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Commentary and Reflections

The work of two legal advocates for battered immigrants—Reena Ganju and Elizabeth Saylor—was critical to the investigation and development of the *M.K.B.* case. Ganju's decision to participate as a fact witness rather than as cocounsel was instrumental in enabling the plaintiffs to prove pervasive and systemic violations at trial. The assistance of a large team of attorneys and paralegals at the New York law firm of Hughes Hubbard & Reed LLP, led by Ronald Abramson, was essential to the successful prosecution of the case. In addition to the direct representation of a number of clients and legal research and drafting, Hughes Hubbard & Reed furnished critical technical and logistical support (including an extranet where over 35,000 pages of discovery and all pleadings, depositions, filings, and research were posted and available online and in court).

During the investigation and preparation phase, the plaintiffs carefully considered the scope of the class. Ultimately the class definition was narrowed to focus on those categories of noncitizens for whom violations were most pervasive. This decision enabled counsel to focus resources on the areas of greatest concern and maximized the likelihood of proving systemic violations.

In negotiating the proposed settlement, we emphasized training, monitoring, and quality assurance measures in an effort to ensure that changes in policies and procedures mandated by the settlement would be translated into effective actions at the frontline, worker level. In formulating procedures for classwide retroactive relief, we strove to ensure that a significant part of the class would receive retroactive benefits without having to request such relief by responding to a classwide notice. We also focused on ensuring that class members who received "automatic" case reviews would be evaluated for relief for all benefit programs (cash public assistance, food stamps, and Medicaid) and that retroactive benefits would be issued for the full period authorized by the statute of limitations through the present. To preserve gains achieved in preliminary injunction orders, we ensured that the settlement would make those orders final and would require the defendants to comply fully with them.

For further information about the *M.K.B.* settlement or to contact plaintiffs' counsel, visit www.mkbsettlement.org/.

[**Editor's Note:** Case documents in *M.K.B. v. Eggleston* (Clearinghouse No. 56,101) are available in our Poverty Law Library at www.povertylaw.org.]

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National Class Action Alleging Federal Government Fails to Protect Medicaid Beneficiaries in Medicare Prescription Drug Program Will Proceed; Class Is Certified

Situ v. Leavitt is a national class action brought in federal district court on behalf of the 6.4 million Medicaid beneficiaries who were transferred into the Medicare Part D program in 2006 and had trouble accessing their medically necessary prescriptions.[1] The case was filed in April 2006 against the federal government for failing to enroll these vulnerable beneficiaries properly into the program or to subsidize their costs or both. The suit seeks declaratory and injunctive relief. Representing the U.S. Department of Health and Human Services (HHS) Secretary Michael O. Leavitt, the U.S. Department of Justice moved to dismiss the case and objected to the certification of the class on every conceivable ground.

In this case note I describe the circumstances that led to the filing of the lawsuit, some of the key challenges presented in the case, and the plaintiffs' recently defeating a motion to dismiss and obtaining nationwide certification of the class. I describe how privatization in government benefit programs presents obstacles to accountability and enforcement on behalf of low-income consumers.

New Prescription Drug Benefit

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added Medicare Part D, a new prescription drug benefit, to the Medicare program.[2] The Medicare Part D program is intended to give Medicare beneficiaries access to prescription drug benefits through private insurance plans. The addition of Part D was made with much political fanfare and marked the biggest change in government-provided health care since Medicare and Medicaid were first created in 1965.

With a hotly disputed multibillion-dollar price tag and partisan bickering over the passage of the legislation, Medicare Part D has been controversial since its inception. The relative merits of the program will likely be debated for years to come. Its early harmful impact on Medicare's most vulnerable recipients and the problems created for the Medicaid population, however, have been widely reported and virtually undisputed, except perhaps by the current administration and the Centers for Medicare and Medicaid Services (CMS) administering the program.

Medicare Part D is a voluntary program for most of the 43 million Medicare beneficiaries who are eligible for it. For the dual eligibles, those Medicare beneficiaries who are also eligible for Medicaid, the benefit is essentially mandatory. When Medicare Part D became effective on January 1, 2006, each of the 6.4 million Medicaid beneficiaries who are eligible for Medicare

[1] *Situ v. Leavitt*, No. C06-2841, 2007 WL 127993 (N.D. Cal. Jan. 12, 2007).

[2] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

lost their entitlement to coverage of prescription drugs under the Medicaid program for virtually all medications. To ensure a smooth transition for the dual eligibles, the Medicare Modernization Act had mandated that the HHS secretary establish a procedure to enroll all dual eligibles automatically into a Part D prescription drug plan to ensure that they had continual access to prescription drug coverage. CMS, however, failed to ensure that adequate safeguards were in place. Thus the millions of dual eligibles who lost their Medicaid eligibility on January 1, 2006, were transferred into the complicated Medicare Part D without sufficient protections to maintain their access to medically necessary medication.

Dual Eligibles

The elderly people and people with disabilities on both Medicare and Medicaid are poorer and sicker than other Medicare beneficiaries. Forty percent of dual eligibles have some type of cognitive or mental impairment. Most need assistance with activities of daily living. Many are poorly educated and speak a primary language other than English. Most do not have access to or know how to use computers and the Internet. Yet they depend heavily on prescription drugs and take an average of ten drugs more per month than the average Medicare beneficiary. Since many take fifteen, twenty, or thirty-five different prescriptions at the same time, assured access to these medications is essential.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Part D program was enacted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and mandated automatic enrollment into a Part D prescription drug plan for dual eligibles. As described below, automatic enrollment was less than successful.

This Act also established a program called the Low-Income Subsidy to waive the monthly Part D premium and annual deductible for the dual eligibles as well as to reduce the normal cost-sharing requirements for dual eligibles and others who meet the Low-Income Subsidy financial eligibility criteria. While most low-income beneficiaries must apply for Low-Income Subsidy, dual eligibles are supposed to be subsidy eligible without any action on their part. The HHS secretary is obliged under the law to inform the prescription drug plan in which the individuals are enrolled of their status as subsidy-eligible individuals. Granting all dual eligibles an ongoing special enrollment period, known as an SEP, Congress enabled them to change prescription drug plans at any time. Since each of the private prescription drug plans has its own formularies—limited lists of drugs to which members are entitled—the right of the dual eligibles to change to a plan that covers their medically necessary prescription is vital. They, unlike other beneficiaries, cannot afford to pay out-of-pocket for uncovered drugs.

Complexity, Privatization, and Accountability

An important aspect of the prescription drug law is the imposition of a privatized health care system for all of Medicare's forty-three million beneficiaries. Medicare Part D employs a complex system administered through thousands of different private plans offered in different regions throughout the country. In 2006 there were 1,429 private prescription drug plans (PDPs) and 1,314 managed care plans offering a drug benefit (MA-PD). There are even more in 2007. Benefit design, premium costs, deductibles, and coinsurance or copayments, formulary composition, and the procedure for obtaining coverage for drugs not on the formulary may change from year to year.

For dual eligibles, many entities other than the private plans are involved with the Part D program. Medicare is run by CMS. The Social Security Administration and state Medicaid agencies administer the Low-Income Subsidy Program. Dual eligibles are identified by individual state Medicaid agencies, and the agencies transmit to CMS that information by computerized files; CMS randomly enrolls them into various private plans. The plans contract with pharmacies to fill prescriptions. Plan and subsidy information is supposed to be made available to the pharmacists by computer. Consequently, when things go wrong, there are many entities to blame and fingers to point. If the federal government shirks responsibility for supervision and oversight of a benefit program involving private plans, low-income beneficiaries are at a tremendous disadvantage.

January 2006—Public Health Crisis

The new Part D program not only is extremely complex but also was implemented on a rapid time schedule. Although enrollment in Part D plans began in fall 2005 for coverage to take effect January 1, 2006, accurate information about plans and coverage was not readily available until December 2005. Even then, the information was sometimes incomplete, inconsistent, and primarily available only through the Internet. General enrollment began on November 15, 2005. The dual eligibles were reportedly enrolled in plans before that time. The federal and state governments sent numerous notices advising beneficiaries of these changes. Nonetheless, the process overall was chaotic and fraught with errors, computer glitches, and confusion. In early January the computers were so jammed that determining an overall error rate for pharmacists attempting to access the system was impossible. By January 3 pharmacists attempting to use the new system reported errors in obtaining drugs for the dual eligibles 99 percent of the time. By mid-January matters had improved, but the error rate was still approximately 20 percent. Given the vulnerability of the dual eligibles and their impaired access to medically necessary prescriptions, this error rate was still dangerously high. Recognizing a serious public health problem for their poor residents, virtually every state by the end of the first quarter of 2006 enacted some type of emergency program to provide prescriptions for elderly people and people with disabilities in their Medicaid population groups who were struggling with the Part D program.

At the same time, the federal government was touting the program as a success. Problems facing the dual eligibles were at first completely denied and then minimized. Only when headlines appeared in major newspapers were problems acknowledged. Then CMS described the major computer and drug access problems as minor "glitches" that were being

resolved. The administration appeared to have significant political reasons for sweeping these issues and problems affecting hundreds of thousands, perhaps millions, of low-income people under the rug. Low-income attorneys and advocates across the country reported problems and horror stories. Yet the federal government claimed that the problems were isolated, asked for specific documentation for each problem, and insisted that reported error rates were inaccurate. CMS steadily refused to supply any objective data demonstrating how many dual eligibles had trouble obtaining their medicine at the pharmacy level.

Legal aid attorneys, aging advocates, and State Health Insurance Program counselors assisting dual eligible clients grappled with hundreds of thousands of problems like this across the country. Usually the problems could be resolved, but doing so often took hours, days, weeks, or sometimes even months of persistent effort. Of course, many individuals have no advocate or relative assisting them and may be leaving pharmacy counters without medically necessary medication.

Situ v. Leavitt Filed April 2006

On behalf of individually named plaintiffs representing elderly people and people with disabilities from all around the country, the National Senior Citizens Law Center and the Center for Medicare Advocacy filed a class action lawsuit in district court in San Francisco in April 2006.[3] Legal services programs unable to participate in class actions referred many plaintiffs, and others came from State Health Insurance Programs or aging organizations. The case addresses the inability of dual eligibles to access Medicare Part D coverage and obtain medication without paying more than a nominal copayment. Some plaintiffs were in no plan; others were in the wrong plan, more than one plan, or were being charged excessive copayments or premiums or both. Each person experienced in 2006 a problem obtaining a medication that would have been available under the state Medicaid program in 2005. Since dual eligibles are by definition poor, they did not have the funds to pay the excessive copayments, premiums, or full out-of-pocket costs for the medication.

The plaintiffs' counsel was concerned that individual problems might be resolved and their cases considered moot. They filed a motion for class certification along with the initial complaint. They also filed two amended complaints in rapid succession, adding plaintiffs to the lawsuit each time. The second amended complaint was filed on June 30, 2006, and named thirteen individual plaintiffs and four organizations representing a class of 6.4 million dual eligibles experiencing problems with Medicare Part D enrollment, disenrollment, or the subsidy or all three. The plaintiffs alleged that the HHS secretary's failure to provide Medicare Part D benefits to dual eligibles violated 42 U.S.C. §§ 1395w-101(b)(1)(C) and 1395w-114 and the implementing regulations, as well as the due process clause of the U.S. Constitution.

Jurisdiction is alleged under 28 U.S.C. §§ 1331 and 1361 as well as 42 U.S.C. § 405(g).[4]

Plaintiffs' Motion for Class Certification Vacated

The defendant opposed the plaintiffs' motion for class certification and indicated his intention to file a motion to dismiss for lack of jurisdiction. Exercising its inherent discretion to manage its docket, the court *sua sponte* vacated the plaintiffs' motion for class certification without prejudice. The court noted that the defendant planned to file a dispositive motion and that consideration of the class issue should be deferred until after a determination of this motion. The court relied on a 1974 case, *Boyle v. Madigan*, for this action.[5] This put the plaintiffs in an untenable position. The plaintiffs filed the class motion at the same time as their complaint due to concern about individual claims becoming moot before the class motion could be considered. Waiting for the motion to dismiss to be fully briefed and argued could take months. Moreover, an appeal on the motion was also likely.

Following a local procedure, the plaintiffs moved for leave to file a motion for reconsideration of the order vacating the class motion and were given permission to treat that motion as a motion for reconsideration. The plaintiffs cited *Wade v. Kirkland* as superseding *Boyle v. Madigan*, at least with respect to cases raising transitory claims.[6] The court denied the motion but reinstated the class motion to be heard concurrently with the motion to dismiss.

Motion to Dismiss and Jurisdiction

Vigorously challenging the plaintiffs' action, the defendant claimed that twelve of the thirteen individual plaintiffs lacked standing, that all four organizational plaintiffs lacked standing, that several of the plaintiffs' claims were moot, and that the plaintiffs had not met the jurisdictional requirement of first presenting their claims to CMS. After a full briefing, the parties appeared before the court on a discovery matter. The defendant had sought a protective order to delay discovery until after a determination of the motion to dismiss. The court denied the protective order and allowed discovery for purposes of establishing jurisdiction. The plaintiffs believed that they could establish jurisdiction without discovery. That the court believed that jurisdiction was in question and was interested in receiving evidence on the issue, however, became apparent in oral argument and in the court's subsequent order.

The defendant's challenge to the plaintiffs' standing and jurisdiction ran the gamut. The defendant claimed that the plaintiffs' injuries were merely speculative when they had not actually paid for medications or suffered identifiable physical harm from going without medicine. Being billed for prescriptions, premiums, or copayments was not sufficient harm to meet Article III standing, according to the defendant. The defendant claimed that many of the plaintiffs' problems had been

[3]I am the lead counsel in the case. Gill Deford, Patricia Nemore, and Vicki Gottlich of the Center for Medicare Advocacy are cocounsel.

[4]42 U.S.C. § 405(g) is incorporated into the Medicare statute by 42 U.S.C. §§ 1395ff (b)(1)(A), 1395w-22(g)(5), 1395w-104(h)(1).

[5]*Boyle v. Madigan,* 492 F. 2d 1180, 1182 (9th Cir. 1974)

[6]*Wade v. Kirkland*, 118 F. 3d 667, 669–71 (9th Cir. 1997)

resolved, and therefore their cases were moot. The defendant claimed that the plaintiffs each had to present their claims to CMS before they could bring a court action. The defendant alleged that none of the problems could be traceable to CMS. Rather, the defendant claimed that the problems were due to actions by the plans, the pharmacy, the state, or the plaintiffs themselves.

In deciding the motion, the court did not take the plaintiffs' allegations in the complaint as true but ruled that the plaintiffs had to rebut the defendant's jurisdictional allegations with evidence and applied a summary judgment standard to its review. The plaintiffs believed that CMS' responsibility to oversee the Medicare program could be decided as a matter of law and was not a factual issue in the case. The court, however, made it clear that the plaintiffs had to prove the defendant's responsibility and oversight of the Medicare Part D program. At the very beginning of the case, the plaintiffs found themselves in the unusual posture of needing to collect and present evidence to prove their case. This experience highlighted for counsel the effect of the complexity of the Part D program and the legal implications of private plans delivering the prescription drug benefit for proceeding in court.

The plaintiffs faced an enormous challenge. Two prior similar cases filed on behalf of dual eligibles had been dismissed for lack of jurisdiction.[7] The plaintiffs were allowed to file a supplemental brief of only eight pages. Nonetheless, counsel compiled a voluminous factual record, attaching to declarations numerous exhibits with evidence of CMS' admissions of its oversight responsibility. Many documents were public record; others were obtained in discovery.

Court's Decision

Ultimately, the court ruled for the plaintiffs. The court rejected all of the defendant's attempts to dismiss the case for lack of standing and jurisdiction and allowed the case to go forward.[8] The court found that the plaintiffs' allegations of anxiety and distress distinguished them from hypothetical, speculative, or future injuries.[9] After carefully reviewing the evidence presented to the court, the judge found that the plaintiffs' alleged problems regarding autoenrollment and premium and copayment overcharges were fairly traceable to CMS' conduct. The court found that the organizational plaintiffs did not have standing to sue on their own behalf but gave them leave to amend their complaint to set forth additional facts about their members to allege representational standing. Holding the defendant to the stringent burden of demonstrating that it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur," the court rejected the defendant's mootness claims.[10] The court held that the plaintiffs were required to "present" their claims to CMS before seeking court review. However, construing the requirement liberally, the court held that making complaints to a Part D plan or state Medicaid office is sufficient to satisfy the presentment requirement.[11]

Class Certification

The defendant also opposed the motion for class certification on virtually every basis, including numerosity. In a separate order, the court found that the plaintiffs had met all of the grounds for a Federal Rule 23(b)(2) class.[12] The court certified a nationwide class, modifying the plaintiffs' proposed definition slightly to ensure that only actions or problems caused by the HHS secretary were included in the case.

Conclusion

The challenges of proving the case have only just begun. Analyzing the data delays involved in the complicated computer program and proving CMS' oversight responsibility over the various entities involved in the Part D program are formidable tasks.

The factual complexity of the case makes it an unusual one for a legal services organization to undertake. The case differs from a typical benefits case in that the plaintiffs are not challenging a specific policy or practice of the government; CMS has not actually refused to give benefits to the dual eligibles. Rather, the plaintiffs allege that CMS' implementation of the program is so inadequate that it violates the Medicare Modernization Act as a matter of law because so many beneficiaries are unable to access their benefits.

The plaintiffs are hopeful that through discovery they will be able to obtain the statistical information showing the large numbers of people affected by the system failures. Once this information comes to light, CMS is more likely to cease its whitewash of the problems that poor Medicare beneficiaries face and seriously tackle the impediments to prescription drug access that the dual eligibles now face.

[**Editor's Note:** Case documents in *Situ v. Leavitt* (Clearinghouse No. 56,102) are available in our Poverty Law Library at www.povertylaw.org.]

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[7]*Independent Living Center v. Leavitt,* No. 2:06 CV 0435 MCE, 2006 WL 1409621 (E.D. Cal. 2006), and *New York Statewide Senior Action Council v. Leavitt*, 409 F. Supp. 2d 325 (S.D.N.Y. 2005).

[8]*Situ v. Leavitt,* No. C06-2841, 2006 WL 3734373 (N.D Cal. Dec. 18, 2006).

[9]*Id.* at 7.

[10]*Id.* at 17.

[11]*Id.* at 20.

[12]*Situ v. Leavitt*, No C06-2841, 2007 WL 127993 (N.D. Cal. Jan. 12, 2007).

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