1997 WL 33544217 (C.A.2) (Appellate Brief)
United States Court of Appeals,
Second Circuit

Concetta DESARIO and Betty Emerson, Individually and o/b/o all persons similarly situated,
Plaintiffs-Appellees,
Caroline Stevenson, Thomas Slekis, and Howard Wolan, Individually and o/b/o all persons similarly situated,
Intervenor-Plaintiffs-Appellees,
v.
Joyce A. THOMAS, Commissioner, Connecticut Department of Social Services, Defendant-Third-Party
Plaintiff-Appellant,
Donna Shalala, Commissioner, United States Department of Health and Human Services,
Third-Party-Defendant.

No. 97-6027.
May 13, 1997.

On Appeal from the United States District Court for the District of Connecticut

Brief of the Plaintiffs-Appellees and the Intervenor-Plaintiffs-Appellees

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*1 I. *STATEMENT OF THE CASE*

This Section 1983 class action challenges two policies of the defendant Commissioner of the Connecticut Department of

Social Services (hereinafter "DSS") which limit Medicaid coverage for items of durable medical equipment (hereinafter "DME") as violative of the federal Medicaid Act, 42 U.S.C. § 1396, *et*. *seq*., and the United States Constitution. The first policy, Connecticut Medical Assistance Provider Manual (hereinafter "MAP Manual") § 189.E.II.a., provides that only items of DME on the Commissioner's exclusive fee schedule for Medical Equipment, Devices, and Supplies (hereinafter "MEDS fee schedule") are covered by the Commissioner's Medicaid program. (Joint Appendix, hereinafter "A-", 35). The other policy, MAP Manual § 189.E.III.a., states that certain items of DME are specifically excluded from coverage under the Department's Medicaid program, including humidifiers, air purifiers, air conditioners, and electric stair glides. (A-36).

Each of the named plaintiffs submitted a request for prior approval of Medicaid coverage for equipment that either was not on the Commissioner's MEDS fee schedule or was specifically excluded from Medicaid coverage. Each plaintiffs request was denied by the Commissioner based on the challenged policies. On January 10, 1997, the district court preliminarily enjoined the Commissioner to reconsider her denials of Medicaid coverage for the equipment requested by the named plaintiffs without regard to the two challenged policies. The district court left it to the Commissioner to decide, on reconsideration, the medical necessity of the plaintiffs' requested items (based on updated medical evidence), whether the non-listed items are DME, and whether there were listed items which equally ***2** met their needs. (A-1757-60).[1] That injunctive relief was subsequently extended to the plaintiff classes on March 6, 1997. (A-1797).

A. *FACTS RELATING TO THE NAMED PLAINTIFFS*[2]

1. Concetta DeSario.

Plaintiff Concetta DeSario is a double-amputee who has Muscular Dystrophy and is quadriplegic except for minimal use of one wrist. (A-91). Although she is confined to lying constantly on her right side, on a bed or stretcher, she is fully mentally alert and continues to live in her own apartment. (*Id*.). Her physician prescribed a Quartet Simplicity Series Environmental Control Unit (hereinafter "ECU") for which Ms. DeSario sought Medicaid coverage. (*Id*.). The Commissioner denied her request under MAP Manual § 189.E.II.a. because no ECUs are included on the Commissioner's MEDS fee schedule. (A-92). Ms. DeSario requested an administrative fair hearing and the fair hearing officer upheld the denial based on MAP Manual § 189.E.II.a. (A-90-93).

***3** Although upholding the denial, the fair hearing officer found that the prescribed ECU is the only way Ms. DeSario can control her environment. (A-91). He found that a properly-functioning ECU[3] would enable Ms. DeSario to reposition her bed, make and receive telephone calls, turn lights on and off, open her apartment door, and control her heat and electricity (A-91-92). Without such an ECU, Ms. DeSario is completely dependent on outside assistance and at risk of medical harm from, *interalia*, being unable to reposition her bed when she has respiratory distress and being unable to use a telephone or open her door to obtain necessary medical help. (*Id*.).

Most significantly, the fair hearing officer found that, without a new ECU, Ms. DeSario is at risk of being placed in a long-term care facility. (A-92). Based on the specific findings of the Commissioner's fair hearing officer, in particular the risk of institutionaliza tion, the district court found "little question that Plaintiff DeSario is suffering irreparable injury from defendant's refusal to provide her with a new environmental control unit." (A 1721-22).

2. Thomas Slekis.

Plaintiff Slekis moved to intervene in the instant action on December 13, 1996 after being denied Medicaid coverage for a specialized mattress known as the RIK mattress under MAP Manual § 189.E.II.a because this mattress is not on the Commissioner's MEDS fee schedule. (A-607-611). He sought preliminary injunctive relief because he was threatened with the DME distributor's imminent removal of the mattress from his home. (A-612-614). ***4** Based on two days of testimony (A-679-1190) and the evidence introduced at the hearing (*see*, *e.g.*, A-1227, 1228, 1342), the district court found that Mr.

Slekis would suffer irreparable injury from the loss of this "uniquely efficacious" mattress. (A-1746).

Mr. Slekis has been paralyzed since a car accident in 1979. (A-713, 1741). He suffers from severe, recurring, skin breakdown, known as decubiti, for which he has been repeatedly hospitalized and subjected to surgery. (A-715, 1741). As a result of skin breakdown, approximately 15 to 20 "flap" surgeries have been performed on Mr. Slekis since 1985 (A-1018-19, 1741), and he is nearing the maximum number of such surgeries that can be performed on his body. (A-1024, 1741-2). The district court found that "Mr. Slekis is more prone to skin breakdown than many paraplegics due to his numerous flap surgeries, his prior history of skin breakdown, and his regular transfers from bed to wheelchair and back again." (A-1745). During a recent hospitalization in October, 1996, Mr. Slekis had flap surgery and his lower left leg had to be amputated due to severe skin deterioration. (A 1021-22, 1742).

Mr. Slekis' plastic surgeon, Dr. Richard Kostecki, prescribed a RIK mattress, following the October, 1996 hospitalization (A-1021-22), which was supplied to Mr. Slekis, at his home, by a DME distributor. (A-1744). The RIK mattress is filled with an oil-based liquid and covered with exceptionally-loose fitting sheets. (A-834-35). Mr. Slekis' doctor testified that the RIK mattress is more beneficial than any of the mattresses on the Commissioner's MEDS fee schedule in dealing with the problem of "shearing,"[4] which the ***5** doctor considers to be a major cause of Mr. Slekis' skin breakdown problems. (A-1010, 1014, 1030, 1032, 1043-44, 1132-33, 1135). Dr. Kostecki testified that significant improvement occurred with respect to pre-decubitus blemishes while Ms. Slekis was using the RIK mattress (A-1032, 1744), a fact which the Commissioner's own medical expert, Dr. Joel Deutch, testified was an "important finding." (A-1188). For these reasons, the district court credited Dr. Kostecki's testimony that, in his opinion, multiple future hospital admissions could be prevented by the use of a RIK mattress. (A-806, 1267, 1743).

3. Howard Wolan.

Plaintiff Howard Wolan moved to intervene in the instant action on November 26, 1996, after being denied Medicaid coverage for an augmentative communications device ("ACD") known as the Dynavox Communications Device which has been prescribed for him by his physician and speech and language pathologist. (A-582). As a result of cerebral palsy, Mr. Wolan has severe dysarthria of speech which renders his speech largely unintelligible (A-601). He also has quadriplegia and mental retardation and has a chronic esophageal condition which requires medical management and monitoring to prevent choking. (*Id*). The Commissioner denied coverage of the Dynavox because no ACDs are on her MEDS fee schedule. (A-602). Following the denial of his request, Mr. Wolan requested an administrative fair hearing. (A-602).[5] The Commissioner's denial was upheld pursuant to Conn. MAP Manual § 189.E.II.a. (A-602-606).

***6** Nevertheless, the fair hearing officer made the following factual finding with respect to the harm Mr. Wolan suffers daily as a result of his inability to communicate:

> [Mr Wolan]. . .has a chronic esophageal stenosis which requires constant monitoring and medical management. During these episodes, [Mr. Wolan] chokes. Due to discomfort related to this disability, [he] often screams and has been unable to effectively communicate his pain. Additionally, there are certain situations which make [him] nervous: when his wheelchair is tilted or his food is too hot. During these times, he has not been able to express himself successfully or in a timely fashion. Behavior programs and the augmentative modes currently in place have not eliminated [his] screaming. (A-601).

At the same time he renewed his motion to intervene, Mr. Wolan also sought preliminary injunctive relief. (A-566). On February 10, 1997, the parties filed a joint stipulation allowing Mr. Wolan to intervene in the instant action as a named plaintiff and to receive the same preliminary injunctive relief with respect to reconsideration of his request for coverage for the Dynavox as plaintiffs DeSario and Slekis received. (A-1792-96).

4. Betty Emerson.

Ms. Emerson is permanently disabled from Multiple Chemical Sensitivity ("MCS") for which she receives Social Security Disability Insurance benefits. (A-100-101). According to her physician, MCS renders Ms. Emerson "highly susceptible to severe reactions to air-borne environmental toxins". (A-102). Her physician prescribed an air conditioner and air purifier for her because "[s]uch reactions can only be prevented by the use of air conditioners and air purifiers which can remove these toxins." (A-102). The Commissioner denied Ms. Emerson's request because air conditioners and air purifiers are specifically excluded from coverage under MAP Manual § 189.E.III.a. (A-104). Ms. ***7** Emerson requested an administrative fair hearing. The fair hearing officer upheld the Commissioner's denial in accordance with § 189.E.III.a. (A-107).

Based on her doctor's prescription and his statements in support of that prescription, (A-100-102), the district court found that, "[i]f Ms. Emerson does not receive the relief that she seeks, she will exacerbate an already seriously disabling condition, potentially activating severe systemic reactions including respiratory distress." (A-1722).

5. Caroline Stevenson.

Like Ms. Emerson, Ms. Stevenson is permanently disabled from MCS for which condition she receives Social Security Disability Insurance Benefits. (A-273). According to her physician, it is essential for Ms. Stevenson to control exposures to airborne molds, pollutants, pesticides, scented products, and chemical cleaning agents. (A-273-75). For this reason, her physician has prescribed an air purifier and a humidifier. (A-273-75). As with Ms. Emerson's request, Ms. Stevenson's request for Medicaid coverage for these two items prescribed by her physician was denied by the Commissioner pursuant to § 189.E.III.a., which specifically excludes coverage for air purifiers and humidifiers. (A-279).

Ms. Stevenson requested a fair hearing and the fair hearing officer upheld the denial under § 189.E.III.a. (A-281). The district court found that, "[b]ased on the unrefuted medical evidence [A-268-82], Ms. Stevenson will suffer irreparable harm from the described multiple symptomology should the injunction not be granted". (A-1723).

8 B.** ***FACTS RELATING TO THE COMMISSIONER'S POLICIES ON MEDICAID COVERAGE FOR DURABLE MEDICAL EQUIPMENT.

The MEDS fee schedule in place at the time plaintiffs filed this action was effective June 1, 1993. (A-317-33). A new MEDS fee schedule subsequently became effective on June 1, 1996. (A-442, 1332-1338). At the hearing on May 20, 1996, Elizabeth Geary, Health Program Supervisor in the Medical Operations Division of DSS since 1988[6], testified that both the 1993 and 1996 MEDS fee schedules were developed solely by a handful of DSS employees, including Ms. Geary (A-443, 454), without input from any physician, including the medical doctor whom the Commissioner employs in Ms. Geary's building. (A-1174)[7].

Neither the 1993 nor the 1996 MEDS fee schedules were published or otherwise subject to any public comment before their effective dates. (A-442). The current MEDS fee schedule includes such equipment as walkers; canes; manual, power, and customized wheelchairs; wheelchair seats; hospital beds; specialized mattresses and mattress coverings; hearing aids; artificial larynx; and bathtub seats and transfer devices. (A-445-46, 1332-38). Ms. Geary testified that, while the Commissioner's objective in developing the fee schedule is to ". . .try to maintain very excellent standards of care, quality of care, and cost contain ment" (A-465-66), the Commissioner has no formal protocol by which she determines what items to include on her list. (A-953-56, 959).

***9** Only DME listed on the MEDS fee schedule is covered by the Commissioner under OSS' Medicaid program. (A-465,

1708-09). MAP Manual § 189.E.II.a. Also, certain items such as electric stair glides, air conditioners, humidifiers, and air purifiers, although identified as DME by MAP Manual § ISQ.E.III.a,, are specifically excluded from coverage by that policy. (A-460-62). Since this specific provision applies to the items sought by named plaintiffs Emerson and Stevenson and members of the "Emerson" class, and a specific provision controls over an arguably inconsistent general provision,[8] the general test for DME upon which the Commissioner relies, MAP Manual § 189.B.I., is not controlling as to these items; they must be considered to be excluded DME.[9]

Further, as the district court found, there are no "reasonably available procedures for either seeking either modifications or exceptions [to either of the challenged policies]." (A-1730). Ms. Geary testified that a fair hearing officer has no authority to grant coverage for DME which is not on the Commissioner's MEDS fee schedule no matter how great the recipient's medical need for an item may be and no matter how costly -- fiscally and emotionally -- the alternative may be. (A-465). The same is true for items specifically excluded under §189.E.III.a. A recipient seeking coverage for a non-listed or specifically-excluded item of DME can request an administrative exception from the Commissioner, but Ms. Geary could not remember any instance of an administrative exception having been ***10** granted to permit Medicaid coverage for such an item. (A-462). Moreover, as the district court observed (A-1727-28), recipients are not informed of the procedure for requesting an administrative exception. (A-466-67).

Ms. Geary testified that the MEDS fee schedule is not regularly updated. (A-438). Moreover, between June of 1993 and June of 1996, not one item of DME was added to the fee schedule. (A-444)[10]. Just as there are no procedures for public or outside professional comment on the MEDS fee schedule, before it becomes effective, there are likewise no procedures for the public -- whether an individual recipient, a physician, or a provider of DME -- to request that a newly-available, or previously-unconsidered, item of DME be added to the Commissioner's fee schedule. (A-1727). She conceded that there are items of DME which are not on the exclusive fee schedule. (A-456). However, she offered no evidence to the district court as to the nature of the items excluded.

Indeed, how an item "happen[s] to be covered" by the fee schedule (App. Br. at 39) is purely happenstance, as illustrated by the consideration given to the two items of equipment sought by plaintiffs DeSario and Slekis, respectively.[11] Neither of these items of ***11** equipment -- the Quartet Simplicity Series ECU or the RIK mattress -- was ever investigated by the Commissioner in connection with the development of the MEDS fee schedule.[12] In the case of the Quartet Simplicity Series ECU, Ms. Geary testified that she was aware of two requests for Medicaid coverage for this item, both by severely disabled recipients. (A-449-50). However, neither she nor any of the other DSS employees who developed the 1993 and 1996 fee schedules ever reviewed any literature on ECUs, or ever discussed the Quartet or other ECUs with any specialists in physical medicine, any specialists in the area of rehabilitation equipment, or with any medical societies. (A-447-50, 454-55, 459).

***12** The same lack of research was true of the RIK mattress. Notwithstanding a May, 1996 letter to Ms. Geary's unit from the distributor of the RIK mattress, offering literature on the RIK mattress and inviting DSS personnel to inspect the item and receive in-service training (A-928, 1262), DSS made no effort to research the product. (A-956). No one in Ms. Geary's unit ever responded to the distributor's letters, which advised her unit of Medicare coverage for the RIK mattress, or accepted the distributor's offer to allow an inspection of the equipment. (A-932). Ms. Geary defended her unit's lack of response by claiming that the distributor's information "wasn't adequate"[13] and, in the opinion of her unit's employees, the MEDS fee schedule already had a "variety of products to address this issue". (A-936, 943-44)[14] .

Without any follow-up on the distributor's invitation to consider the RIK mattress, Ms. Geary testified that a specific decision was made *not* to add the mattress to the 1996 MEDS fee schedule. (A-908). This "decision" was made in the absence of any consultation between Ms. Geary or her staff and the distributor of the RIK mattress about its product. ***13** More significantly, it was made in the absence of any consultation between DSS and *any* medical personnel. (A-940-41). This included the agency's own medical doctor whom the Commissioner called as a witness before the district court. (A-1174). Finally, it was made in the absence of any inquiries to any of the hospitals or nursing homes using the RIK mattress or to the private insurance companies which cover this product (A-949), which also was being paid for by the Connecticut Department of Mental Retardation. (A-882, 946).

II. *SUMMARY OF ARGUMENT*

The Commissioner's argument regarding the availability of administrative procedures to challenge the denial of Medicaid coverage for requested equipment and of state court procedures for the review of adverse administrative decisions, as constituting adequate alternative remedies at law, is irrelevant to the plaintiffs' request for injunctive relief in this action under 42 U.S.C. § 1983. The district court correctly treated the Commissioner's argument as an argument to abstain and correctly concluded that there is no legal ground for a district court to abstain in the absence of any ongoing state procedures, administrative or judicial.

The district court also correctly concluded that the doctrine of claim preclusion does not bar the entry of preliminary relief. Under *University of Tennessee v. Elliott*, 478 U.S. 788 (1986), only the factual findings of administrative hearing officers are binding on the federal courts in an action under 42 U.S.C. § 1983.

The district court correctly concluded that plaintiffs are likely to prevail on their claim that the challenged state policies are invalid under federal Medicaid law, 42 U.S.C. § 1396. *etseq*. No court has ever allowed a state Medicaid agency to exclude entirely an item or ***14** service falling within a covered category of Medicaid services when there was no equally effective alternative available under the Medicaid program for meeting the individual's medical need. The great weight of authority has construed the federal Medicaid statutes and regulations as barring such a categorical exclusion. The Commissioner's reliance upon the test of whether the needs of the Medicaid population as a whole are met by her exclusive list is misplaced, as that test has been applied only to "amount" or "duration" limitations pursuant to which the Medicaid recipients received *some* substantial quantity of a needed type of service.

Furthermore, the Commissioner's use of an exclusive fee schedule is in any event an unreasonable standard, prohibited by 42 U.S.C. § 1396a(a)(17), because her selection of which equipment to cover under Medicaid is arbitrary, and because she has no regular procedures for either updating the list or allowing recipients to petition for the addition of new items. The list was developed without any input from physicians knowledgeable about the types of equipment involved, and without consideration of the vast information available about the products which were excluded. The list has been updated only once since 1993, and has continued to exclude medically necessary DME which recipients and DME providers have repeatedly called to the Commissioner's attention.

The record fully supported the district court's entry of a class-wide preliminary injunction based on a risk of irreparable injury to the plaintiffs. With the exception of Thomas Slekis, as to whom the district court ordered his requested item to be provided after two days of hearings on the issue of his medical need, the medical need of the plaintiffs was not necessary to be established in order to establish their likelihood of success on the merits. ***15** With respect to all other class members, their medical need for the requested items sufficient to demonstrate irreparable injury absent injunctive relief is established based on the Commissioner's own requirement that any request for prior authorization be supported with a physician's prescription.

III. *ARGUMENT*

A. *THE DISTRICT COURT CORRECTLY HELD IT WAS NOT REQUIRED TO ABSTAIN FROM EXERCISING JURISDICTION OVER PLAINTIFFS' MOTION FOR INJUNCTIVE RELIEF DUE TO AVAILABLE BUT UNINITIATED STATE ADMINISTRATIVE AND JUDICIAL PROCEDURES*

The Commissioner argues that equity principles barred the granting of federal injunctive relief to the plaintiffs herein because each had an adequate alternative remedy at law. Specifically, the Commissioner argues that the availability of an administrative fair hearing procedure for plaintiff Slekis constituted an adequate remedy at law which precluded preliminary injunctive relief. (Appellant's Brief on Appeal, hereinafter "App.Br." at 12). Similarly, the Commissioner claims that the availability of state court procedures to review the unfavorable administrative fair hearing decisions received by plaintiffs

DeSario, Emerson, and Stevenson constituted adequate remedies at law for those plaintiffs. (App. Br. at 12-14). The Commissioner's argument must be rejected as a thinly-veiled attempt to overturn settled doctrines under 42 U.S.C. § 1983.

As the Commissioner concedes (App. Br. at 17), the United States Supreme Court has held that Section 1983 plaintiffs are not required to exhaust either administrative or judicial remedies before initiating a Section 1983 action. *Patsy v. Board of Regents*, 457 U.S. 496 (1982); *Monroe v. Pape*, 365 U.S. 167, 183 (1961), *overruled on other grounds*; *Monell v.* ***16** *Department of Social Services*, 436 U.S. 658 (1978). To hold that an available, but uninitiated, administrative procedure constituted an adequate remedy at law for Mr. Slekis would fly in the face of *Patsy*, which recognized that Congress enacted Section 1983 to provide immediate access to the federal courts by individuals alleging a violation of federal law or the federal constitution. *Id*. at 504. Indeed, even under traditional equity principles, the availability of a fair hearing could not possibly have been considered an "adequate" remedy for a disabled man faced with the imminent loss of medically-necessary equipment as a result of an arguably illegal policy which denies Medicaid coverage for such equipment. This is particularly true where, as here, that policy is *binding* on the hearing officer.

With respect to the other plaintiffs, who voluntarily initiated unsuccessful administrative proceedings, the availability of state judicial review proceedings did not constitute an adequate remedy at law. All of the cases cited by the Commissioner in support of this claim involved federal court injunctive relief with respect to on-going or threatened state criminal proceedings, *O'Shea v. Littleton*, 414 U.S. 488, 494 (1974); *Wallace v. Kern*, 520 F.2d 400, 407 (2d Cir.), *cert. denied*, 424 U.S. 912 (1975); *Potwora v. Dillon*, 386 F.2d 74, 77-78 (2d Cir. 1967), *or* state-threatened civil enforcement actions, *Morales v. Trans World Airlines*, 504 U.S. 374, 112 S.Ct. 2031, 2035 (1992). None of these cases hold that available, but unfiled, state procedures for judicial review of plaintiff-initiated administrative decisions constitute an adequate remedy at law barring the granting of injunctive relief to a Section 1983 plaintiff.

17** The district court correctly applied the abstention doctrine of *Younger v. Harris*, 401 U.S. 37 (1971), raised by the Commissioner below, in determining whether it should decline to exercise jurisdiction over plaintiffs' request for preliminary injunctive relief,[15] In *Younger v. Harris*, the Supreme Court held that principles of comity and federalism require a federal court to stay its jurisdictional hand with respect to any interference with *ongoing* state criminal proceedings. *Id*. at 44-45. This was extended to ongoing state civil enforcement proceedings in *Huffman v. Pursue. Ltd.*, 420 U.S. 592 (1975). *Younger* is premised, in part, on the Court's acknowledgment of the traditional equity doctrine that equity should not be permitted when the movant has an adequate remedy at law. 401 U.S. at 43-44. As the district court observed (A-1713), application of *Younger* abstention requires three affirmative findings by the court. There must be *on-going* state proceedings; there must be an important state interest implicated by the proceedings; *and* the plaintiff must have an avenue for state court review of constitutional claims. *Cecos Int'l. Inc. v. Jorling*, 895 F.2d 66, 70 (2d Cir. 1990). Because *no state proceedings* were pending when the named plaintiffs initiated this action, sought to intervene or were granted preliminary injunctive relief, the district court correctly concluded that *Younger* abstention was not appropriate. ***18SeePlanned Parenthood of Dutchess-Ulster. Inc. v. Steinhaus*, 60 F.3d 122, 126 (2d Cir. 1995)(holding that a district court has little discretion to abstain in a case which does not meet the clearly-delineated abstention principles).

The *Younger* doctrine has *never* been held to preclude the granting of federal injunctive relief, in a Section 1983 civil rights action, merely because the federal plaintiffs *could* have, but did *not*, initiate available administrative or state court procedures. In fact, federal courts have refused to abstain where the litigant initiated, but subsequently *withdrew*, a state court appeal of administrative action. *See* *Thomas v. Board of Medical Examiners*, 807 F.2d 453, 457 (5th Cir. 1987)(holding no abstention where state court appeal filed, but subsequently withdrawn), *seealso* *Bray v. New York Life Insurance*, 851 F.2d 60, 64 (2d Cir. 1988)(suggesting no preclusive effect if state judicial review withdrawn). Thus, the district court's decision not to stay its jurisdictional hand with respect to the plaintiffs' request for preliminary injunctive relief was legally correct.

B. *THE DISTRICT COURT CORRECTLY HELD THAT INJUNCTIVE RELIEF WAS NOT BARRED BY PRINCIPLES OF ADMINISTRATIVE RES JUDICATA*.

The Commissioner similarly argues that the district court was bound by the Commissioner's unreviewed administrative hearing decisions in the appeals of plaintiffs DeSario, Emerson, and Stevenson as a matter of administrative *resjudicata*. She argues that, because these plaintiffs did not avail themselves of the opportunity for state court review of their adverse decisions, their Section 1983 claims were barred before the district ***19** court.[16] (App.Br. at 17-20). The district court correctly held that, while preclusive effect must be given to the administrative fair hearing officer's *factual* findings, *University of Tennessee v. Elliott*, 478 U.S. 788, 799 (1986), that same preclusive effect does not apply to the hearing officer's legal conclusions simply because the plaintiffs did not appeal these decisions to state court. *See Huffman*, 420 U.S. at 609 n.21.

In *Elliott*, the Supreme Court held that preclusive effect must be given to agency *fact-finding* if the federal civil rights plaintiff had a full and fair opportunity to litigate the *factual* issues in the administrative forum:
[W]hen a state agency "acting in judicial capacity . . . resolves disputed issues of *fact* properly before it which the parties have had an adequate opportunity to litigate," federal courts must give the agency's *factfinding* the same preclusive effect to which it would be entitled in the State's courts.

478 U.S. at 799,*quoting United States v. Utah Construction & Mining Co*., 384 U.S. 394, 422 (1966)(citation omitted)(emphasis added). This Court has followed the majority of courts which have considered the scope of *Elliott*'s ruling and concluded that its holding on preclusive effect is limited to agency fact-finding and does *not* extend to legal conclusions. *See Bray*, 851 F.2d at 63; *Kirkland v. City of Peekskill*, 828 F.2d 104, 107 (2d Cir. 1987).[17]

***20** The Commissioner cites *Greenberg v. Board of Governors of the Federal Reserve System*, 968 F.2d 164 (2d Cir. 1992), suggesting that this Court has given preclusive effect to unreviewed agency factual determinations *and* legal conclusions in a Section 1983 civil rights action. *Greenberg* was not a Section 1983 action; rather, it was a federal administrative review under the Administrative Procedures Act of a decision by the Board of Governors of the Federal Reserve System barring the plaintiffs from any further participation in the affairs of any federally-supervised financial institution. *Greenberg* examined the preclusive effect of an earlier federal administrative determination on subsequent proceedings *by the same agency*. It did not examine the preclusive effect of a state administrative determination on a subsequent federal court Section 1983 civil rights action, and it did not even *discuss* the scope of *Elliott's* holding, let alone proceed to overrule this Court's previous decisions following the majority rule. The district court correctly concluded that *Greenberg* does not support the Commissioner's position.[18] (A-1716).

Even if this Court were to overrule its precedents and follow the minority view, reading *Elliott* as requiring that preclusive effect be given to an administrative agency's legal conclusions, under *Elliott*, preclusion only applies to matters as to which the parties were afforded a "full and fair opportunity to litigate" *in the administrative forum*. *See*, *e.g.*, ***21** *Eilrich v. Remas*, 839 F.2d 630, 631, 634 (9th Cir. 1988)(applying *res judicata* to legal conclusion of no first amendment violation where administrative hearing officer who was a retired state court judge was statutorily authorized to decide this question and where "the parties had adequate opportunity to litigate the first amendment issue" at 14-day hearing). As the district court observed, fair hearing officers in Connecticut are state employees who are not required to be attorneys. (A-1716-17, *citing*Conn. Gen. Stat. 4-166). "There is a 'profound difference between the ability to resolve matters of credibility and fact. . .and the ability to determine the more complex question[s]' of law under federal Medicaid law and the Constitution." (*Id*., *citing Edmundson*, 4 F.3d at 193).

Moreover, as DSS employee Elizabeth Geary admitted in her testimony, fair hearing officers are *bound* by the defendant's Medicaid policies, including the challenged policies at issue in this case. (A-457). They must apply the Commissioner's policies to the facts of the recipient's case. Thus, the fair hearing officers who heard the plaintiffs' administrative appeals had

no *authority* to examine, let alone strike down, the challenged policies as being inconsistent with federal Medicaid law or the Constitution. The plaintiffs clearly had no "full and fair opportunity" to litigate the alleged violation of federal Medicaid rules by those policies.

The Commissioner does not even attempt to argue that the plaintiffs had a full and fair opportunity to litigate his or her legal claims in the *administrative* forum. Rather, she argues, that plaintiffs *would have been* afforded a full and fair opportunity to litigate their ***22** claims in a state court appeal.[19] But the plaintiffs did *not* initiate any state court proceed ings, rendering irrelevant the ability of a state court to adjudicate plaintiffs' federal claims and related state preclusion rules. In *Bray*, 851 F.2d 60, the Court, while giving preclusive effect to a previous state determination, emphasized that, unlike in *Elliott*, the plaintiff in *Bray* sought judicial review in the state system:

Unfortunately for Bray, "[t]he crucial factor is that [she] chose to submit her case to the state *courts* for review." Once a plaintiff has entered the state court system, she is bound by the preclusion rules governing that system, and the federal courts in turn must respect the finality of the judgments that issue from the state court."

851 F.2d at 64 (citation omitted)(alteration in original).

Thus, the preclusive effect that the Connecticut courts apply to administrative decisions is not relevant in this § 1983 federal court action in which *none* of the plaintiffs sought any state court review of their adverse administrative hearing decisions. The only relevant rules of preclusion are those stated by the Supreme Court in *Elliott*, and by this Court in *Bray*, *i.e.*, whether the state administrative agency was acting in a judicial capacity, whether it properly resolved disputed issues of *fact*, whether the parties had a full and fair opportunity to litigate the factual issues, and, if *all* of these other requirements are met, whether the state courts would give the unreviewed *factual* Findings preclusive effect. *See* *Bray*, 851 F.2d at 63; *Kirkland*, 828 F.2d at 107. While the district court properly gave ***23** preclusive effect to the unreviewed factual findings of the plaintiffs' administrative decisions, as would the Connecticut courts, it correctly refused to be bound by the agency's legal conclusions.

Whether under the guise of equity principles, abstention, or claim preclusion, the Commissioner would have this Court effectively overrule *Patsy* and *Monroe* to deny relief to civil rights litigants who do not exhaust all available state administrative *and* judicial proceedings. Such a bar on virtually all access to the federal courts in Section 1983 actions would plainly conflict with congressional intent. *See* *Giellum v. City of Birmingham*, 829 F.2d 1056, 1065 (11th Cir. 1987); *Loudermill v. Cleveland Board of Education*, 721 F.2d 550, 555 (7th Cir. 1983), *aff'd* 470 U.S. 532 (1985). The district court properly refused to erect such roadblocks to the granting of appropriate injunctive relief to the plaintiffs.

C. *THE DISTRICT COURT CORRECTLY HELD THAT PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIM THAT THE COMMISSIONER'S RESTRICTIONS ON MEDICAID COVERAGE FOR DURABLE MEDICAL EQUIPMENT VIOLATE THE FEDERAL MEDICAID ACT.*

1. Connecticut's Medicaid Program Must Be Operated by the Commissioner in Accordance with Federal Medicaid Statutes and Regulations, Including With Respect to its Coverage of DME Which is Within the Covered Category of Home Health Services.

The Medicaid program, enacted in 1965 as Title XIX of the Social Security Act, 42 U.S.C. §§ 1396, *et seq.*, is a federal-state cost-sharing program that provides health care services to specified categories of individuals and families who would otherwise be unable to afford such services. States are not required to participate in the Medicaid program, but once they do, they must conform to federal law. *See****24***Detsel v. Sullivan*, 895 F.2d 58, 61 (2d Cir. 1990). The program is administered on the federal level by the Health Care Financing Administration ("HCFA"), which is an agency within the

United States Department of Health and Human Services ("HHS").

The Commissioner, as the state-level administrator of Connecticut's Medicaid program, is responsible for ensuring that this program complies with the federal Medicaid Act (hereinafter, the "Act"). *Wilder v. Virginia Hospital Assoc.*, 496 U.S. 498, 501 (1990). The Act provides federal funding for a broad array of mandatory and optional categories of Medicaid services under 42 U.S.C. §§ 1396, 1396a, and 1396d(a). The mandatory category of Medicaid service known as home health services must include, as "required services," *interalia*, "medical supplies, equipment, and appliances suitable for use in the home." 42 C.F.R. §§ 440.70(b)(3) and 441.15(a)(3).[20]

The Commissioner is free to choose which of the optional categories of services she will include in her Medicaid State Plan. But once she chooses an optional service, she is subject to all the same federal Medicaid requirements as apply to a mandatory category of services. *See* *Weaver v. Reagan*, 886 F.2d 194, 197 (8th Cir. 1989); *White v. Beal*, 555 F.2d 1146, 1150-51 (3d Cir. 1977); *Hunter v. Chiles*, 944 F.Supp. 914, 919 (S.D. Fla. 1996); *Visser v. Taylor*, 756 F.Supp. 501, 506 (D.Kan. 1990); *Simpson v. Wilson*, 480 F. Supp. 97, 102 (D.Vt. 1979).

Under federal Medicaid statutes and implementing regulations, medical care and ***25** services must be provided in a manner consistent with the "best interests" of the Medicaid recipient. 42 U.S.C. § 1396a(a)(19). The Commissioner must have "reasonable standards... for determining eligibility for and the extent of medical assistance," which are "consistent with the objectives of th[e Medicaid statutes]." 42 U.S.C. § 1396a(a)(17)(A). *See*42 C.F.R. § 440.230(b). The basic objectives of the Medicaid program, as stated in the federal Medicaid statute, are to "enabl[e] each State... to furnish... medical assistance on behalf of... [certain broad categories of individuals] whose income and resources are insufficient to meet the costs of *necessary medical services* and... rehabilitation and other services to help such families and individuals attain or retain capability for *independence and self-care*." 42 U.S.C. § 1396 (emphasis added). Thus, states may only place appropriate limits on a covered category of service based on criteria such as medical necessity or utilization control. 42 C.F.R. § 440.230(d). Even when such limits are imposed, the services provided within a covered category of services must be sufficient in amount, duration, and scope reasonably to achieve the purpose of such services. 42 C.F.R. § 440.230(b).

2. The Commissioner Cannot Justify the Use of an Immutable Exclusive Fee Schedule for Durable Medical Equipment as Being Within Her "Broad" Discretion Under the Medicaid Statute.

The Commissioner argues that she can limit Medicaid coverage to those items of DME which "happen to be covered" in her Department's exclusive fee schedule (App. Br. at 39). What the Commissioner does *not* assert is that her exclusive list is necessary to the administration of the Medicaid program; that it in fact saves money for the Medicaid ***26** program as a whole; that it is a common practice in other states;[21] that it is a practical means to weed out items that should not be approved because they are experimental or ineffective; that it is based on expert consideration of the choices available among products; or even that selections on the list have any rational basis. Lacking any basis for such factual assertions, she rests entirely on the argument that she has "wide discretion to determine the extent to which each category of service will be covered [under the state's Medicaid program]" based on her authority "to limit 'amount, scope, or duration' of each service covered by the state," *citing* 42 U.S.C. § 1396a(a)(10), 42 U.S.C. § 1396a(a)(17), and 42 C.F.R. § 440.230(b). (App. Br. at 25-26, 26-27). As discussed below, these provisions, as construed by the courts, do not give the Commissioner the power that she seeks to arrogate to herself. Indeed, to rule in her favor, this Court would effectively have to overrule virtually every Medicaid case decided in this area in the last twenty years.

a. The Great Weight of Judicial Authority Bars Exclusions of Medically Necessary Items and Services Within a Covered Category of Services if No Alternative Item or Service is Covered.

While the United States Supreme Court, in *Beal v. Doe*, 432 U.S. 438 (1977), stated ***27** that the language of the Medicaid Act affords States "broad discretion" in adopting standards for determining the extent of medical assistance to be provided by the State's Medicaid program, *id*. at 444, the Court *also* noted that this broad discretion is subject to the Congressional requirement that States have "reasonable standards. . .for determining. . .the extent of medical assistance under [their Medicaid] plan which. . .are consistent with the objectives of [Title XIX]." *Id*., *citing* 42 U.S.C. § 1396a(a)(17). The "amount, duration, and scope" requirement of the Medicaid regulations, 42 C.F.R. § 440.230(b), promulgated to implement that requirement, thus, is not an authorization for "wide discretion." Rather, it is a *limitation* on a state's discretion to restrict coverage for services within a mandatory or optional covered benefit category, intended to ensure that the medical assistance provided by a state comports with the "reasonable standards" requirement.[22] As discussed below, a State Medicaid plan which covers home health services for its entire Medicaid population, but categorically excludes all non-listed items of DME, cannot satisfy the requirement of this statutory provision.

Once a state chooses to participate in the Medicaid program, any restriction on the availability of Medicaid coverage for services within a covered category of services must be based on factors reasonably related either to the recipient's individual medical need or to ***28** utilization control. 42 U.S.C. § 440.230(d).[23] While the Court in *Seal v. Doe* held that States do not have to cover unnecessary medical services, the Court did not specifically address the issue of whether States must fund all medically-necessary procedures within a designated benefit category covered by a State's Medicaid plan. However, it noted that "serious statutory questions might be presented if a State Medicaid plan excluded necessary medical treatment from its coverage," given the objectives of the Medicaid Act. 432 U.S. at 444.[24]

Since *Beal*, most federal and state courts have held that a state's failure to provide Medicaid coverage for non-experimental medically-necessary services, within a designated coverage category, is *perse* unreasonable as inconsistent with the purposes and objectives of the Act. *See* *Hern v. Beye*, 57 F.3d 906, 911 (10th Cir.), *cert. denied*, ***29**___ U.S. ___, 116 S.Ct. 569 (I995)("[t]his circuit... interpreted Title XIX and its accompanying regulations as imposing a general obligation on states to fund those mandatory coverage services which are medically necessary"); *Dexter v. Kirschner*, 972 F.2d 1113, 1117 (9th Cir.), *superseded on unrelated matter*, 984 F.2d 979 (9th Cir. 1992)(participating States "must provide assistance to pay for *medicallynecessary* inpatient hospital and physician's services for eligible persons"); *Weaver*, 886 F.2d at 198 (AZT treatment for AIDS; a State must provide "treatment that is deemed 'medically necessary' in order to comport with the objectives of the Act"); *Meyers v. Reagan*, 776 F.2d 241, 243-44 (8th Cir. 1985)(electronic speech device; Medicaid agency's argument it has "discretion to choose what [DME] services will be covered" rejected); *Pinneke*, 623 F.2d at 548 & n.2 (sex reassignment surgery; "standard of medical necessity... has become judicially accepted"); *Hunter v. Chiles*, 944 F. Supp. 914, 919, 922 (S.D.Fla. 1996)("[o]nce a state chooses to cover one of the optional services which could possibly provide Medicaid funding for augmentative communication devices, that state is required to provide [them]," where medically necessary); *DeLuca v. Hammons*, 927 F. Supp. 132, 136 (S.D.N.Y. 1996)(amount of home care services); *Fred C. v. Texas Health and Human Services Commission*, 924 F. Supp. 788 (W.D.Tex. 1996)(augmentative communication device as DME and prosthetic device); *Visser v. Taylor*, 756 F. Supp. at 507 (psychiatric medication; "[a] State may not eliminate funds for medical services certified by a qualified physician as being medically necessary"); *Vogel v. Perales*, [1983-2 Transfer Binder] Medicare and Medicaid Guide (CCH), Para. 32,878, at 9401 (S.D.N.Y. May 11, 1983)(Addendum at 1-12)(list of prescription drugs invalidated); *Simpson v. Wilson*, 480 F. Supp. at 101 (treatment to correct visual refractive error; "federal regulations do not permit ***30** Vermont to decline to provide medically necessary services"); *McCoy v. State Department of Health & Welfare*, 127 Idaho 792, 907 P.2d 110, 112-13 (1995)(exclusion of medically necessary surgery to treat obesity held to be unreasonable and inconsistent with the objectives of the Act); *Jeneski v. Myers*, 209 Cal. Rptr. 178, 189, 163 Cal. App. 3d 18 (Ct. App. 1984), *hearing denied* (1985)(list of prescription drugs invalidated). It should be noted that all of these cases were decided *subsequent to* the 1972 amendments to the Social Security Act which the Commissioner cites as the basic Congressional authority for her broad discretion to limit Medicaid coverage. (App. Br. at 26-27).[25]

Two of the cases cited by the Commissioner in support of her broad discretion argument are abortion cases. One,

Women's Health Services v. Maher, 482 F. Supp. 725 (D.Conn. 1980), has been vacated by this Court, 636 F.2d 23 (2d Cir 1980), while the other is summarily distinguished as governed by a specific federal statutory exclusion.[26] Other ***31** than the abortion cases, there are two state court cases cited by the Commissioner which, at first glance, appear to hold that a state has the authority to exclude specific services under a covered category of Medicaid services. Upon closer examination, one of the cited cases, *Anderson v. Director Department of Social Services*, 300 N.W.2d 921, 925 (Mich. 1980), specifically relied upon the fact that there was an equally effective alternative treatment addressing the medical need at issue, under the same Medicaid category, which was available for recipients,[27] and the other, *Dougherty v. Department of Human Services*, 449 A.2d 1235, 1238 (N.J. 1982), involved an item which did not even meet the state's definition for the coverage group at issue (DME).[28] Neither of these cases support the authority of the ***32** Commissioner categorically to exclude a medically necessary item or service for which there is no alternative within a covered category of Medicaid services.[29]

In addition, by categorically excluding items of DME from coverage, with no opportunity for adding them to the list, the Commissioner irrebuttably presumes, in violation of the Due Process Clause, that such items of equipment can *never* be medically necessary in the fact of undeniable evidence to the contrary. The Commissioner's hearing summaries for the named plaintiffs' hearings say as much (A-90-94, 103-108, 277-81, 601-605). Such irrebuttable presumptions have repeatedly been struck down by the courts, albeit, as with the court below, as part of an analysis of the Medicaid provisions. *See*, *e. g.*, *Weaver*, 886 F.2d at 199; *Pinneke*, 623 F.2d at 548-49 (exclusion of coverage for sex reassignment surgery irrebuttably presumes such surgery can never be medically necessary).*See alsoSimpson*, 480 F. Supp. at 100-01;*A.M.L.*, 863 P.2d at 47;*McCoy*, 907 P.2d at 114;*Jeneski*, 209 Cal. Rptr. at 189.

***33 b. There is No Authority for Applying a "Medicaid Population as a Whole" Test to an Exclusive List of Items or Services.**

Given the paltry authority for her position of unbridled discretion, the Commissioner attempts to defend her use of an exclusive list on the basis that her policies meet the requirements of 42 C.F.R. § 440.230(b), creatively asserting that, "[i]n the absence of any finding that the use of the Department's exclusive list fails to provide meaningful benefits for the *Medicaid population as a whole*, the scope of plaintiffs' 'entitlement' is limited to the package of services and equipment that *happen to be covered* by the Department's Medicaid program." (App. Br. at 39)(emphasis added). Moreover, the Commissioner asserts that it was *plaintiffs*' burden to produce statistical evidence to establish that the list does *not* meet this test, as a condition of establishing eligibility for coverage of any non-listed items. (App. Br. at 40 n.18).

Since the Commissioner's policies are clearly not "amount" or "duration" limitations,[30] she attempts to justify her total exclusions as "scope" limitations (App. Br. at 39).[31] However, "scope" limitations do not involve wholesale *exclusions* of coverage for ***34** the only items or services able to address recipients' medical needs. Examples of "scope" limitations might be lists of *presumptively* covered items or services within a covered category, such that an additional quantum of evidence would be required for any non-listed services, or the non-coverage of specific services where less costly equally effective services in the same category are covered, *see*, *e.g.*, *Anderson*, 300 N.W.2d at 925.

Even if the use of an *exclusive* list of covered items or services could be considered a "scope" limitation under the Medicaid regulations, the Commissioner's argument that the applicable test for the "reasonableness" of such a list is whether the list meets the needs of a particular high percentage of recipients is misplaced. That test has been applied, and can be applicable, only to amount or duration limitations. This is because, in the case of limits on amount or duration, *all* Medicaid recipients are entitled to receive some substantial quantity of the type of service, although a small percentage will have the length or frequency of the service somewhat restricted. *See*, *e.g.*, *Charleston Memorial Hospital v. Conrad*, 693 F.2d 324, 330 (4th Cir. 1982) (limits of 12 days per year of in-patient hospital care and 18 days per year of out-patient hospital care sufficient to meet 42 C.F.R. § 440.230(b) because 99% and 88% of Medicaid recipients would have their needs for such services met by these amounts); *Curtis v. Taylor*, 625 F.2d 645, 651 n.10 (5th Cir.), *modified on other grounds*, 648 F.2d 946 (5th Cir. 1980) (limit on non-emergency physician visits to three per month upheld where 96% of recipients required no more than this

amount); *Virginia Hospital Ass'n* ***35** *v. Kenlev*, 427 F.Supp. 781, 785-86 (E.D. Va. 1977)(durational limit of 21 days per hospital visit valid under predecessor regulation to 42 C.F.R. § 440.230(b) because 92% of all Medicaid recipients discharged in less than 21 days).[32]

In *Alexander v. Choate*, 469 U.S. 287 (1985), relied upon by the Commissioner, the Supreme Court upheld a State Medicaid agency's 14-day annual limitation on payment for inpatient hospital services where 95% of Medicaid recipients had their total need for hospital days met. The Commissioner argues that, in *Alexander*, the Supreme Court upheld a limitation on medically necessary services, establishing that states are free under the Medicaid Act to set limitations on medically necessary services within a given Medicaid coverage category. (App. Br. at 31-32). However, *Alexander* was not brought under the Medicaid Act, but rather, under § 504 of the Rehabilitation Act, 29 U.S.C. § 794. The Court specifically noted that it was not ruling on "whether annual limits on hospital care are in fact consistent with" the Medicaid Act, declining to give any endorsement of *Charleston Memorial Hospital* or *Virginia Hospital Ass'n*, 469 U.S. at 303 n.23. Furthermore, *Alexander*, like the above-cited cases, involved an *amount* limitation; it did not uphold, and has never been cited by a court to justify, an exclusion of any type of treatment within a covered category of services.

***36** By contrast, a class member who needs a specialized type of support surface, an augmentative communication device, an environmental control unit or any other type of item left off the Commissioner's *exclusive* list cannot receive the required service at all, for *any* period of time, at *any* frequency. Such an absolute exclusion, even if properly considered a "scope" limitation, would not be a "reasonable standard" for determining the extent of medical assistance consistent with the objectives of the Medicaid program, 42 U.S.C. § 1396a(a)(17). *None* of the cases cited by the Commissioner, including *Alexander v. Choate* or any of its progeny, applied a "Medicaid population as a whole" test to a limitation, such as the one here, constituting a *totaldenial* of a type of medically-necessary service within a covered category of Medicaid services. Regardless of how many Medicaid recipients have their DME needs met by the Commissioner's exclusive list, the fact that some will not receive medically necessary services under this category demonstrates that the list does not meet the objective of providing medically necessary home care services (including DME) to assist Medicaid recipients residing in the community, 42 C.F.R. § 440.70(b).[33]

***37** The inapplicability of any "percentage of the Medicaid population" test to limitations involving absolute denials of a service becomes apparent from a review of the several cases challenging states' attempts to limit the prescription drugs covered under their respective Medicaid programs, through the use of lists applicable to this *optional* Medicaid coverage category, 42 U.S.C. § 1396d(a)(12). In each of these cases, the court held that the use of an exclusive or non-exclusive list of prescription drugs violated the federal Medicaid Act and regulations if no exception procedure was reasonably available, even with respect to *rarely needed* Pharmaceuticals. *SeeVogel v. Perales*, [1983-2] (CCH) (Addendum at 1-12); *Dodson v. Parham*, 427 F. Supp. 97 (N.D. Ga. 1977); *Jeneski v. Myers*, 209 Cal. Rptr. 178.[34] In *Dodson*, relied upon by the district court, the court found that the Georgia Medicaid agency's *non*-exclusive drug list, which the state's testimony indicated was ***38** designed to be effective in treating "90-95% of the medical problems which a physician might encounter," was inadequate to satisfy the "amount, duration and scope" regulation, 42 C.F.R. § 440.230(b). 427 F.Supp. at 105-107, 108 (emphasis added). *See also Jeneski*, 209 Cal. Rptr. at 189 ("[B]y making certain drugs totally unavailable, [defendants] ignored the necessity that some patients have for drugs that might be merely palliative for others.").

Similarly, courts have required that state Medicaid programs pay for the drug Clozapine (marketed as Clozaril), even though this fairly new and expensive psychiatric medication was required by only a fraction of Medicaid recipients suffering from schizophrenia -- those who cannot use the other drugs normally prescribed for such individuals. *SeeAlexander L. v. Cuomo*, 588 N.Y.S.2d 85, 88 (Sup. Ct. 1991)("[c]ost alone, or *unique but necessary* medical care for medicaid recipients have not been a bar to Medicaid coverage") (emphasis added). *Accord Visser*, 756 F.Supp. at 507;[35] *Ruth X. v. Wing*, No. 4844-95 (N.Y. Sup. Ct. Dec. 13, 1995) (voiding exclusion of funding for "off-label" uses of Clozapine)(Addendum at 13-16).

As in the prescription drug cases, the *totalexclusion* of ali Medicaid coverage for non-listed or specifically-excluded items of DME is *not* a permissible limitation based on amount, duration *or* scope. Using exclusive lists for DME, prescription drugs,

or any other mandatory *or* optional category of Medicaid services improperly denies coverage to Medicaid recipients. *SeeMeyers*, 776 F.2d at 243-44 (augmentative communication device under ***39** optional category of physical therapy and related services); *Hunter*, 944 F. Supp. at 919-20 (augmentative communication device under DME). Accordingly, it is irrelevant whether 49%, 51%, 90% or 95% of Medicaid recipients in Connecticut have their medical equipment needs met under the Commissioner's policies. The courts have determined that exclusive lists which categorically preclude coverage of certain necessary treatments, even if rarely needed, are an unreasonable standard inconsistent with the objectives of the Medicaid Act. *SeealsoMorgan v. Dent, of Health and Welfare*, 120 Idaho 6, 813 P.2d 345 (1991) (ordering medically-supervised weight loss program, notwithstanding state regulation barring any treatment for obesity, where necessary to prevent rare condition known as pseudo-tumor cerebri from causing blindness); *Baker v. Commonwealth Department of Public Welfare*, 502 A.2d 318 (Pa. Commw. Ct. 1985) (special wheelchair with 500 pound capacity ordered to be provided). Thus, any evidence as to whether the Commissioner's exclusive list meets the needs of the Medicaid population as a whole was irrelevant to the district court's determination of the plaintiffs' likelihood of success on the merits of their Medicaid claims.[36]

***403. Even if the Commissioner Could Limit Medicaid Coverage for DME to Items Specifically Included on an Exclusive Fee Schedule, the Exclusive Fee Schedule Utilized by the Commissioner Could Not Constitute a Reasonable Standard for Providing Medicaid Coverage For DME as Part of Her Home Health Services Benefit.**

As demonstrated above, the Commissioner may not, consistent with federal Medicaid law, deny coverage for medically necessary items or services within a covered category of services, where no equally effective alternative medical item or service is covered. Even if this were not the case, however, the exclusive fee schedule challenged herein still would be an unreasonable standard, prohibited by 42 U.S.C. § 1396a(a)(17). This is because the Commissioner's selection of which equipment to include on that list is purely arbitrary, and because she has no regular procedures for either updating the list or allowing recipients to petition for the addition of other items.[37] Courts have repeatedly condemned arbitrary exclusions of medically-necessary services within a designated category of covered services. ***41***See*, *e.g.*, *Mitchell v. Johnston*, 701 F.2d 337, 348-52 (5th Cir. 1983); *Montova v. Johnston*, 654 F.Supp. 511, 513-14 (W.D. Tex. 1987); *Vogel*, [1983-2] (CCH), at 9401; *McCoy*, 907 P.2d at 113-14; *Jeneski*, 209 Cal. Rptr. at 189.[38]

The failure of a governmental entity to apply "ascertainable standards" and consider fully and fairly the choices available to it in determining entitlement to government benefits is the essence of governmental arbitrariness. *See* *Mayer v. Wing*, 922 F.Supp. 902, 911 (S.D.N.Y. 1996), *citing* *Holmes v. New York City Housing Authority*, 398 F.2d 262, 265 (2d Cir. 1968). The Commissioner's witnesses and the entire record of this case describe coverage determinations for which there is essentially no rhyme or reason. *See* Statement of the Case, Section I.B. *supra*. A small group of DSS employees, none of whom is a physician, meets irregularly and infrequently to compile a fee schedule of covered items, without any written protocols for making their selections. The Commissioner does not utilize any formal procedures to publish a proposed MEDS fee schedule or to solicit input from Medicaid recipients and others in the community regarding possible additions to or deletions from the list, prior to its effective date. The fee schedule is not regularly updated and therefore cannot fairly include new items of DME which go on the market or which go from the experimental stage to the medically accepted stage in the intervening years. Similarly, the Commissioner has no procedures for allowing recipients to demonstrate either that non-listed equipment prescribed for them meets the Commissioner's definition of DME and ***42** should be added to the list, or that an exception should be made as when the prescribed equipment is the only item that will effectively treat a particular medical condition. This was most graphically illustrated by the lack of consideration given by the Commissioner's MEDS unit employees to the request to add the RIK mattress. *See* Statement of the Case, Section I.A.b., *supra*.

The patently unreasonable nature of the Commissioner's "system" for establishing an exclusive list of covered items of DME is made clear by comparing it to the three prescription drug lists struck down as violative of the Medicaid Act in the cases mentioned above. In *Vogel*, [1983-2] (CCH), New York State's list of Medicaid-covered drugs was ruled to be invalid, even though there *were* procedures for updating the list specifically provided by state statute, and even though there were quarterly meetings of a committee of pharmacists set up pursuant to the statute to consider new drugs as to which petitions had been

submitted. The court ruled that New York's procedure lacked any guidelines by which medically necessary drugs could be added to the list, was too *adhoc* for addressing medically necessary drugs *not* on the list, and, in any event, was not published, thereby denying Medicaid recipients of any meaningful opportunity to petition for the addition of non-listed drugs for which they had a medical need. *Id*. at 9401-402.

Similarly, in *Dodson*, 427 F. Supp. 97, where the Medicaid agency sought to reduce the drug formulary, the court found that "the fatal flaws in the proposed program lie not so much in the drugs delisted, but rather in the absence of what this court considers to be a medically sound and effective prior approval system, *which would make non-[listed] pharmaceuticals available to those who truly need them, in a speedy and efficient manner****43** with the least interference with the relationship of physicians and Medicaid patients...." 427 F. Supp. at 108 (emphasis added). *Seealso* *Jeneski*, 209 Cal. Rptr. at 188-189 (California Medicaid agency's reduced list of covered drugs in violation of federal law and not saved by procedures for obtaining medically necessary drugs *not* on the list).

There is no distinction between lists of DME and lists of prescription drugs. And, unlike in the drug cases, the Commissioner herein has *no* procedure for approval of non listed items, or for individual Medicaid recipients or their physicians to petition the Department for *changes* in the list based on their individual medical need for items not on the list.[39]

The named plaintiffs not only have a medical need for their physician-prescribed items, these are among the *only* items of DME, as defined by the Commissioner, available to treat the conditions from which they suffer. Courts have held that the exclusion of the *onlyavailabletreatment* for a particular condition constitutes an arbitrary denial of benefits. *Pinneke*, 623 F.2d at 549;*McCoy*, 907 P.2d at 113-14.[40] The Commissioner cites no case ***44** upholding such an exclusion.

At the same time, the Commissioner's exclusive fee schedule includes coverage for items of equipment that would clearly be used by far less disabled individuals, such as canes and walkers. Under the Commissioner's fee schedule, individuals such as Ms. DeSario, with a demonstrably *greater* medical need, are denied access to the DME category of services. *SeeSimpson*, 480 F. Supp. at 101;*Ledet v. Fischer*, 638 F. Supp. 1288, 1293 (M.D. La. 1986).

If the justification the Commissioner seeks to interpose for this arbitrary exclusive list is cost containment, this objective is required by the Medicaid Act to be achieved through such methods as utilization controls (such as prior authorization) and limits based on medical necessity, 42 C.F.R. § 440.230(d), or through the selection of less than all optional categories of services. The Commissioner cannot use cost considerations as a justification for denying coverage where there is no less costly, equally effective, alternative treatment to address a recipient's medical need within a covered category of services.[41]

It is plainly inconsistent with the purposes of the Medicaid Act for the Commissioner to maintain an immutable exclusive list of Medicaid-covered medical equipment which ***45** arbitrarily excludes whole groups of medically-necessary equipment and devices, such as environmental control systems and augmentative communications devices. These items are intended to meet *both* of the basic objectives of the Medicaid Act: to provide "necessary medical services" *as well as* "rehabilitation and other services to help . . . individuals attain and retain capability for independence, or self-care." 42 U.S.C. § 1396.

D. *THE FACTUAL RECORD DEVELOPED BELOW FULLY SUPPORTED THE DISTRICT COURT'S ENTRY OF A PRELIMINARY INJUNCTION BASED ON IRREPARABLE HARM TO PLAINTIFFS IN THE ABSENCE OF RELIEF*

The record developed below fully supported the district court's entry of a class-wide preliminary injunction. With the exception of Thomas Slekis, for whom an item of DME was actually ordered to be provided, neither a finding of medical need for their respectively requested items, nor a finding that such items were DME, was necessary for the district court to find a likelihood of the plaintiffs1 success on the merits of their challenge to the Commissioner's policies. Mr. Slekis' medical need for the RIK mattress, and hence irreparable injury in its absence, was established after two full days of testimony by witnesses from both sides, primarily limited to that one issue, while the Commissioner concedes that the RIK

mattress is DME.

The factual findings of the Commissioner's own hearing officers, which are binding upon her under *Elliott*, were clearly sufficient to establish the irreparable injury facing two of the other named plaintiffs, Ms. DeSario and Mr. Wolan.[42] With respect to irreparable ***46** harm for all of the other class members, the standard in this Circuit is whether the plaintiffs face a *probability* of irreparable injury. *See* *JSG Trading Corp. v. Tray-Wrap. Inc.*, 917 F.2d 75, 79 (2d Cir. 1990); *Reuters. Ltd, v. United Press Int'l. Inc.*, 903 F.2d 904, 907 (2d Cir. 1990). *SeealsoHurley v. Tola*, 432 F.Supp. 1170, 1176 (S.D.N.Y.)(irreparable injury met by absent class members), *aff'dmem.*, 573 F.2d 1291 (2d Cir. 1977). As the district court noted (A-1822), under the Commissioner's procedures, the absent class members must all have prescriptions for each of the items of DME they request. Since the treating physician's opinion regarding medical necessity is entitled to great weight, *see* *Weaver*, 886 F.2d at 199; *Pinneke*, 623 F.2d at 550; *Montoya*, 654 F.Supp. at 513; *A.M.L.*, 863 P.2d at 48, a high probability of medical need, and hence of irreparable injury, has been established.

IV. *CONCLUSION*

For all the reasons stated above, the named plaintiffs and members of the plaintiff class respectfully request that the Court affirm the January 10, February 13 and March 6, 1997 orders of the district court granting them preliminary injunctive relief.

Appendix not available.

Footnotes

1 Plaintiff Slekis is the only plaintiff who presently has the item of DME for which he seeks Medicaid coverage, a RIK mattress, in his possession. The district court's ruling enjoins the Commissioner to pay the provider of this mattress a *perdiem* rate for the rental of the item to prevent its removal from Mr. Slekis' home. (A-1759). This *perdiem* rate is $2 more per day than the $26 daily rate for other specialized mattresses included on the Commissioner's fee schedule. (A-883, 1335).

2 Contrary to the Commissioner's argument on appeal (App. Brief at 44-48), the district court *did* make findings of fact regarding the named plaintiffs in support of its ruling on plaintiffs' request for preliminary injunctive relief which were amply supported by an adequate evidentiary record. *See* Section III.D., *infra*. The district court did not make any factual findings as to Mr. Wolan, who intervened, by agreement, after the court issued its initial preliminary injunction ruling.

3 Ms. Desario presently owns a donated ECU which is unreliable and functions erratically (A-91). It does not change the position of her bed. (A-92).

4 "Shearing" occurs when pressure is placed on the skin by horizontal movement across a bed or other hard surface. Shearing is a significant problem for Mr. Slekis in transferring between his bed and wheelchair. (A-1022-23).

5 Mr. Wolan withdrew an earlier motion to intervene, filed in May, 1996, to pursue an administrative fair hearing. (A-564). After issuance of the administrative decision upholding the denial based on the challenged policy, he renewed his motion to intervene.

6 In her capacity as Health Programs Supervisor, Ms. Geary supervises the durable medical equipment and pharmacy units. She is responsible for the development of the MEDS fee schedule as well as for any additions to the fee schedule. (A-902,903).

7 Ms. Geary testified that she is trained as a pharmacist. (A-428). Three of the other DSS employees whom she identified as participating in the development of the 1993 and 1996 fee schedules, Julie Pollard, Susan Simms, and Barbara Siezinski, are trained as a physical therapist, radiology technician, and nurse, respectively. (A-939-40).

8 *See*, *e.g.*, *United States v. LaPorta*, 46 F.3d 152, 156 (2d Cir. 1994); *CarlyleCompressor v. OSHA*, 683 F.2d 673, 675 (2d Cir. 1982); *General Electric Co. v. OSHA*, 583 F.2d 61, 65 (2d Cir. 1978).

9 In her April 8, 1997 Memorandum in Opposition to Plaintiffs' Second Motion for Clarification, page 1, note 1 (Record below), the Commissioner refers to her designation of these items as DME as "unfortunate wording."

10 Furthermore, Ms. Geary could identify only one item of DME on the June 1, 1996 MEDS fee schedule which was not on the June 1, 1993 fee schedule and that was an air loss mattress with a therapeutic overlay (Code E0277). (A- 464, 1332-38).

11 The Commissioner disputes that any of the equipment requested by the plaintiffs, except that requested by Thomas Slekis, constitutes DME (App. Br. 20-22), suggesting that this is a necessary element to obtain preliminary injunctive relief for all class members (*Id*. at 8, 20). However, with the exception of Mr. Slekis, plaintiffs' claims in this case do not seek the provision of any items of equipment, but rather the invalidation of the Commissioner's exclusive list policies, so that they may have an opportunity for a full and fair assessment of their medical need and, where applicable, of the nature of the items requested. Thus, the district court's preliminary injunction ruling made no finding as to whether the ECU prescribed for Ms. DeSario is or is not DME, reserving that issue for the Commissioner to decide upon reconsideration of Ms. DeSario's request without regard to the challenged policy.
Nevertheless, there was substantial evidence from the ECU supplier sufficient to support a finding that Ms. DeSario is likely to succeed in demonstrating that the ECU, which operates hospital beds, etc., is DME as defined by the Commissioner in her policies. (A-357-410). Indeed, ECU's have repeatedly been held to be DME (under the Commissioner's definition) by state Medicaid hearing officers, including one of defendant's own fair hearing officers with respect to a virtually identical ECU made by the same company. *SeeM. L. W.*, No. 944453 (Nov. 21, 1994)(Connecticut DSS) (ordering a Simplicity Series 6 to be provided as DME)(A-126-135); *Alice V.*, No. XD42963G (Feb. 23, 1993)(New York Medicaid agency)(ordering a Quartet Technology Simplicity Series 5 to be provided after concluding it is DME)(Addendum at 25-30). *SeealsoLouis Matteo*. No. 162045 (Mar. 21, 1990)(Addendum at 3***I***-32)(Massachusetts Medicaid Agency agreeing to provide ECU); 130 Code. Mass. Reg. § 409.402(D)(defmition of DME)(Addendum at 70). And, as noted above, the items prescribed for plaintiffs Emerson and Stevenson are defined as DME in the Commissioner's own policies. MAP Manual § 189.E.III.a.

12 In light of the Commissioner's Stipulation with respect to plaintiff Wolan, no evidence was presented to the district court concerning the basis for the Commissioner's exclusion of the Dynavox Communications Device from her fee schedule. However, augmentative communications devices, like the one prescribed for plaintiff Wolan, have repeatedly been held to be DME (under the Commissioner's definition) by federal courts. *See*, *e.g.*, *Hunter v. Chiles*, 944 F. Supp. 914 (S.D. Fla. 1996); *Fred C. v. Texas Health and Human Services Commission*, 924 F. Supp. 788, 791, 792 (W.D. Tex. 1996), *appealpending* (5th Cir.).

13 Ms. Geary testified that the distributor failed to provide her with any objective clinical studies of the product. (A-909). However, as both Mr. Slekis' physician and the Commissioner's physician testified, clinical studies of newer products are exceedingly rare. (A-1178). Moreover, Ms. Geary admitted that she never asked the distributor to obtain such studies (A-961) and she did not know if her unit has clinical studies on other items on the fee schedule. (A-961).

14 Ms. Geary testified that the low air loss mattress with a therapeutic overlay was added to the 1996 fee schedule to meet the needs of recipients with decubiti. (A-91I-12). However, Dr. Kostecki testified, *inter* alia, that the low air loss mattress was less efficacious in preventing skin breakdown from shearing, which is a major cause of Mr. Slekis' skin breakdown problem. (A-1010). He also testified that, in the event of a power failure, the low air loss mattress, which is motorized equipment, would leave Mr. Slekis on a hard surface, a dangerous situation for him. (A-1009). The RIK mattress is non-motorized. (A-1008-1009).

15 The Commissioner asserts that she was not seeking to have the district court abstain, but merely to have it apply traditional equity principles, suggesting that it was the district court which raised the abstention doctrine. However, two of the cases cited by the Commissioner, both to the district court (Defendant's Brief in Opposition, at page 9 (April 23, 1996)) and in her appellate brief (App. Br. at 12), *O'Shea v. Littleton*, 414 U.S. 488 (1974), and *Wallace v. Kern*, 520 F.2d 400 (2d Cir. 1975), were abstention cases. *Potwora v. Dillon*, 386 F.2d 74 (2d Cir 1967), the case from which the Commissioner quotes extensively, was decided in 1967, four years before *Younger v. Harris*. The rationale underlying *Potwora* is essentially the same legal rationale that became the *Younger* doctrine, except that the Court ultimately did *not* abstain in favor of the on-going state criminal proceedings. *Potwora*'s conclusion is of dubious legal validity today under *Younger*.

16 This argument only applies to plaintiffs DeSario, Emerson, Stevenson, and Wolan. Plaintiff Slekis did not initiate any administrative adjudicatory action prior to seeking leave to intervene in the instant action.

17 *Compare* *Thornquest v. King*, 82 F.3d 1001, 1004 (llth Cir. 1996); *Edmunson v. Borough of Kennett Square*, 4 F.3d 186,

193 (3d Cir. 1993); *Gjeilum v. City of Birmingham*, 829 F.2d 1056, 1064-65 & n.21 (11th Cir. 1987); *Peerv v. Brakke*, 826 F.2d 740, 746 (8th Cir. 1987); *Perley v. Palmer*, 157 F.R.D. 452, 457 (N.D. Iowa 1994), *with* *Eilrich v. Remas*, 839 F.2d 630, 634 n.2 (9th Cir.), *cert.denied*, 488 U.S. 819 (1988)(hoiding that unreviewed agency determinations of law and fact are entitled to preclusive effect).

18 The other decision of this Court cited by defendant for its *res iudicata* argument is *Zanghi v. Incorporated Village of Old Brookville*, 752 F.2d 42, 46 (2d Cir. 1985). While *Zanghi* did give preclusive effect to a mixed question of fact and law (whether there was probable cause to believe an individual was driving while intoxicated), it was decided before *Elliott* strictly limited the application of administrative *resjudicata* in § 1983 actions to factual findings. *See* *Pettis Moving Co. v. Roberts*, 784 F.2d 439, 441 n.4 (2d Cir. 1986).

19 She cites for this proposition *Doe v. State of Connecticut Department of Health Services*, 75 F.3d 81 (2d Cir. 1996). Technically, *Doe* was an abstention case. The Court therein upheld the district court's decision to abstain, in the face of a *pending* administrative proceeding which the Court pointedly noted was fully capable of addressing the federal civil rights claim made by the federal court plaintiff. 75 F.3d at 85. As discussed earlier, there was no legal basis for the district court's abstention in the instant action.

20 Technically, under the Medicaid statutes, home health services are mandatory only with respect to persons who would otherwise be eligible for Medicaid coverage for institutional care. 42 U.S.C. § 1396a(a)(10)(D). Connecticut has opted to provide home care services to all Medicaid recipients who have a medical need for such services, regardless of whether they are eligible for institutional care.

21 Other states sometimes use lists of DME, but then allow non-listed items to be covered with prior approval, based on proof of individual medical necessity. *See*, *e.g.*, 130 Code of Mass. Reg. § 409.409(A)(6) (Addendum at 73); N. Dak. Dept. of Human Services Durable Medical Equipment and Supplies Guidelines, pages 5-6 (Addendum at 82-33). *Seealso* Ohio Admin. Code § 5101:3-1-01(C) and (D)("[a] provider may request payment for a medical service, even if that medical service is not ordinarily a reimbursable item, which he/she believes is medically necessary and meets the [general] criteria... of this rule," including that it be "the lowest cost alternative that effectively addresses and treats the medical problem")(Addendum at 84-85).

22 The Commissioner's statement that the statutory definition of "medical assistance" as "payment for '*part* or all' of the listed categories of services suggests that the states may limit the 'amount, scope or duration' of each category of service that they cover..." (App. Br. at 24, note 5)(emphasis in original), ignores the actual language of the provision quoted. That provision, 42 U.S.C. § I396d(a), refers to "payment of part or all of *the cost of* the... [listed] care or services...." (emphasis added). This is a reference to the Medicaid statutory authorization for limited co-payments by Medicaid recipients. *See* 42 U.S.C. § 1396***o***.

23 The requirement that recipients seek prior authorization for more costly items or services such as DME is an example of a permissible utilization control device, which has in fact been adopted by the Commissioner for DME. Another such device might be a *non*-exclusive list of *presumptively* covered items, pursuant to which any non-listed items must be shown by the recipient to meet the Commissioner's general DME definition *and* to be the only item able to meet their individual medical need. This in effect is what the district court ordered, when it required that the named plaintiffs and members of the class demonstrate to the Commissioner, besides that the equipment requested is DME, that nothing on the Commissioner's list could address their individual medical need in an equally efficacious manner. (A-1759).

24 The Supreme Court in *Seal v. Doe* emphasized the importance of professional judgment in determining medical necessity. 432 U.S. at 445 n.9 (noting that abortions which are prescribed by a physician as medically necessary were covered by the Medicaid Act at that time). *See also* *Weaver v. Reagen*, 886 F.2d at 199-200,*citing* S. Rep. No. 404, 89th Cong., 1st Sess., *reprinted in* [1965] U.S. Cong. & Admin News 1943, 1986; *Pinneke v. Preisser*, 623 F.2d 546, 550 (8th Cir. 1980)("The decision of whether or not certain treatment or a particular type of surgery is 'medically necessary' rests with the individual recipient's physician and not with clerical personnel or government officials"); *Montoya v. Johnston*, 654 F.Supp. 511, 513 (W.D. Tex. 1987); *A.M.L. v. Department of Health*, 863 P.2d 44, 48 (Utah 1993).

25 This case does not involve a claim for "comprehensive services," the goal of which was disclaimed by Congress in 1972. States are free to pick and choose among various optional categories of covered services. The state may require prior authorization before the purchase of an item or service to insure that the most cost-effective item or service necessary to meet the recipient's medical need

is approved, or it may apply a list of *presumptively* covered items or services. And the state is not required to cover experimental items or services. Further, as discussed below, the state may also be able to limit the quantity of a particular item or service per recipient, as well the frequency with which items and services will be approved, so long as such limitations meet the needs of the vast majority of recipients.

26 *Preterm. Inc. v. Dukakis*, 591 F.2d 121 (1st Cir.), *cert.denied*, 441 U.S. 952 (1979), dealt with the effect of the Hyde Amendment, limiting the availability of federal funding for Medicaid coverage of abortions, on the Medicaid Act. The court found that the states were not required to fund all therapeutic abortions that the Hyde Amendment excluded. Thus, *Preterm* actually supports the proposition that the states carinot limit coverage of medically necessary abortion services if *not* specifically excluded by another federal statutory provision. In general, the abortion coverage cases support plaintiffs' interpretation of the Medicaid Act, that states are *not* permitted to exclude medically necessary treatments within a covered category of services. *See*, *e.g.*, *Little Rock Family Planning Services. P. A. v. Dalton*, 60 F.3d 497, 502-503 (8th Cir. 1995); *Hern*, 57 F.3d at 910-11. Indeed, since abortion is probably the most controversial medical procedure in the United States today, undoubtedly, if states had the discretion simply to refuse to provide this type of service within the covered category of physician's services, many would do so. The fact that no state has been able to do this reflects the overwhelming judicial view that federal Medicaid rules prohibit a state from categorically excluding any type of non-experimental medical service within a covered Medicaid category, in the absence of an equally effective covered alternative.

27 In *Anderson*, the court upheld a provision in the Michigan Medicaid program that denied coverage for root canals because extraction was found to be an adequate, and more cost effective, alternative. This limitation was allowed by the court in part because the "medically accepted [alternative] treatment . . . would not have caused *anyconsequenthealthproblems* or chewing difficulties for plaintiff." 300 N.W. 2d at 925 (emphasis added). Therefore, this state court decision can be distinguished from the instant case in which the ?? suffer health problems if their respectively requested items of DME, if found by the Commissioner to be medically necessary, are not provided. Where there is no equally effective alternative treatment, cost considerations cannot justify the denial of medically necessary services under a covered category. *See* *Hunter*, 944 F. Supp. at 922.

28 *Dougherty* involved the denial of Medicaid coverage for an air purifier to an asthmatic recipient. The New Jersey Supreme Court did uphold the exclusion from Medicaid coverage of this particular item, but it also noted that the item was not primarily used for medical purposes, 449 A.2d at 1240, and hence it did not meet that state's definition of DME, *see* New Jersey Medical Supplier Manual, Subchapter I, § 1.2 (definition of "Medical Equipment")(Addendum at 76). (The general DME definition used by Connecticut is essentially the same as that used by New Jersey, but, as noted above, Connecticut has a more specific definitional provision applicable to air purifiers, which specifically identifies such equipment as DME. MAP Manual § 189.E.III.a.). While the court did apply an unduly deferential standard of review to the policy at issue, as indicated by the string cite above, the vast majority of both state and federal courts have not followed this approach.

29 *Budnicki v. Seal*, 450 F. Supp. 546 (E.D. Pa. 1978), also cited by the Commissioner, dealt with a Pennsylvania Medicaid provision that provided coverage for orthopedic shoes, an optional service. Because there were many allegations of fraud, not refuted by the plaintiffs in the case, the defendant agency limited coverage for orthopedic shoes. However, it continued to provide coverage where a recipient had a condition of such severity that he or she was not able to wear ordinary shoes. 450 F.Supp. at 549. In other words, the limitation was designed to implement the medical need requirement. *Budnicki* also involved unique facts in that, due to a consent decree, the state Medicaid agency was *prohibited* from implementing a system of prior authorization, the usual method used by states (including Connecticut, for most types of DME) to ensure that the services were only being provided to those who had a genuine need for them.

30 An example of an amount or duration limitation applicable to DME would be a limitation on coverage of no more than one motorized wheelchair every five years. Such a limitation might be permissible if the Commissioner could show that such a limitation is sufficient to meet the needs of the vast majority of Medicaid recipients requiring such equipment.

31 *District of Columbia Podiatry Society v. District of Columbia*, 407 F. Supp. 1259, 1265 (D.D.C. 1975), relied upon by the Commissioner (App. Br. at 33), was a suit by podiatrists seeking to expand the types of services for which they could be reimbursed under Medicaid. Under the challenged regulations, these services were provided to recipients by *other* medical providers. Thus, it was not a true "scope" case but rather involved nothing more than a "turf war between providers and, unlike the present case, no recipient was being denied any type of service. 407 F.Supp. at 1265 n.27.*See alsoDanvers Pathology Assocs. v. Atkins*, 757 F.2d 427 (1st Cir. 1984) (suit by laboratory providers over reimbursement for services provided to hospital patients);

Sandefur v. Cherry, 718 F.2d 682, 686 (5th Cir. 1983)(suit by optometrists challenging coverage of specific services only when provided by opthamologists); *Warr v. Horsley*, 705 F. Supp. 540, 542 (M.D. Ala. 1989) (services covered only when provided by physicians, not by podiatrists).

32 It is significant that each one of these cases under the Medicaid Act was brought not by a Medicaid recipient or group of recipients but by the medical provider itself. This suggests that, in fact, recipients may not even have been restricted in the duration or amount of services, but rather, that the complete services nevertheless were being provided, albeit without full reimbursement to the providers.

33 The Commissioner's references to the Health Care Financing Administrations's 1977 Medicaid Assistance Manual to support an assertion that HCFA authorizes the use of an exclusive list of covered equipment as a permissible "amount, duration, and scope" limitation (App. Br. at 29), is misplaced. What the Commissioner excludes in her quotation is the immediately following language:
A list of reimbursable items, however, may be more restrictive than perhaps the State intended and may cost more than another method.... We suggest, therefore, that in.addition to items on the list a statement "other items available with prior authorization" be included.
Medical Assistance Manual, § 5-50.1-00 (Answer to Question 5). In any event, the Medicaid Assistance Manual and the Action Transmittal cited by the district court and the Commissioner were superseded *in toto*, in July, 1981, by HCFA itself. *SeeDepartment of Human Services v. Secretary of Health and Human Services*, 748 F.Supp. 1120, 1122 (D.N.J. 1990).
Furthermore, the Commissioner's statement that, "[a]t least for twenty years HCFA has interpreted the Act and its implementing regulations as authorizing the states to limit the scope of medical equipment by employing an *exclusive* list of covered equipment," (App. Br. at 30), is incorrect. Submitted to the district court were the minutes of an April 1992 national meeting held between HCFA and state Medicaid directors in which HCFA specifically admonished state Medicaid directors that they could *not* apply an "exclusive list" of DME. (A-120). While HCFA's brief to the district court did attempt to discredit its later statement to the Medicaid directors, it is significant that HCFA's brief did not attempt to defend the use of a list as the *exclusive* determinant of Medicaid eligibility for DME, and that HCFA is not concerned enough by the district court's state-wide preliminary injunction to make such an argument (or any argument) to this Court.

34 *Jeneski* was subsequently limited by *Cowan v. Meyers*, 187 Cal. App. 3d 968, 232 Cal. Rptr. 299 (Cal. App., 3d Dist. 1986, *review denied*, (1987), with respect to Jeneski's holding that decisions on prior approval for prescription drugs could not be made by pharmacists. 232 Cal. Rptr. at pp. 310-11.*Cowan* did not limit *Jeneski's* holding that states have no authority to exclude coverage for medically-necessary services under a mandatory or optional covered category of services.

35 The *Visser* court cited *Alexander v. Choate*, but did not apply a "Medicaid population as a whole" test, even though only a small fraction of Medicaid recipients would ever require Clozapine. 756 F. Supp. at 505, 507. The same is true of the *Weaver* court, which did not apply this test to the drug AZT needed only by Medicaid recipients with AIDS. 886 F.2d at 197, 199-200.

36 Not only does the Commissioner argue for an irrelevant test, she claims that it is the *plaintiffs'* burden to produce the Medicaid statistics necessary to meet this test. The one case she cites for this proposition, *Lavine v. Milne*, 424 U.S. 577 (1976), is readily distinguishable. *Lavine* held that it is an applicant's burden to establish eligibility for a public benefit by supplying information that is within the knowledge of the applicant and is directly relevant to his eligibility for the benefit. 424 U.S. at 587. Individual Medicaid recipients do *not* have access to Medicaid statistics which, as the district court noted, if they exist at all, are in the possession and control of the Commissioner (A-1802), *and* such statistics have no bearing on the individual recipient's medical need for particular items of DME. Under these circumstances, the burden would be on the Commissioner to justify her exclusive list with valid statistics. *See St. James Hospital v. Heckler*, 760 F.2d 1460, 1467 n.5 (7th Cir.), *cert.denied*, 474 U.S. 902 (1985). It is a burden that she did not even attempt to meet.
Even if the "needs of Medicaid population as a whole" test were relevant and it were the *plaintiffs'* burden to show that the Commissioner's exclusive list does not meet this test, there was sufficient information presented to the court below to justify a conclusion that the list could not possibly meet this standard. *See* February 13, 1997 Clarification Order at page 6 (A-1802); Statement of the Case, Section I.B. *supra*, From the testimony of the Commissioner's *ownwitnesses*, and the absence of any regularized procedures or guidelines for considering items of DME, it is clear that the Commissioner could have no idea whether the items that "happen to be covered" on her exclusive list meet the needs of the vast majority (or even the majority) of Medicaid recipients with physical disabilities requiring DME.

37 This in fact was the basis for the district court's order invalidating the defendant's exclusive list. (A-1725). Accordingly, the

Commissioner's statement that the court's finding that the exclusive fee schedule was "'unreasonable was predicated *solely* on the Court's finding of medical necessity for each requested item, for each Medicaid recipient" (App. Br. at 39 n. 16)(emphasis in original), is not correct.

38 Most of these cases are decided under the "amount, duration, and scope" requirements of 42 C.F.R. § 440.230, without specific reference to the "reasonable standards" requirement of 42 U.S.C. § 1396a(a)(17), which the regulation is designed to implement, but the analysis is the same. *Cf.McCoy*, 907 P.2d at 114 (noting that arbitrary exclusion of medically necessary services is unreasonable).

39 The Commissioner's suggestion that this is addressed by the generic state statutory procedure for requesting a declaratory ruling with respect to an existing regulation, Conn. Gen. Stat. § 4-176 (App. Br. at 36 n. 14), is without substance. No Medicaid recipient looking at this statute would think that this applies to requesting that the Commissioner amend her non-regulatory DME fee schedule, which is not even published. *CompareVogel*, at 9394 (invalidating a procedure for updating the list of covered drugs under New York's Medicaid program, even though a state statute *did* specifically refer to that list).

40 This has been extended even to items or services *not* clearly within a covered category of services, where the specific item or service is the only one which can meet a particular Medicaid recipient's medical need, and providing the equipment is cost-effective for the Medicaid agency. *See*, *e.g.*, *Campbell v. Weil*, No. 95CV2211 (Denver Co.D.Ct. Dec. 19, 1995)(van lift ordered to be provided as cost-effective compared to paying for medical transportation)(Addendum at 17-24).

41 Any argument that the Commissioner might make about cost considerations is completely undercut by the facts pertaining to the named plaintiffs, each of whom risks hospitalization or, in the case of Ms. DeSario, *institutionalization*, if they are not provided with the equipment they seek. This is particularly clear in the case of Thomas Slekis. His long-time treating physician testified about the multiple extensive Medicaid-funded hospitalizations he has had in the past, which might be avoided in the future if the RIK mattress, costing only $2 per day more than listed support surfaces, were covered. This Court has recognized the invalidity of a Medicaid rule which involves a net increase in costs, whether to the Medicaid program as a whole or to governmental entities in general. *SeeDetsel v. Sullivan*, 895 F.2d 58, 65 (2d. Cir 1990).

42 The Court should not take seriously the Commissioner's suggestion that these hearing decisions were not properly "authenticated" or properly submitted to the district court (App. Br. at 47), particularly given that she expends several pages of her brief arguing that these same administrative decisions *preclude* any relief for the plaintiffs.