BEFORE THE
DEPARTMENT OF DEVELOPMENTAL SERVICES
STATE OF CALIFORNIA

In the Matter of:

CLAIMANT

and

SAN DIEGO REGIONAL CENTER, SERVICE AGENCY

DDS Case No. CS0004263

OAH No. 2023050090

PROPOSED DECISION

Mary Agnes Matyszewski, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on June 19, 2023, in San Diego, California.

Neil Kramer, Fair Hearings Manager, San Diego Regional Center (SDRC), represented the service agency.

Claimant's mother represented claimant, who was present.

Oral and documentary evidence was received. The record was closed and the matter was submitted for decision on June 19, 2023.

ISSUE

Is SDRC required to use claimant's Self-Determination Program budget to purchase an Oberon bioresonance/biofeedback machine and a compatible computer?

FACTUAL FINDINGS

Jurisdictional Matters

1. Claimant, a 14-year-old male, resides in his home with his parents. According to his Individual Program Plan (IPP), he is eligible for regional center services based on his diagnosis of autism spectrum disorder. Claimant also has speech and developmental delay, attention deficit disorder, obsessive compulsive disorder (OCD), incontinence, anxiety and depression. A January 3, 2023, Family Interview conducted by Lindsey Sparacino, M.A.Ed., documented claimant's request to purchase a biofeedback machine to help with claimant's "mind-body connection and reduce anxiety and stressors." The cost of the device was listed as $6,000.

2. On March 8, 2023, SDRC issued a Notice of Action to claimant advising it was denying his "request to use Self-Determination Program Individual Budget funds to purchase a biofeedback machine." (The Notice of Action also denied claimant's request to fund hyperbaric oxygen therapy sessions, which claimant did not appeal). In support of its decision, SDRC stated: "After review of the drafted Self-Determination Program Spending Plan, the Clinical Department determined a biofeedback machine . . . [is not an intervention that is] evidence-based or empirically established for the improvement of Autism Spectrum Disorder." SDRC cited Welfare and Institutions Code section 4648, subdivisions (a)(16) and (a)(17), in support of its position.

3. On April 24, 2023, SDRC received claimant's Appeals Request setting forth the arguments in support of his request. Claimant asserted: Welfare and Institutions Code section 4648 "is faulty and also not in conformity with the Constitution"; Welfare and Institutions Code section 4648 is discriminative and violates his equal protection rights; SDRC improperly categorized the Oberon bio-resonance/biofeedback machine as a medical device; the Self-Determination Program funds acupuncture and chiropractic services which are not evidence-based or empirically established, and "biofeedback therapy falls under the same umbrella"; SDRC incorrectly concluded the biofeedback machine is experimental; and SDRC wrongly assumed biofeedback therapy "is not a general physician practice."

4. After receiving the Appeals Request, the matter was set for hearing.

Self-Determination Program

5. In 2013, the Legislature enacted Welfare and Institutions Code section 4685.8, requiring the Department of Developmental Services (DDS) to implement a statewide Self-Determination Program to provide individuals and their families with more freedom, control, and responsibility in choosing services and supports to help them meet objectives in their Individual Program Plan. DDS began pilot programs in certain regional centers, including SDRC, and oversaw statewide working groups from various regional centers and consumer groups to develop policies and procedures to implement the program.

6. Starting July 1, 2021, the Self-Determination Program was available to all eligible regional center consumers, who wished to use it. All regional center consumers now have the option to have their services delivered through the Self-Determination Program model or continue to receive services in the traditional model. With the Self-

Determination Program model, while participants have more choice over which services they receive and who delivers those services, participants also have more responsibility because they must manage their own budget resources with the assistance of a Financial Management Service and support from the regional centers. The regional centers must certify that the cost of the Self-Determination Program does not exceed the cost if claimant were to remain in the traditional service model.

7. After the budget is certified, the participant and regional center must develop a spending plan identifying the cost of each good, service, and support that will be purchased with regional center funds. Each item in the spending plan must relate to goals in the participant's IPP and be identified by a specific service code from a list of codes DDS publishes. A participant can annually transfer up to ten percent of the funds in any budget category to other budget categories without regional center approval. Transfers exceeding ten percent require regional center approval.

Claimant's Participation in the Self-Determination Program

8. Per his December 20, 2022, IPP Addendum, claimant began receiving "support with developing a Person Centered Plan to help facilitate exploration of [Self-Determination Program] and possible [Self-Determination Program] services that will meet his needs, through 12/2023."

9. On February 7, 2023, claimant's representative signed the Self-Determination Annual Individual Budget that SDRC's authorized representative certified on February 8, 2023. Claimant's budget was based on a "traditional services blueprint" identifying the type, amount, and cost of traditional services and supports SDRC expected to fund to meet his IPP goals if he remained in the traditional service

model. Claimant's budget identified 90 hours per quarter of respite services for a yearly total of $10,623.60, and a $200 yearly conference fee, for a total of $10,823.60.

10. Claimant's Spending Plan documented that $5,050 from claimant's budget would be used to purchase an Oberon biofeedback machine "to relieve anxiety and help reduce OCD behaviors." This proposed purchase is at issue in this matter.

Documents SDRC Offered Regarding Oberon Biofeedback

11. SDRC offered three documents it had reviewed as part of its decision-making process.

12. A document on Oberon Biofeedback letterhead, titled "Biofeedback," contained a section labeled "How Does Biofeedback Work?" which stated in part:

> Each organ, tissue, and cell in our body has a distinct frequency which is made possible by the rotation of atoms in the cells. When instructions are sent to the body from the brain they use the spinal cord to send those instructions using nerves and other molecular aids. As long as the connection between the brain and the spine is intact, biofeedback systems can use the brain to listen in and pick up the information. Bio-electrical activity of brain neurons is amplified so signals which are practically undetectable by statistical fluctuations, can not only be detected but also isolated and decoded thanks to biofeedback therapy systems.

> Good biofeedback systems, like Oberon, can trace the changes in pathology and infections by observing the characteristics of these wavelengths and the changes in the tissues and cells of the body. This utilization of frequency analysis is based on this incredible discovery in natural science which allows us to analyze the magnetic vortex of any biological object. Biofeedback was designed to not only help laypeople with pain but to enable people to identify the specific biological problem in order to address it with natural Biofeedback therapy.
>
> Biofeedback scanning of organs and tissues is not all that modern biofeedback systems are designed to do. That same theory which was proven by natural scientists applies to therapy. Biofeedback therapy frequencies which are detected by the system can be reversed and sent back to balance out the tissues and bring them back to health. INCREDIBLE! This is how biofeedback works and it's available to everyone! Everyone who is open-minded enough to realize that traditional information is good and as the vast subject of science continues to improve [*sic*].

The Oberon document explained that "bioresonance is a phenomenon whereby all living organisms and their components emit measurable electromagnetic waves, the frequency of which is dependent on their physiological state." Oberon's machines "have sophisticated technology to provide and supplement bioresonance energy externally and thus bringing the tissues to normal healthy levels. This then allows the

cells, tissues, organs, and body to heal and recover to a normal healthy state." The document stated further that "[b]iofeedback technology can take care of pain not only without harm to our organs or body tissues but also improving them while getting rid of pain!" Biofeedback therapy is noninvasive and "uses the brain and central nervous system to apply the therapeutic frequencies to the person VIA Bio-resonance headset [*sic*]." Further:

> Oberon consists of a database which houses all frequencies of pathogens, microorganisms, and healthy tissue as well. When we give biofeedback therapy, we apply the appropriate frequencies to the organ and tissues for recover [*sic*] or destructive frequencies to the harmful microorganisms occupying vital organs. Besides for specific therapy for organs, pain or microorganisms, there are frequencies of therapeutic plants, stones and light frequencies which provide options for therapy and method.

13. A February 2016 article written by Julian Kenyon, M.D., M.B., Ch.B. Medical Director (acronyms not explained), titled "The Dove Clinic for Integrated Medicine, The Oberon Device," stated the Oberon device "is a spinoff from the Russian space programme that was developed at the Department of Medicine, University of Omsk, Siberia." Dr. Kenyon wrote:

> The device is an unusual biomedical device outside of the current medical paradigm. It is based on 20 years of basic research done by a number of Russian teams who worked out, on normal individuals, patterns of frequency responses that correspond to particular organs. Also, they were able to

> work out what the normal frequency response would be for any particular age of either male or female subjects of each organ.
>
> [¶] . . . [¶]
>
> The device involves sitting in front of a receiver with headphones on the head. The relevant frequency patterns are projected through the headphones (these are inaudible as they are well above the audible frequency range). The sensor channels the information which comes off the test subject as a result of having the resonant frequencies passed through the headphones to a computer based device and the readings are shown. Then, relevant medications, which have also had their frequency response determined using the same methods, is [*sic*] titrated against the reading found and as a result, the patient goes away with an optimal set of medications which are most likely to help their current condition. Therefore, from a practical point of view, this is a method of determining ideal medication and is not fundamentally a diagnostic device.

Dr. Kenyon referenced "a range of recent research projects being carried out around the world," including his own, studying the "idea of frequency response being relevant in medicine." He described studies for the treatment of cancer but did not cite to any involving the treatment of autism, OCD, incontinence, anxiety or depression.

14. Dr. Kenyon also authored a February 2016 article titled "A Non-Controlled Open Observational Study of the Oberon Device as an Aid to Functional Status and Treatment in Randomly Presenting Patients with known Pathology" in which he wrote:

> The Oberon Device is a Russian system which measures the magnetic vector potential as an aid to functional status and the treatment of patients. Functional status, [*sic*] relates much more to how traditional Chinese medicine looks at organ function than conventional medicine concepts.

Dr. Kenyon wrote that the Oberon Device was tested on "200 patients who randomly presented with known pathologies," the purpose of which was to "assess and compare the performance of the Oberon practical as an aid to functional changes best summarized by traditional Chinese medicine view of organ function, by correlation with patients know [*sic*] pathology." Dr. Kenyon listed the conditions assessed, none of which were autism, incontinence, anxiety, depression or OCD. Of the 200 patients tested, 170 had "a correlated response to areas of known pathology and areas on dysfunction as shown on the Oberon system" for "an 85% positive response rate." His conclusion was:

> The Oberon system is a useful means of assessing function in terms of how traditional Chinese medicine looks at function and is therefore not a diagnostic device. Further appropriate investigations in order to find the cause of pathological findings are needed as one would do in any medical situation.

15. There was no showing that the Oberon document or Dr. Kenyon's two articles are reliable authorities for purposes of giving the writings any weight regarding the medical value of the Oberon device (Evid. Code, § 721), that the methods or devices referenced in the documents are generally used and relied upon by DDS, regional centers, or other individuals who work with or treat individuals with developmental disabilities (Evid. Code, § 1340), or that these methods and devices are generally accepted as reliable in the scientific community (*People v. Kelly* (1976) 17 Cal.3d 24, 30; *Frye v. United States* (D.C. Cir. 1923) 293 F. 1013, 1014). There was no showing that any of these documents or the studies Dr. Kenyon referenced had been peer-reviewed. The Oberon document appeared to be a promotional writing and Dr. Kenyon's articles were anecdotal commentary, none of which established that the Oberon device and methodology are not experimental.

SDRC Purchase of Services Standards

16. SDRC's Purchase of Services Standards sets forth the criteria to "be used when reviewing the needs of the person served during the team process to develop [IPPs] and Individual Family Service Plans (IFSP)." The Purchase of Services Standards sets forth the "Basic Service Standards" that apply to each funding request. As stated at subsection h), this requires that:

> the service, intervention, treatment or support is evidence-based and is not experimental, is not unproven or potentially harmful to the person, and does not employ potentially aversive behavior techniques [evidence-based services must be peer-reviewed and published in a reputable professional journal such as the Journal of the American Medical Association (JAMA)]

As stated in the section titled "Medical/Dental Services," "[m]edical and dental services are those services provided on an individual basis in order to improve and maintain health." When funding those services, SDRC is "prohibited from purchasing any experimental medical or nutritional therapy, therapeutic services or devices that have not been clinically determined or scientifically proven to be effective and safe."

Email Communications

17. Emails between the parties documented communications regarding claimant's request to use his Self-Determination Budget to fund biofeedback. The emails contained SDRC's investigation into the biofeedback machine as many of its employees were not familiar with the use of a biofeedback device to treat developmental disabilities. One email indicated claimant was the first person to make such a funding request and it was unknown if the device was evidence-based, so Jaime Barea, M.D., an SDRC medical consultant, and Rachel Vedder, Psy.D., an SDRC staff psychologist, were being consulted.

18. Dr. Vedder's February 13, 2023, email stated that "the majority of the studies are not able to empirically establish an improvement of [autism spectrum disorder] symptoms" and SDRC does "not have enough well established and peer-reviewed literature that indicates" biofeedback "is an intervention that is evidence-based."

19. Anna Keller, M.A., SDRC Participant Choice Specialist - Self-Determination Program, sent an email to claimant's SDRC service coordinator on February 14, 2023, advising that the biofeedback item is "not back [*sic*] by empirical science so [it] could not be funded in [the Self-Determination Program].

20. Loralee Bada, B.A., claimant's SDRC service coordinator, sent an email to claimant on February 15, 2023, advising that she had submitted claimant's spending plan to the Self-Determination Program team for review. "The feedback I received was that the [biofeedback machine] in the spending plan [is] not backed by empirical science, therefore could not be funded in [the Self-Determination Program]." Ms. Bada included Dr. Vedder's comments, noted above, in her email.

21. Claimant's mother's response to Ms. Bada's email stated "[i]t doesn't make sense that a horse riding therapy and camping are acknowledged as autism treatment while neurofeedback therapy . . . [is] not, while I see so many parents in cases with successful results. If a desperate parent has done thorough research on what's best for her son, it should be respected as well." Claimant's mother's response stated further, as written in the original:

> If All they follow is just "National Clearinghouse on Autism Evidence and Practice", then [Self-Determination Program] teams own approach should be reassessed. That is a big dogma! All things I request are evidence-based but if evidence comes from parents, they disregard them.
>
> Their statement "not backed by empirical evidence" is not explained by themselves. And this treatment is false by itself too. They are not diligent enough to find empirical science behind those. From what source they concluded this statement and how many minutes they spent to look for neurofeedback's empirical science . . . and what did they find in detail to back this statement?

If they talk just like a traditional Dr, why they started [Self-Determination Program] at all?

22. The emails demonstrated that SDRC researched and evaluated claimant's request for a biofeedback machine, and concluded it could not be funded because there was no empirical evidence to support its use for claimant. Although claimant's last email demonstrated he disagreed with SDRC's determination, nothing in those emails supported claimant's contention, as set out in his Appeals Request and as testified to here, that SDRC had discriminated against him.

Client ID Case Notes (Title 19 Notes)

23. Case notes in claimant's file, commonly referred to as Title 19 notes, documented discussions regarding Self-Determination Program services, including the fact that all purchases must be evidence-based. The case notes also documented various information provided to claimant regarding the Self-Determination Program and his participation in required meetings. The notes contained SDRC's investigation and communications regarding claimant's request for a biofeedback machine, and that claimant was given information regarding the appeals process when he disagreed with SDRC's position. Other notes documented the reminders given to claimant of the applicable deadlines to appeal the Notice of Action. Nothing in the case notes supported claimant's allegation of discrimination.

Claimant's Documents Introduced at Hearing

24. Claimant submitted a number of documents to support his position: January 18, 2023, notes from a "First session" with a licensed marriage and family therapist, documented claimant's mother's report regarding claimant's behaviors, his difficulties expressing his thoughts and feelings, and her concerns. The clinician

advised he would consult for resources that can be helpful and he "explored on [SDRC] services to consult for behavior modification." Claimant's mother was "willing to obtain help with external providers." Nothing in this document refuted SDRC's determination.

25. An April 14, 2023, letter from Kaiser Permanente advised claimant that his request for an Oberon biofeedback machine was denied because it was excluded from his coverage. The letter explained:

> According to [claimant's] 2023 Kaiser Permanente Southern California Federal Brochure, under section "5a. - Durable Medical Equipment (DME)" it states that Durable Medical Equipment (DME) is equipment that is prescribed by a Plan physician, obtained through sources designated by the Plan and consistent with our Plan DME formulary guidelines. Biofeedback machines . . . are excluded from DME coverage.

Nothing in this letter refuted SDRC's determination.

26. An April 22, 2023, letter from Kaiser Permanente advised claimant that his request for applied behavioral analysis therapy was denied. The letter explained the basis for the denial. Nothing in this letter refuted SDRC's determination.

27. An excerpt from a book from a class claimant's mother took, titled "Legal Guidelines For Unlicensed Practitioner," noted that the definition of medical device, "found in Section 201(h) of the Federal Food, Drug, and Cosmetic Act" is "a very broad definition. It basically says a medical device is 'any instrument, machine, contrivance, implant, in vitro reagent that's intended to treat, cure, prevent, mitigate, diagnose disease in man.'" Another excerpt from the book advised that "words to avoid" include those reserved for licensed practitioners such as "cure, diagnose, prescribe, treat and

possibly even the word disease." The book suggested that instead of "cure" other words to use were "restore, help, improve, correct, balance or normalize." Instead of "treatment" use "handle, work with, relieve, balance, normalize, or correct."

There was no showing that this book was a reliable authority or generally accepted in the medical field, and nothing from these excerpts refuted SDRC's determination.

28. A document titled "Self-Determination Program Service Definitions," contained definitions for acupuncture services and chiropractic services. The document indicated that the services are only provided to individuals ages 21 and over and only used to treat pain. Nothing in the document refuted SDRC's determination. In fact, the document supported the testimony offered by SDRC's witnesses, noted below.

29. A Certificate of Conformance for the European Union, dated May 18, 2022, certified that the Oberon Biofeedback/Biosensing Device Model 10 complied with the Protection Requirements of the EMC Directive 2014/30/EU. Nothing in this document contradicted SDRC's determination.

30. Claimant introduced an unsigned and undated document purportedly prepared by Nidia Alduncin, M.D., John Richards Developmental Clinic, Kaiser Permanente. Claimant's mother testified that Dr. Alduncin could not sign the document but supported claimant's request. The document raised several concerns. It was not on Kaiser Permanente letterhead, the typeface of the doctor's letter was the same as the typeface of claimant's mother's "P.S." written at the bottom, and the letter seemed to be merely a summary of conversations with claimant's physicians. Moreover, the statements attributed to Dr. Alduncin supported SDRC's position:

> I do want to help [claimant] but I'm sorry I can not sing [*sic*] that letter as this treatment has not had enough scientific evidence for us to recommend for Autism as a treatment. This does not mean that they do not work or are not safe. It just means that researchers do not have enough information to know for sure.

The P.S. at the bottom of the document stated:

> [Claimant's] primary pediatrician [another physician's name] verbally told me she might consider Oberon for [claimant]. Although she cannot put it in a written form. As many people know, the USA law did take lots of doctors' licenses away because of recommending non-conventional modality. Therefore, these 2 doctors are actually endorsing Oberon for [claimant], just don't want to take any risks to keep themselves safe.

31. Four Facebook posts from two individuals who used the Oberon device with four autistic individuals described the successes of that use. These posts did not constitute reliable authorities or establish that the device is generally accepted.

32. Richard E. Fox, M.D., claimant's homeopathic and naturopathic doctor, wrote a letter dated April 20, 2023 to "give some information of what I think of the [Oberon] bioresonance+biofeedback machine." He explained that the device "is actually a MORA therapy machine. The MORA therapy is a holistic diagnosis and treatment principle with inherent patient oscillations" developed in 1977. The acronym MORA is derived from the first letters in the last names of the two men who developed

the therapy. Dr. Fox described how the therapy worked and that it has "been corroborated by modern research in the field of bioelectromagnetism." He wrote that "years of research by renowned scientists have determined and verified that every human being has an individual oscillation spectrum that can be used therapeutically." Dr. Fox wrote further, as written in original:

> And bioresonance therapy IS evidence based and established for autism because of the following facts:
>
> 1. Depression and incontinence are two of [claimant's] symptoms which belong to autism spectrum symptomology.
>
> 2. NCBI - the National Center for biotechnology information, is part of the United States national library of medicine, (NLM), a branch of the national Institute of Health(NIH), NCBI is approved and funded by the government of USA. Thus pubmed.ncbi.nlm.gov is a credible website.
>
> 3. If you go to NCBI website and search with the number "34104247" or number "35251330", you will find published evidence that proved bioresonance therapy can improve depression effectively without side effects or risks.
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> 4. If you search with number "20243911", you will find evidence that proved biofeedback's effectiveness on improving urinary incontinence.

> Therefore it is evidence-based and empirically established that bio-resonance and biofeedback are safe and effective modality for the improvement of [autism spectrum disorder] without risks or side effects.
>
> NASA(National Aeronautics and Space Administration) owns state-of-the-art technologically advanced and sophisticated electromagnetic equipment. NASA has invested a lot of money into the research on the therapeutic use of electromagnetic waves. They are using it for space travelers as a full body scanning tool, as well as a therapeutic tool.
>
> Compared to the Western world, the Russian experience is extensive; it is estimated that over 7 million treatments have been given, it is used in both civil and military settings, and the Russian Army even uses it as a treatment for alcoholism. The head of the Russian government agency FASIE said recently 'Only someone very lazy does not develop or use bioenergetic for different purposes - medicine, agricultural, etc.'

Dr. Fox referenced a physician in North San Diego County practicing bioresonance therapy, "as wells thousands of medical doctors and practitioners all over the world." He noted the Oberon device only requires the patient wear a "headphone looking scanner" which would work for claimant since he "is too sensitive to things touching his abdomen area." Dr. Fox concluded: "Since Kaiser denied ABA

therapy and psychotherapy to help my patient [claimant], I agree with above alternative medicine approach."

Dr. Fox did not testify in this hearing, nor were any of the studies he referenced introduced. It was also not shown that those studies had been peer-reviewed or that their purported findings were generally accepted.

SDRC Witness Testimony

33. Zachary Guzik is an SDRC Manager of Client Services for Children and Adolescent Services, a unit serving clients ages 6 to 22. Mr. Guzik oversees a team of eight managers, including the manager of claimant's case. He has a master's degree in special education and previously taught transition classes in New York City before coming to SDRC in February 2022. He explained that claimant's request was denied because, after researching and evaluating the request, SDRC determined that a biofeedback machine is not evidence-based, there is no evidence it would ameliorate claimant's developmental disability, and there are standards which govern what regional centers can and cannot pay for with their funds.

Mr. Guzik further explained that SDRC must also receive a denial from claimant's insurer that it will not fund the requested device, but none was received. However, during her testimony, which took place after Mr. Guzik testified, claimant's mother produced the Kaiser insurance denials referenced above, so it appears claimant has now met that requirement. But, this did not change SDRC's position because there was still no evidence that the device was evidence-based.

34. David Webb-Rex is an SDRC Program Manager in the Self-Determination Program. He has a bachelor's degree in elementary education, a California education specialist credential, and taught special education before coming to SDRC in 2021. He

testified that the Self-Determination Program is a service-delivery model for receiving services. The program consists of two governing documents, the Individual Budget which is based on the funds an individual would have received under the traditional model of delivering services, and the Spending Plan which is how the individual would like to spend those funds. Mr. Webb-Rex testified that in the Medicaid waiver for self-directed services, the purchase cannot be experimental nor can it be non-evidence-based. The biofeedback machine was considered experimental which is why the request was denied.

During his rebuttal testimony, Mr. Web-Rex was asked to respond to claimant's contention that biofeedback should be funded because acupuncture and chiropractic services are funded, which are similar services. Mr. Webb-Rex explained that the acupuncture and chiropractic services that are funded are provided to individuals ages 21 and older to alleviate pain. Those services are approved through the "1915(c) Medicaid waiver" because they are provided for a specific evidence-based purpose, pain relief, which is distinct from claimant's biofeedback request.

35. Jaime Barea, M.D., has been an SDRC medical consultant since 2020. He is board certified in both pediatrics and clinical genetics. Dr. Barea explained that when he gets a request for the purchase of a device with which he is not familiar, such as the biofeedback machine requested here, he researches medical websites. He searched the site "Up To Date," a medical evidence-based support tool used by physicians. He could find nothing on that site indicating that the device requested here was evidence-based. He then looked at the "PubMed" website, one that most individuals use, which is a live database of all peer-reviewed articles. On that site he searched biofeedback and autism, and could find nothing to show it was a proven treatment. With all of his

research, he could find nothing to indicate the requested device was proven to be effective to treat individuals with developmental disabilities.

During his rebuttal testimony, Dr. Brea was asked to respond to claimant's contention about funding acupuncture. He explained that acupuncture is funded for very specific purposes where studies have proven it is effective to treat the condition. As with the biofeedback machine at issue here, acupuncture is not funded for other conditions where it has not been proven effective.

36. Rachel Vedder, Psy.D., is an SDRC staff psychologist. She has a Bachelor of Science in biology and psychology, a Master of Science in experimental psychology, a Master of Arts in clinical psychology, and a Doctorate of Psychology in clinical psychology. She is the Coordinator of Psychological Services at SDRC, and her duties include consultations, eligibility reviews, and overseeing all psychological testing. When she receives a request for funding something with which she is not familiar, she performs research. In this case, she looked at peer-reviewed sources, the "PubMed" website, and all sources she could find. She could find no literature that met the peer review standard. There were a few articles that were self-published data, but those did not meet the peer review standard.

Dr. Vedder then reviewed publications from two autism organizations that have been compiling a list of evidence-based practices for decades. Those organizations and the documents she reviewed were the National Autistic Centers - 2015 National Standards Report, and the National Clearinghouse on Autism Evidence and Practices - 2020 Evidence-Based Practices for Children, Youth and Young Adults with Autism. The Oberon biofeedback machine was not listed on either site as a device that ameliorates autism or developmental disabilities. Based on all of her research, Dr. Vedder could not find any evidence that supported the use of this machine. She also testified that Dr.

Kenyon's articles were self-published and contained anecdotal evidence. Her research revealed that he lost his license for a period of time because he was not meeting accepted standards.

During her rebuttal testimony, Dr. Vedder was asked to respond to claimant's assertions regarding biofeedback. Dr. Vedder testified that claimant's mother's testimony, detailed below, did not change her opinions. Dr. Vedder stated that biofeedback has been approved for use, but not for home use. It is used by well-trained practitioners. Her research showed the Oberon device is for home use, and it is not a biofeedback machine when compared with approved biofeedback machines.

Claimant's Mother's Testimony

37. Claimant's mother reiterated and expanded on the points raised in her Appeals Request. She also submitted documents which are summarized above and claimed SDRC acted like it did not hear her. She believes the Welfare and Institutions Code section relied upon by SDRC is unconstitutional because it discriminates against holistic medicine, which violates claimant's equal protection and due process rights. She also believes her son may have been discriminated against because he is black.

Claimant's mother has heard from individuals who practice natural or homeopathic medicine of how it cures their condition; she does not hear from individuals that traditional medicine cures their condition. There are many physicians in both the United States and Europe who sacrifice the loss of their licenses just for pursuing the truth. They are curing their patients and making a difference. They are proud to lose their licenses because alternative medicine works, it is better and safe.

Claimant's mother testified she was told by SDRC that for non-medical therapy, SDRC does not consider whether it is evidence-based or effective, but must consider

that for medical therapy. Claimant's mother also asserted the Oberon device was not a medical device, citing the federal law's definition of medical device which is referenced above. In her holistic medicine studies, she has learned there is terminology reserved for licensed practitioners that non-licensed practitioners may not use. Oberon has never claimed the device is a medical device or that it will diagnose, treat, cure, or prescribe to individuals. The Oberon device is also not nutritional therapy because no supplements are given from machine. She disputed SDRC's determination because it was based on the assumption the Oberon device is a medical device when it is not, so the device does not have to be evidence-based.

Claimant's mother testified that acupuncture and chiropractic services are funded, which are not evidence-based. She claimed those services are not scientifically proven to treat autism, yet they are funded, but biofeedback is not. As such, SDRC discriminates against holistic medicine which is just as serious as discriminating against the LGBTQ community because they, like holistic practitioners, "do not have conventional thoughts."

Claimant's mother also disputed SDRC's position regarding publications about the Oberon device. She said there are credible websites that have published information regarding biofeedback machines. She referenced Dr. Fox's report citing to those websites which prove biofeedback is an effective modality. There are physicians practicing biofeedback, one who is in North San Diego County, and using Google, other physicians practicing biofeedback can be located.

In her rebuttal testimony, claimant's mother refuted the assertion that the Oberon device was not a true biofeedback machine. Biofeedback machines and the Oberon device are both machines and both received feedback from the organism. Biofeedback has been used by NASA and is based on therapy developed in 1977.

LEGAL CONCLUSIONS

Purpose of the Lanterman Act

1. The purpose of the Lanterman Developmental Disabilities Act (Lanterman Act) is to provide a "pattern of facilities and services . . . sufficiently complete to meet the needs of each person with developmental disabilities, regardless of age or degree of handicap, and at each stage of life." (Welf. & Inst. Code § 4501; *Association of Retarded Citizens v. Department of Developmental Services* (1985) 38 Cal.3d 384, 388.)

Burden and Standard of Proof

2. Each party asserting a claim or defense has the burden of proof for establishing the facts essential to that specific claim or defense. (Evid. Code, §§ 110, 115, 500; *McCoy v. Bd. of Retirement* (1986) 183 Cal.App.3d 1044, 1051, footnote 5.) In this case, claimant bears the burden to prove SDRC should fund the service he seeks.

3. The standard by which each party must prove those matters is the "preponderance of the evidence" standard. (Evid. Code, § 115.)

4. A preponderance of the evidence means that the evidence on one side outweighs or is more than the evidence on the other side, not necessarily in number of witnesses or quantity, but in its persuasive effect on those to whom it is addressed. It is "evidence that has more convincing force than that opposed to it." (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1567.)

The Lanterman Act, DDS, and Regional Centers

5. The Lanterman Act is found at Welfare and Institutions Code section 4500 et seq.

6. Welfare and Institutions Code section 4501 sets forth the state's responsibility and duties.

7. Welfare and Institutions Code section 4512 defines services and supports.

8. DDS is the state agency responsible for carrying out the laws related to the care, custody and treatment of individuals with developmental disabilities under the Lanterman Act. (Welf. & Inst. Code, § 4416.) In order to comply with its statutory mandate, DDS contracts with private non-profit community agencies, known as "regional centers," to provide the developmentally disabled with "access to the services and supports best suited to them throughout their lifetime." (Welf. & Inst. Code, § 4620.)

9. A regional center's responsibilities to its consumers are set forth in Welfare and Institutions Code sections 4640-4659.2.

10. Welfare and Institutions Code section 4646 requires that the IPP and the provision of services and supports be centered on the individual and family of the individual with developmental disabilities and take into account the needs and preferences of the individual and the family. The provision of services must be effective in meeting the IPP goals, reflect the preferences and choices of the consumer, and be a cost-effective use of public resources.

11. Welfare and Institutions Code section 4646.4, subdivision (a), requires regional centers to establish an internal process to ensure adherence with federal and state laws and regulations, and when purchasing services and supports, regional centers must conform to the purchase of service policies, utilize generic resources and other sources of funding, consider the family's responsibility, and consider information regarding the individual's need for service, barrier to access, and other information.

12. Welfare and Institutions Code section 4648 requires regional centers to ensure that services and supports assist individuals with developmental disabilities in achieving the greatest self-sufficiency possible. Regional centers must secure services and supports that meet the needs of the consumer, as determined by the IPP. Regional centers must be fiscally responsible and may purchase services or supports through vendorization or contracting. Subdivision (a)(17) prohibits regional centers from purchasing:

> experimental treatments, therapeutic services, or devices that have not been clinically determined or scientifically proven to be effective or safe or for which risks and complications are unknown. Experimental treatments or therapeutic services include experimental medical or nutritional therapy when the use of the product for that purpose is not a general physician practice.

13. Welfare and Institutions Code section 4659 requires regional centers to pursue all possible sources of funding for clients, and prohibits regional centers from purchasing services available from generic resources.

Self-Determination Laws

14. Welfare and Institutions Code section 4685.8 requires DDS to implement a voluntary statewide Self-Determination Program available in every regional center catchment area. The Self-Determination Program provides participants and their families, within an individual budget, increased flexibility and choice, and greater control over decisions, resources, and needed and desired services and supports to implement their IPP.

15. The Self-Determination Program is designed to give the participant increased control over which services and supports best meet the participant's needs and IPP objectives. (Welf. & Inst. Code, § 4685.8, subd. (b)(2)(B).) One goal of the Self-Determination Program is to allow participants to innovate to achieve their goals more effectively. (Welf. & Inst. Code, § 4685.8, subd. (b)(2)(G).)

16. The Self-Determination Program requires a regional center, when developing the individual budget, to determine the services, supports and goods necessary for each consumer based on the needs and preferences of the consumer, and when appropriate the consumer's family, and the effectiveness and cost effectiveness of each option in meeting the goals specified in the IPP. (Welf. & Inst. Code, § 4685.8, subd. (b)(2)(H)(i).)

17. "Individual Budget" means the amount of regional center purchase of service funding available to the participant to purchase services and supports necessary to implement the IPP. (Welf. & Inst. Code, § 4685.8, subd. (c)(3).)

18. "Spending Plan" means the plan the participant develops to use the available individual budget funds to purchase goods, services, and supports necessary to implement the IPP. The spending plan must identify the cost of each good, service, and support that will be purchased with regional center funds. The total amount of the spending plan cannot exceed the amount of the individual budget. A copy of the spending plan must be attached to the consumer's IPP. (Welf. & Inst. Code, § 4685.8, subd. (c)(7).)

19. The Self-Determination Program specifically requires the participant to "utilize the services and supports available within the Self-Determination Program only

when generic services and supports are not available." (Welf. & Inst. Code, § 4685.8, subd. (d)(3)(B).)

Analysis of Claimant's Constitutional Arguments

20. Claimant asserted that SDRC's denial of his request for a biofeedback machine violated his equal protection rights because he was similarly situated with other individuals with developmental disabilities but his request was denied because he sought holistic treatment. He alleged the law relied upon by SDRC was unconstitutional. His argument is denied for the following reasons.

21. DDS, SDRC, and OAH do not have the authority to declare a statute unconstitutional or unenforceable unless an appellate court has made that determination.

22. As Article III, section 3.5 of the California Constitution states:

> An administrative agency, including an administrative agency created by the Constitution or an initiative statute, has no power:
>
> (a) To declare a statute unenforceable, or refuse to enforce a statute, on the basis of it being unconstitutional unless an appellate court has made a determination that such statute is unconstitutional;
>
> (b) To declare a statute unconstitutional;
>
> (c) To declare a statute unenforceable, or to refuse to enforce a statute on the basis that federal law or federal

> regulations prohibit the enforcement of such statute unless an appellate court has made a determination that the enforcement of such statute is prohibited by federal law or federal regulations.

23. There was no showing an appellate court has declared the relevant provisions of the Welfare and Institutions Code at issue here unconstitutional. Accordingly, claimant's request those laws be declared unconstitutional exceeds the authority of DDS, SDRC, and OAH, and must be denied.

24. Even if these agencies were able to declare the laws unconstitutional, claimant failed to establish his rights had been violated. The threshold inquiry in assessing an equal protection claim is whether the law accords "disparate treatment" to similarly situated persons. (*People v. Guzman* (2005) 35 Cal. 4th 577, 584.)

25. There must be a showing that the state has adopted a classification that affects two or more similarly situated groups in an unequal manner. (*Cooley v. Superior Court* (2003) 29 Cal. 4th 228, 253–54.)

26. Different categories which provide different outcomes are permissible when the state has a valid reason for creating the categories. (*People v. Wutzke* (2002) 28 Cal. 4th 923, 942.)

27. Statutory classifications must be rationally related to reasonably conceivable legislative purposes. (*Doe v. Saenz* (2006) 140 Cal.App.4th 960, 992; *Newland v. Board of Governors* (1977) 19 Cal.3d 705, 712.)

28. The categories at issue here are experimental versus non-experimental services and supports. There is a legitimate reason to prohibit funding experimental

and unproven services given DDS's and SDRC's fiscal responsibilities. Allowing a regional center to fund such services or supports would be a misuse of resources. Requiring services and supports to be evidence-based and proven effective to treat the condition for which they are being sought is a sound way to spend public funds. Moreover, holistic therapies, that are evidence-based and non-experimental, such as acupuncture to treat pain, are funded, so claimant is not being denied because he seeks holistic treatment, his request was denied because it is experimental.

Given the requirements of the Lanterman Act, there is a valid reason to distinguish between experimental and non-experimental services and supports. There was no evidence that the use of an Oberon biofeedback device for claimant's condition was evidence-based or non-experimental. As such, SDRC's determination did not violate claimant's equal protection or due process rights.

Evaluation

29. Claimant failed to establish the Oberon device was a generally accepted method for treating individuals with a developmental disability, that its use was evidence-based, or that it was not experimental. SDRC may not use funds to purchase non-evidence-based or experimental devices. Whether the Oberon device is a medical or non-medical machine, SDRC cannot fund its purchase because the SDRC Purchase of Service Standards prohibit SDRC from purchasing any experimental "service, intervention, treatment or support." Claimant did not establish that his equal protection rights were violated or that he had been discriminated against.

Nothing corroborated claimant's claim that SDRC stated it could purchase experimental non-therapeutic devices, and that contention contradicted the clear language of the SDRC Purchase of Services Standards which SDRC relied upon in

reaching its determination. Claimant's assertion that SDRC incorrectly assumed the Oberon device is a medical device, when it is not, so it need not be evidence-based, was also not persuasive. The SDRC Purchase of Services Standards clearly require a "service, intervention, treatment or support" to be "evidence-based" and "not experimental." That mandate is not limited to medical devices in the SDRC Purchase of Services Standards. SDRC properly determined the device was a medical one since it was being requested "in order to improve and maintain [claimant's] health." Even assuming, arguendo, the device is not a medical device, it must still be non-experimental, and the Oberon device did not satisfy that requirement.

No persuasive evidence refuted SDRC's determination it may not fund the Oberon biofeedback device or compatible computer because the machine is a non-evidence-based, experimental treatment, therapeutic service, or device. On this record, claimant's request must be denied.

ORDER

San Diego Regional Center's denial of claimant's request to use his Self-Determination Program budget to purchase an Oberon bioresonance/biofeedback device and a compatible computer is affirmed. Those funds shall not be used to purchase that device or a compatible computer for the device.

DATE: June 26, 2023

MARY AGNES MATYSZEWSKI
Administrative Law Judge
Office of Administrative Hearings

State of California—Health and Human Services Agency
Department of Developmental Services
1215 O Street, Sacramento, CA 95814
www.dds.ca.gov

NANCY BARGMANN
DIRECTOR

GAVIN NEWSOM
GOVERNOR

July 19, 2023

Name and Address removed for privacy

On April 23, 2023, the Department of Developmental Services (Department) received your appeal submitted on behalf of [redacted] The Office of Administrative Hearings (OAH) issued a proposed hearing decision, OAH case number 2023050090, regarding your appeal on June 27, 2023

Welfare & Institutions Code section 4712.5, subdivision (e), gives the Department the authority to review proposed hearing decisions. **The Department has reviewed the proposed decision and adopts that decision as final.** A copy of the proposed decision is enclosed with this letter.

You may seek reconsideration of the final decision only for errors of fact or law, or for clerical errors, or regarding the decision of the hearing officer not to recuse themselves following a request pursuant to Welfare and Institutions Code Section 4712, subdivision (g). The Reconsideration process described in the information packet: https://www.dds.ca.gov/general/appeals-complaints-comments/fair-hearings-complaint-process/lanterman-act-appeals-information-packet/. The Form DS 1824 must be used to request reconsideration. It is within the "Appeal Forms" section of the Lanterman Act eligibility and services appeal process website: https://www.dds.ca.gov/wp-content/uploads/2023/04/DS-1824-English-.pdf.

A regional center also may request reconsideration of this final decision. As described in the information packet, if you or the regional center requests reconsideration, you or the regional center must inform the other party to the decision. The other party may file comments supporting or opposing the request. You may also appeal this final decision through the court system within 180 days.

A regional center is required to implement a final hearing decision within 30 days of the date of this letter. If it cannot, it must notify you and the Department in writing of the exceptional circumstance that makes it impossible to implement within that timeframe,

and the date it expects to be able to implement the decision. More information about this can be found in the "Delayed Implementation of Hearing Decisions Requirements" section of the Department's website: https://www.dds.ca.gov/general/appeals-complaints-comments/fair-hearings-complaint-process/ .

If you need help understanding this decision, the people who may help you are:

- Your service coordinator or other regional center staff, if you ask them.
- Your clients' rights advocate (CRA) at:
  - (800) 390-7032 for Northern California, or
  - (866) 833-6712 for Southern California, or
  - Find the clients' rights advocate at your regional center here.
- The Ombudsperson Offices at (877) 658-9731 or ombudsperson@dds.ca.gov,
- The State Council on Developmental Disabilities (SCDD).
  - To find your local SCDD office, select "Regional Offices" at the top of this webpage: www.scdd.ca.gov, and then choose your area.
  - You also can reach them at (833) 818-9886.
- Disability Rights California (DRC) at:
  - 1-800-776-5746
  - 1-800-719-5798 for TTY call
  - They are available Monday, Tuesday, Thursday, and Friday from 9:00AM – 3:00PM
  - You also can complete DRC's online intake form.
- You also may get help from a Family Resource Center: https://frcnca.org/get-connected/.
- Your regional center may help you find a local parent support group or community-based organization that can help you.

Sincerely,

Original signed by:

NANCY BARGMANN
Director

Enclosure

cc: See next page

cc: Neil Kramer, San Diego Regional Center
Bonnie Sebright, San Diego Regional Center
Susan Formaker, Office of Administrative Hearings
Tom Blythe, Department of Developmental Services
Sean Rashkis, Department of Developmental Services