

2006 Steven M. Goldstein Award for Excellence

Florida Legal Services (Miami), Legal Aid Service of Broward County, Legal Aid Society of Palm Beach County and Legal Aid Society of the Orange County Bar Association

Prescription Drug Access Project

1. Project Summary

a. Major goals and objectives of the project

Our goal is to ensure that low income Floridians receive the due process and medically necessary medications which they are entitled to under federal law. This project is intended to safeguard access to critically needed medications for thousands of impoverished Floridians who suffer from chronic and debilitating health conditions.

b. Time frame of the project

The project has been ongoing since 2002. The need for this advocacy will only grow as the cost cutting and privatization forces driving Florida Medicaid reform and the federal Medicare Part D program significantly restrict access to medically necessary prescriptions.

c. Advocacy and strategies used in the project

We are using a range of strategies including class action litigation, fair hearings, consumer and provider outreach and education, a toll free helpline, attorney and paralegal trainings, and policy advocacy. The first class action, *Hernandez et al v. Medows*, was brought by Florida Legal Services, Inc. (FLS), Legal Aid Society of Palm Beach County, Inc. (LASPB) and the National Health Law Program, Inc. (NHeLP). The case, which challenged the state Medicaid Agency's refusal to provide due process when denying prescription drugs, was favorably settled in May 2003. Under the Settlement, the Agency must ensure that recipients are provided with written notice at the time of all drug coverage denials. For refills, the Agency must also ensure an immediate temporary supply at the pharmacy and ongoing coverage pending the outcome of a fair hearing. Plaintiffs' counsel spent a full year working with the Agency on implementation of the Settlement, and following implementation we provided a series of trainings to providers and advocates on the Medicaid prescription drug program and due process protections.

When 2005 legislation severely restricted drug coverage, FLS established a prescription assistance toll free Helpline. In a 2005 enforcement action against the Agency for violating terms of the *Hernandez* Settlement, data obtained by the Helpline proved instrumental in rebutting the Agency's claim that violations were not systemic and obtaining significant class wide relief. Additionally, Helpline staff provide individual case analysis, advice and assistance, including extended assistance through referral and collaboration with local programs and pharmacy experts on fair hearings.

In 2004 the Agency implemented a new policy asserting that the state has discretion to deny off-label (non FDA approved) coverage. This policy resulted in massive arbitrary denials of Neurontin, a widely prescribed drug used to treat pain and mood disorders. After administrative

advocacy failed, FLS, Legal Aid Service of Broward County (LASBC), Legal Aid Society of Orange County Bar Association, Inc. (LASOCBA), and NHeLP filed *Edmonds et al. v. Levine*.

d. Obstacles overcome during the project

The nature of Medicaid prescription drug litigation requires that Plaintiffs’ counsel understand many technical and arcane issues. The complexity of the Medicaid program is universally acknowledged, and the prescription drug benefit is its most complex benefit, legally and operationally. Nationally renowned Medicaid expert Sara Rosenbaum summarized the obstacles overcome by Plaintiffs’ lawyers in her *Hernandez* fee declaration. (“...the provisions related to coverage of pharmaceutical benefits are particularly intricate, contentious and subject to challenge and interpretation. To litigate any Medicaid case presents a substantial legal undertaking, not only because of the complicated nature of the law, but also, as a result on the interaction between the program’s voluminous legal provisions and the facts of any particular case... [t]his case posed especially serious burdens on plaintiffs’ lawyers because of its legal complexity, its unprecedented nature, the multiple layers of players... and the intricacies of the facts surrounding the state’s utilization management system and its actual operation... .to achieve the excellent settlement....plaintiffs’ lawyers had to put together a case that was sufficiently compelling not only to convince the court of the correctness of their claims....but to allow the court to accurately distinguish between the cost containment options that legally are available to Medicaid drug programs and those that are not.”)¹ (see attachment to # 8).

An additional obstacle in both the *Hernandez* and *Edmonds* litigation is the Defendant’s aggressive litigation strategy. Although both cases involve straightforward issues of law which could have been decided on summary judgment, the Defendant challenged not only the legal basis of Plaintiffs’ claims, but the factual basis as well. Thus, we have been obliged to expend significant time defending Plaintiffs’ factual claims. For example, in *Hernandez*, the state requested leave to take 40 depositions, insisted on the right to take up to 180 depositions and even disputed that the Plaintiffs’ prescriptions were “denied” (notwithstanding the state’s own billing records documenting non-coverage.) In *Edmonds*, the state insisted upon a three day evidentiary hearing on Plaintiffs’ motion for preliminary injunction. As part of our advocacy strategy Plaintiffs then involved a highly experienced pro bono trial attorney, Neil Kodsi, a partner with Carlton Fields. We presented a comprehensive and compelling factual presentation of irreparable injury through our witnesses and experts and effective cross examination of the Defendant’s expert witnesses.

e. The achieved/potential client/community impact

In addition to the benefits that accrue to florida Medicaid recipients in terms of gaining fairness and process through the *Hernandez* settlement, there is also a clear value to recipients in terms of treating disease and limiting pain and suffering. For example, discovery in *Hernandez* showed

¹In recognition of the complexity and significance of the case, Plaintiffs were recently awarded over \$750,000 in attorneys’ fees for litigation on the merits. Due to protracted and contentious fee litigation in which the A.G. objected to over 2,500 time entries and filed 13 untimely motions for extensions , fees for fees amounted to over \$120,000. The total fee award was \$857,000.

that over 50,000 prescriptions per month were denied. While some recipients got an alternative medication, 15,000 recipients per month failed to receive any drug that could treat their condition. Thus, patients with certain serious medical problems, such as tuberculosis went untreated. The due process protections secured by Plaintiffs in *Hernandez*, plus the consumer assistance monitoring capacity provided by the Helpline, make it much more likely that Florida Medicaid recipients will receive necessary medicines.

Although *Edmonds* involves a single drug, it will determine whether or not the state has discretion to deny coverage of any drug if the Agency decides the drug's particular use is not "adequately" supported by scientific evidence. Under such a standard, the state could conceivably deny coverage for most cancer drugs and pain drugs. Further, federal Medicaid law requires a single uniform standard for determining coverage, and state discretion is not allowed. Thus, if the state's policy is allowed to stand, it will undermine the Medicaid statute's detailed and nondiscretionary coverage requirements and seriously limit our clients' entitlement to medically necessary drugs.

As noted above, Helpline data was crucial in obtaining class wide relief in the recent *Hernandez* enforcement action. Among other relief, 53,000 class members were sent both a remedial notice by the Agency and a notice of assistance available through the Helpline. Helpline data and reports will also assist advocates in identifying systemic issues that lend themselves to a litigation response. In particular, we will be monitoring the new Medicaid reform pilot projects in Florida to make sure the private capitated plans comply with federal Medicaid law governing prescription coverage and *Hernandez* due process requirements.

f. Innovative advocacy: Use of experts in litigation and Helpline Database

Both *Hernandez* and *Edmonds* are cases of first impression, and in both cases, advocates have extensively and creatively used experts in supporting our previously untested legal positions. For example, in *Hernandez*, though it is well established under Medicaid case law that denial of a claim for assistance triggers notice and hearing rights, the issue of what constitutes a prescription drug claim, particularly in the context of prior authorization requirements, was not yet settled. Also unsettled was whether the termination of a refill triggers the right to continuing coverage pending the outcome of an appeal. A third issue of first impression was whether substitution of the generic bio-equivalent of a drug for the brand name drug triggers due process. In achieving success of each of these issues, we worked closely with five national experts who provided compelling reports supportive of Plaintiffs' positions. In *Edmonds*, our two experts are not only "expert" in psychiatry and pain treatment, they are also the elected leaders of their respective Florida medical societies. Finally, advocates are continuing to utilize pharmacy experts in Helpline referrals—both in determining whether or not the case is meritorious and in developing an advocacy strategy with field programs for obtaining coverage.

The Helpline data enabled advocates to identify recipients for media around the state who reported on the extreme difficulties experienced as a result of the Medicaid prescription drug restrictions and Medicare Part D problems. This press coverage was likely a significant factor in convincing the Governor to declare a "state of emergency" and agree to provide temporary Medicaid relief for low income Part D recipients. The Helpline is also key in legislative advocacy.

For example, data from the Helpline was used to get an amendment proposed to the 2005 legislation that would address a deficiency in the law and enable many more recipients to obtain medically necessary prescriptions. Finally, the data base will enable advocates around the state to participate in a virtual law firm and have access to our growing body of prescription drug advocacy tools and strategies.

2. Program staff primarily responsible for project

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Resumes are attached.

3. Time expended

Time attributed to *Hernandez* litigation and *Edwards* reflect contemporaneous records, other entries are estimated.

	Hernandez Litigation	Hernandez Implementation	Hernandez Enforcement	Edmonds	Helpline
Miriam Harmatz	2167	400	150	306	100
Anne Swerlick	85	100	20		150
Shirley Sphuler					550
William Fraser	802	50			
C. Shawn Boehringer				59	
Jennifer Wimberly				126	

4. Expenses:

Cost for Litigation approximately \$20,000. Most of these costs were incurred on the *Hernandez* case for depositions, experts, court costs and other litigation costs . Costs to date for Helpline are approximately \$200,000.

5. Writing samples

The following two pleadings are attached as writing samples:

Hernandez, et at v. Meadows: Plaintiffs’ Memorandum of Law In Opposition to Defendant’s Motion for Summary Judgement.

Edmonds et al v. Meadows - Memorandum in Support of Plaintiffs Motion for Preliminary Injunction.

6. Media coverage

Press clippings and editorial comment are attached

7. Litigation

Hernandez, et al v. Meadows, 02-20964 CIV-Gold/Simonton (U.S.D.C., S.D.Fla), Order Approving Settlement Agreement, Settlement Agreement, Report and Recommendation regarding attorneys’ fees, and Final Order regarding fees and costs are attached along with the published

opinion certifying class at 209 F.R.D. 665.

Edmonds v. Levine, 05-2 1215 CIV-Lenard/Klein (U.S.D.C., S.D.Fla)

8. References:

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9. Why this project merits consideration for the Goldstein award

For our sick, elderly and disabled clients, no benefit is more critical or more at risk than prescription drugs. A successful drug therapy can literally mean the difference between life and death, chronic institutionalization and living successfully in the community, or intolerable and manageable pain. (See attachment to #9). Due to increasing government efforts both to control costs and privatize services, many impoverished and sick Floridians are being denied prescription coverage. This project represents a highly successful collaborative response on the part of advocates across the state, pro bono attorneys, national legal experts, and medical experts to ensure that some of our sickest and poorest clients maintain access to necessary prescriptions.