

**JRC: Analysis of FDA Rule Proposal References**

<b>Rule Section</b>	<b>FDA Assertion</b>	<b>Reference Number</b>	<b>Reference Response/Text</b>
II.A.1	FDA conducted an extensive, systematic review of the medical literature for harms, <i>i.e.</i> , 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).	29	<p><b>The following information regarding AEs was presented in Ref. 29:</b></p> <p><b>During the session(s), the therapist provided relaxation if a panic response or anxiety by the participant would be manifested. (p. 238)</b></p>
II.A.1		30	<p><b>The following information regarding AEs was presented in Ref. 30:</b></p> <p><b>Despite the fact that we administered up to 3,764 GED applications to the participants, the only negative side effect found was an occasional temporary discoloration of the surface of the skin that cleared up within a few minutes or a few days. The most common immediate collateral behavior associated with the application of skin shock was a temporary tensing of the body while the application was applied. Other collateral behaviors were avoidance responses such as attempts to remove the device or grab the transmitter, and temporary emotional behaviors. (p. 158)</b></p>
II.A.1	For example, when the recipient does not have control over the shocks and has previously received multiple such shocks,	31	<p><b>There is nothing in the paper cited (Ref. 31) that supports any of the statements in the above passage. In fact, the review comes to opposite conclusions. The entire review is highly critical of the research underlying the concept of PTSD. Consider the following excerpt:</b></p>

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	<p>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.</p>		<p><b>The philosopher of science William W. Bartley (1962) maintained that incisive and informed criticism is the ideal route to scientific progress. By rooting out errors in our web of beliefs, constructive criticism allows us to winnow away erroneous assumptions. <u>In a pursuit to accomplish this goal in the case of PTSD, we have found that most every core assumption underlying the diagnostic construct has met with questionable support, if not falsification...</u>It is therefore ironic that research whose impetus stemmed primarily from the creation of PTSD has provided a database that challenges most every assumption on which the construct was based. PTSD was originally believed to follow only specific types of traumatic events, but this assumption has been disconfirmed. Traumatic events were generally believed to be the largest contributor to clinical outcome, but this is not the case. <u>Evidence for a dose– response relation between stressors and symptoms has been inconsistent and equivocal.</u> PTSD is defined by symptom criteria that overlap substantially with extant conditions, such as depression and better established anxiety disorders (e.g., specific phobia). Concerted efforts to identify distinct pathogenic processes that underlie PTSD, including research on neuroanatomy, psychophysiological markers and memory processes have met with mixed results, if not outright failure. <u>In short, research has called into question most if not all of the construct-to-manifest indicator nodes within the nomological network surrounding PTSD.</u> (p.853, <u>emphasis</u> supplied)</b></p>
<p>II.A.1</p>	<p>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 <i>Diagnosics and Statistical Manual of Mental Disorders</i>).</p>	<p>32</p>	<p><b>The FDA references an article published in 1994 (Ref. 32) that describes three cases that do not meet the DSM-III-R criteria for PTSD. The authors propose a new diagnosis “prolonged duress stress disorder” that was not adopted by DSM-IV, DSM-V, or any ICD version. While one individual witnessed the death of young child, the other two patients developed PTSD from the following circumstances:</b></p> <ul style="list-style-type: none"> <li>• <b>a middle manager receiving extra work from his boss over the course of 18 months (p.72, Case 1)</b></li> <li>• <b>18 months of caring for spouse passing from a progressive neurological disorder. The women had flashbacks about arguments between consultant regarding which department would provide a bed and difficulty obtaining a breathing apparatus to use at home. (p.73, Case 3)</b></li> </ul>

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			<p>The paper does not support the notion that a series of less traumatic events lead to PTSD. The concepts described in the paper were not adopted by any recognized diagnostic system.</p>
<p>II.A.1</p>		<p>31</p>	<p>The FDA misrepresented the content of Ref. 31. First, regarding a series of less traumatic events leading to PTSD, Ref. 31 indicates that research reviews and meta-analyses do NOT support a dose-response relationship. Consider the following excerpts:</p> <p><b>There now exists a substantial and complex literature on dose–response relationships, the adversity–stress model, and risk factors for PTSD. Several reviews (Bowman, 1997, 1999; Bowman &amp; Yehuda, 2004; Breslau, 2002; Davidson &amp; Fairbank, 1993; Gibbs, 1989; Lundin, 1995; McFarlane &amp; de Girolamo, 1996; Ozer &amp; Weiss, 2004), an edited text (Yehuda, 1999), structural equation modeling studies (King, King, Foy &amp; Gudanowski, 1996; King, King, Foy, Keane &amp; Fairbank, 1999; King, King, Fairbank, Keane &amp; Adams, 1998a), and two meta-analyses (Brewin, Andrews &amp; Valentine, 2000; Ozer, Best, Lipsey &amp; Weiss, 2003) provide an overview of the issues. <u>These sources, and research upon which they rely, find that (a) most individuals do not develop PTSD after Criterion A events, (b) a simple dose– response relationship is often not supported, and (c) factors extraneous to the event contribute more variance to clinical outcome than the event itself.</u> (p. 840, <u>emphasis</u> supplied)</b></p> <p>Thus, in the span of three DSM editions, the universe of potentially traumatic events went from direct experiences to only having to hear about a severe misfortune befalling others. Breslau and Kessler (2001) found that the expanded definition of Criterion A in the DSM-IV increased by 59% the total number of events considered traumatic. Rosen (2004) referred to the expansion of events subsumed under Criterion A as “criterion creep,” while McNally (2003a) used the term “conceptual bracket creep.” With the expanded definition, an individual who sees horrific events on the news can technically develop PTSD (e.g., Ahern, Galea, Resnick &amp; Vlahov, 2004; Eth, 2002; Pfefferbaum, Pfefferbaum, North &amp; Neas, 2002; Propper, Stickgold, Keeley &amp; Christman, 2007). (p. 842)</p> <p>The FDA references earlier versions of the DSM. By doing so, the fact that the criteria for PTSD change with DSM-5. Specifically, consider the following from the American Psychiatric Association:</p>

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			<p><b>Compared to DSM-IV, the diagnostic criteria for DSM-5 draw a clearer line when detailing what constitutes a traumatic event. Sexual assault is specifically included, for example, as is recurring exposure that could apply to police officers or first responders. Language stipulating an individual’s response to the event-intense fear, helplessness or horror, according to DSM-IV-has been deleted because that criterion proved to have no utility in predicting the onset of PTSD.<sup>1</sup></b></p>
II.A.1	<p>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.)</p>	33	<p><b>The FDA misrepresented the information contained in Ref. 33. First, the participants in this study are police officers and fire fighters who DO NOT have a diagnosis of PTSD. “Exclusion criteria included any current DSM-IV psychopathology including PTSD and any history of psychiatric or neurological disorders...” (p. 2). Second, nothing in the paper suggests that repeated shocks or similar stimuli presented in a series could lead to stress disorder. Rather, the study found that firefighters do better than police officers on cue reversal learning tasks, and police officers do better on context reversal tasks when compared to firefighters. The authors put forth the deficit is possibly due to exposure to traumatic events (such as might be experienced by police or fire fighters). However, there is an enormous selection bias associated with the groups.</b></p>
II.A.1	<p>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 (<i>e.g.</i>, the shock</p>	n/a	<p><b>Electrical stimulation is easily measured objectively and the observed and self-reported effect on humans have been well documented.<sup>2,3</sup> The FDA is suggesting that regardless of the intensity of shock, it is possible to exceed some subjective minimum that would cause harm. By this logic, any medical device that uses electrical stimulation (ECT, nerve and muscle stimulators, pacemakers, defibrillators) carry the same risk.</b></p>

<sup>1</sup> American Psychiatric Association. Posttraumatic Stress Disorder Fact Sheet. Retrieved from <http://www.dsm5.org/Documents/PTSD%20Fact%20Sheet.pdf> on May 16, 2016.

<sup>2</sup> Bruner, J.M.R. & Leonard, P.F. (1989). *Electricity, Safety and the Patient*. Chicago: Year Book Medical Publishers.

<sup>3</sup> Insert additional references here

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	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).		
II.A.1	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).	34	<b>The key words here are “may” and “initially.” FDA ignored the numerous reports that document the absence of negative side effects and the occurrence of positive side effects. In review after review, authors consistently state that negative side effects are temporary and ameliorated by various methods. Finally, the authors repeatedly note that positive side effects are most often observed.</b>
II.A.1	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).	35	<p><b>As self-destructive behavior is brought down by shock, John avoided attending adults less and also cried less. Apparently, avoiding, crying, and self-destructive behavior fall within the same response class. So far as the behaviors recorded in this instance show, the side effects of shock are desirable. Informal clinical observations further confirm this finding (John was observed by some 20 staff members). (p.89)</b></p> <p><b>It can be observed that shock brought self-destructive behavior immediately to zero and kept it there for the remainder of the study. As with John, generalized behavior change accompanying the shock showed up as a decrease in whining and fussing and a decrease in avoiding attending adults. (p. 90)</b></p> <p><b>While the immediate generalized behavior change due to shock was very favorable, and in that way similar to John and Linda, there is some reason to believe that her aggression towards other children on the ward increased at a later time. Apparently, the reinforcers which maintained the self-destructive behavior were still operative, and since she did not develop a more acceptable behavior form, which seems to be the case in most children (e.g. John and Linda), and was not explicitly trained to behave otherwise, she returned to a form of behavior which yielded large quantities of attention. (p. 91)</b></p>

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			<p><b>This does not mean that aggression was caused by shock. Rather, the authors are suggesting that effectively treating her self-injury with shock led to an increase in the frequency of the next response class member.</b></p>
<p>II.A.1</p>		<p>36</p>	<p><b>As self-destructive behavior was brought down by shock, John avoided the attending adult less and also whined less. Apparently, avoiding, whining, and self-destructive behavior fell within the same response class. These data indicated that the side effects of punishment were desirable. Informal clinical observations further confirmed the finding (john was observed by some 20 staff members), the nurse’s notes reporting less distance and fussing. (p. 149)</b></p> <p><b>He was given two 1-sec shocks on Days 28 and 29. This brought his self-destructive behavior down to zero and retained it at that level until the ned of the experiment, some 18 days later. At the same time as his self-destructive behavior was decreasing, whining also disappeared. (p. 150)</b></p> <p><b>One can observe the same change in nonpunished behaviors with Linda as was the case with John: there was a substantial decrease in both avoiding of the attending adults and whining after shock was administered. (p. 151)</b></p> <p><b>....and the result shows an unambiguous drop in self-destruction. It was consistent with data obtained on Linda and John, i.e., as self-destructive behavior was brought down by the use of shock, there was a concomitant drop in whining. (p. 151)</b></p> <p><b>Finally, both in the changes that we were able to record objectively and in the clinical observations, there was every evidence that the side effects of punishment, instead of being undesirable, were judged to be therapeutically desirable. (p. 153)</b></p>

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II.A.1		37	<p><b>Andy’s initial reaction to this experience was surprise, a cry of pain and immediate fear of the device. Paradoxically, his reaction to the therapist was one of approach and desire for closeness. Tenderness and affection were freely expressed by the therapist and Andy responded warmly to this attention. (p. 443-444)</b></p>
II.A.1		38	<p><b>The first shock evoked neither cry nor scream but rather a startle which was followed by whining.....He also began to wince as soon as he struck himself and to try to avoid the shock device, but there was no vocal indication of extreme distress. As noted earlier, there is no evidence of grossly altered pain sensitivity, yet while the shock was clearly aversive to him his reaction to it was less extreme than anticipated. (p. 463)</b></p>
II.A.1		39	<p><b>Diane attempted to remove the SIBIS stimulus unit on only two occasions but was unable to do so. The only other negative effects observed were occasional perspiration and slightly reddened areas where the SIBIS stimulation unit was applied for extended periods. (p. 496)</b></p>
II.A.1		40	<p><b>John’s reaction to the shock was to show considerable fear and resistance as the experimenter approached with the device, but afterwards to become sullen and quiet. (p. 70)</b></p> <p><b>“John’s extra-experimental behavior has been considerably altered as apparent result of this study and its consequences. One of the experimenters has used these results to guide and encourage attempts to control John’s behavior at home and in the hospital school. Improvement in several behaviors has been reported, including eluding the teacher, fighting with smaller children, and breaking objects at home. Weekends at home have become tolerable for the parent, whereas they were previously rare. Only a few shocks have been used, according to anecdotal reports of staff members entrusted with its use. The resistance to suppression in this study has not been reported in these other environments.” (p.76)</b></p>

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II.A.1		41	<p>No tissue damage resulting from use of the TSD was detected at any time during this study, even when 25 shocks were delivered to the same site in 45 min. No visible damage was produced by the wired remote SS, but arc burns from the handheld SS continued to appear. [note the TSD replaced the SS and is specifically designed for humans]....TSD shocks elicited only a slight local tremor in the thigh. No interruption of ongoing activity (except SIB) was observed. Richard appeared to prefer wearing the TSD, approaching any person who carried the equipment into his ward, and assisting in attaching it to himself. He never attempted to remove the device. Removal of the device provoked tantrum behaviors. He was judged by staff to be happier, calmer, and less clingy to people when wearing the TSD (cf. Linscheid, Pejeau, Cohen, &amp; Footo-Lenz, 1994; Ricketts et al., 1993). A side effect of wearing the TSD was that he became more independently active. More physical activities, especially walking, but also new workshop-type tasks were included in his regular routine. (p. 264)</p>
II.A.1		42	<p>And surprisingly, during successful shock avoidance they appeared happy. These alterations in behavior were only partially generalized to the environment outside the experimental room. (p. 103)</p> <p>Es had expected considerable expression of fear by Ss when they were shocked. Such fearful behavior was present only in the beginning of training. On the other hand, once Ss had been trained to avoid shock, they often smiled and laughed, and gave other signs of happiness or comfort. (p. 108)</p>
II.A.1		43	<p>Mike’s reactions to the shock may be of interest. The first shock elicited a scream. Then, he stood motionless except for rubbing his arm with a facial expression described by the observer as “more like bewilderment than pain or anger”. Within Session 14, Mike began to react differently to Experimenter 1’s entry following an incorrect-button response than to his entry at the end of the regular 10-min intervals. When shock was “due”, Mike ran to a corner of the room, jumped in place, hit himself and yelled. As soon as shock was</p>

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			<p><b>administered, he became quiet. By Session 16 Mike did not seem to behave as if the laboratory or Experimenter 1 were aversive. (p. 206)</b></p>
II.A.1	<p>One article reported a temporary aversion to the experimenter (Ref. 36).</p>	36	<p><b>This statement is false. A discrimination, rather than an aversion was reported. Specifically, the authors note “By Sessions 25, 26, and 27 it can be observed that his rate of self-destructive behavior with the non-punishing adults was climbing alarmingly. In other words, he started to form a discrimination between the adult who punished him for self-destruction, and those who did not. In Session 30, Experimenter 3 also punished John for self-destruction, with the effect of producing generalization across other experimenters. (p. 149) The effect of shock enhance his relationship with adults (see Ref. 36 quotes above)</b></p>
II.A.1	<p>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.</p>	n/a	<p><b>This is pure speculation. Ref. 39 describes sweating from wearing the electrode, not from the delivery of shock. The Graduated Electronic Decelerator has current limits to prevent increases in intensity past a certain threshold.</b></p>
II.A.1	<p>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).</p>	44	<p><b>The FDA misrepresented the statement made in this article. The entire quote states the following:</b></p> <p><b>If the replacement behaviors are desirable that is well and good, although they are often allowed to go unnoticed-or unreinforced. But if the replacement behavior is undesirable, the staff may become quite concerned. It might be remarked that since the behaviors most frequently reinforced in a large, understaffed institution tend to be undesirable ones, the probability that a replacement behavior will be undesirable is quite high, a fact which may have helped give rise to the concept of “symptom substitution.” Should the substitution of one SIB for another occur, it is then necessary to weaken the new SIB as well, perhaps using the techniques which weakened the first SIB. Our experience suggests</b></p>

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			<p>that once most SIB had been eliminated, especially if it was deliberately replaced by new, desirable behaviors, favorable qualitative changes often took place in the behavior of the patients. (p. 68)</p>
II.A.1	Some patients “froze by refraining from showing any sort of behavior” (Ref. 34).	34	<p><b>The following lines immediately followed the above quote: “Relaxation and verbal instructions were then necessary. F. successfully underwent surgical treatment of the cataracts at his both (sic) eyes. He gained vision in one of his eyes.” (p. 299)</b></p>
II.A.1	Similarly, others reported a “pseudocatatonic sit-down,” <i>i.e.</i> , muscular freezing or melting (Ref. 45).	45	<p><b>The following is a complete description of the pseudocatatonic sit-down:</b></p> <p><b>Shortly after the initiation of the aversive therapy program and concomitant with the rapid drop in the incidence of assaultive behavior, we observed and recorded a number of intriguing behaviors which were essentially novel for this patient. Generally, these behaviors lasted only a few days, disappeared, and soon were supplanted by new behaviors. We may depict the sequence of their appearance roughly as follows:</b></p> <p><b><i>Pseudocatatonic sitdown:</i> in STSs, the patient began to show a pseudocatatonic type of behavior, either becoming completely stiff and mute or going utterly limp, in response to the physical closeness, warmth and encouragement shown her by staff members. In the prior base line sessions, this type of response by staff would prove highly provocative to the patient and would often lead to curses, threats or even striking out. We surmised that this global muscular “freezing” or “melting” provided “insurance” for the patient, preventing her from striking out and consequently being punished for doing so. (p. 629-630)</b></p>
II.A.1	One study described temporary tensing of the body and noted attempts to remove the device or grab the transmitter during treatment (Ref. 30).	30	<p><b>See complete quote from Ref. 30 above.</b></p>

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<p>II.A.1</p>	<p>Some patients resorted to hostility and retaliation (Ref. 46), including surrogate retaliation, threats, and warnings (Ref. 45).</p>	<p>46</p>	<p><b>The FDA completely misrepresented what was reported in Ref. 46. First, aggression was the primary treatment target. The authors describe her pretreatment behavior in the following way: “Back at the institution her behavior became increasingly more violent. She attacked someone almost every day. These attacks were unpredictable and intense, often requiring four to five people to subdue her while she was biting, kicking, and choking her victim.” (p. 31) Second, the authors specifically discounted the notion that her posttreatment aggression resulted in “hostility and retaliation”:</b></p> <p style="padding-left: 40px;"><b>This raises the question whether an <i>undisguised</i> punishment program invariably leads to hostility and retaliation on the part of the recipient.....In reference to our case it is difficult to know whether Carol’s infrequent attacks represent retaliation for the punishment. When viewed against the long history of this kind of behavior, this hypothesis is doubtful. Other unconfirming evidence comes from the long period of time (containing many positive reinforcements) between the infrequent aversive stimuli and the assaultive incidents. Indeed, we would argue that if the program were continued, even infrequent attacks would disappear. (p. 36)</b></p>
<p>II.A.1</p>		<p>45</p>	<p><b>The FDA has misrepresented what is described in Ref. 45. First, verbal and physical aggression were existing problems that required treatment. Consider the following description of the clinical situation:</b></p> <p style="padding-left: 40px;"><b>Housed on various locked wards over the years, she had succeeded in terrorizing patients and staff alike. She would bully and threaten patients into giving her cigarettes, money and other articles. In regard to staff, she would threaten to kill them or their families if they did not accede to her wishes or did not leave her alone. Often these threats would be translated into physical assaults. (p. 626)</b></p> <p><b>The authors describe the following specific treatment plan:</b></p>

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			<p><b>In was our plan to establish a hierarchy of responses associated with aggression and then proceed to modify each successive level in this hierarchy in a stepwise manner through the aversive therapy paradigm. (p. 626)</b></p> <p><b>Thus, the authors first treated physical aggression. Subsequently, low intensity aggressive responses labeled “Petit aggressions” (see p. 630), a variety of verbal threats (including surrogate retaliation) (see p. 631), and blaming statement (see. p. 632) were all treated with skin shock. Thus, these responses are not AEs. They are treatment targets that existed prior to the introduction of skin shock and were effectively treated with shock.</b></p>
II.A.1	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).	47	<p><b>The FDA has misrepresented the content of Ref. 47. Ref. 47 has absolutely nothing to do with self-restraint intensifying as a result of skin shock or punishment procedures. The study pertains to the reducing self-restraint through transfer of stimulus control and stimulus fading. In fact the authors say the following regarding etiology: “Unfortunately, these data provide little information related to the etiology of self-restraint.” (p. 388)</b></p>
II.A.1		29	<p><b>The FDA misrepresented the content of Ref. 29. None of the participants in the study experienced an emergence or exacerbation of self-restraint. Instead, the authors simply stated the following in the discussion section:</b></p> <p style="padding-left: 40px;"><b>To mention but a few problems that may be encountered during the often extended course of treatment are the individuals may adapt to the intensity of the electrical stimulus, that self-restraint may emerge or may intensify, that individuals may show SIB at very low intensities that eventually result in tissue damage.” (p. 241)</b></p> <p><b>In any case, self-restraint may be desirable in comparison with the self-injurious behavior.<sup>45</sup></b></p>

<sup>4</sup> Scheitheuer, M., O’Coonor, J., Toby, L.M. (2015). Assessment of self-restraint using a functional analysis of self-injury. *Journal of Applied Behavior Analysis*, 48(4), 907-911.

<sup>5</sup> Hagopian, L.P., Rooker, G.W., Zarccone, J.R. (2015). Delineating subtypes of self-injurious behavior maintained by automatic reinforcement. . *Journal of Applied Behavior Analysis*, 48(3), 523-543.

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<p>II.A.1</p>	<p>Others exhibited lesser self-injury and aggression, non-injurious pinching, emotional behaviors, and napkin-tearing. (See also Refs. 30 and 43.)</p>	<p>30</p>	<p><b>The FDA made false statements about the literature. The FDA Refs. do not include any reference to or discussion about “lesser self-injury” nor “non-injurious pinching.”</b></p> <p><b>The FDA is suggesting that lesser forms of a severe topography is somehow a negative phenomenon. If a patient is biting other people and breaking the skin, and as a result of skin shock treatment, now only places his mouth on others, the FDA views this as a negative. In Ref. 30, this phenomenon is not listed as an adverse event or a negative effect. The authors simply describe the treatment process in the following way:</b></p> <p style="padding-left: 40px;"><b>The topographies treated included not only the ultimate aggressive behaviors themselves, but also antecedent behaviors, attempts and threats to execute the behavior, shaped-down (vestigial) versions that were displayed during the deceleration of the behavior, as well as initial and intermediate members of the chain that included the ultimate aggressive action. (p. 123)</b></p>
<p>II.A.1</p>		<p>43</p>	<p><b>The FDA misrepresented the content of Ref. 43. Napkin tearing was not a side effect of contingent skin shock. Rather, it was a problem that existed prior to the study and occurred in sessions prior to the introduction of skin shock. Consider the following:</b></p> <p style="padding-left: 40px;"><b>Equally unpredictably, he also destroyed objects. Targets of destruction included furniture, decorations (pictures, clocks), toys, and such permanent fixtures as water fountains and electric sockets. It was reported that verbal attempts to stop him were completely ineffective: once he started toward an object, only physical force stopped him. (p. 202)</b></p> <p style="padding-left: 40px;"><b>Napkin tearing was selected as the criterion measure. This behavior was easily recorded, began for no apparent reason, and persisted for 27 sessions. (p. 207)</b></p>

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II.A.1	In some cases, crying increased (Ref. 48).	48	<p><b>The FDA misrepresented the findings of Ref. 48. First, crying decreased immediately following the introduction of skin shock:</b></p> <p style="padding-left: 40px;"><b>With the introduction of contingent shock for head-to-rail responses in phase 5, head-to-rail responses decreased steadily. Crying also decreased steadily during this phase..... (p. 621)</b></p> <p><b>Later, the authors note an increase in crying during the final treatment phase that included reinforcement and shock. However, examination of the charts suggest that reinforcement, rather than shock, was associated with crying (see Figure 3, p. 621). Note that during baseline and shock only conditions (phases 1, 3, and 5), crying either did not occur or occurred no longer than 7 seconds per minute (see phase 3, session 23). On the other hand, when reinforcement was involved (phases 2, 4, 6), crying occurred for longer durations.</b></p>
II.A.1	One study reported that, as measured by rating scales of dependency, affection-seeking increased repeatedly during treatment (Ref. 42).	42	<p><b>The FDA has completely misrepresented the context of this paper by suggesting that affection-seeking among these participants was somehow an AE or negative effect. Consider the following description of the patients in Ref. 42:</b></p> <p style="padding-left: 40px;"><b>The studies were carried out on two identical twins. They were five-years old when the study was initiated and were diagnosed as schizophrenics. They evidenced no social responsiveness; they did not respond in any manner to speech, nor did they speak; they did not recognize each other or recognize adults even after isolation from people; they were not toilet trained; their handling of physical objects (toys, etc.) was inappropriate and stereotyped, being restricted to “fiddling” and spinning. They were greatly involved in self-stimulatory behavior, spending 70 to 80 percent of their day rocking, fondling themselves and moving hands and arms in repetitive, stereotyped manners. They engaged in a fair amount of tantrum behavior such as screaming, throwing objects, and hitting themselves. (p. 100)</b></p>

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			<p><b>When shock was used contingently in treatment, the authors noted the following:</b></p> <p><b>Prior to shock pathological behaviors occurred 65-85 per cent of the time; physical contacts were absent. Shock I suppressed the pathological behaviors immediately, and they remained suppressed during the following eleven months. In addition, social behaviors replaced the pathological behaviors. (p. 102)</b></p> <p><b>During the control sessions [no shock] (sessions 1, 2, and 4) the proportion of time that Ss embraced, or hugged and kissed E was extremely low. Rather, they withdrew from him. During the shock-relevant sessions (sessions 3, 5, and 6) Ss' behavior changed markedly toward increased affection. In a situation where they had received shock avoidance training they responded with affection to E and did not withdraw from him. The fact that this affectionate behavior maintained itself in session 6 demonstrates that the remotely controlled shock can produce transfer of behavior change to a wide variety of situations. (p. 104)</b></p> <p><b>The rating scales that FDA referenced have nothing to do with treatment. The shocks were delivered non-contingently one minute prior to the observation (see p. 104, column 2)</b></p>
II.A.1	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).	49	<p><b>The following is a complete description of the authors' report:</b></p> <p><b>Despite the continuation of drugs, John's initial reaction to the shock-stick stimulation in Phase 1 was an increase in emotionality and in frequency of self-mutilative behaviors. However, by the fifth day of Phase 1 treatment, self-mutilative behaviors were reduced to zero, and emotionality had returned to pretreatment levels. (p. 113)</b></p> <p><b>Examination of the chart of p. 114 shows that self-mutilation increased in only the second, two-hour block after skin shock treatment was initiated.</b></p>

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			<p><b>The following is a complete description of the report of incontinence:</b></p> <p><b>Approximately 150 days after treatment termination [e.g. discontinuation of skin shock] systematic observations (two, two-hour blocks) were once again made. John was observed exhibiting “mild” self-mutilative behaviors on the average of .001 times per minute during the post treatment observation, which is significantly fewer (and less intense) than during the pretreatment observations.</b></p> <p><b>Moreover, attendant staff described John’s post treatment behavior as significantly less dangerous to himself, yet, he has become more actively involved in cottage activities, and John’s post treatment physical health has much improved. On the negative side, it was reported that John had become more incontinent during waking hours since termination of the treatment program. Whether or not this latter behavior could be considered “symptom substitution” is unclear at the present time. (p. 114)</b></p>
II.A.1	<p>Another observed increasing episodic “bursts” of self-injury, eventually reaching the point that extended treatment with the ESD became impossible to maintain (Ref. 50).</p>	50	<p><b>Ref. 50 describes a case of adaptation to the SIBIS devices. That is, after reducing self-injury for 4 years, the SIBIS device lost efficacy. The authors describe the result in the following way:</b></p> <p><b>In this case study, SIBIS produced significant reductions in self-injury across a 4-year follow-up period. It is estimated that this procedure prevented the occurrence of more than 23.4 million SIB responses, or that for every stimulation administered, 860 SIB responses were prevented. For nearly the first three years, self-injury was close to zero. However, after 31 months the effectiveness of SIBIS began to decrease, eventually to the point that, although still producing significant reductions in SIB, SIBIS was no longer sufficiently effective to be clinically useful. (p. 61)</b></p> <p><b>Thus, rather than shock causing bursts, the bursts occurred as the shock lost efficacy.</b></p>

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II.A.1	Some ESDs have been used for conditions other than SIB and AB, <i>e.g.</i> , 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.	n/a	<b>The FDA appears to have left out the word “not” prior to “informative” in the above passage. By this logic, then, patients that can verbally describe AEs should not be restricted from the treatment.</b>
II.A.1	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.	n/a	<b>See response to Section II.A.2 and A.3 Below</b>
II.A.1	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).	51	<p><b>The FDA has completely misrepresented what the author reported. The following is the complete account:</b></p> <p><b>Mrs. C.M., a 35-yr-old housewife, had suffered for 22 yr from recurring obsessive thoughts of a sexual and aggressive nature. Course of disease was steady despite two hospitalizations and over 5 yr of psychotherapy. A moderate improvement was maintained by continued aversion relief sessions-a total of 200 over a 3-yr period. <u>Two attempts to terminate this therapy led to an increase in anxiety and a breakdown in her functioning.</u></b></p>

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			<p><b>Over 100 different obsessive thoughts were elicited and 19 of the most severe and most frequent were selected for therapy. Among them were “eat my private”; “rape and kill the little bitch”; “I am a lesbian.”</b></p> <p><b>The first three sessions produced no change in her obsessive thoughts and, in fact, she seemed more anxious. Mean latency of phrase repetition steadily decreased.</b></p> <p><b>At session four, the instructions were changed to “saying the phrase twice in her mind” before raising her finger. This produced a sizable increase in the mean latency of phrase repetition in sessions four and five and the patient reported that all her obsessive thoughts, even those untreated, were no longer coming to her mind. At this point, however, she terminated therapy.</b></p> <p><b>Two weeks later she reported that many, though not all of her thoughts had come back. Promising to persist until advised to stop, she resumed treatment. During the next 18 sessions the patient was free of obsessive thoughts for increasingly longer periods of time. On session 23, she claimed that by the time she had repeated the phrase once, she had forgotten what it was and so could not recall it to say it again. At this point, she reported absence of obsessive thoughts, and it was decided to terminate therapy.</b></p> <p><b><u>At three months follow-up the patient was obviously psychotic and it was discovered that she had stopped taking the anti-depressants and tranquilizers which she had been taking since the beginning of her illness.</u> (p. 452-453, <u>emphasis</u> supplied)</b></p>
II.A.1	One case-control study on ESDs used to treat alcohol dependence in 12 subjects found that symptoms of experimental repression, such as headaches, restlessness,	52	<b>These are symptoms of alcohol withdrawal.</b>

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	<p>and mild dysphoria, were common and appeared usually within 3 or 4 days of the treatment (Ref. 52).</p>		
<p>II.A.1</p>	<p>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).</p>	<p>54</p>	<p><b>In this paper, the authors summarize comments in behavior modification textbooks. They do not review the applied literature. Consider the following:</b></p> <p><b>In general, these texts develop such statements about the negative side effects of aversive control by either referring to basic experimental research on punishment and avoidance with animals or by providing case study exemplars. In fact, with few exceptions (cf. Bellack &amp; Hersen, 1977; Kanfer &amp; Phillips, 1970; Kazdin, 1980), these texts do not refer to the clinical documentation of negative side effects, and only one (Kazdin, 1980) does so in a systematic fashion. (p. 284)</b></p> <p><b>Most of the research associated with negative side effects of aversive stimuli have to do with the non-contingent, unavoidable presentation of such stimuli. This is not consistent with how aversive stimuli are used in clinical practice.</b></p> <p><b>Regarding the assertion that depression is a possible side effect, the authors stated the following: “Postural freezing (Bolles, 1970), depression, and emotional withdrawal have all been postulated as potential side effects of punishment.” (p. 284) Note, that no documented case of punishment induced depression is cited.</b></p> <p><b>The following is the only reference to anxiety in the entire paper: “For example, a college student who worries about failing a test may begin to drink to reduce this anxiety.” (p. 285) Yet FDA specifically cites this paper as supporting the notion that punishment leads to anxiety.</b></p> <p><b>Finally, the purpose of this paper is to show that reinforcement or reward can evoke or elicit similar negative side effects that are often attributed to aversive stimuli.</b></p>

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II.A.1		55	<p>This paper summarizes various types of punishment procedures and outlines guidelines for utilizing punishment. The authors specifically describe circumstances where skin shock is the appropriate treatment (see page 32, column 1).</p>
II.A.1		56	<p><u>Most published accounts report few, if any, side effects from treatment and are, almost universally, enthusiastic in their accounts of the general improvement and relief from other symptoms, such as whining, misery and aggression, which frequently accompany self-injurious behavior.</u> These questions are considered in detail by Gardiner (1969) in his review. He points out that punishment is frequently not used in behavioural programmes due to the belief that aversive stimuli produce undesirable emotional states and that behavioural rigidity, generalized disruption of cognitive processes, production of neurotic symptoms, suppression effects not specific to the responses punished and chronic emotional maladjustment are but a few of the negative effects attributed to punishment (Holz and Azrin, 1966; Church, 1963; and Soloman, 1964).</p> <p><u>After reviewing the evidence concerning the severely retarded, Gardner cautiously concludes that emotional or behavioural disruption is not a necessary result of punishment.</u> One of the other dangers in using a punishment procedure is that the therapist involved in the treatment may acquire some of the properties of an aversive stimulus and evoke escape and avoidance behavior. Thus social disruption may occur in subjects who need positive social behavior strengthened. Punishment used in inadequately staffed institutions may produce negative reactions to authority figures and in such settings is often inappropriate in its frequency and intensity as well as the proximity to the punished behavior.</p> <p><u>Gardner again concludes that, applied appropriately in a satisfactory setting, punishment does not produce social disruption or negative side effects and, in the case of self-injurious behavior, which in its most severe form, precludes the patient from any positive activity, it may open up, for the first time, the possibility of implementing a positive programme of social interaction.</u> (p.91, emphasis supplied)</p>

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II.A.1		57	<p><b>The authors of this chapter note that the side effects associated with the clinical application of skin shock are positive in nature:</b></p> <p><b>Thus, we have strong evidence indicating that response-contingent shock is a powerful, effective technique for suppressing undesirable behaviors <u>and that the side effects of shock in these situations tend to be of a clinically desirable nature.</u> However, just to say that the procedure works and does not typically produce negative side effects is not necessarily a blanket approval for its use. One must consider other factors. For example, one must remember that shock is a powerful treatment procedure but that it must be used correctly in order to be effective. That is, the shock must be delivered immediately after the target response. It also must be delivered consistently so that the child clearly discriminates the occasion for the punishment. <u>Perhaps one should be more concerned about the direct effects of misapplication of such a powerful procedure, rather than worrying about fictitious negative side effects.</u> (p. 170, <u>emphasis supplied</u>)</b></p>
A1		58	<p><b>This chapter is composed by an anti-aversive advocates and has been described as misleading by experts that truly treat severe problem behaviors. Consider the following:</b></p> <p><b>This book contains misleading and often inaccurate portrayals of the clinical use of aversive procedures based on selective literature interpretation and unsupported data (Boyle, 1991). Furthermore, as noted earlier, nonaversive approaches are described as (a) offering a great deal of evidence of equal or greater empirical validity than aversive approaches and (b) being more likely to result in significant and lasting behavior changes that reflect worthwhile outcomes.</b></p> <p><b>Meyer and Evans (1989) characterized use of punishment or aversives as being associated with homogenous groupings of people, highly restrictive settings, very undesirable side effects, inadequate or inept functional analysis, ignoring human dignity and quality of life, poorly designed interventions, lack of individualization, rigidity of application, and</b></p>

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			<p>increased risk for chemical and physical restraint (which is actually truer of positive approaches, Foxx, 2003).<sup>6</sup></p> <p>Ref. 58 cited by FDA is a chapter with only three citations, none of which have anything to do with basic or applied use of punishment.</p>
II.A.1		59	<p>This review again notes that those citing negative side effects reference basic animal studies where aversive stimuli are delivered non-contingently in the absence of an escape or avoidance response. The following passage summarizes the review of side effects:</p> <p>The effects of punishment on responses that can occur concurrently with the punished behavior or in a different context as the punished behavior also have been studied in basic and applied research. Among these side effects, collateral increases in aggression, escape behavior, and emotional reactions are most commonly described in basic textbooks and literature reviews (e.g., Azrin &amp; Holz, 1966; Mazur, 1998) and by authors who recommend against using punishment in clinical settings (e.g., LaVigna &amp; Donnellan, 1986; McGee, Menolascino, Hobbs, &amp; Menousek, 1987; Parsons et al., 2001).</p> <p><u>Aggression (i.e., attacking nearby subjects, biting inanimate objects) in rats, pigeons, and monkeys has been associated with noncontingent delivery of unavoidable stimuli, including shock and intense heat</u> (e.g., Hutchinson, 1977; Ulrich &amp; Azrin, 1962). Although this phenomenon is often called <i>punishment-elicited aggression</i>, few studies have examined this side effect of punishment.</p> <p><u>Basic findings on the effects of inescapable, intense punishers probably have limited generality to the application of punishment (see Linscheid &amp; Meinhold, 1990, for further discussion).</u> Furthermore, elicited aggression in monkeys and rats has been observed to decrease when the subject could exhibit a response (e.g., lever press) to</p>

<sup>6</sup> Foxx, R. M. (2004a). [Severe aggressive and self-destructive behavior: The myth of the nonaversive treatment of severe behavior](#). In J. W. Jacobson, R.M. Foxx, & J. A. Mulick (Eds.), *Controversial therapies for developmental disabilities* (pp. 295-313). Lawrence Erlbaum Associates.

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			<p>escape from the situation in which the stimulus was delivered (e.g., Azrin, Hutchinson, &amp; Hake, 1966). <u>This finding suggests that elicited aggression may be less problematic during punishment than is commonly assumed because the contingency itself provides an escape response (i.e., delivery of the punisher can be avoided by refraining from the punished behavior).</u> In fact, results of several studies with rats showed that emotional responses in the form of crouching and defecation were more pronounced and persistent when subjects were exposed to unavoidable shock than to response-contingent stimulation (Hearst, 1965; Hunt &amp; Brady, 1955). (p. 453, <u>emphasis</u> supplied)</p>
II.A.1	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).	54	<p>The word “retaliation” appears only once in Ref. 54 in the context of a child throwing a toy in response to punishment delivered by a parent (see p. 286, column 2). There is not a single reference to an applied example of retaliation in Ref. 54. Regarding Refs. 57, 58, 59, 60, please see the comments above.</p>
	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	61	<p><u>NONE</u> of the 4 references make any comparison between an ICD and an ESD.</p> <p>Note that the fear may be due to the constant reminder that the person’s heart may stop: “The 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.” (p. 3)</p> <p>“An ICD patient is continually exposed to the threat of future defibrillation and must live with a visible and tactile reminder of this threat (eg, ICD pocket and scar).” (p. 3)</p> <p>“Clearly, improved understanding, research, and clinical strategies are needed to address PTSD in ICD patients. Future areas of investigation include better description of the experience</p>

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<p>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).</p> <p>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</p>	<p><b>of trauma in ICD patients, empirical validation of methods of prevention of trauma reactions, and investigation of the use of ICD-specific alterations of current empirically validated PTSD treatments. Current research in prevention of psychosocial distress in ICD patients supports the use of education, support, and cognitive-behavioral interventions. [51] However, PTSD symptoms have not been an outcome measure for any ICD intervention research, and there is currently debate in the PTSD literature regarding the efficacy of providing psychoeducation about trauma reactions before trauma as means of prevention. [61,62] Some believe psychoeducation promotes resiliency, hope, and normalization of trauma symptoms,61 whereas others believe it may promote disturbance by suggesting symptoms that would not manifest otherwise. [62] Currently, the evidence is mixed and requires greater study in ICD-related trauma and other trauma populations.” (p. 7)</b></p>
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<p>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</p>		
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	devices, FDA is not considering banning ICDs.		
		62	<b>“ICD shocks and the resultant psychobiological changes are known to contribute to increased levels of anxiety, depression, and post-shock stress symptoms in these patients. Phantom shock is a patient-reported perception of an ICD shock in the absence of any actual shock; however, its pathophysiological understanding is poor.” (p. 205)</b>
		63	<b>“Future research focusing on the timing and efficacy of intervention for patients with ICDs who receive multiple shocks would be helpful in delivering necessary and efficient interventions.” (p. 3)</b>
		64	<p><b>“Survival following life threatening cardiovascular disease conditions (those with a rapid and unexpected onset) is a cause of acute distress and may result in a constellation of symptoms that qualify for the diagnosis of posttraumatic stress disorder (PTSD).” (p. 1)</b></p> <p><b>“To our knowledge, this is the first study to evaluate the effect of negative affectivity on the long-term mortality risk in patients with ICDs and is among the first follow-up studies in cardiac patient populations to apply PTSD symptoms as a mortality risk predictor.” (p. 4)</b></p> <p><b>“The exact nature of PTSD provoked by medical conditions (eg, a life-threatening cardiac event) is unknown. Unlike many types of trauma, the threat to the patient’s life and well-being is not one of experience but is persistent and enduring. Based on the considerations of Mundy and Baum,<sup>1</sup> PTSD threat in medical patients comprises a future-oriented aspect (in contrast to traditional traumas) that represents fears and worries about treatment, survival, recurrence, stigma, the persistence of life threat, and new dangers yet to come. Therefore, patients experiencing PTSD symptoms may be particularly stressed by agonizing rumination and by an involuntary preoccupation with the underlying disease process. This assumption is further supported by the finding that among possible PTSD core features (as measured by the IES-R subscales) illness onset–related intrusive memories accounted solely for the mortality prediction.” (p. 5)</b></p>

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II.A.1	<p><i>b. Physical risks.</i> 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.</p> <p>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).</p>	29	<p><b>There is not a single reference of ESD resulting in skin damage, burns, bruises, reddened/discolored skin in Ref. 29.</b></p>
II.A.1		30	<p><b>Direct quote from the paper:</b></p> <p><b>Despite the fact that we administered up to 3,764 GED applications to the participants, the only negative side effect found was an occasional temporary discoloration of the surface of the skin that cleared up within a few minutes or a few days. (p. 158)</b></p>
II.A.1		39	<p><b>Direct quote from the paper:</b></p>

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			<p><b>The only other negative effects observed were occasional perspiration and slightly reddened areas where the SIBIS stimulation unit was applied for extended periods. (p. 496)</b></p> <p><b>The reddened areas occurred from wearing the device, not from the stimulation provided by the device.</b></p>
II.A.1		41	<p><b>In this report, an older Sabre Six skin shock device not designed (which did cause tiny pinpoint burns) for human use was replaced with a Therapeutic Shock Device designed for humans. The authors note the following: “The stimulus delivery system <u>did not cause burns</u> because electrodes were in continuous contact with the skin, disallowing the possibility of arcing.” (p. 260, <u>emphasis</u> supplied)</b></p>
II.A.1		50	<p><b>Direct quote from the paper:</b></p> <p><b>There were no negative side-effects with the exception of a single case during the 4-year period when, subsequent to reception of multiple stimulations in a brief period of time, SIBIS produced a mark on Michaels’ thigh <u>which resembled a bruise</u> in the shape of the electrode. There was no blistering or peeling of the skin and the mark disappeared in approximately 1 week. (p. 61, <u>emphasis</u> supplied)</b></p>
II.A.1		65	<p><b>The authors specifically noted the absence of negative side effects:</b></p> <p><b>Overall, there was little to suggest the development of adverse side-effects. In fact, some positive side-effects were noted. For example, rather than manifesting punishment-elicited aggression (Ulrich et al., 1972), these subjects appeared more affectionate and socially responsive. And like the subjects of Kircher, Pear and Martin (1971), after the first 20 min of adaptation to the shock procedure, subject 1 reacted much less to the shock than she previously had to being spanked. In the classroom at the school for the</b></p>

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			<p><b>blind, after receiving a shock she would often immediately and calmly resume the task that had been interrupted by self-injurious behavior. (p. 228)</b></p>																		
II.A.2	<p>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.</p>	n/a	<p><b>Since 1980, the literature describes hundreds of people receiving treatment for problems such as self-injury, aggression, and addiction. The following chart shows that</b></p> <p><b>We completed a review of the studies and the number of participants involved and found the following:</b></p> <table border="1"> <thead> <tr> <th><b>Decade</b></th> <th><b>Studies</b></th> <th><b>Participants</b></th> </tr> </thead> <tbody> <tr> <td><b>2000</b></td> <td><b>10</b></td> <td><b>111</b></td> </tr> <tr> <td><b>1990</b></td> <td><b>12</b></td> <td><b>1269</b></td> </tr> <tr> <td><b>1980</b></td> <td><b>8</b></td> <td><b>367</b></td> </tr> <tr> <td><b>1970</b></td> <td><b>36</b></td> <td><b>40</b></td> </tr> <tr> <td><b>1960</b></td> <td><b>12</b></td> <td><b>14</b></td> </tr> </tbody> </table> <p><b>The analysis suggest that since 1980 there are approximately 32 times more people described in the literature who received some variety of skin shock (1747) when compared to the period prior to 1980. There was not a single report of PTSD as a result of skin shock in any participant. The vast majority of the participants since 1980 are capable of describing adverse events as they were receiving skin shock to treat their addiction.</b></p>	<b>Decade</b>	<b>Studies</b>	<b>Participants</b>	<b>2000</b>	<b>10</b>	<b>111</b>	<b>1990</b>	<b>12</b>	<b>1269</b>	<b>1980</b>	<b>8</b>	<b>367</b>	<b>1970</b>	<b>36</b>	<b>40</b>	<b>1960</b>	<b>12</b>	<b>14</b>
<b>Decade</b>	<b>Studies</b>	<b>Participants</b>																			
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<b>1970</b>	<b>36</b>	<b>40</b>																			
<b>1960</b>	<b>12</b>	<b>14</b>																			
II.A.2	<p>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</p>	n/a	<p><b>Comprehensive reviews of the literature pertaining to punishment and skin shock have explicitly noted the low frequency of AEs in comparison to positive side effects. Consider the following excerpts from the literature:</b></p> <p><b>A. Van Oorsouw et al. (2007)</b> examined the side effects of contingent shock treatment in which the GED skin shock device was employed with nine students at the Judge Rotenberg Center. She found that “When treatment was compared to baseline measures,</p>																		

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	<p>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.</p>		<p>results showed that with all behavior categories, individuals either significantly improved, or did not show any change. Negative side effects were not found” (see abstract).</p> <p>The authors provide a useful summary of what researchers have reported regarding whether the side effects of skin shock are positive or negative. “Generally, it is reported that the positive side effects outnumber the negative side effects.” For example, Matson and Taras (1989) reviewed 56 applied studies and reported that 96% of the side effects were positive (i.e., increased social behavior, increased activity levels, increased eye contact). Ball, Sibbach, Jones, Steele, and Frazier (1975) reported that individuals who were treated with CS [contingent shock] treatment became more affectionate and socially responsive. Mudford, Boundy, and Murray (1995) found their participants to be calmer, happier, and less clingy to people during treatment, as compared to baseline. Ricketts et al. (1992, 1993) reported that participants more often smiled and emitted happy vocalizations during CS treatment than during baseline. Also distressed vocalizations (e.g., crying, whining) decreased during CS treatment. Linscheid, Pejeau, Cohen, and Footo-Lenz (1994) and Linscheid and Reichenbach (2002) found an increase of behaviors that may indicate a positive affective state (e.g., laughing, smiling, self-initiated toy play) during CS treatment, as compared to baseline. Negative side effects (e.g., increase of crying and whining) of CS failed to be mentioned in any study. Duker and Van den Muckhof (2007) demonstrated with five individuals who were treated with CS, that wearing a CS device lowered their heart rate, probably indicating lowered stress levels.”<sup>7</sup></p> <p><b>B. Toole et al. (2003)</b> note that the punisher that they used in this study (exclusionary time out for aggression) produced improvements in the subject’s affect. “These findings suggest that , in addition to decreasing problem behavior, the behavioral intervention produced collateral improvements in Holly’s overall affect... These data also suggest that implementation of a behavioral intervention for destructive behavior can increase positive affect even when the intervention includes a response reduction procedure. This</p>
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<sup>7</sup> Van Oorsouw, W. M. W. J., Israel, M. L., von Heyn, R. E., & Duker, P. C. (2007). Side effects of contingent shock treatment. *Research in Developmental Disabilities* (2007), doi:10.1016/j.ridd.2007.08.005.

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			<p>important finding has implications related to the issue of social acceptability of behavioral interventions.”<sup>8</sup></p> <p><b>C. Linscheid and Reichenbach (2002)</b> found no negative side effects and recorded data on several positive side effects including happiness (counted smiles and laughs) and self-initiated communication.</p> <p>They also note that there is no need to expect shock-elicited aggression that was found in some experimental studies because the conditions in the use of contingent shock are entirely different from those in which shock-elicited aggression was noted in animals (“close proximity of the target animal in a confined small area and noncontingent administration of the shock...”)<sup>9</sup></p> <p><b>D. Rush et al. (2001)</b> demonstrated that punishment targeting problem behavior associated with positive affect selectively decreased the problem behavior while minimally affecting affect. In this paper the authors wrote as follows:</p> <p>“Concerns about the negative ‘side effects’ of punishment procedures in clinical settings have been expressed by some (e.g. the Association for Persons with Severe Handicaps, 1987), despite the lack of empirical support. In fact the majority of side effects reported in clinical studies are positive. In a comprehensive review of the applied literature on punishment, Matson and Taras (1989) noted that 93% of the studies that reported collateral effects described positive effects, including increases in social behavior, appropriate play, and compliance. Increases in positive affect have also been reported when using contingent electric shock as punishment for severe self-injury (Linscheid <i>et al.</i>, 1994).”</p> <p>“These findings provide additional evidence that the use of punishment – as part of a reinforcement based intervention – may not produce negative collateral effects on affect.</p>
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<sup>8</sup> Toole, L. M., Bowman, L.G., Tomason, J. L., Hagoian, L.P., & Rush, K. S. (2003). Observed increases in positive affect during behavioral treatment. *Behavioral Interventions*, 18, 35-42.

<sup>9</sup> Linscheid, T.R. & Reichenbach, H. (2002). Multiple factors in the long-term effectiveness of contingent electric shock treatment for self-injurious behavior: a case example. *Research in Developmental Disabilities*, 23, 161-177.

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			<p>In addition, these data suggest that when an undesirable response (i.e. screaming or SIB) co-occurs with a desirable response (positive affect), the undesirable response can be selectively targeted with minimal effects on the desirable response.”<sup>10</sup></p> <p><b>E. Mudford et al. (1995).</b> “Richard appeared to prefer wearing TSD, approaching any person who carried the equipment into his ward, and assisting in attaching it to himself. He never attempted to remove the device. Removal of the device provoked tantrum behaviors. He was judged by staff to be happier, calmer, and less clingy to people when wearing the TSD (cf. Linscheid, Pejeau, Cohen, &amp; Footo-Lenz, 1994; Ricketts et al., 1993).”<sup>11</sup></p> <p><b>F. Linscheid et al. (1994).</b> The introduction to this paper contains the following summary of previous reports on this topic.</p> <p>“Despite anecdotal reports to the contrary, the belief persists that punishment procedures in general, and electric shock in particular, produce numerous side effects (cf., Smith, 1990). Some have even suggested that the emotional side effects of punishment may decrease its effectiveness. For example, Meyer and Evans (1989) write:</p> <p style="padding-left: 40px;">Punishment that is very distressing to the person and/or painful –such as isolation or slapping or shock the person – may produce other emotional responses like anxiety, stress, crying, attempts to escape or strike back. A person who is in pain or feeling a great deal of anxiety may not be able to pay attention to the message of punishment and punishment sometimes creates side effects that might be even more serious than the original behavior. (p. 101)</p> <p>However, research does not support these conclusions.”</p> <p>“Reports of treatment with contingent electric shock often include anecdotal descriptions of side effects and, despite the widely held assumptions, generally suggest more positive than negative side effects by a wide margin (Carr &amp; Lovaas, 1983; Lichstein &amp; Schreibman, 1976). Linscheid et al. (1990) documented almost immediate decreases in</p>
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<sup>10</sup> Rush, K. S., Crockett, J. L. & Hagopian, L. P. (2001). An analysis of the selective effect of NCR with punishment targeting problem behavior associated with positive affect. *Behavior Interventions*, 16, 127-135.

<sup>11</sup> Mudford, O. C., Boundy, K., & Murray, A. D. (1995). Therapeutic Shock Device (TSD): Clinical Evaluation with Self-Injurious Behaviors. *Research in Developmental Disabilities*, 16(4), 253-267.

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			<p>distressed vocalizations and increases in positive affect in an individual who was treated with contingent electric shock using the Self-Injurious Inhibiting System (SIBIS). In addition, positive side effects were noted for all five individuals treated in that study. Barrera, Teodoro, and Labadine (1989) also documented positive side effects, most notably, increases in self-initiated interactions in an individual treated with SIBIS. Anderson (1992) reported increases in positive affect in the form of smiling, hand clapping, and vocalizations as early as the second day of treatment in a 10-year-old girl successfully treated with SIBIS. Ricketts, Goza, and Matese (1992) reported increased indicators of positive affective state (smiling, happy vocalizations) and less distressed vocalization in an individual during treatment with contingent skin shock compared to periods when shock was not used. Most recently, Williams, Kirkpatrick-Sanchez, and Iwata (1993) documented positive side effects in an individual treated with the “Hot Shot” device, which uses a shock intensity much higher than that employed by SIBIS. Of significance is the fact that these positive side effects begin almost with the onset of treatment.</p> <p>“Although there are exceptions (e.g., Romanczyk &amp; Goren, 1975), it appears that widely held suppositions regarding the preponderance of negative side effects of contingent electric shock treatment may be inaccurate because there appears to be more scientifically sound evidence that the opposite is true. This report documents numerous positive side effects observed early in the successful treatment of SIB using contingent electric shock administered via SIBIS.”<sup>12</sup></p> <p><b>G. Williams et al. (1994)</b> noted the following negative side effects: perspiration and temporary reddening of the skin where SIBIS was applied.<sup>13</sup></p> <p><b>H. Matson &amp; Farrar-Schneider (1993).</b> In their review of the literature on aversives, they concluded, “Side effects are positive and negative behaviors are modified during treatment although they were not targeted. These, too, should be evaluated when measuring outcomes (Coe &amp; Matson, 1990). As Matson and Taras (1989) point out, aversive methods are often assumed to generate negative side effects. However, a review</p>
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<sup>12</sup> Linscheid, T. R., Pejeau, C., Cohen, S., & Footo-Lenz, M. (1994). Positive side effects in the treatment of SIB using the Self-Injurious Behavior Inhibiting System (SIBIS): Implications for operant and biochemical explanations of SIB. *Research in Developmental Disabilities, 15*(1), 81-90.

<sup>13</sup> Williams, D.E., Kirkpatrick-Sanchez, S. & Crocker, T. (1994). A long-term follow-up of the treatment for severe self-injury. *Research in Developmental Disabilities, 15*, 487-501.

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			<p>of the literature does not support this contention (Matson &amp; Taras, 1989). Rather, a large number of positive side effects have been reported for positive, aversive, and combination treatments, with only a few negative side effects reported.”<sup>14</sup></p> <p><b>I. Axelrod (1990):</b> “In using extinction, the problem of extinction burst can make the procedure too dangerous to employ. In applying overcorrection procedures, many researchers (e.g. Azrin &amp; Wesolowski, 1975; Lambert, Bruwier, &amp; Cobben, 1975) have found the client’s reaction to be so severe that the procedures had to be discontinued or greatly modified. <i>On the other hand, there is little evidence of harmful side effects of electric shock</i> (Carr &amp; Lovaas, 1983, p. 235).” [emphasis supplied]</p> <p>Similarly, when one examines physical danger to the offender and implementer, as well as time away from the program, procedures such as exclusion time-out and overcorrection should come out worse than electric shock and water mist.”<sup>15</sup></p> <p><b>J. Linscheid et al. (1990)</b> said that their findings “are consistent with previous reviews of the literature indicating that positive side effects generally outnumber negative side effects.”<sup>16</sup></p> <p><b>K. Linscheid &amp; Meinhold (1990).</b> They review the literature that is often cited by those who oppose the use of punishment. They summarize their points in the following way: “...the phenomena of elicited aggression has been studied primarily in lower animals in situations in which alternative responding has been prevented by physical means and aversive electrical stimulations have been programmed noncontingently. In these situations, attack responses are determined by variables, including physical proximity of the animals, species of the animals, opportunities for escape or avoidance, intensity of the stimulation, and general size of the experimental chamber..... Given this summary, application of findings from elicited aggression studies on animals to programmed contingent punishment treatment procedures with humans is questionable. Generally, in behavior modification programs utilizing aversive stimuli as contingent punishment, individuals are not confined to small areas in which they are forced into close physical</p>
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<sup>14</sup> Matson, J. L. & Farrar-Schneider, D. (1993). Common behavioral decelerators (aversives) and their efficacy. *Child and Adolescent Mental Health Care*, 3, 49-64.

<sup>15</sup> Axelrod, S. (1990). Myths that (mis)guide our profession. In A.C. Repp & N.N. Singh (Eds.), *Perspectives on the use of nonaversive and aversive interventions for persons with developmental disabilities* (pp. 59-72). Sycamore, IL: Sycamore.

<sup>16</sup> Linscheid, T., Iwata, B., Ricketts, R., Williams, D. & Griffen, J. (1990). Clinical Evaluation of the Self-Injurious Behavior Inhibiting System (SIBIS). *Journal of Applied Behavior Analysis*, 23, 53-78.

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			<p>proximity with other individual, and human subjects nearly always have available to them responses which serve to escape or avoid contingent presentation of the aversive stimulation. In some cases, the avoidance response is simply the absence of the target behavior (e.g. head banging). Given that some correspondence exists between animal studies and human applications, elicited aggression does not appear to be a necessary by-product of contingent aversive stimulation.”<sup>17</sup></p> <p><b>L. Matson and Taras (1989).</b> This was a review of 382 studies covering a 20 year period (1967-1987). “A frequent criticism of punishment/aversive methods is that many negative side effects result. This position has been a frequent justification to discontinue these treatment methods. An assumption of this type may be based on the early animal literature (Azrin &amp; Holtz, 1966). However, the data obtained in our review of 382 applied studies does not support this contention. Table 5 provides example behaviors which were anecdotally reported in most studies where a side effect was noted. It could be contended that authors may have emphasized the more positive aspects of their studies. However, the studies reviewed were by and large evaluated prior to publication by independent peer reviewers and most of the studies were published before the current controversy over aversives developed. An interesting and striking development was the number of positive side effects (<math>n = 212</math>) to negative side effects (<math>n = 16</math>) reported regardless of treatment. This rate is 93% positive side effects for all side effects reported. Time-out and restraint (<math>n=5</math>), DRO (<math>n=12</math>) and increased activities (<math>n=4</math>) resulted in 100% positive side effects. However, contingent electric shock (<math>n=56</math>), physical restraint (<math>n=24</math>), and combine punishment procedures such as time-out plus restraint, and time-out plus contingent slaps (<math>n=25</math>) resulted in a 96% rate of positive side effects...Also, the severity of the side effects were relatively mild compared to the target behaviors treated in that they did not lead to injury to self or other, the typical target behaviors for which the interventions were used...</p> <p>“These data clearly show that more intrusive procedures result in roughly equivalent rates of positive to negative side effects when compared to positive procedures. Data of this sort should be viewed cautiously. However, previous assumptions have been totally</p>
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<sup>17</sup> Linscheid, T.R., & Meinhold, P. (1990). The controversy over aversives: Basic operant research and the side effects of punishment. In A.C. Repp & N.N. Singh (Eds.), *Perspectives on the use of nonaversive and aversive interventions for persons with developmental disabilities* (pp. 435-450). Sycamore, IL: Sycamore.

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			<p>speculative. Until other data based information is available it would seem reasonable to accept the information presented here.”<sup>18</sup></p> <p><b>M. Foxx et al. (1986)</b> noted a number of positive side effects such as improved social interactions, increased participation in outings and activities, graduation from special education program, transition to vocational setting, and consideration for a community based placement.<sup>19</sup></p> <p><b>N. Newsom, Favell, &amp; Rincover (1983)</b> note that punishment has resulted in increased toy play, reduced self-stimulation, improved eye contact, better attention to task, and attention to peers. They further note that facilitation of social interactions and cooperation is the most frequent side effect of punishment.<sup>20</sup></p> <p><b>O. Lichstein and Schreibman (1976) noted the following:</b> “The reported side effects of shock with autistic children do not appear sufficient to rule out the use of this method of treatment. Although there is evidence to support the various contentions concerning temporary suppression, negative emotional effects, and increase in other undesirable behaviors, such evidence is minimal and does not characterize this treatment modality. The majority of unintended effects reported were of a positive nature. These included response generalization, increase in social behavior, and positive emotional behavior.”</p> <p>“No evidence was found to support the fear that enduring or severe emotional damage occurred. On the contrary, as has been reported earlier in this paper, several authors report positive changes in the children including happiness, social behavior, affection, and calmness. This is consistent with Lovibond’s (1970) conclusion in reviewing aversive techniques in therapy that ‘the danger of producing emotional disturbance, even with severe aversive stimulation is quite remote’ (p. 83) This is in direct contrast to the predictions of those speculating that severe emotional damage would result from the use of shock.”<sup>21</sup></p>
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<sup>18</sup> Matson, J.L. & Taras, M. E. (1989). A 20 year review of punishment and alternative methods to treat problem behaviors in developmentally delayed persons. *Research in Developmental Disabilities, 10*, 85-104.

<sup>19</sup> Foxx, R.M., McMorrow, M.J., Bittle, R.G., & Bechtel, D.R. (1986). The successful treatment of a dually-diagnosed deaf man’s aggression with a program that included contingent electric shock. *Behavior Therapy, 17*, 170-186.

<sup>20</sup> Newsom, C. , Favell, J., & Rincover, A. (1983). The side effects of punishment. In S. Axelrod & J.Apsche (Eds.), *The effects of punishment on human behavior* (285-316). New York: Academic Press

<sup>21</sup> Lichstein, K. L. & Schreibman, L. (1976). Employing electric shock with autistic children: A review of side effects. *Journal of Autism and Childhood Schizophrenia, 6*, 163-173.

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II.A.2	<p>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).</p> <p>In such a case, an AE could go unrecognized because the provider does not understand the individual's response, if any.</p> <p>Worse, some individuals' impaired ability to communicate, express themselves, or associate cause and effect, coupled with</p>	66	<p><b>A substantial number of the people who received skin shock in the literature had verbal abilities and could report adverse events. Second, people with limited verbal repertoires have difficulty expressing adverse events associated with every treatment they receive.</b></p>
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	<p>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.</p>		
II.A.2	<p>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>i.e.</i>, 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</p>	n/a	<p><b>Again, acute stress disorder and posttraumatic stress disorder have never been reported as AEs in the scientific literature concerning contingent skin shock.</b></p> <p><b>The FDA asserts that the psychiatric pathophysiology of conditions such as PTSD changed significantly. However, the pathophysiology of PTSD remains elusive. Consider the following:</b></p> <p><b>In sharp distinction from other medical disorders such as cancer, coronary artery disease and diabetes, which have objective biological tests for diagnosis, severity of illness and response to treatment, biological markers cannot yet independently confirm the assessment of PTSD. Current procedures for diagnosing PTSD rely on self-report screening measures and clinical interviews. Treatment has been limited to symptom management rather than targeting the biological aetiology. To date, drug development in PTSD has been opportunistic, building almost solely on empirical observations with</b></p>

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	not report pain or discomfort as AEs since they were considered the ESDs' intended result and indicators of effectiveness. (See, <i>e.g.</i> , 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.		<b>drugs approved for other conditions. As of today, not a single pharmacological treatment has been developed specifically for PTSD.<sup>22</sup></b>
II.A.2	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).	67	<b>The FDA misrepresented the content of Ref. 67. The authors state the following: “Despite all these precautions, there is little published evidence that the side effects of shock are harmful. In fact, the ratio of positive to negative side effects is about 5 to 1 in favor of the positive side effects (Lichstein &amp; Schreibman, 1976).” (p. 235)</b>  <b>The FDA suggests that there is some AE reporting bias specific to skin shock. AE reporting bias is a widespread phenomenon in the medical literature as well as the FDA’s own regulator system.<sup>23,24</sup></b>
II.A.2	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	n/a	<b>This quote is from a chapter published in 1983. The finding of overwhelmingly positive side effects has been replicated and noted in numerous subsequent papers and reviews.</b>

<sup>22</sup> Bailey, C.R., Cordell, E., Sobin, S.M., & Neumeister, A. (2013). Recent progress in understanding the pathophysiology of post-traumatic stress disorder: implications for targeted pharmacological treatment. *CNS Drugs*, 27(3), 221-232.

<sup>23</sup> McGauran, N., Wieseler, B., Kreis, J., Schler, Y., Kolsch, H., & Kaiser, T. (2010) Reporting bias in medical research – narrative review. *BioMed Central*, DOI: 10.1186/1745-6215-11-37

<sup>24</sup> Mann, J.M. (2015). FDA adverse event reporting system: recruiting doctors to make surveillance a little less passive. *Food and Drug Law Journal*, 70(3), 371-394.

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	<p>that some investigators have been predisposed to see only the positive side effects.”</p>		
<p>II.A.2</p>	<p>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.</p> <p>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</p>	<p>n/a</p>	<p><b>This is a straw man fallacy. The purpose of the patient histories was to describe individual patients that have greatly benefited from contingent skin shock.</b></p>

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	<p>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.</p>		
<p>II.A.3</p>	<p>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.”</p>	<p>n/a</p>	<p><b>Neither depression nor peripheral nerve injury have ever been reported at JRC or the contingent skin shock literature.</b></p>

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II.A.3	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.	n/a	<b>None of these effects have been attributed to GED or documented in any JRC client or the literature.</b>
II.A.3	Under the heading “Conclusion”, Dr. Smith recommend additional research and regulation and noted the following:	n/a	<b>However, research does show that aversive conditioning devices can be effective for severe SIB and aggression in some people with IDD and that alternative interventions are sometimes ineffective and unsafe. Accordingly, I believe it is more prudent to restrict the use of aversive conditioning devices than to ban them. Restrictions could include requirements for (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.</b>
II.A.3	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	n/a	<p><b>The GED and GED-4 have been evaluated by national medical and engineering experts in electrical safety. These experts have actually examined the GED and GED-4 devices, received applications, and examined all technical parameters associated with the GED.</b></p> <p><b>Dr. Eason has never been to JRC, examined the GED, and was retained by an extremely biased group (The Disability Law Center).</b></p> <p><b>He appears to have missed a basic reality of the GED which is that it utilizes DC, not AC current. The mA necessary to evoke the various reactions he describes are much higher when DC current is used.<sup>25</sup></b></p>

<sup>25</sup> Department of Defense Handbook: General Guidelines for Electronic Equipment. Retrieved from <http://www.dsccl.dla.mil/downloads/milspec/docs/mil-hdbk-454/hdbk454.pdf>

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	<p>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.</p>		<p><b>The output of the GED and GED-4 fall within the FDA's own recognized standards for nerve and muscle stimulators<sup>26</sup></b></p>
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<sup>26</sup>[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard\\_identification\\_no=31290](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=31290);  
<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073783.pdf>

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<p>II.A.4</p>	<p>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</p>	<p>70</p>	<p><b>This is misleading for several reasons. Note that the investigation found that the GED was applied by staff that failed to follow procedure and safeguards, and received the instructions from a former student posing to be calling as a DVR monitoring staff.</b></p> <p><b>The Investigation determined:</b></p> <p><b>“The Staff failed to follow JRC policy and training regarding medical treatment and failed to communicate relevant information to nursing regarding residents [redacted] and [redacted] condition. This resulted in delay of medical attention for both residents. . . . The staffs (sic) failed to follow JRC policies and procedures as it relates to behavior management. The staffs (sic) used poor judgment and failed to follow resident [redacted] and [redacted] Treatment plan and Daily Recording Sheets. . . . The staff failed to monitor the resident in a manner that assured the [ ] health and safety. The staff failed to provide a safe environment for the residents in care. The staff violated the programs [sic] communication policy and neglected their responsibilities as a mandated reporter. Staffs [redacted] and [redacted] were neglectful in their responsibilities as monitoring staff thus compromising the supervision and the safety of the residents.” (p. 48)</b></p> <p><b>“The licensee reported that both residents [redacted] and [redacted] were evaluated by the JRC nursing staff, JRC’s physician, as well as their treating clinician, Dr. [redacted]. The students were reported to be found to be in good health.” (p. 49)</b></p> <p><b>“Following the reported incident, The [sic] JRC Administrative staff was contacted and an internal investigation was initiated.” (p.49)</b></p> <p><b>“The staff did not verify that the caller was actually a DVR monitoring Staff.” (p. 52)</b></p> <p><b>“The licensee reported that the actual DVR monitor assigned to observe the Stoughton residence was not doing his job by viewing the cameras at the residence therefore DVR monitoring system failed to detect and intervene in the events in a timely manner. The monitoring staff [redacted]</b></p>
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	clear who) believed a stage two ulcer was in the area where skin was missing (Ref. 70).		<b>was consequently terminated from the JRC program. It was reported that staff [redacted] had also been terminated an others were pending.” (p. 58).</b>
II.A.4	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).	71	<b>JRC composed a complete response to the biased and untruthful report issued by NYSED.<sup>27</sup></b>  <b>Note that the school nurse monitors for the potential of skin problems. (p. 8)</b>
II.A.4	NYSED also submitted a comment to the 2014 Panel Meeting docket stating that it has received reports of collateral effects	72	<b>References “one of many peer-reviewed research articles on the effect of stress and trauma and brain functioning” <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3181836/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3181836/</a></b>

<sup>27</sup> JRC Responses to Allegations in NYSED June 9, 2006 Report

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	<p>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 (<i>e.g.</i>, 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).</p>		<p><b>The article referenced by NYSED has nothing to do with the clinical use of contingent skin shock. The article describes a few basic research experiments concerning the classical conditioning and brain imaging.</b></p> <p><b>“Conditioned fear responses are extinguished following repeated exposure to the conditioned stimulus in the absence of the unconditioned (aversive, eg, electric shock) stimulus. This inhibition appears to be mediated by medial prefrontal cortical inhibition of amygdala responsiveness.”</b></p> <p><b>Besides this link, the 3 page letter is devoid of references to support any of its claims.</b></p>
II.A.5	<p>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,</p>	73	<p><b>These quotes do not appear in Ref. 21. In Ref. 73, JRC’s Submission to Docket FDA-2014-N-0298, June 23, 2014: “As presented during the April 24 panel meeting, JRC acknowledged that in rare cases, mild erythema of the skin may result. This erythema is essentially a temporary</b></p>

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	<p>“less than 1% of applications result in &lt;1 mm lesion,” and “it is possible that repeat exposure to the GED skin-shock could result in blistering” (Refs. 21 and 73).</p>		<p><b>redness on the surface of the skin. However, this erythema disappears within an hour to a few days. It also should be noted that less than 1% of applications result in &lt;1mm lesion.” (p. 19)</b></p> <p><b>The possibility of blistering is completely mischaracterized: “As discussed during the panel meeting, certain patients experience mild erythema at the site of the electrode which resolves within 1-2 days. <u>The erythema has not presented with inflammation, pain, or blistering</u> and accordingly does not meet the definition of a burn. <sup>2/</sup> As discussed with FDA in 1994 during the original 510(k) clearance of the device, JRC recognizes that it is possible that repeat exposure to the GED skin-shock could result in blistering, however, such effects have not been observed when the device is used in accordance with its instructions for use. Procedural safeguards to protect against misuse are in placed at JRC including frequent movement of the placement of the GED electrodes and extensive training of the staff. Further, the newly developed GED-3B and GED-4B include activation limits to limit the number of stimulations that can be applied. “As discussed with FDA in 1994 during the original 510(k) clearance of the device, JRC recognizes that it is possible that repeat exposure to the GED skin-shock could result in blistering, <u>however, such effects have not been observed when the device is used in accordance with its instructions for use.” (pp. 7-8)</u></b></p>
<p>II.A.5</p>	<p>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).</p> <p>Malfunctions are fully addressed in the submission:</p>	<p>73</p>	<p><b>As addressed in more detail above, JRC is aware of, and has acknowledged to FDA, that in very rare circumstances, the GED may errantly deliver an unintended skin-shock to a patient. These misapplications have occurred when a trained JRC staff representative intends to deliver a skin-shock to one student and the GED for another student is activated. Other times, a unit may spontaneously activate.</b></p> <p><b>Although JRC acknowledges that these rare misapplications meet FDA’s definition of a product malfunction, they are in no way reportable malfunctions. These events due indeed constitute malfunctions as the GED is not intended to spontaneously activate or deliver a spontaneous skin-shock. Nonetheless, not all product malfunctions are required to be reported to FDA. Rather, only those malfunctions that are likely to cause or contribute to a death or serious injury</b></p>

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			<p>upon recurrence are required to be reported as MDRs. In this regard, JRC does not consider these types of events to be reportable. <u>Specifically, a misapplication has never led to a patient injury and therefore certainly not death or serious injury</u>, as that term is defined by FDA. Moreover, for the reasons set forth in the serious injury analysis above, there is no reasonable likelihood of resultant death or serious injury from a misapplication of the GED (addressing the “upon recurrence” prong). Based on more than 20 years of patient data, and consistent with the reports in the medical literature regarding the risks of ESDs generally, the <u>chance of a patient death or serious injury occurring as a result of a recurrence of a misapplication malfunction is remote, if not less than remote.</u></p>
II.A.5	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).	21	<p><b>JRC does not make any claim that contingent skin shock does not cause pain. The referenced table simply describes where the GED-3 and GED-4A fall in terms of a pre-existing table.</b></p>
II.A.5	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	73	<p><b>“While JRC designed the device intending that it does not deliver severe pain, the GED device is intended to deliver an aversive stimulus. By its definition and for the treatment to be effective, the GED skin-shock must be unpleasant in order to have a deterrent effect. That being said, while the stimulation may be considered painful by some patients, the skin-shocks do not cause impairment to any body functions or damage to any bodily structures of the patient whereas, before treatment with the GED devices, the patient are causing themselves severe and ongoing pain, injury and disfigurement from their self-mutilation and aggression.” (p. 14)</b></p>

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	directly whether the stimulus causes pain at the Panel Meeting, Dr. Nathan Blenkush, JRC's Director of Research, answered “yes.”		
II.A.5	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).	21	<b>This is a mischaracterization. The full sentence is as follows: “JRC has not found any side effects associated with aversive conditioning except the occasional discoloration of the skin that disappears within an hour to a few days and some brief, temporary anxiety just prior to the delivery of the application.” (p. 18)</b>
II.A.5		73	<b>The report continues, “There are, however, many reports of positive side-effects from the GED devices such as the elimination of pain and injury from self-abuse and dramatically improved affect due to the patient’s ability to engage in education, independently spend time with family and friends and integrate into the community. These positive side effects have been readily apparent in all patients at JRC both communicative and noncommunicative.” (p. 14)</b>
II.A.5	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).	74	<b>He further stated, “Any side effects observed were minor and far outweighed by the effectiveness of the treatment.” (p. 3)</b>
II.A.5	JRC concludes, “the medical literature cited by FDA [in the FDA Executive	21	<b>This quote does not appear in Reference 21.</b>

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	<p>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).</p>		<p><b>However, note that “The prior treatment records and judicial findings concerning these patients prove conclusively that the massive dosages of medication, restraint and other intrusive interventions used with them prior to their treatment with the GED device, failed to stop them from causing severe pain and physical damage to themselves, and, in many cases, caused them to suffer painful and permanent side-effects such as the devastating side effects of anti-psychotic medication identified above. The prior treatment records also demonstrate that drugs and restraint will not stop these patients from engaging in their dangerous behaviors so they will still cause severe pain and harm to themselves in addition to receiving these ineffective and intrusive alternative treatments. (p. 20)</b></p>
<p>II.A.5</p>	<p>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</p>	<p>71</p>	<p><b>This statement is made without any source or reference, and therefore should be discounted. (p. 13)</b></p>

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	<p>“[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).</p>		
II.A.5	<p>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.</p>	n/a	<p><b>In fact, the Investigation found that there were sufficient rules in place, they were not followed by staff.</b></p> <p><b>The Investigation determined:</b></p> <p><b>“The Staff failed to follow JRC policy and training regarding medical treatment and failed to communicate relevant information to nursing regarding residents [redacted] and [redacted] condition. This resulted in delay of medical attention for both residents. . . . The staffs (sic) failed to follow JRC policies and procedures as it relates to behavior management. The staffs (sic) used poor judgment and failed to follow resident [redacted] and [redacted] Treatment plan and Daily Recording Sheets. . . . The staff failed to monitor the resident in a manner that assured the [ ] health and safety. The staff failed to provide a safe environment for the residents in care. The staff violated the programs [sic] communication policy and neglected their responsibilities as a mandated reporter. Staffs [redacted] and [redacted] were neglectful in their responsibilities as monitoring staff thus compromising the supervision and the safety of the residents.” (p. 48)</b></p>
II.A.6	<p>Some of the relatives of individuals at JRC who spoke at the Panel Meeting only spoke about the positive effects of the</p>	n/a	<p><b>Confidential Material</b></p>

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	<p>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, <i>e.g.</i>, 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.</p>		
II.A.7	<p>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).</p>	76	<p><b>This is a news article with a quote from the resident’s mother. This statement was not made by a doctor or medical professional. (p. 2).</b></p>
II.A.7	<p>Another comment from a psychologist, who has worked with patients exhibiting SIB and AB, reports witnessing patients waking up screaming from nightmares,</p>	77	<p><b>This is a letter from S. McClennen, PhD. She carefully words her comments in a way that does not affirmatively state that she has treated these patients first-hand. (p.1)</b></p>

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	<p>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).</p>		
	<p>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 (<i>e.g.</i>, Ref. 36).</p> <p>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.</p> <p>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).</p>	<p>29</p>	<p><b>This is a study of eight (8) individuals, none of whom adapted to the skin shock procedure.</b></p> <p><b>“A treatment using electrical aversive stimuli for severe, life-threatening SIB was effective in reducing the degree of mechanical restraints imposed by caregivers over three years. The change in degree of mechanical restraint imposed on an individual with mental retardation and severe SIB is, therefore, used as a measure of the effectiveness of treatment. It is assumed that an individual who has no restraints imposed on him or her exhibits, on average, less SIB than an individual mechanically restrained.” (p. 6).</b></p> <p><b>“To mention but a few problems that may be encountered during the often extended course of treatment are that individuals <u>may adapt</u> to the intensity of the electrical stimulus, that self-restraint may emerge or may intensify, that individuals may show SIB at very low intensities that eventually results in tissue damage, etc. (p. 7)</b></p>

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	<p>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.</p>		
<p>II.B.1</p>		<p>36</p>	<p><b>The FDA incorrectly stated that Ref. 36 showed that participants adapt to skin shock. None of the children adapted to the use of contingent skin shock.</b></p> <p><b>Ref. 36: “These children have demonstrated, through their self-destruction, that they will apparently withstand considerable pain to get attention, and that they may have considerable experience with pain adaptation. To avoid selecting a neutral shock, or a weak one to which the children could adapt quickly, we have used a strong shock which guaranteed quick suppression. By a strong shock is meant a shock which the experimenters experienced as definitely painful (smarterd like a whip, or a dentist drilling on an unanesthetized tooth), and to which the subjects gave every sign of fear and apprehension. The question is sometimes raised as to how, in view of the much more severe pain associated with self-destruction (e.g., pulling own nails out with teeth), the shock works in the first place. We can offer two guesses in this regard: the child has not had an opportunity to adapt to shock, nor has the shock been associated with positive reinforcement, both of which may have occurred with the painful stimuli generated by the self-destruction.” (p. 156-157)</b></p>

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			<p>“We reported five studies, carried out on three children, in which we <u>observed an immediate suppression of self-destructive behavior when aversive stimuli were given contingent upon that behavior.</u> This finding is <u>consistent with data from previous work with aversive stimuli</u> (Lovaas, Schaeffer, and Simmons, 1965) which reported the suppression of tantrums and self-destruction in two 5-yr old autistic boys. Risley (1968), Tate and Baroff (1967), and others (as reviewed by Bucher and Lovaas, 1967) have reported similar findings.” (p. 155)</p> <p>The effects of shock appear to be specific to the situation in which shock is used, with respect to both physical locales and attending adults. This <u>implies</u> that if punishment to suppress self-destruction is to be maximally therapeutic (i.e., durable and general) it has to be administered by more than one person, in more than one setting. Our <u>data amply suggest</u> that each child would revert to self destruction as soon as he returned to the treatment settings from which he came, unless his treatment under those conditions was made consistent with our procedures. The children, in other words, formed discriminations.” (p. 155)</p>
II.B.1		50	<p>Reference 50 shows a 4-year period of durability. The FDA describes this study as demonstrating “no durability.”</p> <p>Ref 50: “In this case study, SIBIS produced significant reductions in self-injury across a 4-year follow-up period. It is estimated that this procedure prevented the occurrence of more than 23.4 million SIB responses, or that for every stimulation administered, 860 SIB responses were prevented. For nearly the first three years, self-injury was close to zero. However, after 31 months the effectiveness of SIBIS began to decrease, eventually to the point that, although still producing significant reductions in SIB, SIBIS was no longer sufficiently effective to be clinically useful. The reasons for this eventual reduction in effectiveness were unclear, though possibly related to the mild level of electric stimulation delivered by SIBIS. A second factor may also be that SIBIS contingencies were unable to be in effect during all waking hours (whenever one-on-one supervision was unavailable), which resulted in frequent non-SIBIS periods which permitted high rates of SIB to be emitted.” (p. 61)</p>

		<p><b>“There were no negative side-effects with the exception of a single case during the 4-year period when, subsequent to reception of multiple stimulations in a brief period of time, SIBIS produced a mark on Michaels' thigh which resembled a bruise in the shape of the electrode. There was no blistering or peeling of the skin and the mark disappeared in approximately 1 week.” (p. 61)</b></p> <p><b>“Although there has been much controversy surrounding the use of aversive procedures in general and SIBIS in particular, SIBIS employs a very mild electrical stimulus. In this particular case, except for the cessation of SIB, there was no outward evidence that Michael even perceived the stimulations, much less found them distressful. This anecdotal observation certainly does not hold true for all, but it should not be surprising that individuals who can inflict severe injuries upon themselves with no apparent feeling of pain may also not experience other normally aversive stimuli as aversive. With Michael, SIBIS may have been successful because the electric stimulation was a novel stimulus and could be administered with great precision as a response interruption procedure. These observations draw into question the notion that presumably non-aversive procedures should be attempted prior to presumably aversive therapies, because we cannot automatically assume that what functions as either a positive or negative stimulus to one person will function similarly in all other persons (Smith, 1990), or that negative side effects result only from "aversive" procedures (Cowdery, Iwata, &amp; Pace, 1990).</b></p> <p><b>Future research should focus on isolating the conditions under which treatments proven to have short term effectiveness, remain durable. With regard to the use of electrical stimulation, future investigations might also attempt to isolate the parameters of shock or other stimuli (e.g., vibration) which reduce maladaptive behavior. That is, it may be found that the production of physical discomfort is not always a necessary component of aversive strategies, but rather that the key factors may be very precise administration of very novel stimuli. “ (p. 62)</b></p>
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		92	<p><b>Six months of durability were demonstrated. The authors note the effectiveness dwindled because the skin shock was not used consistently:</b></p> <p><b>“The optimum long-term result of a program involving contingent shock would be substantial reduction in target behaviors maintained during all waking hours in the natural environment with shock no longer required (Foxx, Bittle, &amp; Faw, 1989). While treatment effects for Suzanne were maintained at low levels during all waking hours for approximately 6 months, maintenance did not endure beyond this period. A number of factors may have contributed to this outcome. First, according to Suzanne's mother, the application of contingent shock was delivered on an intermittent schedule during some home visits (which occurred every 3 weeks for durations of 3 days) because she left Suzanne unattended a number of times. These visits resulted in tissue damage on several occasions. Thus, it is clear that shock was not delivered consistently and that Suzanne was allowed to escape the contingencies, thereby limiting the procedure's effectiveness (Azrin &amp; Holz, 1966). This raises questions about the efficacy of involving parents as primary mediators during extended home visits in the early stages of treatment with contingent shock.” (p. 216)</b></p>
II.B.1	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	59	<p><b>The statement about the need to remain in effect is mischaracterized. The full quote states, “These results suggest that sufficiently intense punishers, including some commonly used clinical procedures (e.g., time-out), may produce lasting reductions in problem behavior as long as the punishment contingency remains in effect.” (p. 448)</b></p> <p><b>The article also states, “basic findings suggest that relatively intense punishers may be associated with successful long-term outcomes.” (p. 450)</b></p>

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	<p>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).</p>		
II.B.1	<p>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).</p>	80	<p><b>In the Summary and Conclusions, the authors questioned the findings of the studies based on the potential lack of follow-up: “The effects of these programs are often immediate and dramatic, but the gains are not usually maintained. Most of the limitations of punishment programs seem to arise after only partial suppression has been obtained. This may result from either the children involved being unusually difficult to control or the punishment program not being long enough and/or intense enough to achieve complete suppression. It is important to obtain complete suppression because it prevents the subject from "testing reality" (Sidman, 1960). After partial suppression the subject quickly finds that the punishment program is not</b></p>

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			being enforced after the first nonpunished response. But after complete suppression, this testing never takes place.” (p. 519)
II.B.1	Another review discussed earlier in this section reported that one author expressed dissatisfaction with the lack of long-term durability (Ref. 57),	57	<p><b>Overall, the author finds many positive benefits to aversive techniques, and calls negative side effects “fictitious.” (p.170)</b></p> <p><b>Prior to this statement, the author states, “One major point is that in <i>all</i> (emphasis theirs) of these studies, electric shock proved to be a highly effective therapeutic agent with autistic children. In all cases the target undesirable behavior was reduced or eliminated using the shock procedure.” (p. 165)</b></p> <p><b>The authors conclude that contingent skin shock should be a treatment option: “To conclude, contingent electric shock has proven to be an effective treatment procedure for autistic children. Also, the reported side effects have proven to be of a generally positive nature. Treatment for autistic children, regardless of modality, is usually slow and difficult. We cannot afford to abandon any therapeutic approach with this population without a careful analysis of the costs and benefits. The decision to use electric shock as a therapeutic agent should be evaluated according to objective criteria including the child's needs, the feasibility of using the procedure in the child's environment, and available alternatives.” (p. 172)</b></p>
II.B.1	and another review similarly noted that the effect appeared to be short-term only, <i>i.e.</i> , symptoms are only “momentarily suppressed” (Ref. 55).	55	<p><b>The full quote states, “It is well-known that physical punishment is ineffective unless it coincides with or immediately follows the response to be eliminated, and unless the punishment is delivered consistently (Azrin &amp; Holz, 1966; Bandura &amp; Walters, 1963). Kushner (1967) has indicated that unless shock intensity is high, the punished behavior is not eliminated, but only momentarily suppressed.” (p. 30)</b></p>

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<p>II.B.1</p>	<p>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.</p>	<p>93</p>	<p><b>Ref. 93: Future research that investigates factors contributing to treatment efficacy, or inefficacy, with punishment procedures is vital for improving our understanding of punishment processes and reducing the frequency of treatment failures.” (p. 482)</b></p> <p><b>Ref. 93: “Overall, the publication of studies examining the utility of punishment procedures as a treatment for the challenging behavior of individuals with developmental disabilities peaked in the early 1980s. Following this period, a gradual decline in the number of studies utilizing punishment was seen in the literature. The current review demonstrated that since 1990, punishment procedures have been used in less than ten published articles each year.” (p. 481)</b></p> <p><b>Ref. 93: But many practitioners are calling for more research: “Continued research into the effects and outcomes of punishment-based procedures remains important. Vollmer (2002) appealed convincingly against the dismissal of punishment’s utility, suggesting that “to ignore punishment as an application is akin to ignoring the benefits and limitations of medical technology” (p. 469). He, and others (e.g., Sidman, 1989), have highlighted the pervasiveness of punishment, planned and unplanned, non-social and socially mediated, in everyday life. Other arguments in favor of the continued research of punishment have also been put forward (e.g., Lerman &amp; Vorndran, 2002; Newsom &amp; Kroeger, 2005). Many studies have shown that, for some individuals at least, reinforcement-based strategies alone are insufficient to reduce challenging behavior to acceptably low levels without the addition of a punishment component (e.g., Fabiano et al., 2004; Grace, Kahng, &amp; Fisher, 1994; Hagopian, Fisher, Sullivan, Acquistio, &amp; LeBlanc, 1998; U.S. National Institutes of Health, 1989). In some instances functionally equivalent alternative behaviors may be unidentifiable or inaccessible to the individual (Newsom &amp; Kroeger, 2005). Punishment procedures may also be more appropriate than reinforcement-based interventions in situations where the rapid reduction, or total elimination, of a behavior is imperative. Reducing the risk of serious physical harm to the individual engaging in the behavior, or to others in their environment, may be a more rapidly observed outcome with punishment procedures than with reinforcement-based procedures (Lerman &amp; Vorndran, 2002; Matson &amp; Kazdin, 1981). Further, there are a number of situations in which reinforcement-</b></p>
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			<p>based procedures have been identified to be either ineffective or unsuitable. For example, behaviors that are identified as automatically reinforced, or for which a source of reinforcement cannot be identified, are typically quite difficult to treat or reduce using reinforcement-based procedures alone (LeBlanc, Patel, &amp; Carr, 2000; Vollmer, 1994). In such cases it may not be possible to alter the existing reinforcement contingencies, either through the withholding of the maintaining source of reinforcement, or through the provision of the reinforcers contingent on an alternative desirable behavior (Vollmer, 2002).” (p. 472)</p>
<p>II.B.2</p>	<p>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</p>	<p>96</p>	<p><b>The FDA failed to understand and/or correctly report on the research design. The authors measured behaviors that WERE NOT specifically treated with skin shock. That is, they measured positive verbal and nonverbal utterances, negative verbal and nonverbal utterances, socially appropriate behaviors, and off task behaviors while the participant’s aggressive and self-injurious behaviors were treated with skin shock. (see pages 515-516) Notably, the study found that, “When treatment was compared to baseline measures, results showed that with all behavior categories, individuals either significantly improved, or did not show any change. Negative side effects failed to be found in this study.” (p. 513)</b></p> <p><b>The FDA failed to understand and/or correctly report on the behaviors treated with skin shock. NO PARTICIPANT RECEIVED SKIN SHOCK FOR INVOLUNTARY MOVEMENTS or REFUSING ACADEMIC TASKS as the FDA asserts. The following describes the behaviors treated: “While the above procedures continued, SIB and aggressive behavior were immediately followed by a single administration of an electrical skin shock.” (p. 516)</b></p> <p><b>The FDA incorrectly stated that “soft” neurological signs were measured. This is a false statement. The topographies (none of which are involuntary/stereotypical or treated with skin shock) that were measured are listed page 516 include the following: appropriate smiling, dancing, singing or talking, crying, making whining noises, spitting, stamping feet, smearing feces, screaming, swearing, making obscene gestures, shrugging shoulders, uttering racial comments, making negative facial expressions, imitating others, raising one’s hand in the classroom, greeting others, politely asking the teacher for help, following directions, and appropriately responding of the teachers’ and staff members’s instructions, placing one’s head</b></p>

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	<p>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, <i>e.g.</i>, 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.</p>		<p><b>down on the table, rejecting academic tasks, and turning one’s head away when a staff member offers beverages or edibles.</b></p>
<p>II.B.3</p>	<p>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</p>	<p>8</p>	<p><b>Dr. Smith writes that “these devices should be restricted but not banned.” (p. 1)</b></p> <p><b>He also calls for further studies: “Given the clear shortcomings of existing treatments and the urgency of helping people with IDD who display severe SIB or aggression, additional research on aversive conditioning devices and alternative interventions is warranted. This research might focus on people with IDD who have not responded favorably to a course of inpatient treatment on a neurobehavioral unit or who are currently receiving restraints or seclusion. Because of the vulnerability of this population and the substantial risks associated with both aversive conditioning and the use of restraints or seclusion, studies would need to adhere to high ethical standards and include meticulous data and safety monitoring plans.” (p. 6)</b></p>

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	<p>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.</p>		
<p>II.B.4</p>	<p>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</p>	<p>72</p>	<p><b>As noted above, the 3 page letter is devoid of references to support any of its claims. The letter does not state how many individuals have been transitioned off the GED. (p. 2)</b></p>

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	<p>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).</p>		
<p>II.B.5</p>	<p>[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</p>	<p>n/a</p>	<p><b>The website does not claim GEDs are 100% effective; rather, it cites to four (4) papers, one of which states 100% effectiveness as part of an article synopsis. Effectiveness is defined as a 90% reduction in the behaviors targeted.</b></p>

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	<p>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.</p> <p>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.</p>		
II.C.1.a	<p><i>Multi-element positive interventions.</i> 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</p>	103	<p><b>Note that in Ref. 103, the article states, “It is practically impossible to provide support or instruction that does not include at least some mildly aversive events. Withholding attention, redirecting from preferred (albeit self-injurious) behavior, making a request to perform a new behavior, and delivering instructional prompts all may be aversive to some degree. If the technical definition of "aversive" is applied, there are few teachers or clinicians who could argue that they implement a totally nonaversive approach.” (p. 4)</b></p>

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	aversive interventions such as contingent skin shock (Refs. 103 and 104).		
II.C.1.a	<p>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).</p>	97	<p><b>Refs. 97, 99, nor 106 support the notion that SIB and AB can be effectively treated with positive behavior support procedures and/or pharmacotherapy.</b></p> <p><b>Regarding Ref. 97: See attached addendum that shows the papers cited by LaVigna and Willis (2012) either a) do not describe the treatment of people with severe behavior problems and/or b) the procedures used were not effective in treating the behavior problem.</b></p> <p><b>Ref. 97 also includes the statement, “While punishment would not be included in a PBS plan, if unavoidable, a restrictive reactive strategy, such as physical management, might be included as a last resort if needed to minimise episodic severity. However, as a last resort, such restrictive and perhaps aversive strategies would only be employed if other nonaversive reactive strategies, such as stimulus change or counterintuitive strategies such as redirecting the person to a preferred activity, did not work to get rapid, safe control over the behavioural episode (LaVigna &amp; Willis, 2002).” (p. 3).</b></p> <p><b>Regarding Ref. 99, this review of PBS procedures indicates that is only successful in 52% of the cases in the published literature. (see p. 45). In addition, In fact, Ref. 99 states that, “[t]he two most substantive and frequently employed alternatives to PBS are the use of pharma-cotherapy (medication) and aversive procedures.” (p.19)</b></p> <p><b>Regarding Ref. 106, this paper has nothing do with efficacy.</b></p>
II.C.1.a		99	

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<p>II.C.1.a</p>	<p>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 (<i>e.g.</i>, loud noise, crowded room) in which the behaviors are more likely to occur (<i>e.g.</i>, Ref. 106 discussing “environmental redesign”).</p>	<p>109</p>	<p><b>According to Ref. 109, FCT with punishment can be characterized as probably efficacious as 7 studies met criteria, however, it bears mentioning that these studies included many participants, and FCT with punishment was effective in 100% of cases. FCT alone conversely had little support (3 studies), thus its use without extinction cannot be supported at this time.</b></p>
<p>II.C.1.a</p>		<p>106</p>	<p><b>Ref 106 provides: “Thus, it has been argued that PBS research must move toward a model that emphasizes (a) the use of interventions across all relevant settings...” (p. 691)</b></p>
<p>II.C.1.a</p>	<p>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).</p>	<p>59</p>	<p><b>Ref. 59 specifically acknowledges a role for punishment in the context of function based treatment: “Nevertheless, punishment may be critical to treatment success when the variables maintaining problem behavior cannot be identified or controlled (for further discussion, see Axelrod, 1990; Iwata, Vollmer, &amp; Zarcone, 1990; Vollmer &amp; Iwata, 1993). Punishment also may be preferable to reinforcement-based treatments when problem behavior must be suppressed rapidly to prevent serious physical harm (Dura, 1991; see also Iwata et al.; Vollmer &amp; Iwata). More important, results of several studies indicate that treatments derived from functional analyses (<i>e.g.</i>, differential reinforcement of alternative behavior [DRA]) may not always reduce behavior to clinically acceptable levels without a punishment component (<i>e.g.</i>, Grace, Kahng, &amp; Fisher, 1994; Hagopian, Fisher, Sullivan, Acquisto, &amp; LeBlanc, 1998; Wacker et al., 1990).” p.432</b></p>

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			<b>Ref. 99 indicates that PBS procedures are only successful in 52% of the cases in the published literature. (see p. 45).</b>
II.C.1.a	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).	109	<p><b>According to Ref. 109, FCT with punishment can be characterized as probably efficacious as 7 studies met criteria, however, it bears mentioning that these studies included many participants, and FCT with punishment was effective in 100% of cases. FCT alone conversely had little support (3 studies), thus its use without extinction cannot be supported at this time.</b></p> <p><b>In addition, Ref. 109 does not mention “Positive Behavior Support” and describes procedures used in applied behavior analysis not PBS.</b></p>
II.C.1.a	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	97	<p><b>Ref. 97 includes the statement, “While punishment would not be included in a PBS plan, if unavoidable, a restrictive reactive strategy, such as physical management, might be included as a last resort if needed to minimise episodic severity. However, as a last resort, such restrictive and perhaps aversive strategies would only be employed if other nonaversive reactive strategies, such as stimulus change or counterintuitive strategies such as redirecting the person to a preferred activity, did not work to get rapid, safe control over the behavioural episode (LaVigna &amp; Willis, 2002).” (p. 3).</b></p> <p><b>Ref. 97 further states, “That is not to say that an aversive procedure could not be used as a last resort reactive strategy to minimise episodic severity (e.g., Berkman &amp; Meyer, 1988), but that it wasn’t used as a behaviour reduction, punitive consequence.” (p. 3)</b></p> <p><b>Regarding Ref. 97: See attached addendum that shows the papers cited by LaVigna and Willis (2012) either a) do not describe the treatment of people with severe behavior problems and/or b) the procedures used were not effective in treating the behavior problem.</b></p>

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	the individual or provide behavioral reinforcement.		
		99	<p><b>Regarding Ref. 99, this review of PBS procedures indicates that is only successful in 52% of the cases in the published literature. (see p. 45).</b></p> <p><b>In fact, Ref. 99 states that, “[t]he two most substantive and frequently employed alternatives to PBS are the use of pharma-cotherapy (medication) and aversive procedures.” (p.19)</b></p> <p><b>“As has been pointed out elsewhere (Carr et al., 1994), intervention agents frequently feel the need for crisis management procedures even when committed to a PBS approach. The perceived need for these procedures cannot easily be dismissed. The important message from our database, however, is that when additional non-PBS procedures seemed necessary, they were relatively benign, and relatively rare.” (p. 81-82)</b></p>
II.C.1.a	<p>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).</p> <p>DBT consists of four components: A skills training group, individual treatment, DBT</p>	110	<p><b>Ref. 110 concludes, “Although these pilot study data do not provide conclusive evidence for the effectiveness of DBT-SS with this population, these preliminary findings merit further studies with more rigorous methodologies.” (p. 298).</b></p>

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	<p>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).</p> <p>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).</p>		
		111	<p><b>This paper specifically supports the use of punishment as a component of inpatient DBT: “If applied thoughtfully and consistently, the use of contingency management in the inpatient setting can be powerfully effective in moving patients toward their targets and in maintaining the necessary limits of the unit. Contingency management is the therapeutic manipulation of behavioral consequences to increase certain behaviors and to decrease others. The most relevant</b></p>

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			contingency management principles include positive reinforcement, negative reinforcement, random intermittent reinforcement, extinction, punishment, and shaping. The staff has endless opportunities every day to reinforce small skillful steps in targeted directions with positive reinforcement, to extinguish dysfunctional behaviors by withholding reinforcement and soothing the patient, and to punish disturbing dysfunctional behaviors if absolutely necessary. Immediate reinforcement is preferred over delayed reinforcement, natural contingencies are preferred over artificial ones, and extinction is preferred over punishment. Because of the necessity of providing a controlled, safe environment for a large number of highly distressed individuals, punishment (not punitiveness) plays a larger role in inpatient treatment than it ordinarily does in outpatient treatment.” (p.313-314)
C1a		105	Ref. 105, which was published in 2013, and appears to be a single-group pilot study, is completely mischaracterized—as it states “research <u>has not yet confirmed that existing treatments adequately reduce CBs in this population</u> , dialectical behavior therapy (DBT) holds promise, as it has been shown to effectively reduce CBs in other emotionally dysregulated populations.” (p. 1) “These findings suggest that modified DBT <u>holds promise</u> for effectively treating individuals with intellectual and developmental disabilities.”
II.C.1.b	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	112	Ref. 112 states, “Some organizations have taken positions against the use of intrusive or aversive procedures . . . whereas others have maintained that there are certain conditions under which the use of aversive strategies may be appropriate (e.g., Mudford, 1995). The Right to Effective Treatment (Van Houten et al., 1988) states that “in some cases, a client’s right to effective treatment may dictate the immediate use of quicker-acting, but temporarily more restrictive procedures” (p. 383). Those who ascribe to this point of view argue that when rapid reduction in a severe behavior problem is needed, it is ethical to use restrictive procedures (Hastings & Noone, 2005).” (p. 213)  “Kahng, Iwata, and Lewin (2002) found that although the use of reinforcement-based interventions for selfinjury has increased during the past decade, the use of punishment-based interventions has decreased only slightly. In general, it would be assumed that the use of aversive strategies (i.e., those that cause pain or discomfort to an individual) would have low

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<p>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).</p> <p>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</p>	<p><b>treatment acceptability in the PBS community—as evidenced, for example, by the lack of published research employing aversive strategies in the Journal of Positive Behavior Interventions. Michaels et al. (2005), however, report that there were differences in perceptions of treatment acceptability <u>among professionals identified as PBS experts when asked about the appropriateness of aversive, consequence-based strategies for individuals with severe problem behaviors (i.e., individuals who engage in extremely dangerous behaviors likely to cause physical harm to self or others). They found that experts in PBS do not consistently agree on what types of interventions are considered acceptable.</u>” (p. 212)</b></p> <p><b>“Treatment acceptability research has focused largely on those variables that contribute to an individual’s determination that a particular treatment is acceptable or unacceptable. Smith and Linscheid (1994) suggested that treatment acceptability is inversely related to a treatment’s perceived aversiveness and restrictiveness, but acceptability increases when those decelerative or restrictive procedures are proposed for more severe or frequent behavior problems (see Michaels et al., 2005, for a more comprehensive review of treatment acceptability).” (p. 212)</b></p>
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	<p>allowing a crisis intervention procedure to turn into a continuous management technique (Ref. 103).</p> <p>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.</p>		
<p>II.C.1.b</p>		<p>36</p>	<p><b>Ref. 36 describes largely positive side effects and almost complete suppression of the problem behaviors treated with skin shock. The authors note “One of the surprising findings on the use of shock pertains to the immediate increase in socially directed behavior, such as eye-to-eye contact and physical contact, as well as the simultaneous decrease in a large variety of inappropriate behaviors, such as whining, fussing, and facial grimacing.” (p. 156)</b></p>
		<p>103</p>	<p><b>“It is practically impossible to provide support or instruction that does not include at least some mildly aversive events. Withholding attention, redirecting from preferred (albeit self-injurious) behavior, making a request to perform a new behavior, and delivering instructional prompts all may be aversive to some degree. If the technical definition of "aversive" is applied, there are few teachers or clinicians who could argue that they implement a totally nonaversive approach.” (p. 4)</b></p>

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II.C.1.b		59	<p><b>Ref. 59 notes that authors “.....have recommended using moderate or high-intensity punishers to treat problem behavior and cautioned against increasing the intensity of punishment gradually over time (e.g. Cooper et al., 1987; Martin &amp; Pear, 1996; O’Brien, 1989). These guidelines may be difficult to reconcile with ethical mandates to identify the least restrictive procedure that is effective.” (p. 441)</b></p> <p><b>This does not mean that moderate or high-intensity punishers should not be used. Rather, it suggests careful consideration of the individual clinical problem.</b></p>
II.C.1.b	<p>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).</p>	113	<p><b>Ref 113 does not support the statement made by the FDA.</b></p> <p><b>Ref. 113 states: “Seven treatment types were statistically significantly better in reducing problem behavior than PECS only interventions: aversive and positive combinations, positive combinations, DRO only, antecedent control only, DRA only, noncontingent reinforcement only, and social stories only interventions.” (p. 2471)</b></p> <p><b>“Aversive and positive combinations as well as positive combination interventions were statistically significantly better in reducing problem behavior than antecedent control only interventions.” (p. 9)</b></p> <p><b>This is a review paper and thus, no direct comparison between individual treatments are made.</b></p>
II.C.1.b	<p>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,</p>	97	<p><b>Regarding Ref. 97: See attached addendum that shows the papers cited by LaVigna and Willis (2012) either a) do not describe the treatment of people with severe behavior problems and/or b) the procedures used were not effective in treating the behavior problem.</b></p>

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	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).		
		101	<b>Ref. 101 did not address severe behavior problems. The dependent variable selected does not actually collect frequency data. Rather, a 3 simply indicates the behavior were occurring weekly and a 2 indicates the behaviors were occurring monthly. Therefore, one cannot determine precisely how the frequency changed. Regardless, the problem behaviors were not eliminated. In addition the “Episodic severity” started at a low intensity at baseline and changed very little.</b>
II.C.1.b		95	<b>The authors of Ref. 95 acknowledge that prior treatment with aversives may have contributed to the long-term success of each student: “It is possible, of course, that the prior invasive treatment contributed to the long-term outcomes presented in this report.” (p. 17)</b>  <b>JRC has follow-up information one of the individuals mentioned. Unfortunately, the report indicated that he burned down his group home and was in a psychiatric hospital.</b>
		114	<b>These patients do not appear to have treatment refractory behavior problems. In fact, it appears that the interventions provided were the first behavioral procedures provided.</b>
		115	<b>“Perhaps the first conclusion worth emphasizing is that the <u>range of opinion among respondents was very large</u>, suggesting that <u>any statements in both the popular media and professional publications claiming that “professionals” think punishment to be ineffective or unethical (or, for that matter, effective or ethical) are not credible</u>. A second general point involves punishment research, or the lack of it—for an issue that generates such heated controversy, we have very little empirical research to guide us, compared to the evidence base for reinforcement. Given recent findings that interventions containing aversive components may be more effective than interventions without punishment in certain circumstances and that individuals have</b>

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			<p>demonstrated preference for these interventions over non-aversive options (Hanley, Piazza, Fisher, &amp; Maglieri, 2005), empirical investigations are warranted. In the past several years, several commentators have called for more research on punishment (e.g., Lerman &amp; Vorndran, 2002) and aversive control (e.g., Critchfield, 2006; Perone, 2003), and based on the findings of the present survey, we would echo that call.” (p. 65)</p>
	<p>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).</p>	<p>111</p>	<p><b>Ref. 111 cites two randomized controlled trials, each reviewed below:</b></p> <ol style="list-style-type: none"> <li><b>1. Linehan (1991) Cognitive behavioral treatment for parasuicidal borderline patients.</b> <ol style="list-style-type: none"> <li><b>a. This is the original article regarding the use of DBT to treat BPD.</b></li> <li><b>b. The inclusion criteria was broad for self-injury: “.....had at least two incidents of parasuicide in the last 5 years, with one during the last 8 weeks” (p. 1061)</b></li> <li><b>c. Patients were excluded if they had bipolar disorder, substance dependence, schizophrenia, or mental retardation (p. 1061)</b></li> <li><b>d. The dropout rates were high. 10 subjects dropped out during the assessment; 7 subjects refused to meet the conditions of the study; 2 subject dropped out of the DBT treatment. Thus 30% of the participants dropped out of the study.</b></li> <li><b>e. All of the participants lived in the community.</b></li> <li><b>f. Over the entire year, the mean rate of parasuicidal behavior per year in the DBT group was 6.82 compared to the 33.54 in the treatment as usual (TAU) group. However, these behaviors were not severe. For those in the TAU group, the average subject required medical treatment 1.76 times per year. In the DBT group, the average subject required medical treatment .64 times per year. (see page 1062, first column, “This difference can be accounted for by more medically treated parasuicide episodes among control subjects (control subjects: mean = 1.76, SD = 2.66; subjects assigned to DBT; mean = 0.64, SD = 1.15....”</b></li> </ol> </li> <li><b>2. Linehan (1993)</b> <ol style="list-style-type: none"> <li><b>a. This is a follow-up to the 1991 study and continues assessment for another year.</b></li> <li><b>b. Again, the rates of parasuicidal (self-injury) behavior remain low. In the DBT group, the average subject had .10 episodes over 6 months (months 13-18) compared to 2.10 in the treatment as usual group. (see the table on page 973). In the final six month period (months 19-24) the DBT group had .72 parasuicidal behaviors compared to 1.06 in the TAU group.</b></li> </ol> </li> </ol>

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			<ul style="list-style-type: none"> <li>c. The behaviors were not severe. In the DBT group, the average subject had .05 episodes that required medical treatment over 6 months (months 13-18) compared to .75 in the treatment as usual group. (see the table on page 973). In the final six month period (months 19-24) the DBT group had .11 episodes that required medical treatment compared to .56 in the TAU group.</li> <li>d. Essentially, after two years of treatment largely outpatient treatment, it did not matter if a subject received DBT or TAU. Self-injury decreased to low levels in both groups and the self-injury that was exhibited was not very intense.</li> <li>e. DBT subjects received therapy at no charge while TAU subject were required to pay for therapy and were only able to seek treatment at settings accepting low-fee clients.<sup>28</sup></li> </ul>
		116	<p><b>Ref. 116 is not a randomized controlled trial. The authors reference the following randomized controlled trial (analysis provided):</b>  <b>Linehan (2006)</b></p> <ul style="list-style-type: none"> <li>a. All participants were people receiving outpatient voluntary treatment. Participants “were excluded if they had (1) a lifetime diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, psychotic disorder not otherwise specified, or mental retardation; (2) a seizure disorder requiring medication; (3) a mandate to treatment; or (4) the need for primary treatment for another debilitating condition.” (p. 758)</li> <li>b. Rate of self-injury was extremely low. “The median number of nonsuicidal acts for the 2 years was 3.0 (interquartile range, 1.0-7.8) for the DBT group and 3.0 (interquartile range, 0.0-8.0) for the CTBE group.” (p. 762) This means the average participant had 1.5 nonsuicidal self-injurious behaviors per year.</li> <li>c. DBT was no better than CBT in reducing self-injury. See Figure 4. (p. 763)</li> <li>d. None of the patients committed suicide during the study. 23% of the DBT group had suicide attempts compared to 46% of the CTBE group).</li> </ul>

<sup>28</sup> See Schell, p. 71, 2<sup>nd</sup> column.

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		117	<b>Ref. 117 is not a randomized controlled trial. The authors cite the same papers described in Ref. 111.</b>
II.C.1.b	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).	97	<p><b>Ref 97 references people with traumatic brain injuries and provides no additional citations: “There are some people for whom an approach that doesn’t rely on consequences may actually have an inherent advantage. For example, some people with traumatic brain injury (TBI) may have such impaired short-term memory and poor impulse control that any consequential strategy may be limited in what it can accomplish on its own.” (p. 6)</b></p> <p><b>Regarding Ref. 97: See attached addendum that shows the papers cited by LaVigna and Willis (2012) either a) do not describe the treatment of people with severe behavior problems and/or b) the procedures used were not effective in treating the behavior problem.</b></p>

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II.C.1.b	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).	99	<b>Ref. 99 states: “With respect to ecological validity, the data (Table 13) show that the type of intervention agent may make a difference. Typical agents (e.g., parents, teachers) produced a success rate of 61.0%, whereas atypical agents (e.g., psychologists, researchers) had a success rate of only 44.3%. With respect to type of setting, the success rates for typical (e.g., home, integrated school) versus atypical (e.g., clinic, institution) were roughly comparable. Comparability in success rates was also seen for interventions that took place in all relevant contexts versus those that did not.” (p. 68)</b>
II.C.1.b		106	<b>Ref 106 provides: “Thus, it has been argued that PBS research must move toward a model that emphasizes (a) the use of interventions across all relevant settings...” (p. 691)</b>
II.C.1.b	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).	36	<b>Ref. 36: “The effects of shock appear to be specific to the situation in which shock is used, with respect to both physical locales and attending adults. This implies that if punishment to suppress self-destruction is to be maximally therapeutic (i.e., durable and general) it has to be administered by more than one person, in more than one setting. Our data amply suggest that each child would revert to self-destruction as soon as he returned to the treatment settings from which he came, unless his treatment under those conditions was made consistent with our procedures.” (p. 155)</b>
II.C.1.b		44	<b>Ref. 44: “In addition, however, Lovaas gave the children almost constant social reinforcement throughout their waking day-except after SIB. When SIB occurred, he administered a painful but completely harmless electric shock to their arms or legs. He thus broke the cycle mentioned</b>

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			<p>earlier. Lovaas reported almost immediate and permanent elimination of the SIB, which had <u>in some cases been sustained a number of years.</u>” (p. 66)</p> <p>“Thus, the purpose of the shock becomes the suppression of SIB, or the reduction of SIB from exceptionally high rates to lower rates, which can be managed practically.” (p. 66)</p> <p>“A number of workers, chiefly Lovaas, have reported permanent and relatively rapid suppression of SIB following strong, response-contingent aversive stimuli, such as shock. Lovaas and others also reported successful elimination of SIB through the use of extinction:the deliberate withdrawal of suspected reinforcers. Unfortunately, the same results were not obtained at Sonoma State Hospital. Although a dramatic reduction of SIB was obtained, the results were disappointing, because the effects of both techniques appeared temporary. Moreover, reduction in both cases was strongly stimulus-specific (i.e., the SIB returned if a new staff member was brought into the program, or if the patient was brought into a different room). Work investigating possible techniques to generalize the reduction of SIB with respect to these and other variables is presently in progress.” (p. 69)</p>
II.C.1.b		59	<p>Ref. 59 describes ways to address problems associated with generalization: The current literature indicates that punishment must be delivered consistently in all relevant contexts. Nevertheless, various generalization strategies described by Stokes and Baer (1977) may be useful for promoting treatment generality when the procedure is extended beyond the initial treatment setting. For example, a variety of stimulus conditions could be arranged in the initial treatment setting (e.g., different caregivers and peers could be present, diverse activities could be scheduled, physical features of the environment could vary). Stimuli common to other settings and contexts in which punishment will be applied could be introduced in the initial treatment setting before the intervention is widely implemented. Treatment generality also may be enhanced by ensuring that reinforcement is implemented consistently across settings, incorporating certain aspects of self-management into</p>

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			<p>treatment (e.g., self-monitoring), and establishing salient discriminative stimuli for punishment in all settings and contexts (see Stokes &amp; Baer for further discussion of generalization procedures).” (p. 452-453)</p>
II.C.1.b		93	<p><b>Ref. 93: “Our findings largely correspond with previous reviews of punishment (Matson &amp; Taras, 1989), of behavioral interventions for self-injurious behavior (Kahng et al., 2002), and of behavioral interventions for the challenging behavior of persons with autism (Heyvaert et al., 2014). Throughout this paper, comparisons of our findings and those of the most recent quantitative review on punishment (Matson &amp; Taras, 1989) have been made. Although separated by 25 years, many of the assertions made by Matson and Taras (1989) also apply to the current review; their review suggested the maintenance of treatment effects for punishment procedures was quite good but that less research support was available for the generalization of punishment’s reductive effects.” (p. 482)</b></p>
II.C.1.b	<p>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).</p>	34	<p><b>The key words here are “may” and “initially.” FDA ignored the numerous reports that document the absence of negative side effects and the occurrence of positive side effects. In “Long-term effectiveness of this kind of treatment varies considerably between individuals and devices.” (p. 294)</b></p> <p><b>“In the present study three categories of effectiveness are distinguished, that is, EAT has been (a) ineffective: this is the case with H. and W.; (b) moderately effective: with M., B., and R., and (c); effective: with C., E., E, We., Wi., J., and A. With the latter four individuals, follow-up lengths are, however, still relatively short.” (p. 300)</b></p> <p><b>“A general pattern of responding to electrical stimuli can be observed with the present individuals. Initially, individuals tend to show a strong response to EAT by suppressing their SIB. Then, after several weeks a relapse occurs, in that the number of shocks to be given</b></p>

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			<p>increases. Such an adaptation to the electrical stimulus poses heavy stress on parents, caregivers, and staff, as the individual involved has demonstrated to withhold SIB. Several measures can then be taken, such as administration of opiate blockers (Ricketts et al., 1992), increasing physical restraint, or using antidepressants or antipsychotics, all in conjunction with electrical stimuli. Researchers have also used a stronger electrical aversive stimulus to control such a relapse (e.g., Williams, Kirkpatrick-Sanchez, &amp; Iwata, 1993). Compelling evidence on the effectiveness of stronger electrical stimuli with severe SIB and aggressive behavior can be found with Israel et al. (1992).” (p. 300)</p> <p>“Despite its effectiveness and its apparent simplicity, a treatment with electrical stimuli is not easy to conduct.” (p. 300)</p> <p>“To conclude, EAT may be viable option for individuals who show severe and life-threatening forms of SIB. Further research should focus on how to deal with the adaptation to the electrical stimulus, how to withdraw the device successfully, and how to increase acceptability in the community for the use of EAT for individuals with severe and life-threatening forms of SIB.” (p. 301)</p>
		36	<p><b>Ref. 36:</b> “This implies that if punishment to suppress self-destruction is to be maximally therapeutic (i.e., durable and general) it has to be administered by more than one person, in more than one setting. Our data amply suggest that each child would revert to self-destruction as soon as he returned to the treatment settings from which he came, unless his treatment under those conditions was made consistent with our procedures.” (p. 155).</p>
II.C.1.b		59	<p><b>Ref. 59</b> describes ways to address problems associated with generalization: The current literature indicates that punishment must be delivered consistently in all relevant contexts. Nevertheless, various generalization strategies described by Stokes and Baer (1977) may be useful for promoting treatment generality when the procedure is extended beyond the initial</p>

		<p>treatment setting. For example, a variety of stimulus conditions could be arranged in the initial treatment setting (e.g., different caregivers and peers could be present, diverse activities could be scheduled, physical features of the environment could vary). Stimuli common to other settings and contexts in which punishment will be applied could be introduced in the initial treatment setting before the intervention is widely implemented. Treatment generality also may be enhanced by ensuring that reinforcement is implemented consistently across settings, incorporating certain aspects of self-management into treatment (e.g., self-monitoring), and establishing salient discriminative stimuli for punishment in all settings and contexts (see Stokes &amp; Baer for further discussion of generalization procedures).” (p. 452-453)</p> <p>Ref. 59 describes examples of the long-term efficacy of punishment: Although brief treatment evaluations are predominant in the applied literature on punishment, an increasing number of studies have examined the long-term efficacy of punishment over the past 10 years. Treatment effects have been examined for 1 to 60 months after punishment was initiated and continued with minor changes to the procedure (Duker &amp; Seys, 1996; Ricketts, Goza, &amp; Matese, 1993; D. E. Williams, Kirkpatrick-Sanchez, &amp; Crocker, 1994), and after the original punishment component was withdrawn (Arntzen &amp; Werner, 1999; Foxx, Bittle, &amp; Faw, 1989; Rolider, Williams, Cummings, &amp; Van Houten, 1991). Results have shown varying success in maintaining the reduction in behavior, yet potential reasons for the inconsistent outcomes have not yet been identified. For example, D. E. Williams et al. (1993) observed a relapse in treatment with contingent electric shock 6 months after punishment was initiated. Conversely, Linscheid, Hartel, and Cooley (1993) found that contingent electric shock continued to suppress 2 individuals’ self-injurious behavior for 5 years. Duker and Seys (1996) examined the long-term efficacy of contingent shock with 12 individuals by obtaining information on the degree of physical restraint each required from 2 to 47 months after the initiation of punishment. Results at follow-up suggested that treatment remained effective for 7 participants, including 1 individual who was evaluated at 36 months and another who was evaluated at 47 months. (p. 48)</p> <p>The authors also pointed out that many punishment procedures have not been evaluated in the long-term with the exception contingent shock: “...the majority of the studies examined the long-term effectiveness of contingent electric shock...” (p. 448)</p>
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II.C.1.b		95	<p><b>Ref. 95 suggests that aversive procedures could be removed and the effect of the treatment was durable with the continuation of differential reinforcement and other behavioral procedures in some cases.</b></p> <p><b>The authors of Ref. 95 acknowledge that prior treatment with aversives may have contributed to the long-term success of each student: “It is possible, of course, that the prior invasive treatment contributed to the long-term outcomes presented in this report.” (p. 17)</b></p>
II.C.1.b	<p>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).</p>	99	<p><b>Ref. 99 implies the opposite, that PBS, as well as many behavioral procedures, must be continually maintained: “First, the database includes a limited number of demonstrations of successful maintenance effects lasting up to 2 years. There is no a prior reason for assuming that the effects cannot be further extended, especially given the excluded research studies and clinical reports, some of which note long-term maintenance. At a conceptual level, one might expect long-term effects if the PBS approach were implemented in a manner more consistent with its general philosophy. To the extent that deficient environments and deficient skills continue to be identified over time, which is almost always the case when one follows an individual over many years in changing life circumstances, PBS strategies would have to be added and/or modified. In other words, intervention never stops. This view is in contrast to many traditional studies in which maintenance is defined as durable success following intervention cessation (Carr et al., 1990). In a truly comprehensive PBS approach, maintenance would be guaranteed because intervention would never stop. Interestingly, an added benefit of such a long-term strategy is that, overtime, the individual is supported in many different situations (a feature that would enhance stimulus generalization) and is taught many different skills (a feature that would enhance response generalization). Thus, comprehensive changes are likely to be facilitated over the protracted periods of time that PBS is in effect. In short, maintenance and comprehensive lifestyle change are intertwined variables.” (p. 89)</b></p>

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II.C.1.b	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).	105	<p><b>Ref. 105, which was published in 2013, and appears to be a single-group pilot study, is completely mischaracterized—as it states “research <u>has not yet confirmed that existing treatments adequately reduce CBs in this population</u>, dialectical behavior therapy (DBT) holds promise, as it has been shown to effectively reduce CBs in other emotionally dysregulated populations.” “These findings suggest that modified DBT <u>holds promise</u> for effectively treating individuals with intellectual and developmental disabilities.” (p. 280)</b></p> <p><b>“Younger participants with BPD, self-injury, or aggression and who do not have IED may be a particularly good match for DBT-SS, but <u>further research is needed to confirm for whom DBT-SS will likely yield better improvement than other treatments.</u>” (p. 297)</b></p>
II.C.1.b	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).	119	<p><b>Refs. 118 and 119 do not have anything to do with the risks of extinction. Ref. 118 had nothing to do with problematic behaviors or therapeutic intervention. The authors note “Finally, we must emphasize the fact that our study focused on the use of extinction, NCR, and DRO strictly as control (i.e., reversal) conditions and not as therapeutic interventions.” (p. 236)</b></p> <p><b>Ref. 119 describes treating 9 and 10 year olds with FCT plus extinction, response blocking, and schedule thinning. It has nothing to do with the general side effects of extinction.</b></p> <p><b>Finally, the most direct effect of an ineffective positive behavior support plan is the continuation of the problem behavior.</b></p>
II.C.1.b	An extinction process reduces a target behavior by withholding the reinforcer, <i>i.e.</i> , the response sought with the target behavior ( <i>e.g.</i> , Ref. 120). Extinction exhibits the potential risk of “extinction bursts,” an upsurge of the actual undesirable behavior, particularly	120	<p><b>“An analysis of 41 data sets in which SIB was treated with extinction revealed that about 40% of cases showed at least one of two side effects (i.e., response bursts or increases in aggression) and that almost 20% of the cases showed both phenomena.” (p. 5)</b></p> <p><b>Ineffective procedures place the person at extreme risks associated with physical restraint and the continuation of the problem behaviors leading to injuries, blindness, or possibly death.</b></p>

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	<p>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.</p>		
	<p>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 (<i>e.g.</i>, Ref. 59), especially when paired with positive approaches (<i>e.g.</i>, 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).</p>	<p>113</p>	<p><b>Ref. 113 states: “Seven treatment types were statistically significantly better in reducing problem behavior than PECS only interventions: aversive and positive combinations, positive combinations, DRO only, antecedent control only, DRA only, noncontingent reinforcement only, and social stories only interventions.” (p. 2471)</b></p> <p><b>“Aversive and positive combinations as well as positive combination interventions were statistically significantly better in reducing problem behavior than antecedent control only interventions.” (p. 2471)</b></p>

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		99 and 113	<b>This statement made by the FDA is illogical. The literature is rife with examples of the contingent application of physical restraint, contingent shock, exclusionary time out, etc that are more restrictive than water mist.</b>
II.C.1.b	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).	115	<p><b>Ref. 115’s findings are actually <u>the complete opposite</u>: “Perhaps the first conclusion worth emphasizing is that the <u>range of opinion among respondents was very large</u>, suggesting that <u>any statements in both the popular media and professional publications claiming that “professionals” think punishment to be ineffective or unethical (or, for that matter, effective or ethical) are not credible</u>. A second general point involves punishment research, or the lack of it—for an issue that generates such heated controversy, we have very little empirical research to guide us, compared to the evidence base for reinforcement. Given recent findings that interventions containing aversive components may be more effective than interventions without punishment in certain circumstances and that individuals have demonstrated preference for these interventions over non-aversive options (Hanley, Piazza, Fisher, &amp; Maglieri, 2005), empirical investigations are warranted. In the past several years, several commentators have called for more research on punishment (e.g., Lerman &amp; Vorndran, 2002) and aversive control (e.g., Critchfield, 2006; Perone, 2003), and based on the findings of the present survey, we would echo that call.” (p. 65)</b></p> <p><b>Ref. 115: “There are several limitations that are worthy of note. First, the <u>response rate was relatively low</u> (29.4%). Since a large portion of the participant pool failed to respond, it is <u>not known the extent to which our sample was representative</u>. It is possible that the present findings would be altered if the response rate was higher. Additionally, this survey targeted members of the Association for Behavior Analysis (ABA); therefore, these findings may not generalize to behavior analysts who were not current members of ABA at the time the participant directory was accessed. Finally, despite being members of ABA and, presumably, having knowledge regarding the definition of punishment, respondents may have rated items using differing definitions and/or had variable understanding of the terminology used. For example, respondents may not have had experience with stimulus avoidance assessments.” (p. 65)</b></p>

		112	<p>Ref. 112 states, “Some organizations have taken positions against the use of intrusive or aversive procedures . . . whereas others have maintained that there are certain conditions under which the use of aversive strategies may be appropriate (e.g., Mudford, 1995). The Right to Effective Treatment (Van Houten et al., 1988) states that “in some cases, a client’s right to effective treatment may dictate the immediate use of quicker-acting, but temporarily more restrictive procedures” (p. 383). Those who ascribe to this point of view argue that when rapid reduction in a severe behavior problem is needed, it is ethical to use restrictive procedures (Hastings &amp; Noone, 2005).” (p. 214)</p> <p>“Kahng, Iwata, and Lewin (2002) found that although the use of reinforcement-based interventions for selfinjury has increased during the past decade, the use of punishment-based interventions has decreased only slightly. In general, it would be assumed that the use of aversive strategies (i.e., those that cause pain or discomfort to an individual) would have low treatment acceptability in the PBS community—as evidenced, for example, by the lack of published research employing aversive strategies in the Journal of Positive Behavior Interventions. Michaels et al. (2005), however, report that there were differences in perceptions of treatment acceptability <u>among professionals identified as PBS experts when asked about the appropriateness of aversive, consequence-based strategies for individuals with severe problem behaviors (i.e., individuals who engage in extremely dangerous behaviors likely to cause physical harm to self or others). They found that experts in PBS do not consistently agree on what types of interventions are considered acceptable.</u>” (p. 214)</p> <p>“Treatment acceptability research has focused largely on those variables that contribute to an individual’s determination that a particular treatment is acceptable or unacceptable. Smith and Linscheid (1994) suggested that treatment acceptability is inversely related to a treatment’s perceived aversiveness and restrictiveness, but acceptability increases when those decelerative or restrictive procedures are proposed for more severe or frequent behavior problems (see Michaels et al., 2005, for a more comprehensive review of treatment acceptability).” (p. 214)</p>
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<p>II.C.1.b</p>	<p>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).</p> <p>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</p>	<p>121</p>	<p><b>Ref. 121: skills acquisition and stimulus-based interventions had 50 and 52 percent success rates, respectively, for Self-injury. For Aggression/Tantrums, the rates were 50% and 42%, respectively. For Aggression and Self-Injury, the success rates were 75% and 17%, respectively. (p. 20)</b></p>
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	<p>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).</p>		
		99	<p><b>“The two most substantive and frequently employed alternatives to PBS are the use of pharmacotherapy (medication) and aversive procedures.” (p.19)</b></p>

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			<p><b>“First, the database includes a limited number of demonstrations of successful maintenance effects lasting up to 2 years. There is no a prior reason for assuming that the effects cannot be further extended, especially given the excluded research studies and clinical reports, some of which note long-term maintenance. At a conceptual level, one might expect long-term effects if the PBS approach were implemented in a manner more consistent with its general philosophy. To the extent that deficient environments and deficient skills continue to be identified over time, which is almost always the case when one follows an individual over many years in changing life circumstances, PBS strategies would have to be added and/or modified. In other words, intervention never stops. This view is in contrast to many traditional studies in which maintenance is defined as durable success following intervention cessation(Carr et al., 1990). In a truly comprehensive PBS approach, maintenance would be guaranteed because intervention would never stop. Interestingly, an added benefit of such a long-term strategy is that, overtime, the individual is supported in many different situations (a feature that would enhance stimulus generalization) and is taught many different skills (a feature that would enhance response generalization).Thus, comprehensive changes are likely to be facilitated over the protracted periods of time that PBS is in effect. In short, maintenance and comprehensive lifestyle change are intertwined variables.” (p. 89)</b></p>
		122	<p><b>Note that the 60% success rate did not reduce 100% of problem behavior: “Across the nine studies in the current analysis, nearly 60% of the comparisons reported 90% reduction in problem behavior.” (p. 12)</b></p>
II.C.1.b		123	<p><b>Table 1 of Ref. 123 specifically lists “Representative Behavioral Treatment Procedures.” The procedures listed include the following: overcorrection, contingent time-out, contingent shock, movement suppression time out, and contingent protective equipment. (see page 66)</b></p> <p><b>“Intrusive behavioral interventions continue to be effective and used. This factor appears to be the case because functional assessment, DRO, additional activities, and related methods have been documented to be treatment failures where contingent punishment</b></p>

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			<p>procedures were effective in some instances (Falcomata et al., 2007; Matson &amp; Taras, 1989; Vollmer, 2002). We concur that with the exception of pharmacotherapy, punishment procedures should be a last resort intervention. However, many drug trials are being initiated without fully exploring, or in some cases attempting, environmentally based interventions. Additionally, in practice, ASD adults with severe ID often present with potent drug cocktails that, to a large degree, immobilize the person and markedly inhibit learning and an active lifestyle. As a rule of thumb, positive methods, then aversives, then pharmacotherapy would seem to be the prudent course. The latter two methods would be add-ons to the positive approaches.” (p. 69)</p>
II.C.1.b		97	<p><b>Ref. 97:</b> “While punishment would not be included in a PBS plan, if unavoidable, a restrictive reactive strategy, such as physical management, might be included as a last resort if needed to minimise episodic severity. However, as a last resort, such restrictive and perhaps aversive strategies would only be employed if other nonaversive reactive strategies, such as stimulus change or counterintuitive strategies such as redirecting the person to a preferred activity, did not work to get rapid, safe control over the behavioural episode (LaVigna &amp; Willis, 2002).” (p. 3)</p>
II.C.1.b	<p>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</p>	113	<p><b>Ref. 113 states:</b> “Seven treatment types were statistically significantly better in reducing problem behavior than PECS only interventions: aversive and positive combinations, positive combinations, DRO only, antecedent control only, DRA only, noncontingent reinforcement only, and social stories only interventions.” (p. 2471)</p>

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	<p>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).</p>		
<p>II.C.1.b</p>		<p>103</p>	<p><b>Ref. 103: “There is not, however, a data base that allows confidence in the ability of available positive programming technology to respond to all severe behavior challenges. The technology of positive programming is still developing and is just beginning to receive adequate empirical support.” (p. 5)</b></p>
<p>II.C.1.b</p>		<p>112</p>	<p><b>Ref. 112: “Kahng, Iwata, and Lewin (2002) found that although the use of reinforcement-based interventions for self-injury has increased during the past decade, the use of <u>punishment-based interventions has decreased only slightly</u>. In general, it would be assumed that the use of aversive strategies (i.e., those that cause pain or discomfort to an individual) would have low treatment accept-ability in the PBS community—as evidenced, for example, by the lack of published research employing aversive strategies in the Journal of Positive Behavior Interventions. Michaels et al. (2005), however, report that there were <u>differences in perceptions of treatment acceptability among professionals identified as PBS experts when asked about the appropriateness of aversive, consequence-based strategies for individuals with severe problem</u></b></p>

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			<p><b><u>behaviors (i.e., individuals who engage in extremely dangerous behaviors likely to cause physical harm to self or others). They found that experts in PBS do not consistently agree on what types of interventions are considered acceptable. According to Michaels et al., some PBS experts, under certain conditions, report that they would consider using the full range of consequence-based decelerative procedures—including sensory punishment, physical punishment, and contingent electric shock. Although it is important to note that responses were limited to what respondents would consider using, not necessarily what they actually did use, it remains clear that the issue of treatment acceptability as a distinguishing variable between the two groups must be questioned.” (p. 214)</u></b></p>
II.C.1.b		124	<p><b>Ref. 124: “The use of reinforcement-based interventions has increased during the past decade, whereas the use of <u>punishment-based interventions has decreased slightly</u>; both of these trends coincide with the increase in the use of functional assessments. Most treatments have been highly effective in reducing SIB; nevertheless, the disorder persists in spite of an abundance of research, suggesting that a greater emphasis should be placed on prevention.” (p. 212)</b></p> <p><b>Ref. 124: “Data on the selection of behavioral interventions revealed a <u>gradual decrease in the use of punishment</u> across years and a dramatic increase in the use of reinforcement-based interventions.” (p. 219)</b></p>
II.C.1.b		103	<p><b>Ref. 103: “At this writing, <u>empirical support for a comprehensive, positive technology is developing but is by no means compelling</u> (Carr, Taylor, Carlson, &amp; Robinson, 1990).” (p. 4)</b></p> <p><b>Ref. 103, from 2005, indicates that the positive programming technology is just beginning, which is at odds with the FDA’s comments: “<u>There is not, however, a data base that allows confidence in the ability of available positive programming technology to respond to all severe behavior challenges.</u> The technology of positive programming is still developing and is just beginning to receive adequate empirical support.” (p. 4)</b></p>

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			<p>Note that in Ref. 103, the article states, “It is practically impossible to provide support or instruction that does not include at least some mildly aversive events. Withholding attention, redirecting from preferred (albeit self-injurious) behavior, making a request to perform a new behavior, and delivering instructional prompts all may be aversive to some degree. If the technical definition of "aversive" is applied, there are few teachers or clinicians who could argue that they implement a totally nonaversive approach.” (p. 4)</p> <p>“Lovaas and Favell (1987), for example, have provided a <u>set of guidelines for using aversive stimuli</u> that precludes use of these procedures in all but the most extremely unusual situations, and then only by a very small number of very well trained and monitored clinicians. The functional difference between the professional guidelines recommended by Lovaas and Favell (1987) and a total prohibition of all procedures that involve pain or harm is minimal in terms of the number of people who would receive aversive stimuli. Clearly, the time has come for limiting the use of stimuli and procedures that are painful, damaging, and dehumanizing. <u>The debate should be not on whether to limit our use of the most severe forms of behavioral intervention, but on how that limitation should occur.</u>” (p. 8)</p>
II.C.1.b	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).	59	<p>Ref. 59: “Results of basic and applied research indicate that current treatment approaches based on punishment have advantages (e.g., they are highly effective) and disadvantages (e.g., there are un-predictable side effects). Nevertheless, <u>punishment is still sometimes needed to reduce destructive behavior to acceptable levels</u> (e.g., Grace et al., 1994; Hagopian et al., 1998; Wacker et al., 1990); punishment may underlie the effects of certain common function based treatments (e.g., Lerman &amp; Iwa-ta, 1996b; Mazaleski et al., 1994); and <u>caregivers continue to use punishment to reduce problem behavior in the natural environment</u> (e.g., Peterson &amp; Martens, 1995).”</p>
II.C.1.b		93	<p>Ref. 93: “Overall, the publication of studies examining the utility of punishment procedures as a treatment for the challenging behavior of individuals with developmental disabilities peaked in the early 1980s. Following this period, a <u>gradual decline in the number of studies utilizing</u></p>

		<p><b>punishment was seen in the literature. The current review demonstrated that since 1990, punishment procedures have been used in less than ten published articles each year.” (p. 12)</b></p> <p><b>Ref. 93: But many practitioners are calling for more research: “Continued research into the effects and outcomes of punishment-based procedures remains important. Vollmer (2002) appealed convincingly against the dismissal of punishment’s utility, suggesting that “to ignore punishment as an application is akin to ignoring the benefits and limitations of medical technology” (p. 469). He, and others (e.g., Sidman, 1989), have highlighted the pervasiveness of punishment, planned and unplanned, non-social and socially mediated, in everyday life. Other arguments in favor of the continued research of punishment have also been put forward (e.g., Lerman &amp; Vorndran, 2002; Newsom &amp; Kroeger, 2005). Many studies have shown that, for some individuals at least, reinforcement-based strategies alone are insufficient to reduce challenging behavior to acceptably low levels without the addition of a punishment component (e.g., Fabiano et al., 2004; Grace, Kahng, &amp; Fisher, 1994; Hagopian, Fisher, Sullivan, Acquisto, &amp; LeBlanc, 1998; U.S. National Institutes of Health, 1989). In some instances functionally equivalent alternative behaviors may be unidentifiable or inaccessible to the individual (Newsom &amp; Kroeger, 2005). Punishment procedures may also be more appropriate than reinforcement-based interventions in situations where the rapid reduction, or total elimination, of a behavior is imperative. Reducing the risk of serious physical harm to the individual engaging in the behavior, or to others in their environment, may be a more rapidly observed outcome with punishment procedures than with reinforcement-based procedures (Lerman &amp; Vorndran, 2002; Matson &amp; Kazdin, 1981). Further, there are a number of situations in which reinforcement-based procedures have been identified to be either ineffective or unsuitable. For example, behaviors that are identified as automatically reinforced, or for which a source of reinforcement cannot be identified, are typically quite difficult to treat or reduce using reinforcement-based procedures alone (LeBlanc, Patel, &amp; Carr, 2000; Vollmer, 1994). In such cases it may not be possible to alter the existing reinforcement contingencies, either through the withholding of the maintaining source of reinforcement, or through the provision of the reinforcers contingent on an alternative desirable behavior (Vollmer, 2002).” (p. 471)</b></p>
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		115	<p>“Perhaps the first conclusion worth emphasizing is that the range of opinion among respondents was very large, suggesting that any statements in both the popular media and professional publications claiming that “professionals” think punishment to be ineffective or unethical (or, for that matter, effective or ethical) are not credible. A second general point involves punishment research, or the lack of it—for an issue that generates such heated controversy, we have very little empirical research to guide us, compared to the evidence base for reinforcement. Given recent findings that interventions containing aversive components may be more effective than interventions without punishment in certain circumstances and that individuals have demonstrated preference for these interventions over non-aversive options (Hanley, Piazza, Fisher, &amp; Maglieri, 2005), empirical investigations are warranted. <u>In the past several years, several commentators have called for more research on punishment (e.g., Lerman &amp; Vorndran, 2002) and aversive control (e.g., Critchfield, 2006; Perone, 2003), and based on the findings of the present survey, we would echo that call.” (p. 65)</u></p>
II.C.1.b	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.	98	<p>This statement by the FDA is false. Most of the papers written since 2000 on the use of ESD were NOT written by JRC employees. Consider the following:</p> <p><b>Barrera, F.J., Viola, R.A., &amp; Graver, E.E. (2007). On the Form and Function of Severe Self-Injurious Behavior. <i>Behavioral Interventions</i>, 22, 5-33.</b></p> <p><b>Duker, P.C. &amp; Van den Munckhof, M. (2007). Heart rate and the role of the active receiver during contingent electric shock for severe self-injurious behavior. <i>Research in Developmental Disabilities</i>, 28, 1, January-February, 43-49.</b></p> <p><b>Duker, P.C., Hendriks &amp; Schroen (2004). Effect of wave frequency of clinical electric shock: pain sensation and startle response. <i>Behavioral Interventions</i>, 19, 2, April, 103- 110.</b></p> <p><b>Salvy, S., Mulick, J.A, Butter, E., Bartlett, R.K. &amp; Linscheid, T.R. (2004) Contingent electric shock (SIBIS) and a conditioned punisher eliminate severe head banging in a preschool child. <i>Behavioral Interventions</i>, 19, 59-72.</b></p> <p><b>Foxx, R.M. (2003). The Treatment of dangerous behavior. <i>Behavioral Interventions</i>, 18, 1-21.</b></p>

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			<p><b>Duker, P.C. (2002).. Effects of single and repeated shock on perceived pain and startle response in healthy volunteers. <i>Research in Developmental Disabilities, 23, 4, July-August, 285-292.</i></b></p> <p><b>Linscheid, T.R. &amp; Reichenbach, H. (2002). Multiple factors in the long-term effectiveness of contingent electric shock treatment for self-injurious behavior: a case example. <i>Research in Developmental Disabilities, 23, 161-177.</i></b></p>
II.C.1.b	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.	30	<b>These statements by the FDA are false. Ref. 30 is a paper published in The Journal of Behavior Analysis of Offender and Victim - Treatment and Prevention. The journal itself and the papers mentioned were peer reviewed.</b>
		94	<b>These statements by the FDA are false. Ref. 94 is a paper published in The Journal of Behavior Analysis of Offender and Victim - Treatment and Prevention. The journal itself and the papers mentioned were peer reviewed.</b>
II.C.1.b	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).	95	<b>This is a false conclusion drawn by the FDA. The fact that in some cases, skin shock can be withdrawn without resumption of problem behaviors does not mean the problem behaviors could have been treated without skin shock in the first place. In addition, JRC learned that in 1999, one of these students burned down his group home and was in a psychiatric hospital.</b>

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II.C.1.c	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.)	3	<p><b>Ref. 3 cites a 2013 Cochrane review<sup>29</sup> that concludes the following:</b></p> <p><b>“This review does not provide evidence for the efficacy of pharmacological interventions in managing SIB in adults with IDs. It therefore has no clear implications for clinical decision-making, leaving clinicians in the unsatisfactory position of having to rely on clinical experience and judgement. This means clinicians should be cautious in the use of these medications which, in many countries, may be prescribed ‘off label’. The paucity of evidence needs to be discussed carefully with patients and carers, and their views need to be taken into account. If prescribed, the effects of medication on individual patients needs to be carefully monitored and regularly reviewed.” (p.20)</b></p> <p><b>The FDA concludes the following in Ref. 3: “There remains debate in the scientific literature with respect to both the effectiveness of pharmacological treatment of SIB and aggressive behavior and when medication management should be considered.” (p. 24)</b></p>
II.C.2	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).	125	<p><b>The reference is to an article by Jennifer Gonnerman in a non-medical or scientific or peer reviewed magazine, Mother Jones, dated August 20, 2007 on JRC which states that O. Ivar Lovaas, a UCLA psychology professor who “pioneered the use of slaps and screams and electric jolts to try and normalize the behavior of autistic kids”, eventually abandoned the approach because he felt that people became inured to the pain.</b></p>
II.C.2	Another expert summarized in an interview that the modern clinical approach is the result of science	126	<p><b>The reference is to another article by Jennifer Gonnerman in Mother Jones dated August 20, 2007 citing Gina Green, “a nationally known psychologist who has worked with autistic children</b></p>

<sup>29</sup> Rana, F., Gormez, A. & Varghese, S. (2013). Pharmacological interventions for self- injurious behavior in adults with intellectual disabilities. Cochrane Database of Systematic Reviews, Issue 4. Art. No., CD009084. DOI, 10.1002/14651858.CD009084.pub2.

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	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). <a href="#">[4]</a>		<b>for nearly 30 years,” who opines “as our science has developed and research has been done, we have come up with better methods for treating severe behaviors.”</b>
II.C.2		107	<b>Murray Sidman argues that punishment should be eliminated or minimized to the greatest extent possible. However, he also acknowledges that positive reinforcement procedures are not always effective: “Many are willing to accept restrictions on the use of coercive therapy, agreeing, for example, to use coercion only when no positive procedure solves the problem. In principle, I cannot dispute that well-meant and sensible condition. In fact, I believe that the prerequisite-nothing else works-is rarely met. I would go so far as to say to anyone who claims to have tried everything else, ‘Tell me what you did. I will then suggest a procedure you did not try.’ Undoubtedly, I would sometimes be unable to do this-but not very often.”<sup>30</sup></b>
II.C.2	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	8	<b>The reference is to an undated article by Dr. Smith entitled “Should the FDA Ban Aversive Conditioning Devices.” Dr. Smith does indeed note that non-aversive interventions can be effective for many, but that is not his conclusion. His conclusion is: “... research does show that aversive conditioning devices can be effective for severe SIB and aggression in some people with IDD and that alternative interventions are sometimes ineffective and unsafe. Accordingly, I believe it is more prudent to restrict the use of aversive conditioning devices than to ban them.”</b>

<sup>30</sup> Sidman, M. (1993). Reflections on behavior analysis and coercion. *Behavior and Social Issues*, 3(1 and 2), 75-85.

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	<p>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 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).</p>		
II.C.3	<p>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)</p>	132	<p><b>The reference is to an affidavit by Elin Howe, Commissioner of the Massachusetts Department of Developmental Services dated February 2013. What the reference does not state, and what the affidavit does not emphasize, is that consisted of 6 patients over 6 years, many of whom were ready for transition because of the efficacy of their behavioral program.</b></p> <p><b>DDS has also failed to successfully transition some individuals.</b></p>
II.C.3	<p>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</p>	131	<p><b>While the reference, Massachusetts Department of Developmental Services Response to Testimony and written Comments to Proposed Amendments to Behavior Modification Regulations, includes opinions from many providers and organizations, nowhere does it say that it has obtained opinions from “virtually every” one. Moreover, it notes that less than half of the states ban treatment that involves pain, which calls into question whether the opinion voiced by the FDA here is as universally held as is indicated.</b></p>

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	<p>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).</p>		
II.C.3		132	<p><b>The reference is to the previously discussed affidavit of E.M.Howe. The affidavit does not say that “virtually every local, statewide or national organization” provided “overwhelming support” for a ban. Rather it says the comments that the Department received from local, statewide or national organizations were overwhelmingly supportive. Nowhere does it say that every local, statewide or national organization provided a written comment.</b></p>

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<p>II.C.4</p>	<p>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).</p>	<p>133</p>	<p><b>The FDA refused an invitation to visit JRC, meet the students receiving aversive interventions, meet the families, and examine treatment records.</b></p> <p><b>The reference is to an article, “The Path to Aversive Interventions: Four Mothers’ Perceptions” by Fredda Brown and Dina Traniello in “Research &amp; Practice for Persons with Severe Disabilities,” 2010, Vol. 35, no. 3-4, 128-136. Four mothers of patients who were dissatisfied with the therapy given their children said in interviews with an opponent of aversive intervention, that they felt they were coerced into agreeing to it.</b></p>
<p>II.C.4</p>	<p>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).</p>	<p>107</p>	<p><b>The reference is to an undated article by Fredda Brown entitled Patients Exhibiting Self-Injurious and Aggressive Behavior. It accurately reports what Ms. Brown says, however, it should be pointed out that Ms. Brown’s sources are her previous article with Ms. Traniello, which in turn relies on the memories of laypersons dissatisfied with the therapy provided their children, and a hearsay statement made personally to Ms. Brown by a Doctor Christopher Oliva, said to have been a member of the New York State Child Exception Panel. Dr. Oliva is said to have reviewed 30 submissions of children sent from New York and found that the submissions did not meet minimum behavioral or educational standards regarding functional behavioral assessments.</b></p> <p><b>Fredda Brown is not a licensed psychologist or a board certified behavior analyst and does not appear to have any certification or license that would allow who to design behavioral programs.</b></p>

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II.C.4	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)	21	<b>The reference does not contain the quoted language. The reference does refer to using an increased output and the possibility of discontinuing the GED, but it does not refer to an alternative behavior program.</b>
II.C.5	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)	133	<b>The reference is to an article, “The Path to Aversive Interventions: Four Mothers’ Perceptions” by Fredda Brown and Dina Traniello in “Research &amp; Practice for Persons with Severe Disabilities,” 2010, Vol. 35, no. 3-4, 128-136. Four mothers of patients who were dissatisfied with the therapy given their children said in interviews with an opponent of aversive intervention, that they felt they were coerced into agreeing to it. In other words the statements are based on four disgruntled parents.</b>
II.C.5	These parents reported feelings of coercion upon admission to the facility and intimidation when attempting to change their children's intervention plans (Ref.	133	<b>The reference is to an article, “The Path to Aversive Interventions: Four Mothers’ Perceptions” by Fredda Brown and Dina Traniello in “Research &amp; Practice for Persons with Severe Disabilities,” 2010, Vol. 35, no. 3-4, 128-136. Four mothers of patients who were dissatisfied with the therapy given their children said in interviews with an opponent of aversive</b>

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	133). <a href="#">[9]</a> 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)		<b>intervention, that they felt they were coerced into agreeing to it. In other words, the statements are based upon four disgruntled parents.</b>  <b>This is not possible. Mechanical restraint is also a Level III procedure and requires the same consents and court approval.</b>
II.C.5	Once at JRC, none of the parents reported the development of prevention or antecedent strategies for their children (Ref. 133)	133	<b>The reference is to an article, “The Path to Aversive Interventions: Four Mothers’ Perceptions” by Fredda Brown and Dina Traniello in “Research &amp; Practice for Persons with Severe Disabilities,” 2010, Vol. 35, no. 3-4, 128-136. Four mothers of patients who were dissatisfied with the therapy given their children said in interviews with an opponent of aversive intervention, that they felt they were coerced into agreeing to it. In other words, the statements are based upon four disgruntled parents.</b>
II.C.6	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).	137	<b>Ref. 137 refers to a letter in support of DDS’ proposed amendments that does not make any references to studies, etc. In fact, the author states that she has never used aversives in her career, and so it is questionable how she can weigh in on a practice without experience or justification for her opinion.</b>
II.C.6		138	<b>Ref. 138 refers to another letter in support of DDS’ proposed amendments that does not make any references to studies, etc. In fact, the author states that she has never used aversives in her career, and so it is questionable how she can weigh in on a practice without experience or justification for her opinion.”</b>
II.C.6	Another commenter on the Massachusetts ban stated that in 30 years working in programs serving individuals with severe behavior challenges and dangerous behavior	131	<b>This comment is mischaracterized by the FDA. In reality, the commenter is stating that he had not seen aversives used in any of the programs he had observed; which is different from the implication that “no program” allowed aversives. Ref. 131 states: “In the past 30 years I have worked in, consulted with, evaluated and monitored at least one hundred programs that served</b>

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	in more than 20 States, no program allowed use of pain to control behavior (Ref. 131).		<b>individuals with severe behavior challenges and dangerous behavior, in more than 20 states. None of them have allowed the planned use of pain to control the individuals' behavior.” (p. 11)</b>
II.C.7	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).	99	<b>Ref. 99 indicates that PBS procedures are only successful in 52% of the cases in the published literature. (see p. 45).</b>
II.C.7		101	<b>Ref. 101 did not address severe behavior problems. The dependent variable selected does not actually collect frequency data. Rather, a 3 simply indicates the behavior were occurring weekly and a 2 indicates the behaviors were occurring monthly. Therefore, one cannot determine precisely how the frequency changed. Regardless, the problem behaviors were not eliminated. In addition the “Episodic severity” started at a low intensity at baseline and changed very little.</b>
II.C.7		106	<b>Ref 106 does not support the statement made by FDA.</b>

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V		132	<b>The reference is to an affidavit by Elin Howe, Commissioner of the Massachusetts Department of Developmental Services dated February 2013. What the reference does not state, and what the affidavit does not emphasize, is that consisted of 6 patients over 6 years.</b>