. Thus, although a shock may need to surpass a minimum subjective threshold to be harmful (*e.g.*, the shock needs to be sufficiently stressful to the recipient), that subjective minimum (what is sufficiently stressful) does not correspond with a particular objective minimum (shock parameters).

Several articles reported aversion, fear, and anxiety in response to ESDs. One article states that ESDs may initially evoke fear, panic, and even aggression responses (Ref. 34). For the most part, researchers have interpreted these events as anticipatory responses prior to or upon stimulus application. In addition to reports of panic and bouts of aggression, others have reported events such as screaming, crying, or shivering upon device application; grimacing; flinching; perspiring; and escape behavior (Refs. 34–43). One article reported a temporary aversion to the experimenter (Ref. 36). Such fear, anxiety, or panic reactions are additionally concerning because when they cause the individual to sweat, they would lead to electrical conductivity changes across the skin that increase the intensity of the electric shock.

Other articles report substitution of behaviors—negative or collateral—that span a range of severity. One author speculated that, in institutional settings, “the probability that a replacement behavior will be undesirable is quite high” (Ref. 44). Some patients “froze by refraining from showing any sort of behavior” (Ref. 34). Similarly, others reported a “pseudocatatonic sit-down,” *i.e.*, muscular freezing or melting (Ref. 45). One study described temporary tensing of the body and noted attempts to remove the device or grab the transmitter during treatment (Ref. 30). Some patients resorted to hostility and retaliation (Ref. 46), including surrogate retaliation, threats, and warnings (Ref. 45). In some patients, another undesirable behavior known as self-restraint, where patients attempt to physically restrain themselves, for example, with their clothing, emerged

or intensified (Refs. 29 and 47). Others exhibited lesser self-injury and aggression, non-injurious pinching, emotional behaviors, and napkin-tearing. (See also Refs. 30 and 43.) In some cases, crying increased (Ref. 48). One study reported that, as measured by rating scales of dependency, affection-seeking increased repeatedly during treatment (Ref. 42).

Temporary or long-term increases in symptoms have also been attributed to ESDs in the literature. One article reported increases in emotionality and the frequency of self-injury, as well as post-treatment incontinence (Ref. 49). Another observed increasing episodic “bursts” of self-injury, eventually reaching the point that extended treatment with the ESD became impossible to maintain (Ref. 50).

Some ESDs have been used for conditions other than SIB and AB, *e.g.*, obsessions or compulsions, according to the same principle of aversive conditioning. FDA believes that reports of AEs from these alternative uses are informative regarding the risks of ESDs for SIB and AB because individuals with ESDs for other conditions generally do not have the same patient vulnerabilities that often accompany SIB and AB. As discussed in sections II.A.2 and A.3, these vulnerabilities generally increase the risk of harm from ESDs for individuals who manifest SIB or AB, so any harms from ESDs for other uses would be at least as likely, if not more so, to cause harm to many patients exhibiting SIB or AB.

One article on the effects of shock on five subjects to reduce obsessions and compulsions reported that one subject demonstrated anxiety and psychotic delusions (Ref. 51). One case-control study on ESDs used to treat alcohol dependence in 12 subjects found that symptoms of experimental repression, such as headaches, restlessness, and mild dysphoria, were common and appeared usually within 3 or 4 days of the treatment (Ref. 52). Another researcher performed a prospective study of ESDs used for smoking cessation in 14 subjects. The author reported that seven subjects exhibited mild transient depression (Ref. 53). FDA acknowledges that confounding factors potentially contributed to these AEs.

Since ESDs are aversive conditioning devices, FDA also considered AEs associated with aversive conditioning more generally. We identified 12 review articles examining AEs associated with punishment or aversive conditioning. Many of the reviews acknowledge the possibility of negative emotional reactions associated with punishment in general, such as fear or avoidance (Refs.

54–59) and anxiety and depression (Ref. 54). Some reviews, similar to the findings specific to ESDs, noted AEs that include retaliation, increased aggression, or substitution of one injurious behavior for another (Refs. 54 and 57–60).

FDA believes that the risks posed by another type of device that delivers a shock to the patient are instructive. Specifically, a comparison to implantable cardioverter defibrillator (ICD) devices further supports the potential for certain psychological risks in patients receiving shocks from ESDs for SIB and AB. While the strength and purposes of the shock differ significantly between ICDs and ESDs, the psychological risks posed by ESDs do not necessarily depend on the strength of the shock, as discussed earlier, and FDA does not believe the different purposes of the shocks undermine the comparison for the following reasons. Treatment with either of these devices entails several similar characteristics that support a comparison, including the lack of patient control over the shocks, the application of multiple shocks, and the startling or unpleasant nature of the shocks. We found that fear of future shocks, in particular, is a trauma that is shared for both the ICD and ESD populations, unlike other trauma experiences in which subsequent trauma (repetition of the experience) is unlikely, indicating that ongoing application worsens the harm (Ref. 61).

The following risks have been reported in the literature for ICDs: The development of PTSD, acute stress disorder, a shock stress reaction (a temporary condition), learned helplessness, depression, and anxiety (Refs. 61–63). A contributing factor in the development of these harms in patients with an ICD may be that treatment with an ICD may act as a constant reminder of the underlying life-threatening disease condition (Ref. 64). A 2011 report observed that “[t]he available research literature can only provide a limited view of whether ICD shock or the potentially life-threatening arrhythmic condition is the primary driver of a PTSD presentation” (Ref. 61). However, Sears and Conti report that “[s]hock is the major distinguishing factor between patients with ICDs and general cardiac patient populations” (Ref. 63), meaning that the presence of an ICD, rather than the underlying cardiac condition, increases the psychological risks. Other authors have reported that ICD shocks may cause distress either from the associated pain, skeletal muscle contraction, and nerve

stimulation or merely from fear of shocks (Ref. 62).

Because of the similar characteristics of the shocks delivered by ICDs and ESDs, and because the identified risks may be attributable to the ICD shock itself, as opposed to the fear of a life-threatening condition, the risks of development of PTSD or a shock stress reaction, learned helplessness, depression, or anxiety may also exist when shocks are applied by ESDs in patients with SIB or AB. FDA notes that due to the drastically different intended uses, patient populations, benefit-risk profiles, and state of the art for these devices, FDA is not considering banning ICDs.

b. Physical risks. Research shows that shock strength and other device characteristics play a role in shaping the physical response to ESDs, such as whether the patient receives burns or experiences pain (see section I.C). We note that the lack of complete information regarding shock characteristics in much of the literature can make it difficult to determine to which ESDs these findings are applicable.

The literature contains many reports of tissue damage or burns from ESDs. Reports of skin damage ranged from burns to bruises to slightly reddened or discolored areas. In all such reports, the effects were temporary (Refs. 29, 30, 39, 41, 50, and 65).

Given that ESDs achieve their intended effects by causing an aversion with an electric shock, it is not surprising that researchers have reported experiencing or observing pain upon ESD application to themselves or their patients. For example, one experimenter stated that he definitely felt pain when he applied the ESD to himself. He described it like a dentist drilling on an un-anesthetized tooth, but the pain terminated when the shock ended (Ref. 36). Another report observed pain upon stimulation by the ESD (Ref. 35), and another observed a tremor in the thigh (Ref. 36). Although ESDs are intended to apply an aversive stimulus, and any pain that results from ESDs may cause an aversive reaction, pain is nonetheless a harm that should be considered in our analysis of risks posed by the device.

Finally, two articles reported misapplication or device failure (Refs. 39 and 65). In such cases, there is a risk that any of the harms discussed in this section may occur but without any possibility of benefit.

2. Likely Underreporting of AEs

The Agency's analysis indicates that the medical literature suffers from some

significant limitations and has likely underreported AEs associated with ESDs for a number of reasons. Perhaps most importantly, the devices have been studied only on a very small number of subjects, many of whom would have difficulty communicating or otherwise demonstrating AEs and injuries. The bulk of the articles describe case reports or series, employing only retrospective reviews of clinical experience, not prospective studies. Further, most of the research articles were published in the 1960s and 1970s, before significant advances in the ability to diagnose and classify psychological AEs such as PTSD. The dated nature of most of the research also means it did not adhere to modern standards for AE monitoring. Simply put, researchers likely did not report AEs because they had not planned to study them separately. None of the articles on the application of ESDs described an attempt to assess AEs systematically, and many articles did not state whether the authors attempted to assess AEs at all. Finally, researcher bias also may have contributed to underreporting of AEs.

As noted, the literature review suggests some subjects' difficulty with reporting AEs due to the subjects' disability likely hindered any assessment of AEs, particularly psychological AEs. Since SIB and AB often present in individuals with cognitive, intellectual, or psychiatric conditions, SIB and AB affect many individuals with diminished communication abilities. Patients who exhibit SIB or AB may not offer—or providers may not recognize—feedback indicating injuries from misfires or other erroneous applications of ESDs. For example, conditions such as an autism spectrum disorder may impair expressions of pain (see Ref. 66 for a discussion of pain sensitivity and expression in autistic individuals). In such a case, an AE could go unrecognized because the provider does not understand the individual's response, if any.

Worse, some individuals' impaired ability to communicate, express themselves, or associate cause and effect, coupled with the difficulty providers may have in distinguishing underlying symptoms from negative effects of ESDs, compounds the dangers posed by these devices. This is because individuals' impairments with communication or stimulus association may prevent the individuals and their health care providers from mitigating or avoiding both physical and especially psychological harms. (See section II.C.1 for a discussion of interventions that do not rely on stimulus association.) In

such circumstances, ESDs are riskier than for other patients on whom ESDs are used.

For the reports of AEs that do exist, many of those researchers published during the 1960s and 1970s, an era when conceptions of disease and how a person's physiology may affect or cause disease, *i.e.*, pathophysiology, differed significantly from current medical science, particularly psychiatric pathophysiology. As a result, those researchers may have interpreted pathological processes differently. For instance, they may not have recognized certain currently accepted disease processes like acute and posttraumatic stress. Some researchers did not report pain or discomfort as AEs since they were considered the ESDs' intended result and indicators of effectiveness. (See, *e.g.*, Refs. 44 and 57). In short, because science has advanced since much of the AE reporting, FDA believes existing AE reports in the literature are likely not comprehensive by current scientific and clinical reporting standards.

The Agency's analysis also suggests the possibility of bias against reporting AEs. As previously noted, the majority of articles did not define a systematic method for assessing AEs. In one review, the authors concluded that there was no evidence associating AEs with ESDs (Ref. 67). However, the authors went on to opine, "in light of the intrusive nature of shock treatment, it is puzzling that so few negative side effects have been reported. In interpreting the existing literature, we might be wise to consider the possibility that some investigators have been predisposed to see only the positive side effects." Similarly, the reports of treatment relapse in the literature may not reflect the actual prevalence in clinical settings because such cases are less likely to be submitted or accepted for publication (Ref. 59).

Potential bias against AE reporting might also have influenced the authors of the article that included the largest group of individuals (60) subject to ESD application in its retrospective review. The review noted only one negative side effect, "temporary discoloration of the skin that cleared up in a few minutes or days" (Ref. 30). However, "temporary emotional behaviors, a temporary tensing of the body, or attempts to remove the device or grab the transmitter noted during treatment were classified as 'immediate collateral behavior' and were not considered adverse events" (Ref. 30). The lead author of this article, Dr. Matthew Israel, may also have been biased in his roles as founder of JRC and Chief Executive

Officer of JRC at the time he co-wrote the article.

In light of the foregoing, FDA believes that researchers, by current clinical and peer-review standards, likely underreported AEs. Many patients on whom ESDs have been used have limited ability to express themselves. Some earlier studies considered certain reactions that we would now consider to be AEs as mere responses or even treatment requirements. Even current researchers may classify AEs as unwanted side effects that then go unreported. For example, of the 66 patient case histories spanning 1991 through 2014 that FDA received from JRC, none reported any AEs, which is highly unusual for so many patients over such a long time (though individual exposure periods varied). Nor did any of these case histories include systematically defined methods for short- or long-term AE monitoring. Thus, even the more recent studies may still reflect outmoded standards. Significantly, because much of the relevant literature was published many years ago, it does not benefit from recent advancements in psychiatric pathophysiology that have expanded researchers' ability to identify and record AEs. In light of the foregoing, we conclude that realized risks and dangers to individuals' health from ESDs are likely greater than reported in the medical literature. As a result, the risks posed by ESDs reported by other sources, discussed in the following sections, warrant careful consideration.

3. Information and Opinions From Experts

FDA presented the following dangers to individuals' health related to the use of ESDs at the Panel Meeting: Negative emotional reactions or behaviors, including aggression; burns and other tissue damage; anxiety; acute stress, or PTSD; fear and aversion or avoidance; pain or discomfort; depression and possible suicidality; psychosis; and neurological symptoms and injury. The panelists generally opined that the list was incomplete, and in some cases, too vague and in need of clarification (see Ref. 68).³

One panelist noted peripheral nerve injury as a possible side effect and was surprised JRC had not reported severe depression, especially since "producing pain in people who have no control over the pain" is "a perfect paradigm for the learned helpless," and learned helplessness is used in drug studies

"because it produces in animals something analogous to depression and it can be used to test antidepressants."

Another panelist stated that cardiac effects, renal effects, muscle damage, and neurological symptoms, such as neuropathy, could be happening at low levels but go unreported because there has not been a systematic look at these types of potential injury over the last 40–50 years.

Other panelists recommended specific additions and refinements to the list of risks and dangers, including: Equipment malfunction; long-term effects of pain; delineation of range of pain; trauma from falls; mistrust of providers; learned helplessness; chronic stress; generalized behavioral suppression; small, repetitive damage of other tissues; cognitive impairment; neuropathy; ventricular fibrillation if the electrodes are placed transthoracically; neuropsychiatric symptoms; and emotional sequelae.

Several Panel members echoed the concerns discussed earlier regarding the likelihood of underreporting of AEs. For example, one Panel member pointed out that the populations treated with ESDs are very vulnerable and may not be able to self-report AEs. Panelists also indicated that because clinicians have little understanding of the breadth and the range of pain experienced by ESD patients, clinicians may mistakenly attribute adverse effects to the patients' cognitive, intellectual, or psychiatric conditions rather than to the device. Some panelists observed that many of the risks and dangers of ESDs resemble co-morbidities in the individuals subject to treatment; as a result, adverse effects of the device would be difficult to distinguish from symptoms of the disability. This could result in AEs being misperceived as underlying symptoms, the likelihood of which is supported by the lack of systematic evaluation of AEs in the literature discussed in section II.A.2. Panel members similarly expressed concerns about communication and diagnosis difficulties exacerbating the harms experienced by patients on whom ESDs are used.

In his expert report, Dr. Smith explains that ESDs for SIB or AB "necessarily involve inflicting pain on a person with [an intellectual or developmental disability]," and notes the risks of fear and agitation observed in one study. Dr. Smith details several limitations to the studies on ESDs in the literature, including the failure of any of the studies to have a prespecified, systematic plan for monitoring AEs, which may have resulted in underreporting of AEs. He also discusses the possibility that the

publication process may also introduce a bias against reporting AEs in the retrospective single-patient studies relied on by many researchers of ESDs. This is because, according to Dr. Smith, when studying only one patient, researchers tend to emphasize data that epitomize experimental control rather than an average response to the device (Ref. 8). Further, researchers generally tend to publish clear-cut results rather than less-clear outcomes (Ref. 8). Although he notes that the "overall strength of evidence is low" with respect to both benefit and harm, Dr. Smith concludes that "existing evidence shows that aversive conditioning with electric shock can be safe and effective in at least some cases, but that it can also be misapplied, risking severe, negative consequences" (Ref. 8).

A comment submitted by the Disability Law Center includes a 2014 expert affidavit from Dr. James Eason, a university instructor of biomedical engineering with a Ph.D. in biomedical engineering and a B.S. in electrical engineering who has particular expertise on ICDs (Ref. 69, attachment 2). Dr. Eason opines on the potential hazards posed by three ESDs: The SIBIS (cleared by FDA in 1986), the GED–1 (cleared by FDA in 1994), and the GED–4 (not FDA cleared or approved). Focusing on peak current, based on his views on the relationship between certain electrical stimulus parameters and pain, Dr. Eason compares the SIBIS (4.1 mA), GED–1 (30 mA), and GED–4 (90 mA), with an electrical fence (4 mA), a dog training collar (2–4 mA), and a cattle prod (10 mA), respectively.

Dr. Eason opines that, when applied to non-sensitive locations such as the arm or leg, the SIBIS shock falls below the range usually considered painful; the GED–1 shock falls within the range of pain thresholds, meaning some would find it painful and some may not; and the GED–4 shock would be painful or extremely painful to anyone. According to Dr. Eason, when the electrodes are placed on sensitive parts of the body, such as hands, feet, underarms, torso, or neck, all three ESDs are capable of inflicting extreme pain on anyone. Dr. Eason explains that sweating, which may be caused by stress or anxiety about receiving a shock, lowers skin resistance, which in turn may lower one's pain threshold, and that one's pain threshold may also be lowered by repeated shocks. He further concludes all three devices are capable of producing tissue damage due to strong muscle contractions, and all are capable of causing superficial skin burns under certain circumstances.

³ Unless otherwise noted, all references to statements and opinions expressed at the Panel Meeting are taken from Ref. 68.

Dr. Eason also concludes that the ESDs “are likely to induce an immediate increase in physiological stress ranging from mild to severe. Further, the long-term effects of receiving numerous painful and uncontrollable shocks will be an increased risk for developing ASD or PTSD.” His conclusion is based partly on observations of people who have ICDs, which have been shown to induce psychological trauma, including PTSD, as discussed in section II.A.1. Finally, Dr. Eason believes the GED-4 presents a risk of heart palpitations, long-term psychological disorders, and neurological effects.

Dr. Eason’s expert opinion is consistent with other available data and information demonstrating that ESDs can be painful, particularly when placed on sensitive areas, and that physiological and psychological factors contribute to the experience of pain. However, as explained in section I.C, because an individual’s experience of pain varies significantly based on many factors, pain predictions based on peak current are subject to considerable uncertainty. As such, although higher peak currents correspond to greater risks of physical illness or injury, the peak current is but one factor in an individual’s experience. Similarly, pain is but one risk of physical harm that ESDs pose. The devices pose serious risks of other short- and long-term psychological and physical harms, as discussed in the literature and at the Panel Meeting.

4. Information From State Agencies and State Actions on ESDs

FDA reviewed complaints regarding ESD use made to the Massachusetts Disabled Persons Protection Committee (DPPC) from August 30, 1993, to July 28, 2013. Of 53 complaints, DPPC screened out 18 as not meeting complaint criteria; DPPC found 22 more were unsubstantiated. The remaining 13 complaints described the following AEs: Burns or tissue injury (6 reports), inappropriate device use (3 reports), negative emotional reactions (3 reports), and PTSD (1 report).

In 2007, the Massachusetts Department of Early Education and Care (DEEC) conducted an investigation of JRC’s Stoughton Residence, where GED devices were used on individuals living there (Ref. 70). According to the Investigation Report, an individual reported waking up because his roommate was screaming; his roommate had been asleep but was shocked by a GED, waking him and causing him to scream. JRC staff reported that “the skin was off of the area” of the leg where GED shocks had been applied, that the

GED was removed from the leg “because the area on was too bad to keep the device,” and either the individual who received the shocks or the staff (it is not clear who) believed a stage two ulcer was in the area where skin was missing (Ref. 70).

In 2006, the New York State Education Department (NYSED) conducted an onsite review of JRC’s behavior intervention programs, with purposes including identification of any health and safety issues relating to JRC’s use of aversive interventions (Ref. 71). The review was conducted by NYSED staff and three behavioral psychologists serving as independent consultants. It included a review of school policies, student records, observations of school and education programs, and interviews with staff and randomly selected individuals living at JRC. The reviewers witnessed staff rotating GED electrodes on individuals’ bodies at regular intervals to “prevent burns that may result from repeated application of the shock to the same contact point” (Ref. 71).

During interviews, individuals reported “pervasive fears and anxieties related to the interventions used at JRC,” which include other interventions in addition to the GED devices. Although not reported as relating specifically to GED use, one patient stated she felt depressed and fearful, that her greatest fear was having to stay at JRC past her 21st birthday, and that she thought about killing herself every day. The review notes various other potential negative effects that may result from aversive behavioral strategies, such as depression, social withdrawal, aggression, and worsening of PTSD symptoms in individuals diagnosed with PTSD, though it did not report any specific instances of these adverse effects related to GED use.

NYSED also submitted a comment to the 2014 Panel Meeting docket stating that it has received reports of collateral effects from the use of these devices, such as increases in aggression and increases in escape behaviors or emotional reactions. NYSED states it has received “numerous reports of students who have incurred physical injuries (burns, reddened marks on their skin) as a result of being shocked and for whom parents and students themselves have reported short-term and long-term trauma effects as a result of use of such devices or watching other students being shocked (e.g., loss of hair, loss of appetite, suicidal ideation).” NYSED believes it is well established that stress and trauma impair brain functioning. According to NYSED, one student explained, “I am scared and sometimes

I feel like my life is in danger. There are days when I am scared to even say a word to anyone. I am afraid to wake up because I never know what is going to happen to me. I think I should not have to live in fear and be scared . . . I get so depressed here I wish my life by fast” (Ref. 72).

5. Information From the Affected Manufacturer/Residential Facility

JRC acknowledges the risk of physical harms to the skin, that “in rare cases, mild erythema of the skin may result” that disappears within an hour to a few days, “less than 1% of applications result in <1 mm lesion,” and “it is possible that repeat exposure to the GED skin-shock could result in blistering” (Refs. 21 and 73). With respect to psychological adverse effects, JRC states, “there also may be brief, temporary anxiety just prior to the delivery of the application as well as occasional harmless avoidance responses (e.g., tensing of the body, attempts to remove the electrode in some cases)” (Ref. 21). JRC also acknowledges that, “in very rare circumstances, the GED may errantly deliver an unintended skin-shock to a patient,” either when the shock is delivered to the wrong patient or due to spontaneous activation (Ref. 73).

In line with the decades-old research that considered pain or discomfort to be merely an indicator of effective treatment (see section II.A.2), JRC does not include pain in its discussion of AEs caused by the device. Two tables provided by JRC in one of its submissions suggest its GED devices may not cause pain based solely on their peak current levels (Ref. 21). However, as discussed in section I.C, conclusions regarding pain based on peak current alone are difficult to draw, and the stimulus-pain matching tables in some of the sources cited by JRC are not based on shock sources akin to ESDs. JRC elsewhere acknowledges “the stimulation may be considered painful by some patients” (Ref. 73), and when asked directly whether the stimulus causes pain at the Panel Meeting, Dr. Nathan Blenkush, JRC’s Director of Research, answered “yes.”

Except for the harms described earlier, JRC maintains that it “has not found any side effects associated with aversive conditioning” (Ref. 21) and “there are no confirmed reports or confirmed medical evidence that patients have any negative psychological side effects related to any discomfort experienced due to therapy with the proper use of the GED devices” (Ref. 73). FDA’s review of records collected as part of a 2013 inspection of

JRC did not reveal any AEs reported by JRC for individuals with ESDs. A former JRC clinician commented that he “did not observe any permanent negative side effects” (Ref. 74). JRC concludes, “the medical literature cited by FDA [in the FDA Executive Summary for the Panel Meeting] did not show any evidence of profound, sustained, or significant harm or patient injuries resulting from use of ESDs” (Ref. 21).

However, with respect to psychological harms, JRC’s records provide compelling evidence of risks of such harms that may result from GED use. For example, a JRC document entitled, “Procedures to Facilitate the Assessment of Possible Collateral Effects,” dated June 14, 2012, directs staff to note “any sign of any adverse effect on the student that may be resulting from the use of aversive interventions,” and “look for any collateral effects that may be related to the administration of an aversive intervention.” The collateral effects listed in the JRC document include, but are not limited to: Nightmares, intrusive thoughts, avoidance behaviors, marked startle responses, mistrust, depressions, flashbacks of panic and rage, anger, hypervigilance, and insensitivity to fatigue or pain. The corresponding section of the training manual headed “Responding to Collateral Effects” further directs staff to look for “signs of any form of distress or discomfort,” including but not limited to: Changes in sleep patterns, loss of appetite, confusion, irritability, lack of energy, sadness, mood swings, significant weight loss, loss of interest, fatigue and lack of energy, difficulty concentrating, agitation, restlessness, or irritability, withdrawal from usual activity, and feelings of helplessness. Another JRC document entitled “Pre-Service Training Manual,” dated September 11, 2012, contains the same information.

Although the patient records submitted by JRC do not indicate occurrences of any of these harms, and JRC’s comments claim they adequately train their staff, monitor individuals on ESDs, and report adverse events, FDA has reason to doubt that none of these harms occurred. As discussed earlier, impairments with patient communication and provider recognition pose difficulties in identifying harms caused by the device, even for vigilant staff. State agencies in Massachusetts and New York have reported problems with staff supervision of individuals and monitoring of adverse events at JRC. For example, the 2006 NYSED review of JRC’s program found that the collateral effects of punishment “are not

adequately assessed, monitored, or addressed,” and “[t]here does not appear to be any measurement of, or treatment for, the possible collateral effects of punishment such as depression, anxiety, and/or social withdrawal.” Further, “[s]kin shock has the potential to increase the symptoms associated with PTSD, yet there is no evidence of data measuring these possible side effects or therapies designed to treat these symptoms” (Ref. 71). The 2007 Massachusetts DEEC investigation resulted in several determinations of deficiencies in patient oversight at one of JRC’s residential facilities, including lack of necessary training and experience among staff, problems regarding communication of medical issues, monitoring staff neglect of responsibilities that “compromis[ed] the supervision and the safety of residents,” and staff failure “to monitor the residents in a manner that assured their health and safety” (Ref. 70). Given these findings, patient records may well fail to capture occurrences of harms.

6. Information From Patients and Their Family Members

Although three individuals formerly at JRC who spoke at the Panel Meeting either did not mention any harms or stated the GED did not harm them, two other individuals formerly at JRC described a variety of harms related to their experience with the GED, including panic and a fear of authority and being controlled, severe muscle cramps that would last 1 to 2 days, skin burn marks, terrible pain from the site of GED application on the leg down to the foot, loss of sensation in the leg and skin, frequent misfires, nightmares, freezing up upon hearing certain sounds associated with GED application, and flashbacks.

Three individuals formerly at JRC interviewed by FDA clinicians asserted the following additional serious AEs resulting from GED use: Heart palpitations, seizure, depression, and suicidality. These individuals described the GED shock as “a thousand bees stinging you in the same place for a few seconds,” a “bad bee sting,” and “extremely painful,” and gauged the pain level from 5 to 8, depending on the GED model and the location of the shock on the body.

Some of the relatives of individuals at JRC who spoke at the Panel Meeting only spoke about the positive effects of the GED devices and did not recount any adverse effects. Family members of individuals at JRC and a JRC parent association also commented that individuals at JRC have not suffered any side effects from the GED devices (see,

e.g., Ref. 75). However, one parent of an individual formerly at JRC described the following adverse effects from use of the GED: Burns, fear, pain, PTSD, catatonia, and deep vein thrombosis caused by catatonia.

7. Information From Other Stakeholders

At the Panel Meeting, organizations concerned with the treatment and rights of individuals with disabilities cited risks of the following harms posed by ESDs based on first- or second-hand accounts: Pain, fear, anxiety, panic, depression, attempts to avoid or escape, nightmares, hyperarousal, flashbacks, burns, scars, loss of sensation, muscle contractions, learned-helplessness responses, nerve damage, muscle cramps, soreness, and neurological injuries such as seizures. The presenters stated that, in some cases, ESDs hindered the development of the very skills and behaviors necessary to control SIB or AB.

The written comments from disability rights organizations, as well as health care professionals and other concerned citizens, identified the following risks based on first- and second-hand accounts of the use of ESDs: PTSD and other effects on brain function from stress, including memory loss, loss of verbal communication, and sleep pattern disturbances; severe psychological trauma; depression with possible suicidal ideation; anxiety; increase in aggression; increase in escape behaviors and emotional reactions; fear and aversion or avoidance; seizures; migraine headaches; burns or red marks on the skin; loss of hair; loss of appetite; pain; misuse of the device (misfires and erroneous applications); persistent numbness and other neurological injuries; and ear problems.

One comment from a disability rights group cites a media report quoting an expert in a lawsuit filed by a parent of an individual formerly at JRC against JRC, describing the individual’s state after he was shocked repeatedly with a GED device: “He was essentially in what we would call a catatonic condition That means a condition that happens with people that are acutely psychotically disturbed” (Ref. 76).

Another comment from a psychologist, who has worked with patients exhibiting SIB and AB, reports witnessing patients waking up screaming from nightmares, which only happened after ESDs were used on them. The psychologist reported that other patients have “waking nightmares, in which horrible memories of shock, pain, and restraint suddenly overcome

them, even during an otherwise happy event” (Ref. 77).

8. Conclusion

Based on the scientific literature regarding ESDs for SIB, AB, and other unwanted behaviors, and regarding aversive conditioning generally, FDA has determined that ESDs for SIB and AB present the following risks: Depression; fear; escape and avoidance behaviors; panic; aggression; substitution of other behaviors such as freezing and catatonic sit-down; worsening of underlying symptoms, such as increased frequency and bursts of self-injury; pain; burns; tissue damage; and device misapplication or failure. Based on the scientific literature regarding ICDs, FDA has determined that ESDs for SIB and AB also present the risks of PTSD or acute stress disorder, shock stress reaction, and learned helplessness. This literature also provides support for the risks of depression, anxiety, fear, and pain.

Experts in the field of behavioral science and State agencies that regulate ESD use provide further support for the risks of depression, PTSD, learned helplessness, fear, anxiety, substitution of collateral behaviors, pain, burns, tissue damage, and inappropriate use. They indicate ESDs have been associated with the additional risks of short- and long-term trauma including suicidal ideation, chronic stress, acute stress disorder, neuropathy, heart palpitations, and trauma from falling. JRC’s internal policies include long lists of risks for aversives they use. Although these are not specific to ESDs, FDA finds these lists further support that ESDs pose the risks of depression, fear, anxiety, panic, learned helplessness, and substitution of collateral behaviors, and they support that ESDs are associated with the additional risks of nightmares, flashbacks, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and withdrawal from usual activity. Comments from individuals on whom ESDs have been used, their family members, disability rights groups, and others, provide additional support for the risks previously identified, and suggest ESDs may pose the additional risks of severe psychological trauma, catatonia, seizures, nerve damage, loss of sensation and numbness, migraine headaches, impaired brain function due to stress, memory loss, and muscle cramps.

B. Effect on Targeted Behavior

1. Scientific Literature

FDA conducted an extensive, systematic review of the medical literature for information assessing the clinical benefits of the use of ESDs for SIB or AB. We identified a total of 45 studies, including 41 case reports or case series, a case-control study conducted outside the United States (Ref. 29), a within-subjects comparison trial conducted outside the United States (Ref. 78), a retrospective review of 60 patient charts (Ref. 30), and a questionnaire followup study of 22 subjects on whom ESDs were used for aversive conditioning (Ref. 79). (See table 3 of Ref. 3 for a summary of these 45 studies.) The 45 referenced studies showed that ESDs can have some immediate impact on the targeted behaviors in some patients, *i.e.*, they interrupted the target behavior.

We also evaluated 12 articles reviewing some of these 45 studies that included specific clinical information on individual subjects and examined the effectiveness of ESDs for various pathologies, *e.g.*, AB, SIB, or problematic behaviors more generally. (See Ref. 3 for additional details.) These reviews generally support the conclusion that ESDs used on patients exhibiting SIB or AB caused the immediate cessation of the target behavior in some patients.

One review article specifically examined reports of applying ESDs to autistic children (Ref. 57). The authors noted that “in all of these studies, electric shock proved to be a highly effective therapeutic agent with autistic children.” They estimated that positive effects compared to negative effects occurred at a ratio of 5 to 1. However, they also reported that setting-specificity (the specific setting affects the results) may be an obstacle to an overall satisfactory effect (see also Ref. 44). Similarly, a comparison of different treatments for controlling behavior in individuals with intellectual impairments or schizophrenia noted that, in terms of immediate effects, “punishment was the quickest means of suppressing behavior” (Ref. 80; see also Ref. 36). These studies show that ESDs can interrupt SIB or AB, causing an immediate cessation of the behavior.

One study observed that a patient adapted to the stimulus intensity (Ref. 29), and another study showed that the application of ESDs can lead to adaptation (*e.g.*, Ref. 36). Adaptation means that a patient no longer responds at a particular level of stimulation—in the case of ESDs, a particular shock strength—though the evidence is

inconclusive as to whether this occurs. Some, including JRC, believe that adaptation occurs, and that when an individual adapts, the shock strength must be increased in an attempt to achieve the same effects. However, experts in the field, including at the Panel Meeting discussed in section II.B.3, have explained that what has been characterized as adaptation is really evidence of ineffectiveness, regardless of shock strength. Thus, for some individuals, shocks are ineffective, including with respect to immediate interruption or cessation of the target behavior.

Twenty-two of the 45 literature studies reported on durability of the effects of ESDs (Refs. 29, 30, 34, 36, 39, 40, 46, 50, 65, 79, and 81–92). A durable effect is one where an individual develops a conditioned response, so the target behavior, along with the numbers of shocks, is greatly reduced either while the individual continues to wear the ESD or after the ESD is removed. Twenty of the studies reported a durable effect that lasted from months to years. Two of the 22 studies reported no durability (Refs. 50 and 92). However, all 22 suffer from various flaws and limitations, as described in the next section.

Several of the literature reviews, which include reviews of many of these 45 studies, made observations regarding durability. One review opined that the use of ESDs might have long-term durability and concluded that results of aversive conditioning studies “suggest that sufficiently intense punishers . . . may produce lasting reductions in problem behavior” (Ref. 59). However, this conclusion included the qualifier, “as long as the punishment contingency remains in effect,” which implies that the authors were not discussing behavioral conditioning durability after the removal of the punisher. The authors also noted several limitations on the studies’ findings. Importantly, the available studies had methodological limitations that prevent generalizing research findings to a treatment setting (Ref. 59). One major limitation is that, because of the long duration of the studies, unplanned changes or other uncontrolled conditions hinder attributing observations to ESDs. The authors concluded that, “[u]ntil additional research on long-term maintenance is conducted, practitioners and caregivers should not assume punishment will remain effective over the long run” (Ref. 59).

Other reviews were much more doubtful regarding the durability of ESD effects. One of the reviews discussed earlier in this subsection reported that,

“[i]n marked contrast to [short-term effects], punishment and extinction programs seemed to have the least durable success” of any of several behavioral treatments reviewed (Ref. 80). Another review discussed earlier in this section reported that one author expressed dissatisfaction with the lack of long-term durability (Ref. 57), and another review similarly noted that the effect appeared to be short-term only, *i.e.*, symptoms are only “momentarily suppressed” (Ref. 55). A more recent review found that research into durability has continued to lag (Ref. 93). See section II.C describing the state of the art for a more comprehensive explanation of the reasons that the research has lagged.

2. Literature Limitations

The medical literature described in the previous section on the effect of ESDs on SIB and AB suffers from a number of deficiencies that limit confidence in the results. Most importantly, study design deficiencies render these studies inadequate to draw any definitive conclusions. As discussed in the previous section, 41 of the 45 studies that the Agency’s analysis identified were case reports or series, which have limited evidentiary value in this patient population, as discussed in the paragraphs that follow. Another study was a retrospective analysis of patient charts (Ref. 30) that suffers from various flaws, discussed later in this section. Another study reported results from a questionnaire sent to 22 authors of case series publications, of whom only 11 responded (Ref. 79), used an unscientific sampling method (questionnaires were sent only to authors of published articles, some published more than 5 years prior), and asked questions that do not constitute validated measures of effects. The one prospective case-control study examining ESDs for SIB and AB (Ref. 29) only included 16 subjects (8 in the device group and 8 in the control group) and did not use a direct measure of SIB or AB as the primary outcome (instead, it measured a decrease in mechanical restraint). Finally, the within-subjects comparison study looked at heart rate changes as a measure of stress in five subjects, and it showed that active treatment with ESDs correlated to a statistically lower mean heart rate than when subjects were not wearing the ESD (Ref. 78). The authors surmised that heart rate was an indicator of stress but this correlation has not been demonstrated to be a valid marker of anxiety, and direct measures of reduction in SIB and AB were not taken.

No randomized controlled trials directly examined ESDs for SIB or AB.

Generally, a study’s strength or weakness is related to design in a number of ways, particularly through randomization, control, and the number of study subjects. Randomization distributes characteristics that could affect the results evenly across conditions. This equalizes the influence of nonspecific processes not under study, *e.g.*, the effects of participating in a study, being assessed, receiving attention, or self-monitoring. Control conditions attempt to subtract other influences to ensure observations do not have alternative explanations. They enable a comparison to a baseline in order to distinguish effects, if any, of the device being studied. A larger number of subjects provides greater confidence that the same results can be expected for any given person under the same conditions. Randomization and controls allow the researcher to determine cause-and-effect, as opposed to mere coincidence, with greater confidence. As a general rule, these study design features improve the strength of conclusions, which is particularly useful in cases with potentially significant confounding factors, subtle outcomes (including AEs), or potential bias.

In most cases, a study that is not randomized, controlled, inclusive of a sufficient number of subjects, or that suffers from more than one of these deficiencies, will yield weaker conclusions, and thus more uncertain predictions. Studies that fail to account for AEs will also yield weaker conclusions with respect to the benefit-risk profile, because such a study would not fully account for the risks.

In the case of ESDs used for SIB or AB, randomization, control, large numbers of subjects, and AE reporting are critical to understanding the benefit-risk profile. Many factors contribute to the manifestation or reduction of target behaviors and therefore can be significantly confounding. Those factors may include, but are not limited to, the underlying condition, environmental cues, transient psychological and physical states, and the treatment plan details. ESDs used for SIB or AB may also produce subtle outcomes, especially when the individual has intellectual or developmental disabilities that can impair communication. Subtle outcomes may include, but are not limited to, the development of stress disorders, fear and anxiety, pain and suffering, or learned helplessness. In light of such circumstances, drawing conclusions about the effectiveness of ESDs for SIB

and AB, especially with respect to durable conditioning, is difficult in the absence of randomized controlled trials.

In a randomized controlled trial, the researcher will randomly assign each subject to one group, at least one of which is a control group. A randomized controlled trial is prospective; the researcher creates different conditions across groups at the outset and will observe outcomes in the future. The researcher will eventually compare the outcomes across groups, with the control group providing confidence that the researcher-set conditions were responsible for any differences. A randomized controlled trial is one of the best designs for strong conclusions in most cases, including the use of ESDs for SIB and AB. In reviewing all the evidence, FDA did not identify any randomized controlled trials studying the effects of ESDs for SIB or AB.

Other designs are often considered to provide weaker evidence, which is the case for ESDs used for SIB and AB. For example, a case-control study is usually considered to be weaker because it does not observe randomized subjects but, instead, retrospectively compares two types of subjects (one acting as the control) by observing different outcomes and working backwards to explain the cause of one set of outcomes. Retrospective reviews are often considered weaker still because they do not include a control group. Case reports or series are even weaker because they report on, and attempt to explain, the experiences of single individuals.

Conclusions drawn from these other designs are generally considered weaker because they do not rule out other causes for any differences in results, including subject selection bias, as effectively. Designs that take an outcome as given and then work backwards in an attempt to explain it are more vulnerable to bias than prospective designs. Single-subject designs such as case studies are less likely to yield outcomes that would be typical for other such subjects. The conclusions drawn from randomized controlled trials are therefore generally considered much more reliable than these other designs. The general rule applies to ESDs used for SIB or AB because of the known multiple confounding factors, possible subtle outcomes (including unassessed AEs), and because bias is of particular concern. Thus, the reliance on weaker study designs for trials on ESDs limits the conclusions that may be drawn regarding their effectiveness.

Other weaknesses stem from the fact that the majority of research articles

were published in the 1960s and 1970s. Specifically, researchers published 26 articles before 1980, 12 from 1980 to 2000, and 7 since 2000. Consequently, most of the articles do not adhere to current, more exacting peer-review standards for study conduct and reporting. This is evident not only from the time of publication but from the information provided regarding study design, conduct, and reporting. (See also section II.A.2, discussing likely underreporting of AEs.)

Some of the papers have significant methodological limitations in addition to those already discussed. For example, the 2008 review by Dr. Israel and colleagues (Ref. 30), which provides a retrospective analysis of 60 subjects purporting to show all achieved successful treatment (defined as at least a 90 percent reduction in the targeted behavior), failed to explain, among other standard disclosures, data collection procedures, whether it was retrospective or prospective, and why and how staff made certain decisions that differed from patient to patient (e.g., the number of GED electrode sets applied). In short, that review did not take certain standard precautions that help to identify and eliminate bias and variability in order to understand results objectively.

A 2010 review by Dr. Israel and colleagues is a series of case reports on seven individuals at JRC (Ref. 94). The authors investigated the addition of punishment-based techniques to behavioral modification plans for people for whom positive-only techniques and pharmacotherapy had been reported to have failed previously, and reported success from skin-shock treatment at JRC. A review of case reports could be useful to examine initial results for continued investigations of an intervention; however, it was retrospective and covered few subjects. The authors also failed to describe how they chose the specific case reports, meaning that the authors may have overlooked or omitted individuals for whom punishment-based techniques did not affect the outcome. In contrast, studies that do not suffer from such methodological limitations have found that the removal of punishment techniques did not lead to an increase in problem behaviors (e.g., Ref. 95).

A paper by Dr. van Oorsouw and Dr. Israel, et al. investigated the effects of GEDs, but it too suffered from significant limitations (Ref. 96). The authors claim that contingent shock (another term for aversive conditioning with ESDs) significantly improved some individuals' behaviors; however, in each of the categories measured, no more

than four out of nine subjects demonstrated improvement. The other subjects "did not show any change." Regarding measurements, the investigators apparently included "soft" neurological signs and symptoms, especially involuntary movements, which are common for individuals who exhibit SIB or AB. They apparently applied shocks for such involuntary movements even though the patients would not be able to consciously control those behaviors. The investigators also appeared to consider certain behaviors, such as refusing academic tasks, as target behaviors even though such behaviors are not clinically considered aggressive or self-injurious. Thus, the related results do not actually reflect the use of the devices for SIB or AB. Additionally, the investigators studied a small group with highly varied characteristics, e.g., intellectual capacity and primary diagnoses. Such high variability among so few patients suggests that the investigators may not have obtained results that could be generalized to other patients, even without the aforementioned deficiencies.

Further, the 2008 and 2010 reviews by Dr. Israel and colleagues were published in *The Journal of Behavioral Analysis of Offender and Victim Treatment and Prevention* (JOBA-OVTP). JOBA-OVTP no longer appears to exist, and we determined that when it was active, it was not a peer-reviewed source because the articles were only reviewed by the journal's editorial board rather than an expert whose sole role was to verify accuracy and validity. Failure to conduct peer review indicates that the source is unreliable because its articles were not subjected to independent expert critiques that help ensure unbiased, evidence-based conclusions.

FDA also identified conflicts of interest relevant to some of the articles. While possible conflicts of interest do not on their own discredit results, certain safeguards help maintain the credibility of the authors. Authors commonly disclose possible conflicts in their papers, allowing readers to consider the information accordingly, and authors do not normally decide whether to accept their own papers for publication. However, FDA has particular concern with the bias that may have influenced many of the papers about the effects of ESDs on SIB or AB. For example, Dr. Israel, the founder of JRC, was an author of several of the 45 articles; Dr. Blenkush, the facility's Director of Clinical Research, has co-authored several papers with him. At the time some of those papers were published in JOBA-OVTP, Dr. Israel

was on the journal's editorial board and thus part of the reviewing and approving body. Considering the lack of peer review of these papers, any potential bias, intentional or not, in favor of the company or Dr. Israel's personal interests apparently went unquestioned before publication. In addition, without the expected conflict disclosures, readers were not adequately notified of any potential bias, which could affect their interpretation of the papers in consideration of the source.

The evidence in the scientific literature of the effects of ESDs on individuals' SIB or AB is therefore generally weak, and it is particularly weak with respect to the effectiveness of ESDs in achieving durable, long-term conditioning. This is not only because fewer studies considered long-term effectiveness, but more importantly, these studies failed to control for other treatment interventions applied over time, meaning that any effects observed may or may not have been due, in whole or in part, to ESDs. Thus, although the scientific literature indicates some individuals may stop engaging in the target behavior as an immediate effect of ESD application, the serious limitations discussed previously mean that durable long-term conditioning has not been established.

3. Information and Opinions From Experts

The Panel Meeting convened by FDA to consider the benefits and risks of ESDs generally held opinions consistent with our review of the literature. When asked whether the evidence presented at the Panel Meeting demonstrates that ESDs provide a benefit, the Panel was divided. However, approximately half the Panel agreed that there was a benefit, but they qualified their answers by explaining that the evidence showed a benefit from the interruption and immediate cessation of the target behavior. They noted the weaknesses in the evidence, including some of the limitations discussed previously. Three panelists were undecided, with one indicating that anecdotal reports suggest benefit for an ill-defined subpopulation. About one-third of the Panel answered no, the evidence does not show that ESDs provide a benefit to patients; they cited the poor quality of the evidence, the lack of recent data, and the failure to examine long-term effects.

At the Panel Meeting, one of the experts in the field observed that intervention with an aversive stimulus should not entail increasing the intensity, especially with ESDs, and that what might be characterized as adaptation or habituation to a particular

shock level actually indicates that skin shock is ineffective for that individual. As he explained, “the way this whole process works is that within a given range in terms of interventions that we use, some are effective and some are not, and if they’re not effective, you go on to something else. . . . To use an analogy, a small amount of lemon juice might be another aversive event, but if that doesn’t work, we don’t put acid on the tongue.” With respect to ESDs, because the shock is designed to be effective very quickly, when it appears an individual has habituated to the stimulus, “it’s not really habituation; that is, they haven’t adapted to it. It’s simply ineffective, and you would move on rather than to step up the voltage, so to speak.” Thus, what may be characterized as adaptation to a particular ESD shock level would be evidence of ESD ineffectiveness regardless of shock level.

Pointing to evidence FDA has considered, Dr. Tristram Smith’s expert opinion characterizes the results of the studies on aversive conditioning with electric shock as “highly favorable,” indicating that aversive conditioning reduces or eliminates severe SIB and aggression. As discussed in section II.A.3, he concludes that ESDs can be effective in at least some cases, but he is careful to note that the overall strength of the evidence is low (Ref. 8). Dr. Smith highlights many of the same evidentiary limitations discussed earlier, especially that the results may not be generalizable because they are based on small numbers of subjects and seldom provided information on key parameters, including recruitment, retention, standardization of measures, and participants’ treatment history. Dr. Smith echoes the concerns discussed earlier that the ability to reproduce the studies’ results in clinical practice is unclear because of differences between medical research and treatment settings, and notes that publication bias weighs in favor of reporting a clear effect on SIB and AB, since reports of clear effect are more likely to be published (Ref. 8). Finally, he observes that most of the few available studies have only evaluated short-term effectiveness and not long-term outcomes.

4. Information From State Agencies and State Actions on ESDs

According to NYSED, in 2006 it promulgated regulations to prohibit future use of ESDs in public and private schools serving New York State students, and require review of each student who continued to receive a behavioral intervention with an aversive conditioning device by independent

panels of three behavior experts. NYSED reports that, “in almost every instance over a 6-year period of time, these panels have determined after reviewing student-specific information that use of such a device was not warranted.” The panels “consistently reported that the data presented regarding the use of an aversive conditioning device lacked evidence of effectiveness.” NYSED also found that the long-term use of ESDs further demonstrates the lack of efficacy. Specifically, many students remain subject to ESDs for several years, and many continue to receive shocks long into their adult lives. In 2006, NYSED documented that 17 New York citizens remained subject to ESDs for 3 to 7 years (Ref. 72).

5. Information From the Affected Manufacturer/Residential Facility

JRC asserts that its ESDs provide substantial benefits to individuals by causing a meaningful decrease in the aggression, self-injury, or other harmful behaviors they exhibit, and that the literature evidences more positive side effects than negative ones. JRC representatives have stated that they have observed multiple positive side effects: The individuals “are no longer a threat to themselves or others. They are happy, they are healthy, they are medication and restraint free, and for the first time in their lives they are learning.” In many individuals, JRC staff “see a dramatic improvement in the affect and the way that they present. Many of them are able to receive medical treatment that they wouldn’t otherwise have been able to receive. They’re able to enjoy time with their family.”

Regarding the effectiveness of the devices in conditioning patients’ behavior, the JRC representatives stated at the Panel Meeting that, of 83 individuals whose treatment plans included use of the GED devices, 12 no longer wear the devices, 11 additional individuals have stopped using ESDs altogether, and 6 have not received any applications in the past 6 months. The representatives gave a detailed account of an individual who they claim was successfully treated with a GED device. In their view, banning ESDs would mean many individuals “are going to go back to the state of being restrained, of losing access to education, and are going to lose access to the vocational progress they have made, and they are going to return to a life of mechanical restraint and high doses of drugs.”

In its comments to the docket for the Panel Meeting, JRC submitted patient data purporting to demonstrate the durability of the effects of GED devices

in reducing or eliminating SIB and AB. However, this evidence lacks key information and provides only weak support for the durable effectiveness of ESDs. Importantly, the ESDs were part of multi-element interventions and thus were not solely responsible, if at all, for any long-term changes in individuals’ behavior. As section II.C.1 explains, multi-element treatment plans that do not involve the use of ESDs can be expected to result in durable effects (*e.g.*, Ref. 97).

Although JRC claims on its Web site that its devices are 100 percent effective (Ref. 98), at the Panel meeting JRC’s Director of Research acknowledged, “The GED and skin shock is not 100% effective for everybody . . . there are cases in the literature that show that some people it doesn’t work for.” He acknowledged that sometimes patients adapt to ESD shocks:

[O]ne of the things that happens sometimes when you use these types of devices is that there’s a phenomenon of adaptation, which means that the skin shock device no longer functions as a punisher and the behaviors return. And that comes from using it over and over again, and the frequency of the behaviors accelerates and it no longer functions as a punisher, it no longer controls the behaviors. So when that happens, then you move—one of the things you can do is move to higher levels of stimulation . . . [W]hat JRC found in the ’90s was that if you start off at a level of 15, then you’re less likely to encounter that adaptation. And then we’ve also found that, in the rare cases where there is adaptation to the GED, we can move to the GED-4 and we generally don’t see adaptation at all after that.

He later stated that JRC has “even seen adaptation to [the GED-4] in a few cases, and we’ve had to put in special protocols to help those particular people,” which include “a very comprehensive alternative behavior program” that has been “very effective” for at least one individual.

6. Information From Patients and Their Family Members

At the Panel Meeting, a member of a JRC parent association explained that her child’s treatments were not successful until they tried JRC’s GED device. The speaker thought that the skin shock quickly and effectively targeted specific behaviors while other treatments did not stop dangerous or self-abusive actions. The three individuals formerly at JRC who expressed their opposition to a ban at the Panel Meeting described their severe behavior issues and the failures of alternative treatments. They described successful outcomes after application of GED devices at JRC, and they described how they are now independent, well-

functioning members of society and, in one case, married with children. The family members of individuals at JRC who opposed a ban described the serious SIB and AB that the individuals exhibited and the various treatments that they tried and that failed (pharmacological treatments, physical restraints, and positive behavioral interventions) prior to application of a GED device at JRC. They stated that as a result of GED application, their family members have exhibited less SIB and AB, are happier, and are improving their lives.

One of the parents' associations submitted a comment that included 32 letters from family members of individuals at JRC reporting success stories for the GED devices. One letter includes seven case reports of individuals said to have been successfully treated at JRC with ESDs. The letters contend ESDs were the only successful treatment for their family members. They describe the individuals' severe behaviors prior to GED use, some life-threatening, including eye-gouging, suicidality, depression, swallowing sharp objects, cutting wrists, biting themselves, head-banging, hitting themselves with hard objects, running into walls, jumping out of windows, scrotal tearing, rumination, and projectile vomiting. The family members describe how previous treatments failed, leading many schools to reject or expel the individuals; in contrast, they described successful treatment with ESDs at JRC.

7. Information From Other Stakeholders

One speaker at the Panel Meeting, who described himself as a doctor who worked in the field for over 25 years, said that he had published peer-reviewed articles on both positive behavior support and punishment technologies. He opposes a ban "in the spirit of the right to effective treatment." He believes that for some individuals, "primary salient punishment is what's necessary in order to compete with their repertoires."

Several of the written comments we received from disability rights advocates assert that ESDs provide little if any benefit, and they criticize the scientific integrity of some of the sources cited by JRC in support of effectiveness. One comment from an advocate concludes that "the existing literature demonstrates only that electric shock aversives have inconsistent short-term efficacy with absolutely no long-term efficacy in reducing or eliminating destructive and self-injurious behaviors." The comment criticizes the evidence relied upon by JRC to support

effectiveness as "published internally with the sole involvement of their own personnel or those closely connected to their facility with no meaningful external review." For example, the comment states that JRC's Web site represents a self-published followup study on 65 individuals at JRC as data-based research, yet no related paper was accepted for peer review and there is no explanation or context for the methods of data collection.

8. Conclusion

Our search of the scientific literature regarding the effect of ESDs on SIB and AB revealed a number of studies showing that ESDs result in the immediate interruption of the target behavior upon shock, and some of the literature also suggested varying degrees of durable conditioning. However, these studies suffer from serious limitations, including weak study design, small size, and adherence to outdated standards for study conduct and reporting. Also, the conclusions of several of the studies are undermined by study-specific methodological limitations, lack of peer review, and author conflicts of interest. There is also evidence that the shocks are completely ineffectual for certain individuals. FDA has determined that the evidence shows that ESD shocks generally interrupt and cause immediate cessation of the target behavior when applied at the onset of such behavior, but the evidence is otherwise inconclusive and does not establish that ESDs improve the underlying condition or successfully condition individuals to achieve durable long-term reduction of SIB or AB.

C. State of the Art

FDA considers the reasonableness of the risks of ESDs relative to the state of the art, *i.e.*, the current state of technical and scientific knowledge and medical practice (see 44 FR 29214; May 18, 1979).

1. Scientific Literature

In our systematic review of the scientific literature, FDA found that the weight of the evidence indicates the state of the art for the treatment of SIB or AB relies on multi-element positive methods, especially positive behavioral support (PBS), sometimes in conjunction with pharmacological treatments, and has evolved away from the use of ESDs. The first published studies of contingent skin shock (the stimulus delivered by an ESD) took place in the 1960s (see Ref. 3, summarizing published research). Since then, advances in science and medicine have led to a better understanding of the

environmental triggers and organic origins of SIB and AB, improved behavior analysis methodology, and heightened ethical and human rights concerns regarding the use of ESDs, particularly in vulnerable patient populations (*e.g.*, Refs. 99 and 100). We found that the state of the art has progressed along with these advancements, which have led to treatments that are successful in treating SIB and AB, and hold greater promise for achieving long-term results, while avoiding the risks posed by ESDs.

a. Multi-element positive interventions. Elements, sometimes called components, of multi-element positive methods such as PBS, span several categories for a wide variety of purposes (*e.g.*, Refs. 101 and 102). The term "positive" can apply to many different treatment modalities, such as educative programming, functional communication training, and non-aversive behavior management, but it does not include aversive interventions such as contingent skin shock (Refs. 103 and 104).

Positive-intervention treatments incorporate the scientific and medical developments of recent decades as their foundation. For example, researchers have learned that behavioral treatment strategies should account for emotions and self-invalidation (rejecting the validity of one's own thoughts or emotions), which can be underlying factors associated with challenging behaviors (*e.g.*, Ref. 105). Relative to approaches in previous decades, multi-element positive interventions broaden the scope for treatment of SIB or AB to include such factors. Pharmacotherapy (the use of medications) has similarly evolved in terms of understanding the relationship between underlying factors and SIB or AB (discussed in more detail in this section). In essence, medical approaches now treat SIB and AB as results of environmental cues and biological processes rather than subdue them through punishment-based techniques (Refs. 99 and 106).

The key to creating a plan to address these cues and processes was the development of a formalized analysis, called a functional behavioral assessment (Ref. 106). Such an assessment is an analytical tool that facilitates various methods of applied behavioral analysis (ABA), which tailors treatment to the specific patient, particularly with respect to preventive measures. ABA is a fairly large family of treatment models that has existed as a general category for several decades. Although different authors define its scope differently, and older ABA models included aversives, in reviewing

the state of the art, we have focused on behavioral treatment models descended from ABA that are based on current scientific and medical research. Overall, ABA and its progeny treatment models have led the treatment of SIB and AB beyond ESDs toward multi-element positive interventions, sometimes alongside pharmacotherapy, designed for the individual patient (Refs. 97, 99, and 106).

To design the intervention, clinicians first conduct a comprehensive functional behavioral assessment to identify the target behaviors and the environmental and social triggers that contribute to them. This includes identifying the frequency of the unwanted behaviors as well as the social context and other environmental conditions (e.g., loud noise, crowded room) in which the behaviors are more likely to occur (e.g., Ref. 106 discussing “environmental redesign”). Failure to conduct a functional behavioral assessment may actually lead to harm because the resulting plan may inadvertently reinforce and consequently increase the problem behavior (Ref. 107). Following the functional behavioral assessment, a behavioral treatment plan is developed utilizing a positive behavioral therapy approach, such as those discussed in the paragraphs that follow. Clinicians would ordinarily try multiple treatment interventions if the initial treatment is not successful.

One particular type of positive behavioral therapy discussed in the literature is PBS. PBS uses functional behavioral assessment to develop a treatment strategy geared toward teaching new behaviors (Refs. 59, 99, and 108). These new behaviors proactively displace undesirable behaviors such as SIB and AB by teaching patients to express themselves with behavioral substitutions that will not cause harm to themselves or others. Functional communication training is one such approach. This process examines the communicative intent of the problem behaviors (what the individual is trying to tell or obtain from others), and then focuses on teaching the individual a functionally equivalent, but non-problematic, behavior (Ref. 107; see also Ref. 104). Several studies have demonstrated the value of functional communication training, especially when included as part of a comprehensive, multi-element intervention such as PBS (see Ref. 109 for a review of 29 studies).

PBS also relies on reinforcing desired behaviors, altering the environment to prevent or avoid triggers, and is explicitly nonpunitive. Thus, PBS

treatments exclude physical aversive conditioning techniques, which react to self-injurious or aggressive behavior rather than prevent such behavior from occurring in the first place, and can often lead to the escalation of the same events they are trying to prevent (Refs. 97, 99, and 101). Although proactive in nature, PBS plans may include rapid-reaction strategies for potentially serious problem behaviors that might pose a risk of harm to the subject or others to reduce the severity of an episode of problem behavior (Ref. 97). In contrast to a punishment technique, such plans are not intended to condition the individual or provide behavioral reinforcement.

Another more recently developed positive-based behavioral therapy for SIB and AB is dialectical behavioral therapy (DBT). Like PBS, DBT grew out of ABA principles (Ref. 105). DBT is a cognitive behavioral treatment that was originally developed to treat chronically suicidal individuals diagnosed with borderline personality disorder, and it is now recognized as a standard psychological treatment for this population (Ref. 110). Research has shown that it is also successful in treating a wide range of other disorders such as substance dependence, depression, PTSD, and eating disorders.

DBT consists of four components: A skills training group, individual treatment, DBT phone coaching, and a DBT therapist consultation team. Similar to PBS, DBT is a multi-element, empirical approach to treatment that relies on a behavioral analysis and emphasizes empathy, acceptance, and collaboration (Refs. 105 and 111). In both therapies, the goal is to impart new skills such as mindfulness, distress tolerance, interpersonal effectiveness, and emotion regulation (Refs. 105 and 111). However, because DBT was developed to treat certain conditions that may give rise to SIB and AB, such as borderline personality disorder, it differs subtly from PBS and centers on treating emotional dysregulation (Refs. 105 and 111). Thus, even though two patients may manifest SIB, DBT may be suited to treat one more than the other, depending on the underlying condition (Ref. 105).

b. Evolution of the state of the art away from ESDs and toward positive interventions. During the 1960s and 1970s, aversive conditioning procedures were often used because they potentially offered a relatively easy way to immediately, if only temporarily, stop problem behaviors such as SIB or AB (Ref. 112). In one study of contingent skin shock, the authors observed that patients in treatment wards exhibiting

such behaviors often went untreated because of staffing inadequacies, including lack of training in reinforcement techniques (Ref. 36). In an overwhelmed ward, contingent shock potentially offered a quick fix (Ref. 36). The authors noted, however, that to get such results, they chose “a strong shock which guaranteed quick suppression,” one they felt was “definitely painful” (Ref. 36).

Despite the apparent convenience, researchers have long raised ethical concerns about purposefully subjecting patients to the harms caused by physically aversive stimuli (Refs. 36 and 103). Patients subject to ESDs “gave every sign of fear and apprehension” associated with pain and anxiety (Ref. 36), yet decades ago, there was little oversight by human rights or behavior committees (Ref. 112). Indeed, experiments in punishment contributed to the development of behavior committees, and eventually the modern institutional review boards that are now mandatory for human research. As discussed in section II.A.1, patients may adapt to a particular shock level, which may lead to stronger shocks, thereby escalating ethical concerns (Ref. 59). Given the ethical implications, experts were cautioning as early as 1990 against allowing a crisis intervention procedure to turn into a continuous management technique (Ref. 103).

Whereas ethical and human rights concerns related to the risks posed by aversive techniques, especially ESDs, were drivers of the movement in the medical community away from these techniques (Refs. 106 and 112), the rise of positive behavioral interventions appears to be attributable to their success in treating problem behaviors while posing little to no risk. The literature supports a finding that newer, positive treatment approaches that are not combined with any aversive techniques are equally successful as approaches that use both positive and aversive techniques, regardless of the problem behavior targeted (Ref. 113). Indeed, providers and researchers have found that PBS is successful in the treatment of even the most challenging behaviors (Refs. 97 and 101), including in community and home settings (Refs. 95, 114, and 115). A review of 12 outcome studies for multi-element positive interventions, for a total of 423 patients, also concluded that PBS appears to be successful for the most challenging behaviors (Ref. 97). Similarly, randomized controlled trials have demonstrated that DBT successfully reduces self-injury in patients with borderline personality

disorder and adolescents with SIB (Refs. 111, 116, and 117).

PBS is also more adaptable than aversive conditioning techniques because it can achieve durable results for patients for whom aversive conditioning cannot. In particular, a consequential strategy such as aversive conditioning cannot achieve behavioral conditioning for some patients who have conditions that impair their ability to understand consequences and react by changing their behaviors. For example, a patient exhibiting SIB or AB may have severely impaired short-term memory and impulse control such that that any consequential strategy (like ESD shocks delivered in consequence of exhibiting a target behavior) may be limited in what it can accomplish (Ref. 97). Since PBS relies on preemptively identifying and reducing the problem behaviors' triggers, proactively reducing the problem behavior and not reactively relying on consequences, it has an inherent advantage over aversive conditioning techniques for such patients (Ref. 97).

The adaptability of PBS is also intentional, resulting from providers' efforts to translate positive treatment outcomes that were demonstrated in clinical settings (inpatient treatment facilities) to community settings (Refs. 99 and 106). The relatively little basic clinical research on contingent shocks (shocks given in response to certain behaviors), such as those applied by an ESD, is difficult to translate into treatment plans because aversive conditioning-based techniques, including the application of ESDs, are context-sensitive and may not remain effectual in different physical environments, from different providers, or for different patients (Refs. 36, 44, 59, and 93). Further, as discussed in section II.B.2, the available evidence does not demonstrate that aversive conditioning-based techniques provide durable long-term effectiveness (Refs. 34, 36, 59, and 95). In contrast to continual application of physical aversive conditioning techniques to suppress problem behaviors, PBS can achieve durable, successful treatment in community and home settings by targeting the underlying causes of the behavior and imparting the skills needed to address it (Refs. 99 and 106).

Like PBS, DBT is adaptable and has been shown to be successful in individuals with intellectual disabilities, in particular in reducing the severe SIB or AB of such individuals (Ref. 105). DBT also appears to achieve durable results after in-patient treatment (Ref. 117), and recent research suggests that, for some people, DBT approaches

can effectively treat SIB on an outpatient basis (Ref. 116).

The only risk FDA found to be associated with positive behavioral treatments is one posed by "extinction," a common, integral component of behavioral plans (Refs. 118 and 119). An extinction process reduces a target behavior by withholding the reinforcer, *i.e.*, the response sought with the target behavior (*e.g.*, Ref. 120). Extinction exhibits the potential risk of "extinction bursts," an upsurge of the actual undesirable behavior, particularly manifested in the early stages of the intervention. If this upsurge in behavior poses a danger to the individual or others, then an extinction paradigm may not be a feasible option (Ref. 120). In general, however, positive behavioral therapies pose little to no risk to patients.

Not all treatment providers follow a positive-only behavioral treatment model such as PBS (Refs. 113 and 115). As explained in section II.B.1, FDA's review of the available data and information did reveal that aversive conditioning techniques may provide some effect of immediate cessation (*e.g.*, Ref. 59), especially when paired with positive approaches (*e.g.*, Ref. 113). As such, providers may believe that aversive conditioning techniques offer a viable option of last resort (Refs. 36, 99, and 112). However, the literature contains reports that when health care providers have resorted to punishers, the method was usually no more intrusive than water mist, and the addition of punishers proved no more successful than PBS-only techniques (Refs. 99 and 113). Reflecting this trend, a 2008 survey of members of the Association for Behavior Analysis found that providers generally view punishment procedures as having more negative side effects and being less successful than reinforcement procedures (Ref. 115).

The comments submitted by JRC question the effectiveness of positive behavioral interventions, citing three case review studies of "positive-only" approaches covering successive time periods. In JRC's characterization, a study covering 1969 to 1988 found a success rate of 37 percent for such an approach (Ref. 121), one covering 1985 to 1996 found a 52 percent success rate (Ref. 99), and the third, covering 1996 to 2000, found a 60 percent success rate (Ref. 122). JRC also cites a literature review to support its claim that positive-only interventions sometimes require supplementation with punishment techniques (Ref. 123).

These studies do not alter FDA's conclusions regarding the effectiveness

of positive behavioral interventions or the state of the art for the treatment of SIB and AB. We note that the first review cited by JRC (Ref. 121) includes comparative assessments of positive-only approaches showing that, for the category of behaviors referred to by JRC (positive-only approaches targeting SIB), skills acquisition and stimulus-based interventions had 50 and 52 percent success rates, respectively, during the reviewed time period. FDA recognizes that positive behavioral interventions may not always be successful on their own for all problem behaviors in all patients. However, we note the substantial progress in non-aversive approaches for the treatment of SIB and AB as providers have gained experience with them over time, which is evident in the increasing success rates cited in JRC's comment.

Further, one review cited by JRC (Ref. 123) studied the addition of punishment procedures generally and did not address the use of ESDs in particular. Punishment procedures can take a wide variety of forms in addition to ESDs, such as daily point deductions, verbal reprimands, or food deprivation. Although the authors concluded that aversives appeared to improve some patients' outcomes, they did not conclude ESDs were a necessary aversive, and the intervening years have yielded even more favorable results for positive-only approaches (Ref. 97).

Review of the current scientific literature confirms that, in recent decades, medical practice has shifted away from restrictive physical aversive conditioning techniques such as ESDs and toward treating patients with SIB and AB with positive-based behavioral interventions (Ref. 113). PBS emerged beginning in the 1980s (Refs. 97, 106, and 112), and continued to develop in the ensuing years, emphasizing empirical analysis and applicability to non-clinical settings (Ref. 106). One analysis showed that, beginning in the 1990s, the use of positive techniques increased while the use of punishment techniques, which include physical aversives, dropped (Ref. 124). A survey of experts in the related fields of PBS and ABA found that the largest dropoff in usage of punishment techniques occurred between the 1980s and 1990s (Ref. 112). Such surveys show the ABA field as a whole moved away from intrusive physical aversive conditioning techniques such as ESDs 2 decades ago (Refs. 103 (reprinted from 1990) and 112).

Correspondingly, many authors have noted that research of punishment-based techniques—which includes a broad range of consequences, from the

application of ESDs, to food deprivation, down to deducting daily points—has dwindled for decades (Refs. 59, 93, and 115). Most of the papers written since 2000 on the use of ESDs are by JRC employees and JRC consultants (Ref. 98), which raises questions regarding their impartiality, as discussed earlier in section II.B.2. Although the anecdotal reports in two of JRC's self-authored papers purport to provide evidence of persons refractory (resistant) to all behavioral controls except ESDs (Refs. 30 and 94), these findings were not published in a peer-reviewed journal, and they suffer from a number of methodological shortcomings that raise questions about their validity, as discussed earlier in section II.B.2. In direct contrast, one study that followed up on adults on whom ESDs were used in an unnamed residential facility in the northeast United States (most likely JRC) found that less restrictive interventions successfully treated SIB and AB after ESDs were removed (Ref. 95).

c. Use of pharmacotherapy to treat SIB and AB. In current medical practice, the treatment of SIB and AB with positive behavioral interventions (e.g., PBS or DBT) is sometimes supplemented with pharmacotherapy. Drugs that act in the brain may provide clinical benefit, although the biochemical pathways that may contribute to SIB and AB are not well understood.

SIB and AB are seen in patients with a variety of diagnoses, including autistic disorder, Fragile X syndrome, Lesch-Nyhan syndrome, and other developmental disorders. There are currently two drugs that have been approved by FDA for the treatment of irritability associated with autistic disorder in children, a population representing a small subset of all patients with SIB and AB. RISPERDAL (risperidone) was approved in 2006 for the treatment of irritability associated with autistic disorder based on clinical trials in patients ages 5 to 17 years old, and ABILIFY (aripiprazole) was approved in 2009 for the same indication based on clinical trials in patients ages 6 to 17 years old. In the trials conducted for approval, SIB and AB were among the emotional and behavioral symptoms of autism that were measured in the overall evaluation of irritability.

The most common adverse reactions observed in the trials conducted for approval of these two drugs were sedation, increased appetite, fatigue, constipation, vomiting, and drooling. Other serious adverse reactions with the use of these drugs may include

neuroleptic malignant syndrome, tardive dyskinesia, and metabolic changes.

Published literature describes the clinical use of pharmacotherapy for the treatment of SIB and AB, which includes the use of atypical antipsychotics such as risperidone and aripiprazole as well as drugs from other pharmacological classes. (See Ref. 3 for a review of relevant literature examining the use of pharmacotherapeutic interventions in the treatment of SIB and AB.) Reports describing the use of certain atypical antipsychotic drugs (e.g., risperidone and aripiprazole) are the most common, which may be in part because safety data on their use in pediatric patients are already available and because two of them (risperidone and aripiprazole) have been approved by FDA for use in the subset of patients with SIB and AB who have irritability associated with autistic disorder.

2. Information and Opinions From Experts

FDA asked the Panel whether treatment options other than ESDs, including behavioral, pharmacological, alternative, and experimental therapies, are adequate to address SIB or AB. Most of the Panel opined that other treatments are not adequate for all individuals who exhibit SIB or AB, citing a lack of sufficient data demonstrating efficacy, especially when evaluating the durability of benefits, drug side effects, and that “it’s unfortunately rare that any treatments in psychiatric or behavioral issues are universally effective.” FDA also asked the Panel whether a specific subpopulation of patients exhibiting SIB or AB exists for whom pharmacological and behavioral treatment options other than ESDs are inadequate. The panel unanimously concluded that such a subpopulation seems to exist but is very difficult to define and recommended additional research into refractory subpopulations.

Based on the available data and information, FDA is not aware of any recognized clinical criteria to identify refractory patients. We could not find rigorous or systematically collected data that distinguish a refractory subpopulation that does not respond to other available treatments. Even assuming a subpopulation exists for which treatments other than ESDs are not adequately effective, that does not mean ESDs are effective for that subpopulation. As with other psychological or neurological conditions, there may simply be a subpopulation of patients for whom there is no adequate treatment option.

As discussed previously, although some evidence suggests ESDs reduce SIB and AB in some patients, no randomized controlled clinical trials have been conducted to demonstrate effectiveness generally or that ESDs are effective for behavioral conditioning when other options fail.

Accordingly, the Agency agrees with the observation made by one of the Panel experts: Although other treatments may not completely reduce or eliminate SIB or AB in all patients, that does not mean ESDs should be used. In determining whether to ban these devices, FDA balances effectiveness against the risks they pose and assesses the reasonableness of such risks in light of the state of the art. The state of the art is to use positive behavioral interventions, sometimes in conjunction with pharmacotherapy, even for the most challenging SIB and AB; the unsubstantiated claim that ESDs are uniquely effective for refractory individuals does not alter that conclusion. As the Panel expert cited previously explained, “the statements of professional programs and the fact of wholesale abandonment of aversive electrical shock therapy by the peers in this field show that it is unreasonable to conclude that these devices are part of the standard of care for this class of patients . . .”.

Epitomizing the decades-long shift away from ESDs, one of the device's pioneers has publicly repudiated contingent shock for its lack of effectiveness (see Ref. 125). Another expert summarized in an interview that the modern clinical approach is the result of science establishing better methods, compared to ESDs, for the treatment of severe problem behaviors (see Ref. 126), and another expert repudiated behavioral treatments that use punishment techniques more broadly as early as 1989 (see Ref. 107 for a summary).⁴

FDA also considered information and opinions on state-of-the-art treatment for SIB and AB in the expert reports it obtained. Dr. Smith's opinion notes similar trends that FDA has identified regarding the development of positive interventions for SIB and AB based on a functional behavioral assessment, which allows the customization of a treatment plan to meet the individual's needs. In his view, the data do not support a precise estimate for success rates of positive interventions in patients exhibiting SIB or AB, but he notes the rapid increase in reported effectiveness, from a 1990 review that

⁴ Sidman, M., *Coercion and Its Fallout*. Authors Cooperative: 1989.

found a success rate of 50 percent to a recent unpublished result of 84 percent. Dr. Smith concludes that non-aversive interventions can be effective for most, but not all, people with intellectual or developmental disabilities, which is true of any such treatment (Ref. 8).

Dr. Brown's report provides additional detail on the development of the PBS field. She believes 20 years of empirical evidence demonstrate that plans designed around a functional behavioral assessment can effectively address even the most serious problem behaviors. She contrasts this evidence base with that for contingent skin shock, for which she identifies a sharp decline beginning in the 1990s. In her view, dated research on contingent skin shock is not particularly relevant to current perspectives on people with disabilities, especially given that such research does not meet modern standards for study conduct or comport with the current medical understanding of serious psychological disorders.

One of the developments that Dr. Brown highlights is the understanding that the "[r]eduction of problem behavior is an important, but not the sole, outcome of successful interventions" (Ref. 107). Instead, an effective PBS intervention will enhance quality of life, acquisition of valued skills, and access to valued activities (Ref. 107; see also Refs. 127–129).

Dr. Brown also contrasted the amount and availability of publication and training between PBS and contingent skin shock. In particular, several books and peer-reviewed journals focus specifically on PBS, and graduate training programs and organizations foster the competent development and implementation of PBS. In contrast, to her knowledge, "no journals, books, graduate programs, or organizations focus [] on the skills necessary to use contingent electric shock or other aversive interventions" (Ref. 107).

Dr. Brown further points out that while no professional organization publishes standards of practices for the use of ESDs, the Association for Positive Behavior Supports has adopted standards of practice for the elements that comprise PBS (Ref. 107).⁵ To meet the current standards of practice, a PBS plan must: (1) Address the communicative intent of the problem behavior, e.g., with functional communication training; (2) identify and implement curricular and environmental modifications; and (3)

focus on the patient's choice and control. In Dr. Brown's opinion, "professionals who are willing to use [contingent electric shock] are likely those that do not have any expertise in the use of PBS" and so would not have previously implemented plans that meet the standards of practice, reducing their likelihood of success (see also Ref. 101).

Similar to Dr. Brown's conclusions, Dr. LaVigna's expert report also emphasizes that a positive-only treatment plan developed according to specific guidelines will adequately address even the most challenging behaviors, regardless of the individual's diagnosis or functioning level (Ref. 130). He separates possible elements of a PBS plan into four categories: (1) Ecological strategies, which address a mismatch between the individual's needs and the environment; (2) positive programming strategies, which teach new skills with specific instructional methods; (3) focused support strategies, which reduce or eliminate the behavior primarily through antecedent control; and (4) reactive strategies, which, unlike a punishment-based method, are intended only to reduce the immediate behavior (Ref. 130).

Dr. LaVigna elaborates on the relatively recent development of a new outcome measure and principles to define challenging behaviors, including episodic severity as well as the principles of resolution and escalation (Ref. 130). Episodic severity allows a provider to account for more than the frequency of the target behavior by adding data about how severe the particular occurrence was (Ref. 130). In this way, progress can be measured more completely by including a reduction in severity, rather than merely looking at the number of occurrences. The principles of resolution and escalation allow a provider to categorize outcomes of interventions, which means they "can explicitly take responsibility" for strategies to achieve reductions in episodic severity (resolution) rather than increases in severity (escalation) (Ref. 130).

With the advent of PBS, along with refinements such as improved outcome measures and definitions, Dr. LaVigna points to recent literature that studied over 500 patients and found that PBS was effective (Ref. 130). He also recounts an example of a patient for whom ESDs had been recommended, observing that correctly implemented positive-only methods were able to treat the patient instead (Ref. 130). He asserts that, not only is PBS highly effective even for the most challenging behaviors, but that it can be implemented in community and institutional settings

cost effectively and accessibly (Ref. 130). He concludes that "[p]unishment is unnecessary, and is not the accepted standard of care in the relevant treatment community" (Ref. 130).

The limited and generally outdated evidence base supporting the use of ESDs contrasts markedly with the extensive, current, and growing evidence base for PBS. While ESD use is founded upon research that incorporates outmoded assumptions and in practice has often sought compliance with staff-determined norms rather than focusing on clinically relevant behaviors, PBS reflects modern medical advancements and emphasizes patient choice, participation, and skills acquisition, even for patients with the most challenging behaviors. PBS enjoys thriving academic support and PBS practitioners can refer to practice guidelines published by a professional organization, while academic interest in aversive conditioning has languished and the use of ESDs is not contemplated in a comparable publication.

3. Information From State Agencies and State Actions on ESDs

FDA considered the actions of States with respect to ESDs and aversive interventions generally, and we found that many already prohibit the use of these devices. 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, 2011.⁶ According to the Massachusetts DDS response to comments on its proposed regulation, 20 States as well as the District of Columbia specifically prohibit aversive interventions (Ref. 131). Massachusetts' finalization of its regulations brings the number up to 22 jurisdictions. According to a comment from NASDDDS on the 2014 Panel Meeting, 40 States and the District of Columbia "have adopted regulations or policies that expressly prohibit the use of interventions that cause pain, are humiliating, and violate human rights."

These State laws prohibiting or restricting the use of ESDs provide further support that these devices are

⁵ Association for Positive Behavior Supports, *Positive Behavior Support Standards of Practice: Individual Level*, 2007, available at <http://apbs.org/standards-of-practice.html>.

⁶ Massachusetts DDS specifically addressed comments that sought an extension of the prohibition to patients with court-approved treatment plans that include the use of ESDs. However, noting the many guardians and family members of individuals receiving treatment with ESDs believe this is the only form of effective treatment for their loved ones, DDS expressed a desire not to repeat the history of extensive litigation over access to these devices (Ref. 131).

not part of the state-of-the-art treatment for SIB or AB. The fact that only one site in the United States uses ESDs on individuals with SIB or AB (Ref. 73), and that the individuals subject to ESDs are predominantly from two States, and from fewer than a dozen in total,⁷ strongly suggest the overwhelming majority of patients exhibiting SIB and AB throughout the country are being treated with methods that do not involve ESDs. Given that, as discussed in section I.B, at least 330,000 individuals in the United States exhibit SIB or AB, JRC (with fewer than 300 residents) observes a very tiny fraction of all such individuals.

In fact, the Massachusetts DDS has successfully transitioned several patients who were subject to ESDs at JRC to providers who do not use ESDs (Ref. 132; see also Ref. 95). FDA agrees with the assessment of the current standard of care by the Massachusetts DDS:

The Department concludes that there has been an evolution in the treatment of severe behavioral disturbances in persons with intellectual disability over the past thirty years, and particularly in the last two decades, which has moved towards forms of treatment that are non-aversive and involve positive behavioral supports.

The Department bases this opinion both on the body of empirical evidence showing the effectiveness of other less intrusive forms of treatment that do not involve pain; on the overwhelming support of this position by virtually every local, statewide or national organization supporting individuals with intellectual disability, and by providers and clinicians whose practice demonstrates that non-aversive treatment can modify difficult or dangerous behaviors effectively and for the long-term, while aversive interventions, in addition to causing pain and anxiety in such individuals, have no proven long-term efficacy.

(Ref. 131; see also Ref. 132.)

Evidence from other States further corroborates our conclusions. For example, as discussed earlier, according to NYSED, following promulgation of regulations in 2006 by NYSED prohibiting future introduction of ESDs in public and private schools and requiring review of students then subject to ESDs, independent panels of behavior experts determined that ESDs were not warranted in almost every instance over a 6-year period. Similarly, at the Panel Meeting, the Assistant Attorney General for the State of Utah, representing his State's agencies that

provide services and protection for individuals with disabilities, observed that programs in Utah and across the nation effectively treat SIB and AB without ESDs.

4. Comments From the Affected Manufacturer

At the Panel Meeting, the presenters for the manufacturer stated that the data demonstrate a clear clinical need for these devices. In their view, therapy for these individuals has failed at all other treatment centers, and other treatments have failed at JRC prior to the utilization of their GED devices. They asserted that a wide range of therapeutic interventions over long periods of time have been ineffective for their residents on GED devices, and that typically 12 to 15 other facilities have expelled or rejected these residents before they come to JRC. They stated that the individuals on whom ESDs are used are those with extraordinary behavior disorders. JRC's position is that few other treatment facilities, if any, will accept patients who have not improved without aversives, and that the only other options besides ESDs would be psychotropic drugs and various restraints (Ref. 21).

FDA has found no basis to believe that the patients on whom ESDs are used at JRC are patients with the most severe SIB and AB in the United States. FDA also has reason to doubt whether all alternatives were adequately attempted before resorting to ESDs. As noted in section II.C.5, we are aware that some parents have reported that JRC did not attempt positive approaches based on functional behavioral assessments, and the parents felt pressured into accepting the necessity of ESDs (Ref. 133). Similar to the NYSED review discussed in sections II.A.4 and II.B.4, another review revealed that the facility using ESDs for SIB and AB either did not conduct a functional behavioral assessment or did so in a non-standard way, which could reduce the effectiveness of the resulting behavioral intervention (Ref. 107). Although there is anecdotal evidence that treatments other than ESDs were tried on individuals at JRC and failed prior to use of ESDs, there is evidence in the literature that patients have been successfully treated with alternatives after ESDs were used (Ref. 95).

Further, evidence of failures of treatments other than ESDs is not evidence that ESDs safely or successfully treat patients or are within the state of the art. To cope with patients' apparent adaptation, the manufacturer itself acknowledges that increasing the electric current may be

necessary, and if that does not work, the ESD may need to be replaced with "an alternative behavior program" (Ref. 21). In fact, consistent with our understanding of the state of the art, JRC touts positive behavioral therapies, for example on the "Unparalleled Positive Programing" page on its Web site, but its Web site does not even mention its use of ESDs (Refs. 134 and 135).

The comments submitted by JRC question the effectiveness of positive behavioral interventions based on its belief that there does not appear to be any clinical data supporting such, an absence of research concluding that "all problem behaviors can be effectively treated using only PBS procedures," and "literature stating that PBS is not always effective for self-injurious behaviors." The comment from a former JRC clinician also asserts that PBS and medications are not effective for all individuals with serious behavior disorders.

Contrary to JRC's assertion, there are clinical data supporting the effectiveness of positive behavioral interventions such as PBS and DBT in treating SIB and AB, as discussed earlier in this section. Further, even though positive behavioral interventions may not always be successful on their own for all problem behaviors in all patients, this does not mean they are not generally effective, sometimes used in conjunction with pharmacotherapy, or that they are not state-of-the-art treatments for SIB and AB. Rather, the literature provides evidence showing that multi-element positive interventions are at least as successful as methods that include use of aversives regardless of the behavior targeted, as discussed earlier in this section.

JRC also submitted a paper by Dr. Blenkush, the Director of Clinical Research at JRC, purporting to show that ESDs have a more favorable side effect profile than antipsychotic medications (Ref. 21). FDA notes that no peer-reviewed literature compares treatment regimens. Further, the JRC paper makes comparisons that may not be relevant to the selection of treatment for an individual. For example, the paper compares frequency of specific side effects from pharmacotherapy to the frequency of different categories of side effects from ESDs. However, aggregate frequency data on dissimilar effects across different patient populations provide scant basis for a comparison of treatment regimens. Comparing a comprehensive list of the side effects of several antipsychotic medications against the side effects of a single device, which the paper admits "have not been evaluated in the same depth or

⁷ Although JRC stated at the Panel Meeting that it serves patients from 11 States, according to one of JRC's comments, the 82 patients on whom GED devices had been used as of April 2014 are from only 6 States, and 60 of them are from either New York or Massachusetts (Ref. 21).

with as many participants” (Ref. 21), does not represent a valid comparison.

The comment from a former JRC clinician asserts the standard of care for treatment resistant individuals such as those at JRC includes consideration of aversive conditioning devices such as the GED, citing a textbook that discusses punishment techniques including the use of ESDs.⁸ FDA notes that the cited chapter reviews information on the SIBIS, not the GED, and except for a SIBIS case report, the chapter relies on pre-1990 studies. Furthermore, it concludes with the observation that electric shock is usually not necessary and can be replaced with “more acceptable aversive outcomes” such as a squirt of lemon juice or a reprimand. This evidence does not demonstrate that ESDs are currently considered by the scientific and medical community to be an acceptable option for patients exhibiting SIB and AB.

5. Comments From Patients and Family Members of Patients

The three former JRC residents who opposed a ban at the Panel Meeting described their severe behavior issues and the failures of alternative treatments (psychotropic medications, physical restraints, and reward systems). One stated that the drugs made him feel like “a walking zombie.” Comments from family members of JRC residents similarly describe numerous failed alternative treatment attempts prior to finding success with ESDs at JRC. Many family members report that the side effects of drugs are much worse than ESDs and included: Extreme sedation, not recognizing or interacting with others, bizarre behavior, toxicity effects (such as damage to internal organs), loss of personality, and lack of learning. One parent listed 26 drugs her child had tried and other treatments that failed, including electroconvulsive therapy (which is different from ESD application and not the subject of this proposed rule). One mother noted that the behavior medications interacted with her child’s seizure medications and caused an increase in seizures.

FDA understands that family members of individuals exhibiting SIB or AB face very difficult choices regarding treatment options, and FDA does not doubt their best intentions, the sincerity of their belief that an ESD is the best or perhaps only option for their loved one, or that they have tried alternative treatments without success. However, FDA does have reason to

question the information provided to these family members by JRC. One article reports that some parents who consented to the use of GEDs on their children did so only under pressure (Ref. 133). These parents reported feelings of coercion upon admission to the facility and intimidation when attempting to change their children’s intervention plans (Ref. 133).⁹ The parents reported facing a choice between restrictive aversive strategies justified as measures of last resort, such as between the GED and use of a four-point restraint board, and chose the GED as the lesser evil (Ref. 133).

Although the facility touts itself as accepting refractory patients, all of the parents interviewed provided information suggesting that interventions in public schools prior to JRC admission did not attempt all treatment options, such as using a functional behavioral assessment to develop prevention or antecedent strategies (Ref. 133). Once at JRC, none of the parents reported the development of prevention or antecedent strategies for their children (Ref. 133). Given that functional behavioral assessments, as well as prevention and antecedent strategies such as those in a positive multi-element intervention, are generally successful even for challenging SIB and AB, such patients may well have been responsive to PBS techniques had they been attempted.

FDA acknowledges that these reports are only from certain parents who volunteered to share negative experiences, and we cannot conclude that these reported experiences were shared by others or are generally representative of families’ experiences at JRC. Nevertheless, the reports do indicate that at least some parents felt pressured by JRC to continue to agree to the use of GEDs on their children, and for at least some children, alternative treatments were not exhausted. For them, GEDs were not in fact applied as a last resort.

6. Comments and Information From Others

Information from other Federal agencies, behavioral psychologists, disability rights groups, and the United Nations corroborates FDA’s conclusions regarding the risks of ESDs relative to the state of the art. For example, in its comment, the U.S. Department of Justice (DOJ) explained that it has concluded that ESDs are outside the generally

accepted standard of care (Ref. 136). DOJ enforces the Civil Rights of Institutionalized Persons Act (42 U.S.C. 1997 *et seq.*), which entitles eligible patients to receive services that meet generally accepted standards of care. In order to protect that right, DOJ must determine relevant standards of care, giving DOJ experience in comparing treatment to that which providers generally accept as the standard. In DOJ’s view, far from the standard of care, ESDs are physically and psychologically harmful punishments that have uncertain efficacy. According to DOJ, the current, generally accepted professional standards of care for individuals with intensive behavioral needs require PBS, implemented according to individualized plans, and not restrictive methods such as ESDs. DOJ asserts that thousands of people throughout the country with similar behavioral needs receive effective treatment without being subjected to the risks posed by ESDs.

Behavioral psychologists who have practiced for decades treating patients with SIB and AB indicated in comments on the Massachusetts ban that they have not had to resort to aversives such as ESDs, describing painful aversives as “unnecessary, unacceptable, and not supported by the professional literature” (Refs. 137 and 138). Another commenter on the Massachusetts ban stated that in 30 years working in programs serving individuals with severe behavior challenges and dangerous behavior in more than 20 States, no program allowed use of pain to control behavior (Ref. 131). At the Panel Meeting, disability rights groups’ presentations concurred that positive behavioral interventions have been shown to result in long-term reduction or elimination of challenging self-injurious or aggressive behaviors.

Finally, the United Nations Special Rapporteur on torture and other cruel, inhuman, or degrading treatment or punishment, has determined that the application of ESDs violates the rights of individuals at JRC under the United Nations Convention Against Torture, as well as other international standards, and supports a complete ban on “electroshock procedures.” Although the United Nations is composed of many countries in addition to the United States, the fact that this multi-nation body does not merely consider ESDs to be inappropriate or unacceptable treatment, but considers them to constitute torture, suggests that there is great distance between these devices and state of the art for treatment of SIB and AB. Although JRC claims ESDs are used for SIB and AB in other

⁸ Malott, R.W. and J.T. Shane, “Punishment (Positive Punishment),” in *Principles of Behavior*. 7th ed. 2013, Boston, MA: Pearson.

⁹ The authors do not identify the facility by name. However, they are clear that the ESD in question was the GED, refer to JRC’s Web site, and rely on an article about JRC when characterizing the facility.

nations, it has not provided any examples, and FDA is unaware of one.

7. Conclusion

FDA has determined, on the basis of all available data and information, that state-of-the-art treatments for SIB and AB are positive-based behavioral approaches, sometimes alongside pharmacotherapy, as appropriate, and do not include ESDs. We focused on data in the scientific literature, current clinical practices, and information about the evolution of treatments for SIB and AB.

Significant scientific advances have yielded new insights into the organic causes and external triggers of SIB and AB. Although researchers have much yet to learn, the advent of functional behavioral assessment, and, subsequently, approaches like PBS and DBT, have allowed providers to move beyond aversive conditioning techniques such as the contingent shocks delivered by ESDs. The state of the art represents the achievements of an empirical response to the inadequacies of such techniques from both a safety and effectiveness standpoint. The scientific community has long recognized that addressing the underlying causes of SIB or AB, rather than suppressing it with painful shocks, not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits.

As a result, the use of aversive conditioning techniques overall, and ESDs in particular, has diminished considerably over the past several decades, while the use of positive behavioral methods has risen. The overwhelming majority of remaining providers who employ some type of aversive conditioning use methods that are much less intrusive than contingent shock. ESDs are only used at one facility in the United States on individuals from a small number of States; almost half of the States have specifically prohibited their use. Practitioners in the field with decades of experience have asserted that they have never had to resort to ESDs, and surveys of experts show that such views are common. Meanwhile, modern positive behavioral treatments have been demonstrated to work in complex environments like community settings and achieve durable results while posing very little risk (Refs. 99, 101, and 106). Although positive behavioral interventions such as PBS may not always be completely successful on their own for all behaviors in all patients, the literature indicates that they are generally successful, sometimes alongside pharmacotherapy, regardless of the severity of the behavior targeted,

and the success rates continue to improve.

III. Determination That ESDs for SIB and AB Present an Unreasonable and Substantial Risk of Illness or Injury

As discussed in section I.F, section 516 of the FD&C Act authorizes FDA to ban a device intended for human use by regulation if it finds, on the basis of all available data and information, that such a device presents substantial deception or an unreasonable and substantial risk of illness or injury.

In determining whether a deception or risk of illness or injury is “substantial,” FDA will consider whether the risk posed by the continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing (see § 895.21(a)(1)). With respect to “unreasonable risk,” FDA analyzes the risks associated with the use of the device relative to the state of the art (44 FR 29214 at 29215). Thus, in determining whether a device presents an “unreasonable and substantial risk of illness or injury,” FDA analyzes the risks and the benefits the device poses to patients, comparing those risks and benefits to the risks and benefits posed by alternative treatments being used in current medical practice. Actual proof of illness or injury is not required; as Congress explained when it amended the medical device banning provisions in the FD&C Act, FDA need only find that a device presents an “unreasonable and substantial risk of illness or injury” on the basis of all available data and information (H. Rep. 94–853 at 19; 44 FR 29214 at 29215).

FDA has considered evidence from a wide variety of sources, including the scientific literature, experts in the field, State agencies that also regulate ESD use, the affected manufacturer/residential facility, individuals on whom ESDs have been used and the views of their family members, disability rights groups, and other government entities. In weighing each piece of evidence, FDA took into account its quality, such as the level of scientific rigor supporting it, the objectivity of its source, its recency, and any limitations that might weaken its value. Thus, for example, we generally gave much more weight to the results of a study reported in a peer-reviewed journal by an objective author than we did to anecdotal evidence.

As discussed in section II.A, the scientific literature demonstrates that ESDs for SIB and AB pose a number of psychological harms including

depression, PTSD, anxiety, fear, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness, as well as the physical risks of pain, and skin burns. These risks are not exclusive, and their harmful impact is magnified when an individual experiences two or more of them together. Misapplications of shocks present the same risks without any possibility of benefit. FDA determined that AEs have very likely been underreported due to various methodological limitations in the scientific literature as well as the impaired ability of many subjects to recognize and communicate AEs, which also increases the risk of harm to these individuals. Because of the likely underreporting of AEs in the literature and the fact that actual proof of harm is not required, FDA carefully considered the risks identified through other sources, which provide further support for the risks reported in the literature and indicate that ESDs are associated with additional risks such as suicidality, chronic stress, neuropathy, and injuries from falling. Although JRC has only publicly acknowledged the risks of pain and erythema, JRC’s own records provide compelling evidence that aversive interventions such as ESDs are associated with several other risks, including nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and withdrawal from usual activity.

As discussed in section II.B, the studies reported in the scientific literature show that ESDs can immediately interrupt SIB or AB upon shock, and some studies suggest varying degrees of durable conditioning. However, the studies in the literature suffer from various limitations, such as weak study design, including failure to control for concomitant treatments, small size, other methodological limitations, lack of peer review, and author conflicts of interest. As a result, the evidence is inadequate to establish that ESDs improve individuals’ underlying conditions or successfully condition individuals to reduce or cease the target behavior to achieve durable long-term reduction of the target behavior. Further, to the extent ESDs do cause immediate interruption for some, the evidence also suggests that the shocks are completely ineffective for others, regardless of shock strength. Regardless of whether adaptation is the correct characterization, even JRC has acknowledged that its strongest ESD sometimes becomes ineffective,

necessitating the use of an alternative behavior program instead of an ESD.

As discussed in section II.C, FDA has determined that state-of-the-art treatments for SIB and AB are positive-based behavioral approaches along with pharmacotherapy, as appropriate, and do not include ESDs. The medical community now broadly recognizes that addressing the underlying causes of SIB and AB, including environmental ones, rather than suppressing behaviors with shocks not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits. As a result, research about and use of aversive conditioning techniques overall, and ESDs in particular, has diminished considerably over the past several decades, while research about and use of positive behavioral methods has increased and continues to increase. ESDs are only used at one facility in the United States with individuals from a small number of States. Almost half of the States prohibit ESD use, and there is evidence that the overwhelming majority of patients exhibiting SIB and AB throughout the country are being treated without the use of ESDs. Although positive behavioral interventions such as PBS may not always be completely successful on their own for all behaviors in all patients, the literature shows that they are typically successful (on their own or in conjunction with pharmacotherapy), regardless of the severity of the behavior targeted, even in community settings, and can achieve durable long-term results while avoiding the risks posed by ESDs.

FDA has determined that the risks posed by ESDs for SIB and AB are important, material, or significant in relation to the benefit to the public health from their continued marketing. FDA recognizes that ESDs can cause the immediate cessation of self-injurious or aggressive behavior; however, the immediate effects the ESDs provide are outweighed by the numerous short- and long-term risks discussed earlier in this section. For many individuals who exhibit SIB or AB, these risks are magnified by their inability to adequately communicate the harms they experience to their health care providers. Even when immediate cessation is achieved, without durable conditioning the target behavior will recur over time and necessitate ongoing shocks to cause immediate cessation, magnifying the risks. If adaptation occurs, it would render the shocks wholly ineffective and could lead to stronger shocks with no effect. Thus, the degree to which the risks outweigh the benefits increases over time.

FDA has also considered the risks posed by ESDs for SIB and AB relative to the state of the art. Decades ago, health care providers had a poor understanding of the causes of SIB and AB and very limited options to treat SIB or AB. Contingent skin shock was used even though the result was fleeting and continual shock administration was needed. Since then, state-of-the-art treatment for SIB and AB has evolved considerably. Today we know that careful functional assessment, which identifies specific unwanted or undesired behaviors, the frequency and severity of these behaviors, and their specific triggers, allows for the development of positive-based behavioral therapy that provides greater benefit and poses less risk than using ESDs. Although they may demand more health care provider training and effort than ESDs, various multi-element positive interventions such as PBS and DBT are now very much viable options for treatment of SIB and AB. These interventions pose little risk and, on their own or alongside pharmacological treatments, have been shown to be successful in treating even the most severe behaviors in both clinical and community settings, and to achieve durable long-term results.

Several individuals have been successfully transitioned from ESDs at JRC to positive-based therapies elsewhere. Thus individuals exhibiting SIB or AB have alternative options to ESDs that pose less risk and provide greater benefit through durable long-term effectiveness in both clinical and community settings.

Based on a careful evaluation of the risks and benefits of ESDs for SIB and AB and the risks and benefits of state-of-the-art treatments for SIB and AB, FDA has determined the risk of illness or injury posed by ESDs for SIB and AB to be substantial and unreasonable. A majority of the expert Panel also found that ESDs for SIB and AB present a substantial and unreasonable risk of illness or injury. The Panel members who opined that this standard is not met generally had concerns about foreclosing the possibility that new ESDs may be developed in the future and used in a way that can safely and effectively treat SIB and AB. In this regard, FDA notes that a banned device is not barred from clinical study under an investigational device exemption pursuant to section 520(g) of the FD&C Act. However, any such study must meet all applicable requirements, including but not limited to, those for: Protection of human subjects (21 CFR part 50), financial disclosure by clinical investigators (21 CFR part 54), approval

by institutional review boards (21 CFR part 56), and investigational device exemptions (21 CFR part 812). Other panelists were reluctant to agree that the banning standard had been met because it could be possible to develop ESDs to treat SIB or AB without being noxious. In response to these concerns, FDA notes that devices that are not noxious are not within the scope of this ban.

Other than JRC and the former JRC clinician, the only comments in opposition to a ban either at the Panel Meeting or through submission of comments to the Panel Meeting docket were from three former JRC residents, family members of individuals on whom ESDs were used at JRC (one of the parents association comments included 32 letters from family members), a Massachusetts State Representative, and one concerned citizen. As discussed earlier, FDA recognizes that family members of individuals now and previously on ESDs at JRC have had to make some very difficult decisions regarding the care of a loved one, and FDA does not doubt their intentions or question the sincerity of their belief that ESDs are the best or only option available. However, as discussed in section II.C.5, FDA has reason to believe at least some of these family members were pressured into choosing ESDs, and FDA questions whether these family members were provided with full and accurate information regarding the risks and benefits of ESDs and alternative treatment options, and whether all other options were adequately attempted prior to ESD use.

IV. Labeling

FDA has determined that labeling, or a change in labeling, cannot correct or eliminate the unreasonable and substantial risk of illness or injury. At the Panel Meeting, only members who opined that ESDs present an unreasonable and substantial risk of illness or injury (a majority of the entire Panel) were asked whether labeling could correct or eliminate this risk, and all concluded that labeling could not correct or eliminate the risks or dangers.

As explained in section II.A, the risks posed by ESDs fall under two broad categories, psychological and physical, and these risks are heightened when the devices are used to treat patients who exhibit SIB or AB because of these patients' vulnerabilities. As explained in sections I.C and II.A.1, individuals demonstrate great variability in their experience of ESD shocks, including with respect to pain and the psychological harms discussed. A person's physical state naturally

changes continuously, so the body's reaction to ESD shocks will change continuously, and a person's mental state further shapes the experience. The same electric shock, as characterized by electrical current and stimulation site, may affect any given person in a variable manner from one shock to another. This variability is seen across different individuals, which prevents providers from using one person's experience as a guide for another person, and within the same individual over time, which prevents providers from using a single person's past experience as a predictor of future experiences.

Labeling cannot correct or eliminate the risks or dangers because conditions under which providers could overcome the underlying inter- or intrapersonal variability cannot be defined. Predicting an individual's resulting experience would require knowing the initial psychological and physical states of the person, which is subjective information that providers cannot reliably know, especially when making a split-second decision whether to apply a shock. Further, individuals, especially ones with intellectual or developmental disabilities, may not be able to accurately and reliably communicate information regarding their physical or psychological state. Thus it would be impossible to create broadly applicable labeling that could account for these variables; labeling could only warn the provider that it is impossible to account adequately for all relevant factors. Because labeling cannot correct or eliminate the fact that providers lack knowledge required to mitigate the risk of harm, it cannot correct or eliminate the risks or dangers posed by ESDs for SIB or AB.

Labeling also cannot correct or eliminate ESD risks or dangers by specifying output parameters, for example, maximum current or optimal electrode placement. As explained in section II.A.1, the subjective experience, especially in terms of psychological harms, does not necessarily vary in proportion to shock strength. Even a relatively mild stimulus can trigger or contribute over time to a more serious psychological reaction (*e.g.*, Refs. 31–33). Thus it would not be possible to provide warnings regarding output parameters to correct or eliminate the risks and dangers.

Labeling also cannot limit the risks to only the most refractory patients. As explained, although evidence indicates that a subpopulation of refractory individuals may exist, that subpopulation is difficult if not impossible to define. The labeling of the

GED devices, the only ESDs currently in use in the United States of which FDA is aware, already includes the statement that “[t]he device should be used only on patients where alternate forms of therapy have been attempted and failed.” Yet the available evidence, discussed in section II.C.5, casts doubt on whether JRC in fact applies the devices as a last resort after attempting all other approaches, and shows that patients JRC considered to be refractory were transitioned successfully to other treatments. Thus labeling has failed to limit use of the device to patients who do not have other adequate treatment options. Further, even if a refractory subpopulation could be defined, as discussed in section II.C.4, the possibility that some patients are refractory to treatment does not necessarily mean that ESDs would be an effective treatment or that the benefits of ESD use outweigh the risks. Thus labeling cannot correct or eliminate the substantial and unreasonable risk posed by ESDs.

In his report, Dr. Smith recommends against banning and that FDA should instead impose the following restrictions: “(1) A prescription and ongoing, periodic review by a board-certified physician, licensed psychologist, or licensed behavior analyst and (2) prior approval and ongoing, periodic review by an independent patient-rights committee convened by a healthcare organization that is accredited by an organization such as the Joint Commission.” Although FDA does not have to consider whether restrictions would obviate the need for a ban, we have considered Dr. Smith's proposal and do not believe restrictions would correct or eliminate the substantial and unreasonable risk posed by ESDs. The only ESDs currently in use are prescription devices and, as explained by JRC, “require multiple levels of review, approval, consent and oversight.” FDA has determined that JRC's measures do not adequately mitigate the unreasonable and substantial risk posed by these devices. While the measures Dr. Smith recommends are perhaps stronger, there is not enough information to determine that such measures would adequately mitigate the risks.

V. Application of Ban to Devices in Distribution and Use

FDA is proposing that the ban apply to devices already in commercial distribution and devices already sold to the ultimate user, as well as devices sold or commercially distributed in the future (see § 895.21(d)(7)). This means

ESDs currently in use on individuals would be subject to the ban and thus adulterated under section 501(g) of the FD&C Act and subject to FDA enforcement action.

FDA is proposing this because the risk of illness or injury to individuals on whom these devices are already used is just as unreasonable and substantial as it is for future individuals on whom these devices could be used. Indeed, as safer and more effective alternative treatments continue to be developed, it is the individuals on whom ESDs are currently used for whom the ban may have the most impact. The majority of the Panel agreed that, if FDA were to ban ESDs, the ban should apply to devices already in use.

JRC believes that any action “that would precipitously remove or require the eventual removal of the GED from the patients who currently rely on this court-ordered therapy would have dire consequences from a patient safety and health perspective” (Ref. 21). According to JRC, the GED “is the only treatment available to these patients”; all others were tried and failed. As an example of what could result from a mandated, sudden removal of the GED from a patient, JRC explains that one patient whose GED was removed against the medical advice of JRC health professionals soon resumed self-injurious scratching and picking behaviors that led to serious blood and bone infections, paralysis of his legs, and eventual death 3 years after leaving JRC (Ref. 139).

As discussed in section II.C, FDA does not agree that ESDs are the only treatment available for individuals exhibiting SIB or AB, no matter how severe the behavior may be, and FDA has reason to doubt whether all other treatment options were attempted for individuals prescribed these devices. FDA has not been able to verify the accuracy of JRC's account regarding an individual removed from the GED. However, even if accurate, that does not mean that the GED was not harmful to the individual, nor does it speak to the extent to which other treatments were tried after he left JRC. The only support JRC offers for this anecdote is a post on its Web site by Dr. Israel that does not include information regarding possible harms from GED use or details regarding treatment after the patient left JRC, and JRC states it offered the post as an editorial to the *New York Times* but was rejected. In contrast to JRC's assertions, we again note that one study described in the literature found that less restrictive interventions successfully treated SIB and AB in individuals after ESDs were removed (Ref. 95), and that

Massachusetts DDS has successfully transitioned several patients who were subject to ESDs at JRC to providers who do not use ESDs (Ref. 132).

However, FDA recognizes that, for certain individuals currently subject to ESDs, immediate cessation could possibly result in a significant increase of SIB or AB before appropriate alternative therapies are in effect, and a more gradual reduction toward complete removal may be necessary for some patients, especially those who have been subject to ESDs for a considerable amount of time. Thus, to account for this possibility, in appropriate circumstances, FDA does not intend to enforce the ban for a limited period of time with respect to ESDs that continue to be used on patients after the effective date. We intend to consider, for example, whether the patient has a documented medical need for gradual transition to an alternative therapy, as determined by an independent psychiatrist, psychologist, or similar State-licensed behavioral expert. We welcome comment on how long transitions may take. FDA does not intend to enforce against individual patients.

VI. Proposed Effective Date

FDA is proposing that any final rule based on this proposed rule become effective 30 days after the date of its publication in the **Federal Register**. FDA requests comment on the proposed effective date for this proposed rule.

VII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental effects of this proposed rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of disposal of unused ESDs that will need to be handled after the effective date of the proposed rule.

The environmental assessment (EA) considered each of the alternatives in terms of the need to provide maximum reasonable protection of human health without resulting in a significant impact on the environment. The EA considered environmental impacts related to landfill and incineration of solid waste. The proposed action would result in an initial batch disposal of used and unused ESDs primarily at a single geographic location followed by a gradual, intermittent disposal of a small number of remaining devices in this and other affected communities where these devices are used. The total number of devices to be disposed is small, *i.e.*, approximately less than 300 units. Overall, given the limited number of

ESDs in commerce, the proposed action is expected to have no significant impact on landfill and solid waste facilities and the environment in affected communities.

The Agency has concluded that the proposed rule would not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. FDA invites comments and submission of data concerning the EA and FONSI.

VIII. Economic Analysis of Impacts

A. Introduction

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 (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). 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.

B. Summary of Costs and Benefits

FDA is proposing to ban ESDs for the purpose of treating self-injurious or aggressive behavior. Non-quantified benefits of the proposed rule include a reduction in adverse events, such as the risk of burns, PTSD, and other physical or psychological harms related to use of the device in this patient population.

We expect that the proposed rule would only affect one entity that currently uses these devices to treat residents of their facility. The proposed rule would impose costs on this 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. To account for this uncertainty, we use a range of potential alternative treatment costs. At the lower bound, we assume that alternative treatments would cost the same as the current treatment. We use reimbursement data from the State of Massachusetts to estimate a potential upper bound for alternative treatments. 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 to \$60.1 million at a 3 percent discount rate, and from \$0 to \$51.4 million at a 7 percent discount rate. Annualized costs range from \$0 million to \$6.8 million at a 3 percent discount rate and from \$0 million to \$6.8 million at a 7 percent discount rate. The lower-bound cost estimates only include administrative costs to read and understand the rule with no incremental costs for alternative treatments. Additionally, there would be transfer payments between \$11.5 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. The proposed rule's costs and benefits are summarized in table 2, “Economic Data: Costs and Benefits Statement.”

We also examined the economic implications of the rule as required by the Regulatory Flexibility Act. 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.

The full discussion of economic impacts is available in Docket No. FDA-2016-N-1111 at <http://www.fda.gov/>

[AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm](http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm).

TABLE 2—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Low estimate (million)	Primary estimate (million)	High estimate (million)	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits: Annualized. Monetized \$millions/year. Annualized Quantified. Qualitative	Reduction in physical and psychological adverse events related to use of the device.
Costs: Annualized	\$0	\$3.4	\$6.8	2015	7	10	
Monetized \$millions/year	0	3.4	6.8	2015	3	10	
Annualized. Quantified. Qualitative	
Transfers: Federal. Annualized.							
Monetized \$millions/year	From:			To:			
Other Annualized	11.5	13.3	\$5	2015	7	10	
Monetized \$millions/year	11.5	13.3	15	2015	3	10	
	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.						

IX. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to “construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain Federal requirements applicable to devices. (See section 521 of the FD&C Act (21 U.S.C. 360k); *Medtronic v. Lohr*, 518 U.S. 470

(1996); and *Riegel v. Medtronic*, 128 S. Ct. 999 (2008)). If this proposed rule is made final, it would create a Federal requirement under 21 U.S.C. 360k that bans ESDs for AB and SIB.

XI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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List of Subjects*21 CFR Part 882*

Medical devices, Neurological devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 882 and 895 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Amend § 882.5235 by revising paragraph (b) to read as follows:

§ 882.5235 Aversive conditioning device.

* * * * *

(b) *Classification.* Banned when used to reduce or cease aggressive or self-injurious behavior. See § 895.105. Otherwise, Class II (performance standards).

PART 895—BANNED DEVICES

■ 3. The authority citation for 21 CFR part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

■ 4. Add § 895.105 in Subpart B to read as follows:

§ 895.105 Electrical stimulation devices to treat aggressive or self-injurious behavior.

Electrical stimulation devices to treat aggressive or self-injurious behavior are devices that apply a noxious electrical stimulus to a person's skin to reduce or cease aggressive or self-injurious behavior.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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