USE OF A MEDICAID DATABASE TO ANALYZE THE EFFECT ON PRESCRIBING MIX AND EXPENDITURES WHEN A DRUG IS ADDED TO A NEGATIVE DRUG LIST

BY

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DEDICATION

I would like to dedicate this to my wife, Jeri, whose love, patience, understanding, and support have guided me throughout my graduate studies and, in so doing, furthered my personal and professional growth and development.

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CHAPTER ONE

INTRODUCTION

The evolution of our health-care system began when the first cave person applied some mud to a fellow cave person to soothe an injury.[1] This was a system in which individual health-care practitioners applied limited medical knowledge to heal the sick or comfort the dying, and it was a system without organization in which care was dependent upon family and individual practitioners. By the mid-1930s, the health-care system was in transition as advances in medical science and a structure of "infirmaries," clinics, and hospitals in industrial areas developed and as health insurance evolved.[2]

Evolution continued in 1946-1948 with the Hill-Burton program, an ongoing, massive federal commitment to hospital construction, and aid to schools, colleges, and individuals seeking to enter the health professions. This period was characterized by the growth of technology, human and physical resources, and the expansion of health insurance coverage to the general population that culminated shortly after Medicare was established in 1965.

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1. Sharon M. Enright, "Effect of Reaganomics on the U.S. Health-Care System," American Journal of Hospital Pharmacy (39:7) July 1982, p. 1169.

2. Ibid., p. 1170.

Development of Federal and State Medicaid Programs

Medical Assistance (MA) was established in 1965 when Congress passed Title XIX of the Social Security Act so that eligible poor people could obtain adequate health-care in the mainstream of American medicine.[3] Medicaid is a program of MA funded by the federal government and the states for impoverished individuals who are aged, blind or disabled, members of families with dependent children and others. The services were to be provided primarily by the private medical care system beginning January 1, 1966.

The program operates on the basis of a state and federal division of responsibilities. The federal government establishes regulations, guidelines, and policy interpretations which describe the broad outline within which states can tailor their individual programs. States assume control and direction of operations. Funding is shared between the two bodies with the federal government matching state health care provider reimbursements of an authorized rate between 50 and 83 percent depending on the state's per capita income.[4]

The intent of the variable matching is to reduce interstate cost differences in the program. Federal law governs certain aspects of Medicaid, and requires that all persons who qualify for Aid to Families with Dependent Children (AFDC) and most persons who qualify

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3. The National Pharmaceutical Council, Inc., Pharmaceutical Benefits Under State Medical Assistance Programs (Washington, D.C., September 1986), p. 2.

4. Ibid.

for Supplemental Security Income receive Medicaid coverage. The federal government requires states to provide a basic set of services to people eligible for Medicaid and to reimburse providers of those services in certain ways.

Administration of the state Medicaid program is vested in single state agencies under a state's Department of Health and Social Services or similar agencies. Within each agency, state plans must designate a Medical Assistance unit responsible for developing, analyzing, and evaluating the Medicaid program. The law further requires the states to establish medical care advisory committees to advise the Medicaid agency director about health and medical services. Activities for administering the state Medicaid program include: (1) program administration, (2) Medicaid Management Information System (MMIS), (3) claims processing activity, (4) state administration, and (5) waivers.[5]

The states' control over eligibility is substantial because states establish eligibility for AFDC which establishes eligibility for Medicaid. Also, states may voluntarily extend Medicaid coverage to additional groups of people and expand the range of services covered. Moreover, states have considerable freedom in choosing reimbursement methods for physicians and other health care providers. Medicaid services for which federal funding would be received are grouped into seven major categories (see Table 1). In order to participate in Medicaid, there are certain basic services that must be offered in a

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5. Ibid., p. 3.

TABLE 1

MEDICAID SERVICE
(Mandatory Services Indicated by Capital Letters)

I. **Professional Services**

PHYSICIAN SERVICES
Chiropractors' Services
Podiatrists' Services
Optometrists' Services
Other Practitioners' Services
Dental Services (for persons 21 years of age and older)

II. **Nursing Care Services**

HOME HEALTH CARE SERVICES (for persons 21 years of age or older)
Personal Care Services
Private Duty Nursing
NURSE-MIDWIFE SERVICES
Adult Day Treatment Services

III. **Nursing Home Services**

SKILLED NURSING FACILITY SERVICES (for persons 21 years of age or older)
Intermediate Care Facility Services
Skilled Nursing Facility Services (for persons under 21 years of age)

IV. **Hospital and Clinic Services**

INPATIENT HOSPITAL SERVICES
OUTPATIENT HOSPITAL SERVICES
RURAL HEALTH CLINIC SERVICES
Clinic Services
Emergency Hospital Services

V. **Drugs, Supplies and Equipment**

Prescribed Drugs
Dentures
Eyeglasses (for persons 21 years of age and older)
Hearing Aids (for persons 21 years of age and older)
Prosthetic Devices

VI. Special Services and Therapy

INDEPENDENT LABORATORY AND X-RAY SERVICES
EARLY AND PERIODIC SCREENING, DIAGNOSIS AND TREATMENT (EPSDT) OF CHILDREN (under 21 years of age)
FAMILY PLANNING SERVICES
Diagnostic Services (for persons 21 years of age and older)
Screening Services (for persons 21 years of age and older)
Preventive Services
Physical Therapy
Occupational Therapy
Treatment for Speech, Hearing and Language Disorders

VII. Institutional Care

Inpatient Psychiatric Services (for persons under 22 years of age)
Care in Tuberculosis Institutions (for persons age 65 or older)
Care in Mental Institutions - Intermediate Care Facility Services (for persons age 65 or older)
Care in Mental Institutions - Skilled Nursing Facility (for persons age 65 or older)

VIII. Other

TRANSPORTATION TO AND FROM MEDICAL SERVICES
Enrollment in Medicare - Part B, Title XVIII, Supplemental Medical Insurance
Enrollment in Medicare - Part A, Title XVIII, Hospital Insurance Benefits

In addition to the services listed as being mandatory or optional, Title XIX specifies that "any other medical care, and any type of remedial care recognized under state law, specified by the Secretary of the Department of Health and Human Services," is acceptable as a Medicaid service and thus eligible for federal support.

SOURCE: The National Pharmaceutical Council, Inc., Pharmaceutical Benefits Under State Medical Assistance Programs (Washington, D.C., September 1986): 6-7.

state's Medicaid program. These mandatory services are shown by capital letters. In addition to the mandatory services, the participating states may elect optional services, including a prescription drug program.

Expenditures In Federal and Wisconsin Medical Assistance Programs

From the inception of Medicare and Medicaid in 1965, the nation's access to care has increased dramatically. However, policy changes in 1972[6] set the stage for explosive growth in Medicaid expenditures throughout the 1970s. Up through fiscal year 1981, Medicaid experienced double-digit annual growth rates, with hospitals and nursing homes representing three-quarters of total national expenditures.[7] Federal expenditures for Medicaid alone went from $741 million in 1966 to an estimated $23.6 billion in 1987 (see Table 2).[8] In addition, Medicaid as a percentage of GNP has increased since 1973. Moreover, low office-based physician participation rates, especially in the nation's highly urbanized

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6. The 1972 Social Security Amendments that liberalized eligibility for Medicaid to include SSI recipients (cash assistance to poor elderly, blind, and disabled) and, at state option, certain optionally categorically needy groups and certain medically needy people who would otherwise qualify for the cash assistance programs if it were not for moderately excessive income or resources.

7. The National Pharmaceutical Council, op. cit., p. 17.

8. Helen Darling, "The Role of the Federal Government in Assuring Access to Health Care," Inquiry (23:3) Fall 1986, p. 287.

TABLE 2

FEDERAL OUTLAYS FOR SELECTED ASSISTANCE PROGRAMS, FY 1966-1991

Fiscal Year	Medicare		Medicaid		Food Stamps	
	In Millions of $	% of GNP	In Millions of $	% of GNP	In Millions of $	% of GNP
1966	-	.01	741	.10	70	.01
1967	3,172	.35	1,121	.14	114	.01
1968	5,126	.54	1,729	.20	185	.02
1969	6,299	.61	2,191	.24	248	.03
1970	6,784	.63	2,612	.26	577	.06
1971	7,478	.63	3,210	.30	1,568	.15
1972	8,364	.65	4,438	.39	1,909	.17
1973	9,040	.63	4,385	.34	2,208	.17
1974	10,680	.68	5,549	.39	2,845	.20
1975	14,121	.85	6,524	.43	4,599	.30
1976	16,942	.93	8,150	.48	5,632	.33
1976tq	4,584	.95	2,124	.47	1,325	.30
1977	20,779	1.00	9,343	.48	5,399	.28
1978	24,275	1.05	10,060	.46	5,499	.25
1979	28,160	1.08	11,701	.48	6,822	.28
1980	33,954	1.20	13,232	.50	9,117	.34
1981	41,267	1.31	15,913	.53	11,253	.38

Fiscal Year	Medicare		Medicaid		Food Stamps	
	In Millions of $	% of GNP	In Millions of $	% of GNP	In Millions of $	% of GNP
1982	49,167	1.48	16,466	.52	11,014	.35
1983	55,499	1.58	18,049	.54	11,839	.36
1984	60,951	1.56	18,992	.51	11,561	.31
1985	69,649	1.67	21,393	.54	11,701	.30
1986(est.)	72,744	1.64	23,401	.56	11,667	.28
1987(est.)	75,754	1.55	23,620	.52	11,504	.25
1988(est.)	83,192	1.55	24,674	.50	11,868	.24
1989(est.)	92,091	1.58	26,009	.49	12,117	.23
1990(est.)	101,625	1.61	27,313	.49	12,322	.22
1991(est.)	111,707	1.65	28,545	.48	12,482	.21

SOURCE: Government Research Corporation report, prepared from data and tables in Gene Falk, "1987 Budget Perspectives: Federal Spending for the Human Resource Programs" (Washington, D.C.: Library of Congress, Congressional Research Service, Feb. 26, 1986). Cited by Helen Darling, "The Role of the Federal Government in Assuring Access to Health Care," Inquiry (23:3) Fall 1986, p. 289, table 1.

areas, drive large numbers of Medicaid recipients to costly hospital based settings for routine primary care, thus higher costs per recipient.

Expenditures for nursing home services is the largest and most rapidly growing component of national Medicaid outlays.[9] From fiscal year 1982 through fiscal year 1985, Medicaid expenditures for nursing home care increased from $12.9 billion to $16.3 billion. Inpatient hospital services are the second largest component of Medicaid expenditures nationwide, accounting for $10.6 billion or 28.3 percent of Medicaid outlays in fiscal year 1985.[10] Expenditures for physician services are the third largest component of Medicaid expenditures.[11] In fiscal year 1985, physician services accounted for $2.3 billion, or 6.1 percent of Medicaid expenditures nationwide.

Medicaid is the largest single state-administered program in state budgets, constituting about 10 percent of state general fund expenditures.[12] In federal fiscal year 1983, the state share of Medicaid outlays was $15.6 billion and the federal share was $18.9 billion.[13] In comparison, Medicaid accounts for approximately 3.6 percent of federal general fund outlays. Medical Assistance (MA) is

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9. The National Pharmaceutical Council, op. cit., p. 19.

10. Ibid.

11. Ibid., p. 20.

12. Rick Curtis, "The Role of State Governments in Assuring Access to Care," Inquiry (23:3) Fall 1986, p. 280.

13. Ibid., p. 277.

Wisconsin's largest program of aid to individuals, and it provided $942.2 million in medical benefits to 473,319 elderly, disabled or public assistance recipients in 1985 (see Table 3).[14] Of the total cost, $542.1 million (58%) was financed by federal funds. The remaining $400.1 million was paid through the state general purpose revenue budget.[15] Table 3 also shows MA recipient and expenditure levels for 1975, 1980, and 1985. The number of MA recipients rose, with the majority of growth occurring since 1980. One reason for this rise was that the number of persons eligible for public assistance programs, including MA, increased during the economic recession which occurred in the early 1980s. Several factors that contributed to the increase in MA expenditures included: (1) the rising cost of medical care, (2) the increase in the number of recipients, and (3) greater utilization of health care services by recipients.

Table 4 shows the distribution of Wisconsin Medical Assistance recipients and benefits. Benefits for the elderly and disabled were disproportionate to their numbers because of their need for high-cost nursing home or other institutional care. As Table 5 shows, the elderly category (age 65 years or older) accounted for the largest segment of expenditures due to long-term nursing home care. Nursing home or other institutional care also was the principal reason expenditures in the disabled category were higher than average.

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14. "Wisconsin Medical Assistance." The Wisconsin Taxpayer (54:6) June 1986, p. 1.

15. Ibid.

TABLE .3

TRENDS IN WISCONSIN MEDICAL ASSISTANCE

Recipients and Expenditures, 1975, 1980 and 1985

				Percent Increase		
	1975	1980	1985	1980 over 1975	1985 over 1980	1985 over 1975
Recipients						
Number	418,562	424,503	473,319	1.4%	11.5%	13.1%
Per 1,000 State Population	91.36	90.21	99.04	-1.3	9.8	8.4
Expenditures						
Amount (millions)	$361.2	$685.9	$942.2	89.9	37.4	160.9
Per Recipient	$863.04	$1615.73	$1990.53	87.2	23.2	130.6
Per Capita	78.84	145.76	197.14	84.9	35.2	150.1

Note: Population for 1980 from federal census; for 1975 and 1985, Wisconsin Department of Administration estimates.

SOURCE: Compiled by the Wisconsin Taxpayers Alliance from information from the Wisconsin Department of Health and Social Services; also see note above. (54:6) June 1986, p. 7.

TABLE 4

DISTRIBUTION OF

WISCONSIN MEDICAL ASSISTANCE

RECIPIENTS AND BENEFITS

By Eligibility Category, 1985

Category	% of Recipients	% of Benefits
AFDC	71%	20%
Elderly	14	42
Disabled	12	36
Blind & Other	3	2
Total	100%	100%

SOURCE: Compiled by the Wisconsin Taxpayers Alliance from information from the Wisconsin Department of Health and Social Services. (54:6) June 1986, p. 1.

TABLE 5

WISCONSIN MEDICAL ASSISTANCE

RECIPIENTS AND EXPENDITURES

By Eligibility Category, 1985*

Category	Recip-ient**	Exp. (millions)	Exp. Per Recipient
Elderly	74,635	$394.6	$5,286
Disabled	64,721	339.7	5,249
AFDC	388,755	192.4	495
Blind	1,146	5.1	4,432
Other	15,250	10.4	680
Total	473,319	$942.2	$1,991

*Federal fiscal year: October 1, 1984 to September 30, 1985.

**Numbers do not add to total because some recipients are in more than one eligibility category.

SOURCE: Compiled by the Wisconsin Taxpayers Alliance from information from the Wisconsin Department of Health and Social Services. (54:6) June 1986, p. 2.

Expenditures for AFDC families were lower than the previous two categories because most services were for physician or short-term inpatient hospital care.

Finally, Table 6 shows the number of recipients who received Medical Assistance for different types of health services in 1985, along with total MA expenditures and benefits per recipient. Most institutional services were for the elderly or disabled. The greater need of the elderly and disabled for institutional services explains why those groups, 26 percent of all recipients, received 78 percent of total MA benefits as previously noted (Table 4 above). The cost of noninstitutional care was $161 per recipient, which was about seven percent of the $2,317 cost per recipient for institutional care.

Prescription Drug Reimbursement

Prescription drug reimbursement conforms to the maximum allowable cost (MAC) system in effect since 1976. The MAC system is a listing of drugs with the maximum amount that will be reimbursed per unit by a state. This has led to some uniformity in drug-specific payments across states for some multisource products; however, states vary in community pharmacy dispensing fees, recipient copayments, limitations on use, over-the-counter exclusions, and formulary status for legend drugs. Table 7 shows Wisconsin prescription reimbursement characteristics for fiscal years 1984 and 1985. The Wisconsin MA program covers prescribed and certain non-prescribed drugs. Drugs are included as an optional service to prevent deterioration of health and

TABLE 6

WISCONSIN MEDICAL ASSISTANCE RECIPIENTS AND EXPENDITURES
By Type of Service, 1985*

Type of Service	M or O=2	Recipients=1		Expenditures		
		Number	% of Total Recipients	Amount (millions)	% of Total	Per Recipient
Institutional						
Skilled Nursing Care	M	36,550	7.7%	$300.3	31.9%	$8,215
Intermediate Care-Mentally Retarded	O	2,384	0.5	68.1	7.2	28,582
Other Intermed. Care	O	22,683	4.8	177.1	18.8	7,808
Hospital-Inpatient	M	59,672	12.6	131.3	13.9	2,200
Hospital-Outpatient	M	194,947	41.2	40.9	4.3	210
Mental Health Facil.	O	1,574	0.3	18.8	2.0	11,928
Subtotal		317,810	---	$736.5	78.2%	$2,317
Noninstitutional						
Prescribed Drugs	O	302,129	63.8%	$47.7	5.1%	$158
Physician Services	M	262,381	55.4	38.4	4.1	146
Dental Services	O	145,732	30.8	9.3	1.0	64
Other Practitioners	O	66,544	14.1	4.3	0.5	64
Clinic Services	O	172,249	36.4	21.6	2.3	125
Lab & X-ray Services	M	241,499	51.0	14.3	1.5	59
Home Health Services	M	8,569	1.8	16.9	1.8	1,977
Family Planning	M	46,498	9.8	7.9	0.8	169
Other	O	179,010	37.8	45.3	4.8	253
Subtotal		1,273,929	---	$205.7	21.8%	$161
TOTAL		473,319	---	$942.2	100.0%	$1,991

*Federal fiscal year.
[1]Numbers do not add to total because some recipients receive more than one service.
[2]M = Mandatory. O = Optional.
SOURCE: Compiled by the Wisconsin Taxpayers Alliance from information from the Wisconsin Department of Health and Social Services. (54:6) June 1986, p. 7.

TABLE 7

WISCONSIN MEDICAL ASSISTANCE PRESCRIPTION
REIMBURSEMENT PROGRAM CHARACTERISTICS FOR
FISCAL YEARS 1984 AND 1985
(Fiscal Year Ending June 30)

PROVISIONS	1984	1985
A. PRESCRIPTION CHARGE FORMULA		
1. Traditional (non-unit) dose	LOWEST OF: Estimated Acquisition Cost (EAC) plus $3.50 dispensing fee, MAC plus $3.50 dispensing fee or provider's usual and customary charge to the general public.	LOWEST OF: Estimated Acquisition Cost (EAC) plus $3.61 dispensing fee, MAC plus $3.61 dispensing fee or providers usual and customary charge to the general public. Increase of 0.11 (3.14%)
2. Unit Dose Dispensing	LOWEST OF: EAC plus $5.40 dispensing fee, MAC plus $5.40 dispensing fee or providers usual and customary charge to the general public. Reimbursement limited to one unit dose fee per drug per month.	LOWEST OF: EAC plus $5.56 dispensing fee, MAC plus $5.56 dispensing fee or providers usual and customary charge to the general public. Increase of 0.16 (2.96%) Reimbursement limited to one unit dose fee per drug per month.

PROVISIONS	1984	1985
B. COPAYMENT	All legend and over-the-counter drugs except family planning drugs are subject to a $0.50 copayment. Residents of Skilled Nursing Facilities (SNF) or Intermediate Care Facilities (ICF), subsidized adoption recipients, children under age 18, and HMO enrollees are exempt from the copayment (copayments limited to 10 per month).	All legend and over-the-counter drugs except family planning drugs are subject to a $0.50 copayment. Residents of Skilled Nursing Facilities (SNF) or Intermediate Care Facilities (ICF), subsidized adoption recipients, children under age 18, and HMO enrollees are exempt from the copayment (copayments limited to 10 per month).
C. PRESCRIBING OR DISPENSING LIMITATIONS		
1. Quantity of Medication	Not more than 34-day supply of a legend drug.	Not more than 34-day supply of a legend drug.
2. Renewals	Maximum of 11 renewals during a 12-month period for non-scheduled medications.	Maximum of 11 renewals during a 12-month period for non-scheduled medications.
3. Dollar Limits	None.	None.
D. GENERAL EXCLUSIONS		
1. Legend	Laxatives and nonprenatal vitamins.	Laxatives and nonprenatal vitamins.

PROVISIONS	1984	1985
2. Non-Legend	All except insulin, antacids, and analgesics.	All except insulin, antacids, and analgesics.
E. FORMULARY	No - No drug list but certain categories excluded from reimbursement.	No - No drug list but certain categories excluded from reimbursement.
F. STATE MAC PROGRAM	Yes - 134 entities.	Yes - 145 entities.

more costly expenditures for institutional services. In terms of the number of recipients and expenditures, drugs were the largest noninstitutional service funded by the MA program in 1985 (see Table 6 below). As Table 6 shows, 302,129 recipients (63.8%) received drugs with a total expenditure of $47.7 million (5.1%), and a cost per recipient of $158.00.

Medicaid Cost Containment

The growth of the Medicaid program in terms of government expenditures has been a problem since its early years.[16] In addition, given the prominence of Medicaid in state budgets, restrictions on state spending, and weakened economies in a number of states, it is not surprising that Medicaid cost containment has been an ongoing priority in most states over the last several years. In the late seventies through 1980, states tried, with varying levels of success, to contain costs of the program through the use of more stringent eligibility requirements, imposition of service cutbacks and limitations, tighter administrative controls, and postponing of increases in physician and pharmacy reimbursement. Although the number of recipients declined nationally, the cost per recipient continued to rise.[17]

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16. "APhA Position on Medicaid Reimbursement Reform," APhA Pharmacy Weekly (25:33) 22 August 1986, p. 143.

17. The National Pharmaceutical Council, op. cit., p. 17.

The first significant legislative step to control expenditure increases came in 1980 with the Omnibus Reconciliation Act of 1980 (PL 96-499).[18] This act implemented prospective reimbursement methodologies to replace cost-based provider reimbursement for hospitals and nursing homes. The second significant step in reforming Medicaid provider reimbursement came with passage of the Omnibus Reconciliation Act of 1981 (PL 97-35).[19] [20] This act, among other things, gave states the flexibility to develop more cost-effective delivery and financing structures. For example, states now could enter into prepaid service arrangements with non-federally qualified Health Maintenance Organizations (HMOs).

The third significant piece of legislation affecting Medicaid provider reimbursement policies was the Tax Equity and Fiscal Responsibility Act of 1982.[21] This act contained provisions asking for a system of prospective reimbursement for the Medicare program which might apply to the Medicaid inpatient reimbursement setting. Moreover, the act authorized an expansion of limitations on hospital charges from routine hospital costs per day to the cost per case, including ancillary costs.

The fourth legislative step to reform Medicaid provider

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18. Ibid.

19. Ibid.

20. Curtis, op. cit., p. 280.

21. The National Pharmaceutical Council, op. cit., p. 17.

reimbursement was the Social Security Act Amendments of 1983.[22] This act mandated a three-year phase-in of a case rate prospective reimbursement system for Medicare that could also be adopted by state Medicaid Agencies. A final legislative step was enactment of the Balanced Budget and Emergency Deficit Control Act of 1985, known as Gramm-Rudman-Hollings after its chief congressional sponsors. This has forced Congress and the executive branch to consider concrete action to reduce the federal deficit. As a result, pressure for more health benefits cuts will continue.

Cost-containment measures adopted by both federal and state governments have reduced Wisconsin's Medical Assistance expenditures by an estimated $65 million per year in total federal and state funds for 1985.[23] The largest savings have come from stricter MA eligibility provisions, lower benefits, limits on dental services, and from changes in the method used to determine reimbursement for inpatient hospital services adopted by the state in 1981. In addition, certain services to the medically needy were eliminated, and coverage for some drugs and podiatry services were discontinued. Finally, states have expanded Medicaid recipient enrollment in health maintenance organizations and similar plans by 164 percent since 1981.[24]

In Wisconsin, AFDC recipients in Milwaukee and Dane Counties have

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22. Ibid.

23. "Wisconsin Medical Assistance," op. cit., p. 7.

24. Curtis, op. cit., p. 280.

been required to enroll in a HMO of their choice from those available. Although federal expenditures for prescription medication under the Medicaid program account for only a small portion of total program expenditures, the U.S. Department of Health and Human Services has applied a substantial amount of effort to make sure that prescription drug expenditures are held to a minimum. In addition to the Maximum Allowable Cost/Estimated Acquisition Cost program, the State of Wisconsin has implemented utilization review and peer review designed to impact program quality and effectiveness. Also, a Negative Drug List has been implemented to curtail costs. However, the effectiveness of the Negative Drug List is limited by the lack of information concerning substitution effects among products.

History of Formularies

The role of formularies in third-party payment plans, in state Medicaid programs, and in health insurance plans continues to be a topic of interest. Drug formularies, written about 3000 B.C., date back to the clay tablets of the Sumerian civilization.[25] Since that time, many types of formularies have been devised to categorize drugs and drug preparations. The philosophy of the formulary system had its origins in the attempt to adapt some of the principles of national

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25. Glenn Sonnedecker, Kremers and Urdang's History of Pharmacy, Fourth Edition, (Philadelphia/Toronto: J. B. Lippencott Company, 1940-1976), 1:4.

pharmacopoeias to individual hospitals having a high concentration of practicing physicians.[26]

A pharmacopoeia is primarily a book of standards for strength and purity of drugs, and a hospital formulary is primarily a selection of drugs that meet pharmacopoeial standards. The first European pharmacopoeia was published in Florence in 1498 and, in the United States, the Massachusetts pharmacopoeia of 1808 was the first nonmilitary published.[27] Later, the first edition of the United States Pharmacopeia appeared in 1820.

The formulary system and hospital formularies have existed in this country since the days of the American Revolution when the Lititz Pharmacopoeia was published in 1778 for use by the Continental forces.[28] The first nonmilitary hospital formulary in the United States was called the Pharmacopoeia of the New York Hospital published in 1816. Other early American hospital formularies were those of Bellevue in 1868, German Hospital in 1902, and the "Official Formulae of American Hospitals" in 1885.[29] Later, Dr. W. J. Stainsby, a physician at New York Hospital, who, with the pharmacologist

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26. Donald E. Francke, "The Formulary System: Product of the Teaching Hospitals," Hospitals (41:22) November 16, 1967, p. 110.

27. Ibid.

28. "The Formulary System: Brief History and 1960s Perspective," American Journal of Hospital Pharmacy (43:11) November 1986, p. 2838.

29. Francke, op. cit., p. 112.

Dr. Robert A. Hatcher, formulated the first guiding principles for the operation of the formulary system and greatly influenced the development of formularies in American hospitals.[30]

Rationale For Formularies

Formularies and formulary systems have been perceived as effective instruments for controlling the rapid rate of drug obsolescence, drug utilization, therapeutic redundancy, and costs. The formulary system is a method of achieving the safe, effective, and cost-conscious use of medications for patients.[31] Moreover, it is a system that is accepted by medicine, health-care administration, pharmacy, and the pharmaceutical industry. Some authors believe the need for a formulary system continues because of the escalating number of drug products, the increased volume of drugs dispensed to Medicaid patients, rising drug prices, and more aggressive pharmaceutical marketing.[32] [33]

Abramowitz and Fletcher write that the formulary system can be one of the most effective methods of ensuring rational drug therapy, controlling drug costs, and opening avenues for clinical pharmacy

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30. "The Formulary System: etc.," op. cit., p. 2838.

31. William A. Zellmer, "Rethinking the Formulary System Concept," American Journal of Hospital Pharmacy (43:11) November 1986, p. 2829.

32. Ibid.

33. "The Formulary System: etc.," op. cit., p. 2839.

services.[34] In addition, they believe a well planned system would provide structure and flexibility, and should encompass the selection of drugs and criteria for drug use. Smith identified the advantages and disadvantages of a Medicaid formulary system as follows:[35]

A. Advantages:

1. It defines drugs for which reimbursement will be granted.
2. It simplifies administration and coding.
3. It facilitates control of expenditures.
4. It allows control of recipient utilization.

B. Disadvantages:

1. Physicians often ignore formularies.
2. Formularies interfere with prescribing freedom.
3. Formularies experience rapid outdating.
4. Formularies are inflexible.
5. Formularies do not meet the needs of the total population.

Limiting the number of drug entities and drug products routinely available from the pharmacy may produce substantial patient care (particularly) financial benefits. These benefits can be greatly increased through the use of generic equivalents (drug products considered to be identical with respect to their active components, e.g., two brands of tetracycline hydrochloride capsules), and therapeutic equivalents (drug products differing in composition or in their basic drug entity that are considered to have similar pharmacologic and therapeutic activities; e.g., two different antacid

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34. Paul W. Abramowitz and Courtney V. Fletcher, "Counterpoint: Let's Expand the Formulary System and Renew its Vigor," American Journal of Hospital Pharmacy (43:11) November 1986, p. 2834.

35. David M. Smith, "Consumer Response and Economic Impact of the Elimination of Selected Drug Products in the Michigan Medicaid Program" (M.S. thesis, Wayne State University, 1982), p. 17.

products or two different alkylamine antihistamines).[36] However, two coexisting conditions are necessary if the financial benefits are to achieve any importance: (1) the cost differential between the two products has to be large (taking into account volume of use), and (2) the decision to carry only one of the drug products requires constant enforcement.[37]

In addition to cost savings, generic product selection policies should stimulate bioequivalency comparisons and help to prevent the stocking of less than optimal products.[38] Thus, an important benefit of the formulary system is that it serves to limit the use of both ineffective or suboptimal drugs and drugs with undesirable adverse effects. Also, the formulary allows grouping of drugs by therapeutic categories and selection of the most appropriate products for use. Yet, these benefits in terms of costs are difficult to measure. Furthermore, there has been considerable discussion and some controversy over the advisability and benefits of closed and open formularies.

Under existing federal policy, the use of a formulary or limited drug list in a Medicaid program is optional for a state. The policy says, "the basic objective is to enable doctors and pharmacists

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36. "ASHP Statement on the Formulary System," American Journal of Hospital Pharmacy (43:11) November 1986, p. 2840.

37. Jeffrey A. Green, "Point: The Formulary System and the Emperor's New Clothes," American Journal of Hospital Pharmacy (43:11) November 1986, p. 2830.

38. Abramowitz, op. cit., p. 2834.

throughout the state to join in a mutually beneficial selection of high quality drugs of recognized therapeutic value, produced by reputable manufacturers, and broad enough to cover virtually any situation."[39] A drug formulary or list of pharmaceutical products is either open (unrestricted) or closed (restricted). Each state's Medicaid program determines its own formulary status. An open formulary is a list of virtually all prescription drugs approved by the FDA and allows the prescriber to choose the most medically appropriate drug to treat each patient. A closed formulary is a limited list of drugs for which reimbursement will be granted under the state Medicaid program. Any drug that is not contained in the list is not covered without prior approval by the state.

Need For The Study

With the inauguration of Ronald Reagan, changes in the health-care sector began. The Administration's goals for health-care are stated in its "Mandate For Leadership" and listed below:[40]

1. Develop alternatives to regulation to promote cost containment and quality control through competition;
2. Increase the role of state and local government and the private sector to increase competition.

These goals were aimed to help the Reagan Administration reach its two basic domestic policy goals: cutting federal social spending and

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39. The National Pharmaceutical Council, op. cit., p. 26.

40. Enright, op. cit., p. 1170.

reducing taxes. Thus, the Omnibus Budget Reconciliation Act of 1981 called for a three-year reduction in federal Medicaid payments to the states. Federal payment reductions were three percent in 1982, four percent in 1983, and four and one-half percent in 1984.[41] In the period 1981 to 1985, over one million people have been declared ineligible for Medical assistance through legislated changes in the rules. As a result, pressures on all levels of government to moderate the growth of their budgets and the movement to redefine medical care as an economic product rather than a social good are exacerbating the always difficult problem of financing care for people without insurance. Moreover, in the fall of 1982, unemployment peaked at a rate of ten percent of the work force.[42] Currently the rate remains higher (7.2% in 1985) than unemployment averages of the 1950s (4.4%), 1960s (4.3%), and the 1970s (6.1%). With a civilian labor force of 114 million people, every percentage point in the unemployment rate translates into 1.1 million workers without jobs.[43] Thus, state governments and the hospital industry are striking out in a variety of directions in search of answers.

Medical Assistance (MA) is Wisconsin's largest program of aid to individuals. As stated previously, the number of MA recipients and total expenditures in Wisconsin have increased dramatically since

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41. John K. Iglehart, "Medical Care of the Poor - A Growing Problem," New England Journal of Medicine (313:1) July 4, 1985, p. 61.

42. Ibid., p. 60.

43. Ibid.

1975. Cost-containment measures adopted by both federal and state governments have slowed the rate of Wisconsin's MA expenditures, but further cost savings are desired in specific areas, including prescribed drugs. Expenditures for prescribed drugs in Wisconsin's MA program are greater than those for any other covered noninstitutional service. With the increasing costs of prescribed drugs and federal budget cuts, additional cost-containment initiatives are being implemented.

In Wisconsin, the expansion of a Medicaid Negative Drug List is one method used in an attempt to control costs. The development of a Negative Drug List required the application of both medical and economic judgment. The deletion of particular drugs is motivated by an effort to promote rational drug therapy by reducing utilization of particular drugs which may not serve as the best form of therapy for the patient. However, the exclusion of specific drugs requires an assessment of the risk-to-benefit ratio, relative product efficacy, costs, and the substitution effect.

The political risk-benefit ratio of enforcing a formulary system can be high given the fact that prescribed drugs represented only 5.1 percent of WMAP expenditures in 1985. Also, the emotional impact on physicians and pharmacists may create a situation of much greater magnitude and eventual ramifications. Yet, the unpopularity of a formulary or Negative Drug List should not deter a department from implementing this system if the department can show economic benefit and fully intends to enforce the restrictions. The purpose of this study is to utilize computer reports generated by the Wisconsin

Medicaid Management Information System to examine the effect on prescribing mix and expenditures for internal analgesics after propoxyphene napsylate was added to the Negative Drug List.

Four groups should be interested in determining whether inclusion of a drug into a Negative Drug List increases or decreases the cost of prescribed drugs. The four groups are: (1) pharmacy managers, (2) Medicaid administrators at the state and federal levels, (3) pharmaceutical companies, and (4) public aid recipients. Community pharmacies have experienced considerable growth over the past decade in that proportion of their business which is derived from patients covered by Medicaid prescription programs.[44] There is recent evidence to show disparity among reimbursement rates from the Medicaid program and private-pay patients that has contributed to a problem known as "cost shifting."[45] Cost shifting in pharmacy occurs when one group of patients (i.e., patients covered by Medicaid prescription programs) does not pay the full price for services rendered and, therefore, another group of patients (i.e., private-pay patients) pays a price beyond the cost of services rendered to compensate for the lost revenue in order to cover the normal expenses incurred in doing business.

Data that evaluate formulary restrictions will enable pharmacy

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44. "APhA Position on Medicaid Reimbursement Reform," op. cit., p. 144.

45. Ibid. Cost shifting is the practice of charging more to one group of customers because another group of customers is not paying the full price for a particular product or service.

managers to take active steps to improve profitability. Medicaid administrators would benefit from knowing whether formulary restrictions are associated with higher or lower costs to help decide future proposals. The pharmaceutical industry also would benefit from this analysis because the exclusion of a drug from a formulary of this magnitude may have a significant impact on company profits and market share. Finally, public aid recipients are the persons ultimately affected by decisions on how Medicaid drug costs are controlled. Though not directly involved in establishing cost controls, this is the group that will experience the results of any changes in the Medicaid drug program. For example, was the medication discontinued or paid for out-of-pocket, or was an equally or more effective medication substituted?

Definitions

For the purposes of this study, the following terms and phrases are defined as follows:

1. Expenditures:
   Under Medicaid, "expenditures" refers to an amount paid by a state agency for the covered medical expenses of eligible participants. This refers to drug product and drug entity costs established by Wisconsin Medicaid for reimbursement purposes plus dispensing fees.

2. Institutional Medicaid recipients:
   Long-term care facility (LTCF) patients or nursing home patients receiving prescribed drugs through a provider.

3. Negative Drug List:
   A drug list established by the Wisconsin Medical Assistance Program (WMAP) that includes drug products not covered because it

has been determined that they have little or no therapeutic value or may be replaced by other more cost-effective drugs.

4. Noninstitutional Medicaid recipients:
Noninstitutionalized persons receiving prescribed drugs through a pharmacy or physician separate from any long-term care facility.

5. Prescribed Drugs:
Drugs dispensed by a licensed pharmacist pursuant to the prescription order of a practitioner licensed by law to administer such drugs, and drugs dispensed by a licensed practitioner to his/her own patients. This does not include a practitioner's drug charges that are not separable from his other charges, or drugs covered by a hospital's bill.

6. Prescription (prescribing) mix:
Drug entities commonly used within a particular therapeutic class currently listed in the Medicaid State Operations Manual. More specifically, the prescription mix examined in this study includes scheduled analgesics (II, III, IV), nonsteroidial anti-inflammatory drugs (NSAIDs), and over-the-counter analgesics. Some drugs in the prescription mix have multiple uses but, for this study, it was assumed their use parallels that of propoxyphene napsylate.

Study Objectives

This study has the following objectives:

1. Establish the integrity of the Medicaid data base via literature references to show the data can provide useful information.

2. Analyze what effect the addition of propoxyphene napsylate to the Negative Drug List had on prescribing mix and expenditures within the internal analgesic therapeutic class for noninstitutional Medicaid recipients.

3. Determine if the number and size of prescriptions between periods varied for noninstitutional Medicaid recipients.

4. Analyze what effect the addition of propoxyphene napsylate to the Negative Drug List had on prescribing mix and expenditures within the internal analgesic therapeutic class for institutional Medicaid recipients.

5. Determine if the number and size of prescriptions between periods varied for institutional Medicaid recipients.

6. Determine if any relationships exist between the institutional and noninstitutional recipients. For example, did the availability of a consultant pharmacist result in a larger proportion of

propoxyphene napsylate prescriptions being switched to propoxyphene hydrochloride prescriptions in the institutional population?

Research Hypotheses

The following hypotheses were derived from the study objectives:

1. There was no change in expenditures per internal analgesic recipient for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

2. There was no change in expenditures per internal analgesic prescription for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

3. There was no change in expenditures per internal analgesic unit for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

4. There was no change in the number of prescriptions per internal analgesic recipient for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

5. There was no change in the number of units per internal analgesic recipient for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

6. There was no change in the number of units per internal analgesic prescription for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

7. There was no change in expenditures per internal analgesic recipient for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

8. There was no change in expenditures per internal analgesic prescription for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

9. There was no change in expenditures per internal analgesic unit for institutional Medicaid recipients at the 95 percent level of

confidence after propoxyphene napsylate was added to the Negative Drug List.

10. There was no change in the number of prescriptions per internal analgesic recipient for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

11. There was no change in the number of units per internal analgesic recipient for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

12. There was no change in the number of units per internal analgesic prescription for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

13. There was no difference in the proportion of propoxyphene napsylate switched to propoxyphene hydrochloride between institutional and noninstitutional Medicaid recipients after propoxyphene napsylate was added to the Negative Drug List.

CHAPTER TWO

LITERATURE REVIEW

There are a number of published studies evaluating the performance of formularies or restriction policies in hospitals and state Medicaid programs. In 1966, the Task Force on Prescription Drugs estimated a potential material savings of 41.5 million dollars obtainable by using lower cost nonproprietary drugs for 63 multiple source products.[1] In 1971, Strom, Stolley and Brown calculated that a national savings of at least 224 million dollars annually could be realized if the acquisition cost of the least expensive product was used for 100 of the most frequently used nonproprietary drug products in the United States during 1971.[2]

Rucker has stated that cost savings generated by using the lowest cost generically equivalent items are not likely to exceed six percent.[3] However, he goés on to say that these savings are not

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1. U.S. Department of Health, Education and Welfare, Task Force on Prescription Drugs: Final report - Government Printing Office, Washington, D.C., 1969. Cited by Robert G. Swift, Jr. and Michael R. Ryan, "Potential Economic Effects of a Brand Standardization Policy in a 1000-bed Hospital," American Journal of Hospital Pharmacy (32:12) December 1975, pg. 1243.

2. B. L. Strom, P. D. Stolley, and T. C. Brown, "Drug Substitution Studies: Estimate of Possible Saving by Repeal of Antisubstitution Laws," Drugs In Health Care (1:2) Fall 1974, p. 99.

3. Donald T. Rucker, "Drug Insurance Formularies and Pharmacy," Medical Marketing and Media (6:10) October 1971, p. 16.

insignificant in multibillion dollar drug programs, but the savings could be offset by increased prices of sole source items and increased administrative expenses. Wolfe found in studying approximately 20 of 95 Western Pennsylvania hospitals that drugs with generically equivalent alternatives constituted 29.5 percent of all drug orders and accounted for 16.8 percent of total drug costs. A savings of 21.2 percent of this drug cost was predicted if the lowest cost generically equivalent drugs were always purchased and other considerations were ignored.[4] Wolfe concluded that an overall savings of 3.57 percent of total drug costs amounting to $600,000 for all Western Pennsylvania hospitals could be realized. The data were further extrapolated to predict a national hospital drug cost savings of approximately $42 million annually.

Formularies In Hospitals

During the mid 1960s, Rosner recommended that, ". . . a pharmacist who institutes a formulary system in his hospital will measure the financial status of his pharmacy, both before and after this event, to determine how the formulary affected its operation."[5] Francke et al., suggested that, ". . . chief pharmacists evaluate the formulary

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4. Harvey Wolfe, "How Cost-Effective Are Generics?" Hospitals (47:9) May 1, 1973, pp. 100-104.

5. Martin M. Rosner, "The Financial Effects of Formularies in Hospitals," American Journal of Hospital Pharmacy (23:12) December 1966, p. 674.

system for its effects on expenditures for drugs and inform their medical and administrative staffs of their findings."[6] If nonformulary status did not control inappropriate use, then restricted drug policies were considered as alternatives. Use of restricted drug policies has become widespread. Approximately 25 percent of short-term hospitals subject some drugs to some type of prescribing restrictions.[7] In addition, 57 percent of major teaching hospitals and 30 percent of community hospitals in one area used them for antibiotics.[8 9]

Rosner evaluated the economic effects of formularies in Chicago area hospitals using 24 nonteaching, voluntary hospitals ranging in size from 216 to 417 beds.[10] The study measured the correlation of hospital size and three types of formulary systems to the drug cost per inpatient day and inventory turnover rate of pharmaceuticals. The three types of formulary systems studied were: (1) unrestrictive, (2)

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6. Donald E. Francke et al., "Mirror to Hospital Pharmacy" (Washington D.C.: American Society of Hospital Pharmacists; 1964). Cited by Jeffrey A. Green, "Point: The Formulary System and the Emperor's New Clothes," American Journal of Hospital Pharmacy (43:11) November 1986, p. 2830.

7. Michael H. Stolar, "National Survey of Hospital Pharmaceutical Services-1985," American Journal of Hospital Pharmacy (42:12) December 1985, p. 2678.

8. Deborah L. Klapp and Reuben R. Ramphal, "Antibiotic Restriction in Hospitals Associated with Medical Schools," American Journal of Hospital Pharmacy (40:11) November 1983, p. 1960.

9. Gerard J. Hatheway and Steven L. Barriere, "Areawide Survey of Antimicrobial Restriction Policies and the Role of Hospital Pharmacists," Hospital Formulary (17:8) August 1982, p. 1105.

10. Rosner, op. cit., p. 675.

brand standardization, and (3) restrictive. Size and university affiliation were controlled in order to provide a sample of hospitals which would have similar goals and therapeutic activities. Under the unrestrictive system, all brand name products were available to the physician. With brand standardization, all nonproprietary drugs were available to the physician, but brand name products of identical nonproprietary drugs were restricted. The restrictive formulary system allowed for the use of only those nonproprietary drugs approved by the hospital and present on the formulary list. The data show that:

1. As the restrictiveness of the formulary increased, drug cost per inpatient day increased and inventory turnover rate decreased.
2. Brand standardization allowing the pharmacist greater authority to dispense a brand drug other than the one prescribed was associated with a decrease in drug cost per inpatient day and an increase in inventory turnover rate.
3. As the number of items in inventory increased, drug cost per inpatient day increased and inventory turnover rate decreased.
4. Increases in hospital size were associated with decreases in drug cost per inpatient day and increases in turnover rate.

Among his conclusions, Rosner stated that, ". . . formulary systems can be used to further financial performance only if the pharmacist has the power to actually use it to restrict inventories." Many institutions do not collect data on the cost savings achieved with implementation of a formulary system. Total cost savings are difficult to estimate because of added variables including drug price increases, additions of new drugs, and changes in prescribing patterns. As a result, no comprehensive estimation of the cost-effectiveness of the formulary system has been published. However, there are examples of cost savings for specific drug groups to indicate the formulary system can work.

No single category of drugs has come under closer scrutiny by pharmacy and therapeutics committees than the antimicrobials.[11] These agents can represent a substantial portion of a hospital's drug budget. For example, at a 719-bed nonprofit teaching hospital the annual expenditure for antibiotics was approximately 32 percent of the total drug budget.[12] Other centers have reported similar percentages.[13] Cost savings resulting from restrictive antibiotic programs have been well established.[14-17] Hayman and Sbravati recently reported that a pharmacy and therapeutics committee restriction program at their institution resulted in a reduction of nearly $200,000 in antimicrobial expenditures during the first

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11. Richard Gleckman and Nelson M. Gantz, "Cost-Effective Antibiotic Prescribing," Pharmacotherapy (3:4) July-August 1983, p. 239.

12. Louis P. Jeffrey et al., "Hospital Restriction Policy for Newly Marketed Antimicrobial Agents," American Journal of Hospital Pharmacy (43:9) September 1986, p. 2230.

13. William A. Craig, et al., "Hospital Use of Antimicrobial Drugs," Annals of Internal Medicine (89:5) November 1978, p. 795.

14. Olga H. DeTorres and Robert E. White, "Effect of Aminoglycoside-Use Restrictions on Drug Cost," American Journal of Hospital Pharmacy (41:6) June 1984, pp. 1137-1139.

15. Michael W. Noel and James Paxinos, "Cephalosporins: Use Review and Cost Analysis," American Journal of Hospital Pharmacy (35:8) August 1978, pp. 933-935.

16. Edward E. Katz and Samuel S. Schamowitz, "Savings Achieved Through Cephalosporin Surveillance," American Journal of Hospital Pharmacy (35:12) December 1978, pp. 1521-1523.

17. Randell M. Phelps and Harold N. Godwin, "Pharmacy and Therapeutics Committee Review of the Parenteral Cephalosporins," American Journal of Hospital Pharmacy (35:1) January 1978, pp. 73-75.

12 months of implementation.[18] Jeffrey estimated that by restricting cefoperazone alone, a savings of nearly $10,000 would result for the 1986 fiscal year.[19] Moreover, Dzierba et al. showed an annual cost savings of $122,235 from substitution of cefazolin for cefamandole in surgical prophylaxis.[20] Britton et al. reported a savings of $55,715 in drug costs when cefazolin was chosen as the primary injectable cephalosporin.[21] Finally, other studies have quantified direct drug and inventory cost savings by restricting antimicrobials.[22] [23]

Unfortunately, few data exist documenting cost savings from restricting other classes of drugs. However, Anandan did show annual savings of $16,301.71 from limiting the number of theophylline preparations on a hospital formulary, and Durfee showed cost savings

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18. Jimmy N. Hayman and E. Clyde Sbravati, "Controlling Cephalosporin and Aminoglycoside Costs Through Pharmacy and Therapeutics Committee Restrictions," American Journal of Hospital Pharmacy (42:6) June 1985, pp. 1343-1347.

19. Jeffrey, op. cit., p. 2232.

20. Steven H. Dzierba et al., "Cost Savings Achieved Through Cephalosporin Use Review and Restriction," American Journal of Hospital Pharmacy (43:9) September 1986, p. 2197.

21. H. Lynn Britton et al., "Cost Containment Through Restriction of Cephalosporins," American Journal of Hospital Pharmacy (38:12) December 1981, p. 1900.

22. Harold Rubin and Darc D. Keller, "Improving a Pharmaceutical Purchasing and Inventory Control System," American Journal of Hospital Pharmacy (40:1) January 1983, pp. 67-69.

23. Phillip N. Johnson and Louis P. Jeffrey, "Restricted Cephalosporin Use in Teaching Hospitals," American Journal of Hospital Pharmacy (38:4) April 1981, pp. 513-517.

of an enteral products formulary.[24] [25] Packer et al. showed small cost savings from strict formulary management; they projected yearly savings of $6,438, but did not delineate which drug products were represented by this savings.[26]

Authors have reported failures in their efforts to contain costs through formularies or restriction policies in hospitals. Weintraub concluded that studies analyzing the outcome of economically oriented formulary decisions lack uniformity, and some were defective in various respects.[27] Two assumptions that limit many available studies include the constancy of drug utilization between time periods and the comparability between hospitals. Other limitations of existing studies include lack of long-term follow-up data, missing variables, exclusion of administrative costs as part of the economic analysis, and extrapolating savings on one drug category to include all drugs.

Daniels and Wertheimer noted little solid evidence for cost control

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24. J. V. Anandan, "Reducing the Number of Formulary Theophylline Preparations," American Journal of Hospital Pharmacy (38:4) April 1981, pp. 511-513.

25. Donna D. Durfee and Virginia M. Skinner-Domet, "Cost-Effectiveness of an Enteral Products Formulary," American Journal of Hospital Pharmacy (41:11) November 1984, pp. 2352-2354.

26. Lorrie A. Packer et al., "Effect of Pharmacists' Clinical Interventions on Nonformulary Drug Use," American Journal of Hospital Pharmacy (43:6) June 1986, pp. 1461-1466.

27. M. Weintraub et al., Controlling the Use of Therapeutic Drugs, An International Comparison, Part I, pp. 31-55, American Enterprise Institute for Public Policy Research, Washington, D.C., 1978. Cited by David M. Smith, "Consumer Response and Economic Impact of the Elimination of Selected Drug Products in the Michigan Medicaid Program," (M.S. thesis, Wayne State University, 1982.)

via formularies.[28] Their data showed that this system did not automatically produce lower inventory values, and that the formulary review process was used inefficiently. Sylvester and Sudds showed that restricting four drug categories resulted in a yearly savings of $681, which did not include any costs involved with supporting the program (e.g., monograph preparation, secretarial support and duplicating).[29] Also, the data show topical corticosteroid costs increased after formulary implementation. In addition, as mentioned previously, Rosner showed that inpatient drug costs per day increased as formularies became more restrictive.[30]

Cost savings also must be evaluated against costs incurred because of the restrictive formulary. Time is consumed in meetings, preparation, and by supportive personnel. Rucker's evaluation of the use of restricted formularies notes that if price considerations are applied rigorously (e.g., products priced significantly above the true economic cost of production and distribution are excluded from the formulary), many first and second choice drugs may not be available for patient treatment.[31] Under such conditions, program expenses

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28. Charles E. Daniels and Albert I. Wertheimer, "Analysis of Hospital Formulary Effects on Cost Control," Topics In Hospital Pharmacy Management (2:2) August 1982, pp. 32-47.

29. K. L. Sylvester and T. W. Sudds, "Cost Savings Through Formulary Implementation and Group Purchasing in Four Therapeutic Categories," Hospital Formulary (21:3) March 1986, pp. 357-370.

30. Rosner op. cit., p. 674.

31. Donald T. Rucker, "Drug Insurance, Formularies and Pharmacy," Medical Marketing and Media (6:10) October 1971, p. 16.

could actually rise as treatment is prolonged due to the fact that drugs of second choice or last resort may often be substituted for the medication of choice. A physician denied his "drug of choice" may prescribe larger quantities of another drug or additional supportive therapy or both to treat the illness.[32] The preferred (not reimbursed) therapy may speed patient recovery, reduce the need for hospitalization and additional visits to the physician's office, or other health care expenses. Moreover, it has been noted that if the physician prescribes a drug which is not listed, there is some possibility the patient will not obtain the medication and a good part of the already provided diagnosis and treatment will be wasted.[33]

Rucker reviewed the number and kinds of drug products approved for hospital and Medicaid drug formularies.[34] The data base for the survey consisted of 52 formularies prepared by private hospitals with 500 or more beds (44 were affiliated with medical schools and 23 with colleges of pharmacy), and 12 formularies adopted by Medicaid drug programs. The hospital sample contained a total of 2,801 different entities. However, only 69 of the entities were present on every formulary. Drugs listed infrequently (by less than 10% of the

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32. Robert W. Hammel, "Insights Into Public Assistance Medical Care Expenditures," Journal Of The American Medical Association (219:13) March 27, 1972, p. 1742.

33. J. A. Bachynsky, "Some Aspects of Drug Distribution Under Tax Supported Programs" (Ph.D. dissertation, University of Wisconsin-Madison, 1967).

34. T. Donald Rucker, "Drug Formularies: Do They Work?" American Pharmacy (NS19:1) January 1979, pp. 31-33.

hospitals) totaled 1,425. Given this low level of certification, Rucker contended that more than half of the drugs listed were superfluous. A similar pattern characterized the Medicaid formularies which included 2,017 different entities, and 900 of these chemical agents were approved by only one or two states. Moreover, Rucker professed 275 items did not possess therapeutic properties sufficient to warrant inclusion on a single reference issued by a hospital. Finally, Rucker found a strong statistical relationship between increased formulary size and the proportion of inferior drugs carried.

In a separate publication of the same formulary study, Rucker noted the wide range of performance in the ability of the source documents to minimize the listing of inferior pharmaceutical products.[35] In his opinion, these included reference materials that were incomplete, and nomenclature encumbered by redundancy, mystification, and even deception. The median percent of inferior pharmaceutical products carried by hospital formularies was 20 percent, while the comparable statistic for the Medicaid formularies was nearly double that. Rucker proposed that if an acceptable limit of questionable agents might be two to three percent, the sample formularies exceeded this threshold by a large margin (even the best performing hospital was unable to score below 9.3%).

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35. T. Donald Rucker, "Drug Information: Findings From a Major Study of Formularies," Drug Information Journal (13:1) January/June 1979, pp. 41-45.

Formularies In State Medical Assistance Programs

Some studies have demonstrated that utilization of benefits, including drug benefits, increases following implementation of a Medicaid program.[36] [37] Smith and Garner compared prescription drug availability and utilization in a selected area of Mississippi in similar three-month periods before and after enactment of a Medicaid drug program.[38] Prescription audits and personal interviews were used. The data show prescriptions per patient increased from 5.43 pre-Medicaid to 9.48 post-Medicaid. The number of different drugs used per patient increased from 2.68 pre to 3.64 post-Medicaid. Also, the average quantity of tablets or capsules prescribed on a single prescription order before Medicaid was 45.00; the average quantity after Medicaid was 48.35. The average price for all prescriptions increased from $3.58 to $4.49, and the average number of different physicians utilized increased from 1.28 to 1.43 per patient between the periods studied. The authors concluded that drug utilization increases with the advent of a Medicaid program.

As a result of this increased utilization, very early on some

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36. Foline E. Gartside, "Causes of Increase in Medicaid Costs in California," Health Services Reports (88:3) March 1973, pp. 225-235.

37. P. L. Grimaldi, "An Analysis of the Causes of Increases in Medicaid Payments, New Jersey, 1970-1974," Health Services Reports (90:12) November/December 1975, pp. 509-515.

38. Mickey C. Smith and Dewey D. Garner, "Effects of a Medicaid Program on Prescription Drug Availability and Acquisition," Medical Care (12:7) July 1974, pp. 571-581.

states implemented formulary systems to help reduce drug expenditures, and have found savings in terms of standardizing drug products.[39] [40] Meyer et al., described and evaluated the "open-controlled" formulary in the Tennessee Medicaid drug program during 1972.[41] The only drugs excluded from the formulary were over-the-counter drugs (except insulin); anorectic drugs (except when indicated for narcolepsy or hyperkinetic children); compounded prescriptions; non-narcotic analgesic compounds, and a few psychotherapeutic agents. Also, in 1972, the program had price ceilings, similar to the federal MAC program, in effect for 13 drugs. Based on the frequency of claims for the 13 products, and the price differential between the actual cost to the program and the most costly brand, a possible saving of over $400,000 per year was estimated. The authors concluded that a drug utilization monitoring program with a peer review mechanism should be effective in reducing the level of drug expenditures and other medical and hospital costs.

The Michigan Pharmacists Association performed an economic evaluation of the annualized savings under the Medicaid program of a proposed Medicaid Therapeutic Formulary for 12 drug

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39. R. Burack, "Massachusetts Generic Drug Law," New England Journal of Medicine (285:23) December 2, 1971, pp. 1327-1328.

40. "Pennsylvania Welfare Patients Get Prescriptions From Formulary," Hospitals (41) September 16, 1967, p. 108.

41. Marvin C. Meyer, Herbert Bates, and Robert G. Swift, "The Role of State Formularies-Providing Quality Drugs Economically," Journal of The American Pharmaceutical Association (NS14:12) December 1974, pp. 663-666.

entities.[42] The data base period was July 1978, in most cases. The following were projected savings estimated for the two most frequently prescribed drug entities of the 12 from the proposal. First, if all diazepam units were converted to chlordiazepoxide, a drug entity under Medicaid MAC, a projected yearly savings of over $1.6 million was estimated. Second, if all Darvocet-N^{R} 100mg units were converted to propoxyphene hydrochloride the projected net yearly savings would have been over $300,000. However, the Department of Social Services in Michigan rejected the proposal because the results would be a denial of appropriate therapeutic treatment to Medicaid patients. In addition, the department estimated an increase in program costs of between $343,000 and $557,000 due to the higher average prescription cost of drugs which would be substituted, higher administrative costs, and the incentive to use other modes of therapy at greater cost (e.g., hospitalization).

Data are available that show the use of formularies that restrict the number of reimbursable drugs in Medicaid programs have not achieved the desired reduction in expenditures. Smith et al., examined what effect the elimination of minor tranquilizers (Valium, Librium and meprobamate) from the Mississippi Medicaid formulary in

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42. "Economic Impact Evaluation: Proposed Medicaid Therapeutic Formulary," Michigan Pharmacists Association, November 1979. J. Dempsey, "Evaluation of a Proposed Restrictive Medicaid Drug Formulary," Michigan Department of Social Services, December 21, 1979. Cited by David M. Smith, "Consumer Response and Economic Impact of the Elimination of Selected Drug Products in the Michigan Medicaid Program," (M.S. thesis - Wayne State University, 1982.)

1971 had on drug cost and prescribing patterns.[43] Information on Medicaid prescription orders was collected from a stratified random sample of 20 pharmacies based on the dollar volume of Medicaid drug claims submitted in fiscal year 1973. The 20 pharmacies were selected from a population of 416 pharmacies in the northern half of Mississippi. Data from more than 100,000 prescription orders were collected in two six-month periods, January 1 to June 30, 1971 and 1972. The authors multiplied the prices of psychotherapeutic agents in the formulary by the number of prescriptions dispensed in the second six-month period at the 20 pharmacies. The authors then calculated what the cost of psychotherapeutic drugs would have been to the Medicaid program if the minor tranquilizers had remained in the formulary.

The data show total costs of $24,343 in the first analysis and $24,570 in the second analysis - a net saving of $227. The statewide saving was projected to be $13,620 for the year, or 0.01 percent of the state Medicaid budget. Yet, after minor tranquilizers were eliminated, prescription orders increased for major tranquilizers (43%), psychostimulants (103%), combinations (71%), and barbiturates (75%). In addition, the data analysis showed that 40 percent of the patients probably continued to receive prescription orders for minor tranquilizers no longer paid for by Medicaid. This out-of-pocket cost

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43. Mickey C. Smith, Clayton R. Rowland and Dewey D. Gardner - Research from the School of Pharmacy at the University of Mississippi. Cited by John Carlova, "Would a National Formulary Cut Prescription Costs?" Medical Economics (52:12) December 8, 1975, pp. 80-82.

to patients was estimated to be $73,080.

Smith and MacLayton studied the prescribing patterns and economic effects of analgesic drugs before and after implementation of a restrictive formulary in the Mississippi Medicaid program.[44] The authors were particularly interested in whether the use of substitutes resulted in any savings to the Medicaid program. On September 1, 1971, a formulary was adopted with the elimination of all non-narcotic analgesics from coverage with the exception of Butazolidin®, Butazolidin® Alka, Indocin®, Sterazolidin®, acetaminophen, Tandearil®, and Talwin®. Also, aspirin was added. The methodology for selection of pharmacies and prescription orders for analysis was the same as that of the previous study cited. The data analysis used information from 12,183 prescription orders for analgesics. The data show changes in orders for analgesics between the two periods as follows:

Drug Class*	No. of Prescription Orders Open Formulary 1971	Closed Formulary 1972	Percent Change
All Drugs	48,294	53,613	+11.0
Strong Analgesics - Total	562	305	-45.8
Narcotics	66	116	+75.8
Non-narcotics (Talwin®)	1	188	+18,700.0
Combinations (mixtures of strong and/or mild analgesics)	495	1	-99.8
Mild Analgesics - Total	4,838	6,478	+33.9
Derivatives of Strong Analgesics	1,498	43	-97.1
Analgesics-Antipyretics	2,323	4,588	+97.5
Combinations (mixtures of mild analgesics)	1,017	1,847	+81.6
Total Rx for Analgesics	5,400	6,783	+25.6

*AMA Drug Evaluation Classification.

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44. Mickey C. Smith and Darego W. MacLayton, "The Effect of Closing a Medicaid Formulary on the Prescription of Analgesic Drugs," Hospital Formulary (12:1) January 1977, pp. 36-41.

The data show an increase of 25.6 percent in the number of prescription orders for analgesics in comparison with a 11.0 percent increase for all classes of drugs combined. Moreover, the authors found a 45.8 percent decrease in the number of prescription orders for strong analgesics and a 33.9 percent increase for mild analgesics. Calculations from the data show an increase of nearly 42 percent in dollar expenditures for analgesics, and an increase of 12.7 percent in the average prescription charge. However, the authors note that there was an increase in quantity prescribed that paralleled the price increase almost exactly. The authors concluded that for the 20 pharmacies for a six-month period the Medicaid commission spent $2,050.58 more than would have been the case if all drugs remained and if the category followed the trend of other drug classes. Considering that there were approximately 600 pharmacies in the state, and assuming that the 20 were representative, the authors estimated a loss of $121,234.80 for the year.

One of the earliest studies of open versus closed formularies was conducted by Hammel who examined public assistance medical care expenditure data supplied to the U.S. Department of Health, Education and Welfare by nine Western and ten Southern states.[45] Data from states without a drug formulary or with an open unrestricted formulary were compared with those from states maintaining a closed formulary. The author found for a four year period beginning in fiscal year 1967, that the closed formulary states in the West, with the exception of

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45. Hammel, op. cit., pp. 1740-1744.

Oregon, spent more per capita for total medical care expenditures than did the states without restrictions. The same situation was found in the South. When the comparison was made in terms of drug expenditures per recipient, the closed formulary states did not always show lower outlays than did those without restrictions. In the South, all states with restricted formularies spent more per recipient on drugs than did the open formulary states. In the West, a similar comparison showed expenditures to be slightly less in closed formulary states. Hammel concluded that the data showed no support for the existence of a relationship between the use of a formulary and expenditure reductions for all services.

Hefner conducted several studies of the effects of formulary limitations on Medicaid costs. On August 1, 1976, the Louisiana Medicaid drug program implemented a restrictive formulary and eliminated 320 pharmaceutical preparations (265 drug entities) from reimbursement under the Medicaid program. Hefner conducted a longitudinal study and measured the change in expenditures for drug products after implementation of the formulary.[46] Information was gathered from a random sample of 10,482 Medicaid beneficiaries in 1976. A demographically matched set of 10,482 recipients were selected in 1977 to provide an "after" data base. Hefner concluded that although prescription expenditures decreased by 11.4 percent, there was a large increase in demand for non-prescription services

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46. D. Hefner, "A Study to Determine the Cost-Effectiveness of a Restrictive Formulary: The Louisiana Experience" (Washington, D.C.: National Pharmaceutical Council, June 20, 1979).

that resulted in a net increase of 7.3 percent in total program expenditures as measured in constant dollars. When projected to the entire program, prescription drug expenditures decreased by $4.1 million, but nondrug expenditures increased by $25 million. Furthermore, six of seven disease groups identified as being more affected by drug removal exhibited significant increases in diagnoses. The high correlation between the disease classes and the removed products highlights the potential adverse effect that a restricted formulary can have on the health status of Medicaid populations.

In another study of a similar phenomenon, Hefner compared Louisiana (closed formulary) with Texas (open formulary) to determine whether the utilization shifts noted in Louisiana were unique or part of a general shift in Medicaid demand.[47] The study periods were February-July 1976 and February-July 1977. Hefner found the Texas Medicaid program did not exhibit the large utilization increases found in Louisiana. Between 1976 and 1977, the constant dollar increases in total health expenditures was $4.08 per Texas recipient and $23.69 per Louisiana recipient. Expenditures for nonprescription services per recipient increased by $30.11 in Louisiana, but only $3.11 in Texas. Much of the Louisiana increase was attributed to more hospital usage. In contrast, Texas had a decline of 6.14 percent in utilization of hospital services by the same types of recipients during the study period. Finally, two of the disease groups affected by the restricted

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47. D. Hefner, "Cost-Effectiveness of a Restricted Drug Formulary: Louisiana vs. Texas" (Washington, D.C.: National Pharmaceutical Council, May 1, 1980).

drug products that showed increases in diagnoses in Louisiana (heart and central nervous system) exhibited decreases in the Texas Medicaid program. Thus, Hefner's studies provide evidence of the cost-effectiveness of allowing free choice of drugs to the prescribing physician.

Rucker and Morse critiqued the first Hefner study that concluded a restrictive state Medicaid formulary caused an adverse impact on health and increased the cost of nondrug services.[48] The authors criticized the study because they believe Louisiana's drug restrictions were not of major importance. The 265 drug entities constituted less than 3 percent of the universe previously authorized for payment, and represented only five therapeutic categories declared nonreimbursable (anorexics, antacids, cough and cold preparations, minor tranquilizers, and enzymes). Thus, prescribers still had available drugs from 110 not-disapproved categories. Rucker and Morse questioned the reliability of the data because of the simplistic manner in which the before and after data were handled. Also, no distinction was made between correlation and causation. The authors concluded that the statistical significance of the observed increase in nonpharmaceutical services was neither corroborated nor measured against a control within an epidemiological model; the strength of the association was not elucidated; the clinical significance of the alleged association is unfounded; and in their opinion the study's

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48. T. Donald Rucker and M. Lee Morse, "The Medicaid Drug Program in Louisiana: Critique of the Hefner-Pracon Study," American Journal of Hospital Pharmacy (37:10) October 1980, pp. 1350-1353.

premise concerning the exclusion of significant pharmacologic products is inconsistent with current scientific knowledge.

A comparative study by Sudover and Rein of Medicaid drug expenditures in Texas (open formulary) and California (closed formulary) further demonstrated the real and potential savings that can accompany an open formulary.[49] Texas relies on utilization management to control expenditures, but places few restraints on the price and availability of medication. In contrast, California emphasizes restrictions on drug price and availability. The authors estimated that California could have saved $30 million from 1975 to 1978 on total eligible persons had the Texas approach been used. For total program recipients, an estimated $50 million saving could have been realized. Also, the participation rate was lower in California than in Texas, but the cost per person actually receiving drugs was found to be nine percent higher in California than in Texas.

Kennard and Platt examined a range of control mechanisms implemented in five state Medicaid programs.[50] The controls examined in this study alone or in combination were utilization review (UR), peer review (PR), dollar limit, copayment, and drug formulary. It was hypothesized that controls and combinations of controls vary in

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49. S. G. Sudover and S. D. Rein, "Managing Medicaid Drug Expenditures: An Analysis of Divergent Approaches," Journal of Health and Human Resources Administration (1:11) November 1978, pp. 200-230.

50. Lon H. Kennard and W. Gerald Platt, "Comparative Medicaid Drug Cost Control Experiences," Medical Marketing and Media (14:3) March 1979, pp. 38-43.

their relative impact. It was further hypothesized that the six programs studied have an increasing order of relative stringency as follows:

1. Baseline data: having no controls (least stringent)
2. State Program A: having only UR
3. State Program B: UR and PR
4. State Program C: UR, PR, and dollar limit
5. State Program D: UR, PR, and copayment
6. State Program E: UR, PR, and a drug formulary

The general form of the hypothesized "hierarchy of controls" was that as the hypothesized stringency of control mechanisms increases, conformity to rankings under noncontrolled conditions decreases. The more stringent the control mechanism, the less similar the program was to the baseline data. The second general hypothesis was that as actual ranking under noncontrolled conditions decreases, a "flip-flop of rankings" is seen within controlled programs. The baseline data were constructed from a sample of community pharmacies in the United States via the National Pharmaceutical Audit developed by IMS America. The comparative state program data were derived from the joint operational activities of PAID Prescriptions and Health Applications Systems, Inc. including more than 200,000 Medicaid eligibles.

Both data sets report 1974 data and have been adjusted to date of service. The results substantiated the "hierarchy of controls" hypothesis. However, a copayment (Program D) appeared to be a more stringent control than a formulary (Program E). In addition, all the measures of the hypothesized "flip-flop of rankings" supported its existence. The authors concluded that controls vary in their relative impact upon drug products and their relative use, and that the

deviations of program rankings from the baseline data is a function of the relative stringency of the controls implemented within the program.

Smith evaluated the prescribing behavior, consumer response, and economic ramifications of the removal of selected prescription drug products from the Michigan Medicaid drug benefit.[51] Specifically, the objectives included documenting the frequency that alternate legend drugs were prescribed and the extent to which a cost transfer was effected through the payment of out-of-pocket cash. Patient, prescription, and physician information were collected from a total of 17 independent Michigan community pharmacies throughout the lower peninsula. The time frame of the study was a period of six months from October 1981 through March 1982.

Data collection identified 161 patients with prescriptions for at least one of the 32 selected drug products and 135 patients were used for analysis. The data show 55.5 percent of Medicaid recipients on continuous therapy discontinued treatment, but only 16.3 percent had an alternate legend drug prescribed covered under the Medicaid drug benefit and 28.2 percent of the recipients elected to continue therapy at their own expense. The alternate legend drugs prescribed resulted in significantly higher drug costs ($p < 0.05$). The out-of-pocket expense resulted in a cost savings to the Medicaid program, but a cost transfer to those recipients. Smith concluded that the deletion of drugs from the Medicaid drug formulary does not necessarily result in

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51. David M. Smith, "Consumer Response and Economic Impact of the Elimination of Selected Drug Products in the Michigan Medicaid Program," (M.S. thesis - Wayne State University, 1982.)

a reduction in prescription orders directly proportional to the number of orders previously written for the deleted drugs. The assumption that drug deletion will result in savings was attenuated by certain prescribing and consumer behaviors. Alternate drug therapy also was associated with certain therapeutic risks.

Smith and Simmons explored the relationship between a variety of Medicaid drug cost control mechanisms, including formulary restrictions, and three dependent variables: expenditures per eligible person, expenditures per recipient, and participation rate (number of recipients divided by the number of eligible persons).[52] Data for each state with a Medicaid program were collected from 1973 through 1980 via the National Pharmaceutical Council, Pharmaceutical Benefits Under State Medical Assistance Programs. Multivariate statistical analyses included difference between means tests, multiple regression analysis, and factor analysis.

Tests for differences between means suggested that formulary restrictions had little relationship to drug expenditures. In fact, when such relationships were found, formulary limitations often were associated with higher drug expenditures. Exclusion of minor tranquilizers, prescription cough, cold and decongestant remedies, and prescription non-narcotic analgesics were each associated with significantly higher expenditures per drug recipient. Exclusion of prescription cough, cold and decongestant was related to significantly

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52. Mickey C. Smith and S. A. Simmons, "A Study of the Effects of Formulary Limitations in Medicaid Programs," Administration and Policy Journal (2:1) Spring 1983, pp. 169-198.

lower expenditures per eligible.

Regression and factor analysis yielded mixed results about formulary controls. Though a few exclusion categories were associated with lower drug costs per eligible (over-the-counter medicine chest supplies, prescription muscle relaxants, and prescription cough/cold/ decongestant products), some exclusions were tied to increased Medicaid drug costs per eligible (prescription central nervous system stimulants) as well as to a higher participation rate. The most critical finding was that the formulary exclusion variable, "no formulary exclusions," was not statistically significant in the analysis. Thus, patients in open formulary states did not appear to cost significantly more (or less) money, or participate at a significantly higher (or lower) rate in the program than patients in closed formulary states.

Bloom and Jacobs examined the cost effects of a closed pharmaceutical formulary on Medicaid expenditures for peptic ulcer disease.[53] Studies were performed before and after the implementation of a closed formulary. The data were limited to two study periods: June 15, 1981 through March 14, 1982, the open formulary period; and June 15, 1982 through March 14, 1983, the closed formulary period. The data show total Medicaid costs for peptic ulcer treatment declined 15.0 percent from $475,578 in the open period to $404,333 in the closed period. This decline resulted from decreases

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53. Bernard S. Bloom and Jake Jacobs, "Cost Effects of Restricting Cost-Effective Therapy," Medical Care (23:7) July 1985, pp. 872-880.

in inpatient hospital payments (4.0%), physician payments (19.8%), and outpatient pharmaceutical payments (83.6%). However, during the closed formulary period, 316 (21.3%) fewer patients received services. The cost per patient-month of therapy between the two periods increased from $53.44 to $58.49 or 9.4 percent. Also, mean per patient-month hospital payments and physician payments increased 23.6 and 3.1 percent respectively. Pharmaceutical mean per patient-month payments declined by 78.9 percent. Thus, the authors concluded the small short-term savings may have been negated by increased expenditures in the near future when sicker patients, previously denied peptic ulcer drug treatment, reentered the Medicaid system in need of expensive inhospital treatment.

Simmons et al., evaluated the open formulary objectively.[54] The purpose of their study was to dichotomize Medicaid drug programs into high and low-cost groups and to identify the variables that are linked with high or low-cost programs. The authors included "formulary limitations" as part of the independent variable set to help resolve the question of whether a restrictive formulary is linked to low or high-cost programs. Data were collected on all states with Medicaid drug programs from 1973-1980 (National Pharmaceutical Council). Programs were classified as being high cost (> $55 per recipient) or low cost (< $45 per recipient) and assigned as the dependent variables. Multiple discriminant analysis was used to assign state

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54. Susan A. Simmons, Bruce C. Payne and Mickey C. Smith, "Marketing Medicaid Drugs: An Analysis of Cost Factors," Journal of Health Care Marketing (6:3) September 1986, pp. 29-36.

Medicaid drug programs to one of the two predetermined groups, and to analyze 34 independent variables that may influence costs. The data show 11 independent variables were statistically significant.

The authors' major conclusion was that the characteristics of the two programs (low or high-cost) were different. Setting maximum unit quantity of each prescription, setting a dollar limit on prescriptions, and not providing funds to cover patients not on Medicaid were associated with low-cost programs. Also, excluding a few categories of drugs such as over-the-counter combinations drugs, prescription antacids, and miscellaneous prescription drugs not elsewhere categorized tended to lower expenditures. High expenditure programs were found to permit larger pharmacist fees and required a minimum number of units per prescription. The categories of drugs excluded by high-cost programs were prescription supplements (vitamins), central nervous system stimulants, anorectics, and over-the-counter antacids. Notable by its absence as a significant independent variable for either low or high-cost programs was the open formulary. The data show open formulary programs have neither higher nor lower costs than programs with restrictions. This finding is important and upholds previous research results.

To summarize, for more than a decade, studies have supported the concept of an open formulary in Medicaid programs.

Pharmacist Consultant

The Federal Medicare (Title XVIII) and Medicaid (Title XIX)

regulations as revised in 1974 require a pharmacist to perform monthly drug-regimen reviews on each resident in long-term care, skilled-nursing facilities. In intermediate-care facilities, these monthly reviews may be conducted by either a pharmacist or a registered nurse. Effective drug-regimen review performed by the pharmacist has the potential for improving the quality of health care in long-term care facilities. Since 1974, a number of studies have shown decreases in the number of prescriptions per patient, drugs per patient, doses per patient, medication errors, adverse reactions, and drug-related hospitalizations.[55] [56]

Strandberg et al., found that they could reduce prescription drugs by 42.8 percent and doses by 34.6 percent over a seven year period of continuous comprehensive (clinical consultant and distributive) pharmaceutical services.[57] Furthermore, Berchou found that direct clinical involvement of skilled pharmacists in cooperation with other health professionals significantly altered the patterns of medication use in a long-term care facility for the mentally

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55. James W. Cooper and C. Greg Bagwell, "Contribution of the Consultant Pharmacist to Rational Drug Therapy in the Geriatric Long-Term Care Facility," Journal of The American Geriatric Society (26:11) November 1978, pp. 513-520.

56. Samuel W. Kidder, "The Potential Cost-Benefit of Drug Monitoring Services in Skilled Nursing Facilities," Journal of The National Association of Retail Druggists (100:12) December 1978, pp. 21-22.

57. Lee R. Strandberg, et al., "Effect of Comprehensive Pharmaceutical Services on Drug Use in Long-Term Care Facilities," American Journal of Hospital Pharmacy (37:1) January 1980, pp. 92-94.

retarded.[58] Between two institutions, the institution with less direct pharmacy involvement showed significantly more use of antipsychotics (34.2% versus 16.8%) and fewer patients received long-term medications (29.2% versus 43.2%).

The effect of removal of consultant clinical pharmacy services has also been demonstrated. Chrymko and Conrad found that when clinical pharmacy input was removed, both drugs and doses per patient increased.[59] Cooper measured the effect of initiation, termination, and reinitiation of consultant clinical pharmacy services in a 72-bed geriatric long-term care facility.[60] Data were measured at five points in time: initiation (August 1979), termination (October 1979), reinitiation (June 1980), then three months (September 1980) and three years (September 1983) after reinitiation of services. The data show at points two and four when the consultant was retained drug use decreased 46.1 and 42.7 percent respectively. At point three between the termination and reinitiation of services drug use increased 100.0 percent. At each point in time there was no statistically significant difference in the number of established diagnoses per patient. Thus,

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58. Richard C. Berchou, "Effect of a Consultant Pharmacist on Medication Use in an Institution for the Mentally Retarded," American Journal of Hospital Pharmacy (39:10) October 1982, pp. 1671-1674.

59. Margaret M. Chrymko and Wayne F. Conrad, "Effect of Removing Clinical Pharmacy Input," American Journal of Hospital Pharmacy (39:4) April 1982, p. 641.

60. James W. Cooper, "Effect of Initiation, Termination, and Reinitiation of Consultant Clinical Pharmacist Services in a Geriatric Long-Term Care Facility," Medical Care (23:1) January 1985, pp. 84-88.

Cooper concluded that a consultant clinical pharmacist had an impact on drug cost in a long-term care facility.

Medicaid Records As A Valid Data Source

In 1974 Berkanovic discussed the difficulties which were encountered in attempting to analyze cost and utilization data contained in Medicaid claims tapes from a study comparing the effectiveness of two record keeping systems in Oregon.[61] Three classes of problems were encountered, (1) inaccuracy, (2) missing data, and (3) lack of standardized reporting conventions. Taken together, the author noted these problems seriously compromised the ability to make a meaningful analysis of the utilization experience with the data presumably recorded. However, the diversity in Medicaid program benefits and administration from state to state promotes variation in the quality of data collected. Discouraging experiences in specific localities should not deter the assessment and utilization of Medicaid data universally.

Many of the early problems with accurate record keeping have improved due to larger amounts of money allocated for this purpose at the federal and state levels. In addition, advances in computer technology and development of information systems have evolved these machines from simple record keeping systems for fiscal purposes to

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61. Emil Berkanovic, "An Appraisal of Medicaid Records as a Data Source," Medical Care (12:7) July 1974, pp. 590-595.

research tools. For the past 15 years, state Medicaid programs have been mandated by the federal government to generate Medicaid Management Information Systems (MMIS) to assist in the recording, reimbursement and surveillance of all health care activities supported by these programs. In many states, the MMIS has been used primarily for reimbursement purposes and administrative control, with relatively little work being done through it on research questions and quality assurance. Yet, an automated data and retrieval system such as this presents excellent opportunities for both such activities, and states are increasingly broadening the purposes to which their MMIS data set can be put.

One major advantage of the MMIS data set for drug utilization studies is that because the acquisition of data about drug use is part of the reimbursement procedure to pharmacists, the validity of such data is strengthened greatly. That is, there is no need to rely on physician recall or a second set of records kept by pharmacists to learn what drugs have been prescribed. In order for the pharmacist to be reimbursed by Medicaid for drugs dispensed, he must specify the drug name (often in terms of its NDC number), including strength, number of units dispensed, and cost. In addition, the MMIS requires a recipient code as well as a physician code with every drug transaction, making it possible to develop profiles of particular patients or physicians (masked for confidentiality as required) for a variety of research and quality assurance purposes.

A key question centers on the validity of data extracted from MMIS tapes derived in this manner. An important study by Federspiel, et

al., examined this question carefully and found that in the state in which they worked (Tennessee), there was excellent internal consistency of Medicaid computer-based prescribing data.[62] The authors examined the July 1974 month of payment file and found that sex, race, and age were known for all but 0.8 percent of the recipients. Moreover, the study of other variables illustrated the accuracy and consistency of the data. The authors concluded that in a time when available resources are dwindling, the incisive use of Medicaid claims files offers an attractive alternative to expensive new systems of data collection and analysis. Finally, using the same data, Ray et al., demonstrated how these data could be used to investigate statewide prescribing patterns for antibiotics.[63]

Avorn and Soumerai used Medicaid data to identify inappropriate prescribing practices among physicians.[64] In an experimental controlled trial, prescribing records were obtained from the MMIS of four states for all physicians participating in the Medicaid programs of those states. Three categories of drugs that are commonly misprescribed (propoxyphene drugs, cerebral and peripheral

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62. Charles F. Federspiel, Wayne A. Ray and William Schaffner, "Medicaid Records as a Valid Data Source: The Tennessee Experience," Medical Care (14:2) February 1976, pp. 166-172.

63. Wayne A. Ray, Charles F. Federspiel and William Schaffner, "Prescribing of Chloramphenicol In Ambulatory Practice: An Epidemiological Study Among Tennessee Medicaid Recipients," Annals of Internal Medicine (84:3) March 1976, pp. 266-270.

64. Jerry Avorn and Stephen B. Soumerai, "Use of Computer-Based Medicaid Drug Data to Analyze and Correct Inappropriate Medication Use," Journal of Medical Systems (6:4) August 1982, pp. 377-386.

"vasodilators", and cephalexin [Keflex]) were identified, and moderate to high prescribers of these drugs were identified from the MMIS data set. These physicians were then randomly divided into three groups. One group received no intervention, the second group received an innovative series of print materials urging appropriate drug use, and a third group received the print materials and was visited by consultant pharmacists to discuss the drugs in question. The authors concluded that use of Medicaid prescribing data can be an efficient and accurate way of conducting large-scale surveillance of misprescribing, and of targeting interventions that can improve suboptimal drug utilization. Furthermore, use of the same data set in a follow-up period can monitor the effectiveness of each mode of intervention and will measure the degree of behavior change for each physician.

Groves used Medicaid data to identify irregularities in patient drug use.[65] Drug-use review information was provided to prescribers and dispensing pharmacists for the purpose of reducing morbidity related to inappropriate drug therapy. Drug-use review for Medicaid uses the large amount of data entered into the MMIS by Electronic Data System Federal Corporation, the fiscal intermediary for a number of the states including Wisconsin. In the Florida Medicaid program, computer-generated medical history profiles were used to identify patients at risk for drug-induced illnesses. Health care providers

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65. Regina E. Groves, "Therapeutic Drug-Use Review for the Florida Medicaid Program," American Journal of Hospital Pharmacy (42:2) February 1985, pp. 316-319.

then were notified of potential problems with patients' drug regimens and asked for a response. Patient profiles were monitored for changes, and follow-up letters were sent to the health-care providers as warranted. During a nine-month period in 1982-1983, drug therapy was changed in 54 percent of cases after providers were notified of problems. The author concluded that Florida's Medicaid drug-use review program was effective in identifying inappropriate drug therapy that could have lead to increased morbidity and higher health-care costs. Also, the MMIS data could be used to improve the quality of health care rather than only for the detection of fraud and abuse.

Several studies have successfully used Medicaid MMIS data to examine drug use in long-term care facilities (LTCFs). Ray et al., found epidemiological evidence suggesting misuse of antipsychotic medications in nursing homes and related variation in drug use to characteristics of the physician prescribers, the facilities, and the patients.[66] McGhan et al., using 1978 Minnesota MMIS Medicaid data, demonstrated the feasibility of developing multivariate predictive equations for identifying nursing home patients with drug therapy problems.[67] Lipowski et al., developed a profile of Wisconsin pharmacies that provide services to Medicaid recipients in LTCFs and

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66. Wayne A Ray, Charles F. Federspiel and William Schaffner, "A Study of Antipsychotic Drug Use in Nursing Homes: Epidemiological Evidence Suggesting Misuse," American Journal of Public Health (70:5) May 1980, pp. 485-491.

67. William F. McGhan, Albert I. Wertheimer and Clayton R. Rowland, "Using Medicaid Data to Identify Patients with Drug Therapy Problems," Inquiry (19:1) Spring 1982, pp. 79-88.

studied the relationships among pharmacy characteristics and drug use and reimbursement for pharmaceutical services.[68] Computer-generated reports of Medicaid claims of all pharmacies that had received $1000 or more for services provided to LTCFs from July through September 1984 were included in the study; these claims were submitted by 255 pharmacies on behalf of 32,410 recipients.

The reports contained the following individual pharmacy data: (1) geographic location, (2) total dollar payments, (3) total number of Medicaid recipients served, (4) percentage of recipients residing in LTCFs, (5) total number of payments from Medicaid for prescriptions, (6) amount paid to the pharmacy per LTCF recipients as a percentage of total payments, (7) percentage of prescriptions paid at the unit dose rate, (8) the average number of prescriptions per LTCF recipient, and (9) the average cost per LTCF recipient. Among the conclusions, the authors found that a Medicaid data base can be useful for characterizing pharmaceutical services and drug use in LTCFs. In addition, the MMIS could be developed further to enhance its potential in maintaining administrative control, improving the quality of care through therapeutically oriented drug-use review, and as a research tool for developing drug-use models.

In conclusion, this portion of the literature review shows the validity and accuracy of MMIS-derived data, including that of

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68. Earlene E. Lipowski et al., "Use of a Medicaid Database to Analyze Pharmaceutical Services In Long-Term-Care Facilities," American Journal of Hospital Pharmacy (43:6) June 1986, pp. 1467-1472.

Wisconsin. Several states (including Wisconsin) maintain aggressive review programs to determine the fidelity of such data, primarily to detect fraud and abuse. Moreover, serious financial and legal disincentives exist for pharmacists to discourage inaccurate reporting of such data.

CHAPTER THREE

METHODOLOGY

This chapter describes the data collection, statistical methods utilized, and major limitations associated with this study.

Data Collection

The study used two types of research design: exploratory and descriptive research methodology. Exploratory research helped gain insight and ideas through a literature survey, experience surveys, and analyses of selected cases. Tentative explanations found in the exploratory research helped to finalize hypotheses to serve as specific guides for the descriptive study. Descriptive research was thought to be appropriate because the study described what effect the addition of propoxyphene napsylate to the Negative Drug List had on prescribing mix and expenditures within the internal analgesic therapeutic class for Medicaid recipients. More specifically, a cross-sectional descriptive survey versus a longitudinal descriptive methodology was used because the population elements were measured at two different points in time and the elements in the population were different at each time.

Data collection began with secondary data. After the literature and other sources of information were reviewed, the study proceeded

to primary data. Secondary data included internal data from the Wisconsin Department of Health and Social Services, the Center for Health Systems Research and Analysis, and published external data. Primary data were obtained from computer reports generated from the Wisconsin Medicaid Management Information System (MMIS). A small portion of the Fortran computer program used to extract the data is shown in Appendix A. The program was written by individuals working in the Center For Health Systems Research and Analysis.

Data for the Wisconsin MMIS are derived from provider claims maintained by the State's fiscal intermediary, EDS Federal Corporation. Pertinent information is generated every three months for each certified pharmacy. These reports include quarterly data from the previous 15 months, which are organized according to the date that the service was rendered. Pursuant to HSS 107.10(4)(k), drugs included on the Medicaid Negative Drug List are not covered by the Wisconsin Medical Assistance Program (WMAP). Drugs may be included on the Negative Drug List when the WMAP has determined that they have little or no therapeutic value or may be replaced by other more cost-effective drugs. On June 22, 1984, WMAP announced that effective August 1, 1984, propoxyphene napsylate products (e.g., Darvocet-N) would no longer be covered by the program (Appendix B). Physicians wishing to obtain the analgesic properties of these products could have substituted propoxyphene hydrochloride compounds or propoxyphene hydrochloride which were covered by the WMAP. However, Eli Lilly and Company was able to delay the deletion until further examination and a public hearing were completed. On January 15, 1985, the WMAP issued

final notice that effective for dates of service on and after February 1, 1985, propoxyphene napsylate products (e.g., Darvocet-N) would no longer be covered by the program (Appendix C). Propoxyphene napsylate was heavily marketed and used as an analgesic, but the documented efficacy was generally believed to be no better than that of plain aspirin. In order to observe a before/after effect and avoid the time period between first and final non-coverage notice, quarterly data were extracted from the quarter before the first non-coverage announcement (April-June 1984) and the quarter after propoxyphene napsylate was added to the Negative Drug List (April-June 1985). Moreover, the data were separated into institutional and noninstitutional Medicaid recipients. The possibility of seasonal drug utilization patterns was fully recognized. However, the same quarters (April-June) were used each year, and the primary focus of the study is on pre- and post negative formulary comparisons instead of annual drug use patterns. At no point were the identity of patients or physicians known.

To examine more accurately the effects on expenditures after propoxyphene napsylate was added to the Negative Drug List, one needs to compare the expenditures on other prescribed drugs that may have been used to replace it. A reduction in propoxyphene napsylate prescribing may have been accompanied by substitution of propoxyphene hydrochloride as recommended, or by aspirin or acetaminophen. However, it is also possible that propoxyphene napsylate was being replaced by equally expensive (or more expensive) nonsteroidal anti-inflammatory drugs and drugs classified in Schedules II, III,

or IV, which were heavily marketed by their manufacturers during the time periods studied. Moreover, two single entity products might be prescribed for one combination product. For example, a prescription for Darvocet-N^{R} (propoxyphene napsylate and acetaminophen) might be replaced with one prescription for propoxyphene hydrochloride and a second prescription for acetaminophen. As a result, the data were processed in aggregate for drug analgesic entities in Schedule II, Schedule III, Schedule IV, nonsteroidal anti-inflammatory drugs (NSAIDs), and over-the-counter (OTC) analgesics. In addition, the different salts of propoxyphene were examined to obtain more specific information on expenditures. The basic extract for these therapeutic classes for this research project was established prior to data collection (Appendix D).

For noninstitutional and institutional Medicaid recipients, data for the following variables were extracted and calculated:

1. Expenditures per recipient (mean and standard deviation)
2. Expenditures per prescription (mean and standard deviation)
3. Expenditures per unit (mean and standard deviation)
4. Prescriptions per recipient (mean and standard deviation)
5. Units per recipient (mean and standard deviation)
6. Units per prescription (mean and standard deviation)

Expenditures for internal analgesics may change between time periods for a number of reasons, including changes in:

1. the number of recipients and eligibles,
2. the prescription utilization rate per recipient,
3. the size of prescriptions per recipient,

4. wholesalers' and manufacturers' prices for drug products,

5. pharmacists' dispensing fees,

6. physicians' prescribing habits.

Thus, expenditures were calculated on a per recipient basis to control for changes in the number of recipients and eligible persons for Medicaid prescription benefits between the periods studied. In addition, data for expenditures also were examined on a per prescription and per unit basis to study possible before/after differences more specifically. The variables prescriptions per recipient and units per recipient were calculated to determine if the number and size of prescriptions per recipient changed between periods. Significant changes in these two variables will influence expenditures per recipient results. For example, if removal of propoxyphene napsylate caused more prescribing of single entity products versus combination products, the additional fees would be a significant consideration.

Expenditures per prescription also is influenced by the size of prescriptions dispensed, thus the variable units per prescription was determined to help control for this possible difference. Expenditures calculated on a per unit basis were examined to help determine if physicians substituted more expensive drugs for propoxyphene napsylate. Expenditure results examined in relation to these variables provided sufficient evidence to construct research conclusions and more accurately show the effects of the Negative Drug List.

Changes in wholesalers' and manufacturers' prices for drug

products were determined using the Producer Price Index.[1] The Producer Price Index (formerly known as the wholesale price index) is designed to measure average changes in prices of all commodities, at all stages of processing, produced for sale in primary markets in the U.S.[2] It now is based on approximately 3,400 commodity price series, and prices used in constructing the index are collected from sellers. Appendix E shows Producer Price Index data for the net output of selected pharmaceutical preparations for 1984 and 1985.

Based on this information, a mean figure was calculated for each of the selected pharmaceutical preparations for each of the periods studied (Table 8). As Table 8 shows, prescription analgesics and nonprescription analgesics increased by 17.6 and 8.03 percent respectively. However, prescription antiarthritics decreased by 10.4 percent. Prescription drug price growth at the producer level slowed in 1984 below the double digit annual growth rates of the previous three years to 8.2 percent.[3] The 8.2 percent prescription drug price increase in 1984 followed successive price gains of 10.7 percent (1983), 11.5 percent (1982), and 11.3 percent (1981).

The primary cause for the slowdown in prescription price growth in 1984 was the cut in pricing for prescription ibuprofen products -

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1. "Producer Price Indexes Data for January 1984 Through December 1985-Pharmaceutical Preparations" (U.S. Department of Labor, Bureau of Labor Statistics, Washington, D.C.)

2. "Statistical Abstract of the United States: 1986." (U.S. Bureau of the Census, Washington, D.C., 1985.) p. 467.

3. F-D-C Reports (The Pink Sheet) January 21, 1985, p. 6.

TABLE 8

MEAN PRODUCER PRICE INDEX DATA FOR THE PERIODS STUDIED

(Index Base 06/81=100)

PHARMACEUTICAL PREPARATIONS	BEFORE (4/84-6/84)	AFTER (4/85-6/85)	CHANGE
A. PRESCRIPTION			
1. ANALGESICS	145.4	171.0	25.6 17.6%
2. ANTIARTHRITICS	133.2	119.3	13.9 (10.4%)
B. NON-PRESCRIPTION			
1. ANALGESICS-INTERNAL (except antiarthritics)	130.7	141.2	10.5 8.03%

Upjohn's Motrin and Boots' Rufen in July. During the third quarter, prescription antiarthritics at manufacturer catalog prices declined 15.4 percent according to Bureau of Labor Statistics' data.[4] The primary cause for the ibuprofen price decrease was the approval on May 18, 1984 by the Food and Drug Administration of low-dose (200mg per tablet) ibuprofen as a nonprescription product.[5] The two over-the-counter (OTC) ibuprofen products were launched on May 28, 1984, by American Home Products (Advil^{R}) and Bristol Meyers (Nuprin^{R}). Also, OTC prices increased by 7.3 percent in 1984 boosted by the introduction of premium priced OTC ibuprofen. In 1985, prescription drug prices at the manufacturer level increased by 8.9 percent.[6] Prescription analgesics showed a significant price movement in 1985, increasing 16.1 percent; antiarthritics increased 1.9 percent; and nonprescription analgesics increased 6.2 percent.

As a result of the changes in pharmacists' dispensing fees (Table 7 above) and manufacturers'-prices for drug products between the periods studied, Table 9 was constructed to show how the after data were adjusted to constant dollar 1984 levels before statistical comparisons were made. Moreover, the expertise and professional knowledge of the Director, Drug Utilization Review Project for WMAP detected areas where items in the Medicaid prescription mix did not

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4. Ibid.

5. "Nonprescription Ibuprofen Approved," American Pharmacy (NS24:7) July 1984, p. 404.

6. F-D-C Reports (The Pink Sheet) January 20, 1986, p. 14.

PRESCRIPTION MIX	ONAL /85)	MEAN (y)
SCHEDULE II	1. Dec pre by	1. Decrease by 2.96%.
	2. Dec inf	2. Decrease by 17.6%.
SCHEDULE III	1. Dec pre by	1. Decrease by 2.96%.
	2. Inc MAC by	2. Decrease 90% by appropriate MAC amount and decrease 10% by 17.6%.
SCHEDULE IV	1. Dec pre by	1. Decrease by 2.96%.
	2. Dec inf	2. Decrease by 17.6%.

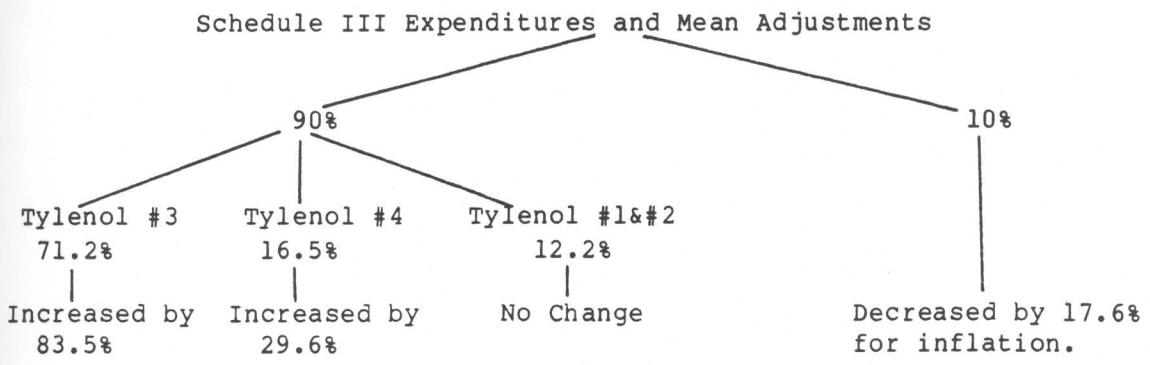
PRESCRIPTION MIX	NONINSTITUTIONAL (4/85 - 6/85)		INSTITUTION (4/85 - 6/8
	EXPENDITURES ($)	MEAN (y)	EXPENDITURES ($)
PROPOXYPHENE NAPSYLATE	Eliminated	Eliminated	Eliminated
PROPOXYPHENE HYDROCHLORIDE	1. Decrease by number of prescriptions multiplied by 0.11¢ each. 2. MAC-no adjustment for inflation.	1. Decrease by 3.14%. 2. MAC-no adjustment.	1. Decrease by number of prescriptions multiplied by 0.16¢ each. 2. MAC-no adjustment for inflation.
NSAIDs	1. Decrease by number of prescriptions multiplied by 0.11¢ each. 2. Increase by 11.6% for disinflation.	1. Decrease by 3.14%. 2. Increase by 11.6%.	1. Decrease by number of prescriptions multiplied by 0.16¢ each. 2. Increase 11.6% for disinflation.
OTCs	1. Decrease by 8.03% for inflation.	1. Decrease by 8.03% for inflation.	1. Decrease by 8.03% for inflation.

ONAL 5)	INSTITUTIONAL (4/85 - 6/85)	
MEAN (y)	EXPENDITURES ($)	MEAN (y)
Eliminated	Eliminated	Eliminated
1. Decrease by 3.14%. 2. MAC-no adjustment.	1. Decrease by number of prescriptions multiplied by 0.16¢ each. 2. MAC-no adjustment for inflation.	1. Decrease by 2.96%. 2. MAC-no adjustment.
1. Decrease by 3.14%. 2. Increase by 11.6%.	1. Decrease by number of prescriptions multiplied by 0.16¢ each. 2. Increase 11.6% for disinflation.	1. Decrease by 2.96%. 2. Increase by 11.6%.
1. Decrease by 8.03% for inflation.	1. Decrease by 8.03% for inflation.	1. Decrease by 8.03% for inflation.

behave the same as for the general population.

For example, drug products in Schedule III had MAC decreases in 1985. So, instead of an adjustment for an increase as shown by the Producer Price Index data, research data were actually adjusted for a decrease in MAC allowances. More specifically, by examining secondary data, it was found that approximately 90 percent of the Schedule III items were acetaminophen with codeine products. Moreover, by extracting brand Tylenol with codeine data, it was found that of this 90 percent, 71.2 percent was Tylenol #3, 16.5 percent was Tylenol #4, and 12.2 percent was Tylenol #1 and #2 combined. Brand Tylenol with codeine data were used to estimate the market share of all acetaminophen with codeine brands.

Furthermore, for fiscal year 1985 (July 1, 1984 - June 30, 1985) WMAP MAC allowance for acetaminophen with codeine #3 decreased from 0.0780/unit (before period) to 0.0425/unit (after period) or a 45.5 percent decline. Also, acetaminophen with codeine #4 decreased from 0.1458/unit to 0.1125/unit or a 22.8 percent decline. WMAP MAC allowances for acetaminophen with codeine #1 and #2 did not change. Thus, the illustration below shows how the Schedule III portion of the prescription mix was adjusted for MAC and inflation changes.



In addition, propoxyphene hydrochloride had MAC levels that did not change between the periods, so no changes were made for inflation. Finally, OTCs were reimbursed by WMAP on a cost plus 50 percent basis, thus only adjustments were made for inflation. Standard deviation was not adjusted throughout the analysis because variation among numbers between periods would not change significantly. In the institutional population, it was assumed that the distribution system was all unit dose. However, based on Lipowski et al., only 80.3 percent of LTCF recipients were serviced by unit dose and 19.7 percent were serviced by a traditional distribution system in Wisconsin.[7]

The population for this study was all prescriptions for members in the prescription mix dispensed to Medicaid eligibles during the two periods studied. This study did not use a sample, but used a complete census of recipients, prescriptions, and units.

Statistical Methods Utilized

A two-tailed statistical test was used for comparing the population means. Because such large numbers of data were extracted, the test statistic is based on the standardized normal z statistic and pooled variances. Appendix F shows the large sample test of an hypothesis between means.

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7. Earlene E. Lipowski et al., "Use of a Medicaid Database to Analyze Pharmaceutical Services in Long-Term-Care Facilities," American Journal of Hospital Pharmacy (43:6) June 1986, p. 1470.

Major Limitations of the Study

1. Causal research designs (experiments) are capable of providing more convincing evidence of causal relationships than are exploratory or descriptive designs as used in this study. In both exploratory and descriptive designs, the criterion variable Y is observed. The analyst then attempts to find one or more causal variables, Xs, which afford plausible explanations as to why a change in Y occurred. This kind of retrospective analysis affords little control of the Xs and, therefore, contains great potential that the occurrence or change in Y is attributable to some other Xs than the ones being investigated. Even though many variables were controlled and accounted for, the descriptive design will still be suspect for establishing causality.

2. In relation to the first limitation above, other factors that may influence drug program expenditures not measured in this study are:

a. consumer factors such as the number of eligibles; the age, sex, and income characteristics of the enrolled population, and the rate of illness among eligibles;

b. physician factors such as prescribing habits regarding price, generics, frequency of prescribing and product use trends;

c. pharmacy costs of operation and service delivery; and

d. nursing home variables such as patient length of stay, patient level of care, and LTCF size and staffing.

3. The operation of a restricted formulary or Negative Drug List

entails additional expenses not measured in this study. These include expenses the state incurs in initiating, revising, and maintaining the formulary plus auditing compliance with its restrictions. The administration of such a program for a state adds an additional "hidden cost." Moreover, cost controls applied to drugs in isolation may increase costs in other sectors of health care.

4. In February 1982, the Department of Health and Social Services received a waiver from the Federal Government which allows the Department to require Medicaid recipients to enroll in a Health Maintenance Organization (HMO), with certain provisions for disenrollment. The effort to increase enrollment of Medicaid recipients in HMOs under this waiver authority has been termed the "HMO Preferred Enrollment Initiative" (HMO PEI). The initiative was implemented in two areas of Wisconsin for recipients eligible for Aid to Families with Dependent Children (AFDC) between the study periods. Enrollment of recipients into HMOs began on July 1, 1984 in Dane County, and on September 1, 1984 in Milwaukee County. At the time of this study, information for these recipients was not computer accessible. As a result, these AFDC recipients in Dane and Milwaukee Counties were eliminated from both the before and after study periods.

5. The data did not include the prescription claim information for approximately 5000 patients residing in state and local government long-term care facilities that are reimbursed for pharmaceuticals on a per diem basis.

6. The adjustments in mean expenditures for professional fee and producer price index changes were liberal because percentages were added and subtracted from the entire number instead of the portion they were appropriate for. As a result, the data are conservative. Moreover, it was assumed that the distribution system in the institutional population was all unit dose, when in actuality, approximately 19.7 percent of LTCF recipients were serviced by a traditional distribution system at a lower professional fee. Thus, the results are more conversative.

CHAPTER FOUR

FINDINGS

The tests of the research hypotheses and other statistical analyses of the study are presented in this chapter.

Tests of The Hypotheses

Hypothesis 1:

There was no change in expenditures per internal analgesic recipient for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

A comparison of expenditures per internal analgesic recipient for noninstitutional Medicaid recipients between periods is presented in Table 10. Overall total expenditures per recipient increased from $24.95 to $29.95 between periods. The test statistic (z) value comparing the mean expenditures per recipient between periods was significant ($z = -21.46$) at $p < 0.05$. Therefore, hypothesis one was rejected and it can be concluded there was a difference in noninstitutional expenditures per recipient between periods. The expenditures per recipient for propoxyphene napsylate decreased significantly, but expenditures increased significantly for Schedule III, propoxyphene hydrochloride, NSAIDs and OTCs.

PRESCRIPTION MIX	NUMBER OF RECIPIENTS	$ EXPENDITURES PER RECIPIENT	TEST STATISTIC (z) VALUE	SIGNIFICANCE
SCHEDULE II	2,158	474	(0.54)	
SCHEDULE III	11,804	1006	(25.38)	(X)
SCHEDULE IV	2,148	483	0.54	
PROPOXYPHENE NAPSYLATE	5,006	1036	63.26	X
PROPOXYPHENE HYDROCHLORIDE	1,031	100	(3.01)	(X)
NSAIDs	15,827	5318	(16.52)	(X)
OTCs	3,838	203	(2.12)	(X)
TOTAL	34,224	8564	(21.46)	(X)

Note: Numbers in ( ) are una

Mean expenditures per recipient in Schedule II and IV did not change significantly between periods. In addition, the data show the number of recipients decreased from 34,224 to 29,220 or 14.6 percent between periods. Possible explanations for this decline are examined later in this chapter.

Hypothesis 2:

There was no change in expenditures per internal analgesic prescription for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

A comparison of expenditures per prescription between periods for noninstitutional Medicaid recipients is presented in Table 11. Total expenditures per prescription increased from $11.74 to $13.09 between periods. The z-value comparing the mean expenditures per prescription between periods was significant ($z = -24.02$, $p < 0.05$). Therefore, hypothesis two was rejected and it can be concluded there was a difference in noninstitutional expenditures per prescription between periods. Expenditures per prescription for Schedule II, IV, propoxyphene napsylate and OTCs decreased significantly. However, mean expenditures for Schedule III, propoxyphene hydrochloride and NSAIDs all increased significantly. Also, the number of prescriptions declined from 72,730 to 66,863 or 8.1 percent between periods.

Hypothesis 3:

There was no change in expenditures per internal analgesic unit for noninstitutional Medicaid recipients at the 95 percent level

TABLE 11

NONINSTITUTIONAL EXPENDITURES PER PRESCRIPTION

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF PRESCRIPTIONS	EXPENDITURES ($)	y $ EXPENDITURES PER PRESCRIPTION	s $ EXPENDITURES PER PRESCRIPTION	NUMBER OF PRESCRIPTIONS	EXPENDITURES ($)	y $ EXPENDITURES PER PRESCRIPTION	s $ EXPENDITURES PER PRESCRIPTION		
SCHEDULE II	4,228	43,981.06	10.40	7.43	4,560	45,512.21 (55,734.87)	9.75 (12.22)	9.92	3.49	X
SCHEDULE III	19,733	105,161.84	5.33	2.68	18,130	136,211.96 (89,280.33)	7.44 (4.92)	2.63	(77.29)	(X)
SCHEDULE IV	3,963	25,926.07	6.54	3.92	3,532	21,163.30 (26,072.14)	5.89 (7.38)	4.82	6.36	X
PROPOXYPHENE NAPSYLATE	9,416	105,254.14	11.18	5.58	17	0 (266.03)	0 (15.65)	8.25	194.42	X
PROPOXYPHENE HYDROCHLORIDE	2,151	10,816.57	5.03	2.03	6,754	36,795.81 (37,538.75)	5.38 (5.56)	2.26	(6.77)	(X)
NSAIDs	27,337	538,310.57	19.69	10.76	28,678	634,874.30 (572,038.36)	21.56 (19.95)	11.81	(19.68)	(X)
OTCs	5,902	24,313.04	4.12	3.39	5,192	20,357.38 (22,134.80)	3.92 (4.26)	3.96	2.84	X
TOTAL	72,730	853,763.29	11.74	9.86	66,863	894,914.96 (803,065.28)	13.09 (12.01)	11.05	(24.02)	(X)

Note: Numbers in ( ) are unadjusted for expenditures ($) and y.

of confidence after propoxyphene napsylate was added to the Negative Drug List.

The comparison of expenditures per unit for noninstitutional Medicaid recipients between periods is presented in Table 12. Total expenditures per unit increased from 0.2338¢ to 0.2432¢ between periods. The z-value comparing the mean expenditures per unit was significant ($z = -59.49$, $p < 0.05$). Thus, hypothesis three was rejected and there was a difference in expenditures per unit between periods. The expenditures per unit for Schedule II, IV, propoxyphene napsylate and OTCs decreased significantly. Yet, the expenditures per unit for Schedule III, propoxyphene hydrochloride and NSAIDs increased significantly. Similar to the decrease in the number of recipients and prescriptions between periods, Table 12 shows a decline in the number of units from 3,651,536 to 3,601,119 or 1.4 percent.

Hypothesis 4:

There was no change in the number of prescriptions per internal analgesic recipient for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

A comparison of the number of prescriptions per recipient for noninstitutional Medicaid recipients is shown in Table 13. The total number of prescriptions per recipient increased from 2.12 to 2.29 between periods. The z-value comparing the mean values was significant ($z = -15.18$, $p < 0.05$). As a result, hypothesis four was rejected and it can be concluded there was a difference in the number

TABLE 12

NONINSTITUTIONAL EXPENDITURES PER UNIT

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF UNITS	EXPENDITURES ($)	y $ EXPENDITURES PER UNIT	s $ EXPENDITURES PER UNIT	NUMBER OF UNITS	EXPENDITURES ($)	y $ EXPENDITURES PER UNIT	s $ EXPENDITURES PER UNIT		
SCHEDULE II	193,505	43,981.06	0.2273	0.1348	301,471	45,512.21 (55,734.87)	0.1476 (0.1849)	0.1750	180.32	X
SCHEDULE III	684,408	105,161.84	0.1537	0.0821	660,369	136,211.96 (89,280.33)	0.2043 (0.1352)	0.0791	(364.03)	(X)
SCHEDULE IV	147,670	25,926.07	0.1756	0.1074	141,324	21,163.30 (26,072.14)	0.1473 (0.1845)	0.1206	66.59	X
PROPOXYPHENE NAPSYLATE	409,278	105,254.14	0.2572	0.0571	979	0 (266.03)	0 (0.2717)	0.0479	2881.67	X
PROPOXYPHENE HYDROCHLORIDE	111,673	10,816.57	0.0969	0.0505	345,769	36,795.81 (37,538.75)	0.1052 (0.1086)	0.0591	(46.11)	(X)
NSAIDs	1,448,301	538,310.57	0.3717	0.2100	1,539,160	634,874.30 (572,038.36)	0.4018 (0.3717)	0.2636	(109.49)	(X)
OTCs	656,701	24,313.04	0.0370	0.0291	612,047	20,357.38 (22,134.80)	0.0333 (0.0362)	0.0276	74.0	X
TOTAL	3,651,536	853,763.29	0.2338	0.1931	3,601,119	894,914.96 (803,065.28)	0.2432 (0.2230)	0.2295	(59.49)	(X)

Note: Numbers in ( ) are unadjusted for expenditures ($) and y.

TABLE 13

NONINSTITUTIONAL PRESCRIPTIONS PER RECIPIENT

PRESCRIPTION PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIP-TIONS	y NUMBER OF PRESCRIP-TIONS PER RECIPIENT	s NUMBER OF PRESCRIP-TIONS PER RECIPIENT	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIP-TIONS	y NUMBER OF PRESCRIP-TIONS PER RECIPIENT	s NUMBER OF PRESCRIP-TIONS PER RECIPIENT		
SCHEDULE II	2,158	4,228	1.96	2.08	2,116	4,560	2.16	2.69	(2.72)	(X)
SCHEDULE III	11,804	19,733	1.67	1.60	10,215	18,130	1.77	1.79	(4.35)	(X)
SCHEDULE IV	2,148	3,963	1.84	1.75	1,774	3,532	1.99	2.02	(2.46)	(X)
PROPOXYPHENE NAPSYLATE	5,006	9,416	1.88	1.69	14	17	1.21	0.41	78.71	X
PROPOXYPHENE HYDROCHLORIDE	1,031	2,151	2.09	1.72	3,135	6,754	2.15	1.92	(0.94)	
NSAIDs	15,827	27,337	1.73	1.07	15,393	28,678	1.86	1.18	(10.16)	(X)
OTCs	3,838	5,902	1.54	1.01	2,992	5,192	1.74	1.21	(7.27)	(X)
TOTAL	34,224	72,730	2.12	1.30	29,220	66,863	2.29	1.50	(15.18)	(X)

of prescriptions per noninstitutional recipient between periods. All categories in the prescription mix showed a significant increase in prescriptions per recipient except for propoxyphene napsylate and propoxyphene hydrochloride. The former had an obvious decrease and the later had no significant change between periods.

Hypothesis 5:

There was no change in the number of units per internal analgesic recipient for noninstitutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

Table 14 shows a difference in the number of units per noninstitutional recipient between periods. The total number of units per recipient increased from 106.70 to 123.24 which was significant ($z = -6.06$, $p < 0.05$). So hypothesis five was rejected and there is a difference in the number of units per recipient between periods. Individually, Schedule III, IV, NSAIDs, and OTCs had significant increases while propoxyphene napsylate decreased in units per recipient. No significant change was found in Schedule II or propoxyphene hydrochloride. The high mean and standard deviation for Schedule II as compared with other categories results primarily from the large unit variance seen between Schedule II morphine injections and prescriptions for morphine oral solution.

Hypothesis 6:

There was no change in the number of units per internal analgesic prescription for noninstitutional Medicaid recipients at the 95

TABLE 14

NONINSTITUTIONAL UNITS PER RECIPIENT

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF RECIPIENTS	NUMBER OF UNITS	y UNITS PER RECIPIENT	s UNITS PER RECIPIENT	NUMBER OF RECIPIENTS	NUMBER OF UNITS	y UNITS PER RECIPIENT	s UNITS PER RECIPIENT		
SCHEDULE II	2,158	193,505	89.67	304.72	2,116	301,471	142.47	1496.39	(1.59)	
SCHEDULE III	11,804	684,408	57.98	125.19	10,215	660,369	64.65	183.68	(3.10)	(X)
SCHEDULE IV	2,148	147,670	68.75	89.42	1,774	141,324	79.66	106.43	(3.43)	(X)
PROPOXYPHENE NAPSYLATE	5,006	409,278	81.76	101.81	14	979	69.93	49.71	56.82	X
PROPOXYPHENE HYDROCHLORIDE	1,031	111,673	108.32	126.42	3,135	345,769	110.29	220.36	(0.35)	
NSAIDs	15,827	1,448,301	91.51	89.66	15,393	1,539,160	99.99	96.74	(8.03)	(X)
OTCs	3,838	656,701	171.10	251.71	2,992	612,047	204.56	365.39	(4.28)	(X)
TOTAL	34,224	3,651,536	106.70	153.78	29,220	3,601,119	123.24	444.34	(6.06)	(X)

percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

A comparison of noninstitutional units per prescription between periods is presented in Table 15. Total units per prescription increased from 50.21 to 53.86 between periods. The z-value comparing the means was significant ($z = -3.72$, $p < 0.05$). Therefore, hypothesis six was rejected and it can be concluded there was a difference in the noninstitutional units per prescription between periods. The statistical analysis shows Schedule III, IV, NSAIDs, and OTCs had significant increases in units per prescription while propoxyphene napsylate had a significant decrease, and Schedule II and propoxyphene hydrochloride had no significant change.

Hypothesis 7:

There was no change in expenditures per internal analgesic recipient for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

A comparison of expenditures per internal analgesic recipient for institutional Medicaid recipients between periods is presented in Table 16. Overall total expenditures per recipient increased from $27.23 to $28.51 between periods. The z-value comparing the mean expenditures per recipient between periods was significant ($z = -3.68$) at $p < 0.05$. Therefore, hypothesis seven was rejected and it can be concluded there was a difference in institutional expenditures per recipient between periods. The expenditures per recipient for

TABLE 15

NONINSTITUTIONAL UNITS PER PRESCRIPTION

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF PRESCRIP-TIONS	NUMBER OF UNITS	y UNITS PER PRESCRIPTION	s UNITS PER PRESCRIPTION	NUMBER OF PRESCRIP-TIONS	NUMBER OF UNITS	y UNITS PER PRESCRIPTION	s UNITS PER PRESCRIPTION		
SCHEDULE II	4,228	193,505	45.77	125.68	4,560	301,471	66.11	905.77	(1.50)	
SCHEDULE III	19,733	684,408	34.68	40.16	18,130	660,369	36.42	49.12	(3.78)	(X)
SCHEDULE IV	3,963	147,670	37.26	23.33	3,532	141,324	40.01	26.54	(4.74)	(X)
PROPOXYPHENE NAPSYLATE	9,416	409,278	43.47	28.68	17	979	57.59	36.93	147.08	X
PROPOXYPHENE HYDROCHLORIDE	2,151	111,673	51.92	49.29	6,754	345,769	51.19	123.08	0.40	
NSAIDs	27,337	1,448,301	52.98	35.61	28,678	1,539,160	53.67	35.03	(2.31)	(X)
OTCs	5,902	656,701	111.27	101.85	5,192	612,047	117.88	167.24	(2.48)	(X)
TOTAL	72,730	3,651,536	50.21	57.18	66,863	3,601,119	53.86	247.58	(3.72)	(X)

TABLE 16

INSTITUTIONAL EXPENDITURES PER RECIPIENT

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF RECIPIENTS	EXPENDITURES ($)	y $ EXPENDITURES PER RECIPIENT	s $ EXPENDITURES PER RECIPIENT	NUMBER OF RECIPIENTS	EXPENDITURES ($)	y $ EXPENDITURES PER RECIPIENT	s $ EXPENDITURES PER RECIPIENT		
SCHEDULE II	666	19,164.07	28.77	36.54	740	20,269.48 (24,903.36)	26.90 (33.65)	56.06	0.75	
SCHEDULE III	2,216	30,825.32	13.91	18.56	2,211	45,332.10 (29,734.41)	20.36 (13.45)	19.90	(11.15)	(X)
SCHEDULE IV	132	2,519.57	19.09	18.90	118	2,008.30 (2,480.14)	16.81 (21.02)	22.07	0.87	
PROPOXYPHENE NAPSYLATE	2,621	71,605.66	27.32	24.76	0	0	0	0	56.49	X
PROPOXYPHENE HYDROCHLORIDE	520	8.020.97	15.42	9.88	2,300	37,569.40 (38,415.48)	16.20 (16.70)	10.74	(1.60)	
NSAIDs	4,981	307,206.17	61.68	36.32	5,184	348,958.86 (314,881.23)	65.78 (60.74)	39.97	(5.42)	(X)
OTCs	14,270	77,206.37	5.41	10.42	13,873	77,304.25 (84,053.77)	5.57 (6.06)	11.78	(1.20)	
TOTAL	18,968	516,548.13	27.23	32.38	18,325	531,442.39 (494,468.39)	28.51 (26.98)	34.61	(3.68)	(X)

Note: Numbers in ( ) are unadjusted for expenditures ($) and y.

propoxyphene napsylate decreased significantly, but mean expenditures increased significantly for Schedule III and NSAIDs. No significant change occurred in Schedules II, IV, propoxyphene hydrochloride or OTCs. In contrast to noninstitutional Medicaid recipients, institutional recipients declined only slightly from 18,968 to 18,325 or 3.4 percent between periods.

Hypothesis 8:

There was no change in expenditures per internal analgesic prescription for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

A comparison of expenditures per prescription between periods for institutional Medicaid recipients is presented in Table 17. Total expenditures per prescription increased from $8.98 to $9.16 between periods. The z-value comparing the mean expenditures per prescription between periods was significant ($z = -2.79$, $p < 0.05$). Therefore, hypothesis eight was rejected and it can be concluded that there was a difference in institutional expenditures per prescription between periods. Expenditures per prescription decreased significantly for Schedule II and propoxyphene napsylate. Significant increase per prescription was found for Schedule III and NSAIDs. No significant change was found for Schedule IV, propoxyphene hydrochloride, and OTCs. The total number of prescriptions declined only slightly from 57,490 before to 57,039 after or 0.8 percent.

TABLE 17

INSTITUTIONAL EXPENDITURES PER PRESCRIPTION

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF PRESCRIPTIONS	EXPENDITURES ($)	y $ EXPENDITURES PER PRESCRIPTION	s $ EXPENDITURES PER PRESCRIPTION	NUMBER OF PRESCRIPTIONS	EXPENDITURES ($)	y $ EXPENDITURES PER PRESCRIPTION	s $ EXPENDITURES PER PRESCRIPTION		
SCHEDULE II	1,683	19,164.07	11.39	11.11	1,903	20,269.48 (24,903.36)	10.47 (13.09)	11.66	2.42	X
SCHEDULE III	4,180	30,825.32	7.37	5.48	4,282	45,332.10 (29,734.41)	10.51 (6.94)	4.54	(28.68)	(X)
SCHEDULE IV	313	2,519.57	8.05	4.87	268	2,008.30 (2,480.14)	7.40 (9.25)	6.40	1.36	
PROPOXYPHENE NAPSYLATE	5,771	71,605.66	12.41	8.13	0	0	0	0	115.96	X
PROPOXYPHENE HYDROCHLORIDE	1,166	8,020.97	6.88	2.63	5,288	37,569.40 (38,415.48)	7.04 (7.26)	2.86	(1.85)	
NSAIDs	12,992	307,206.17	23.64	10.43	13,713	348,958.86 (314,881.23)	24.86 (22.96)	12.06	(8.85)	(X)
OTCs	31,385	77,206.37	2.46	3.54	31,585	77,304.25 (84,053.77)	2.45 (2.66)	4.09	0.32	
TOTAL	57,490	516,548.13	8.98	10.84	57,039	531,442.39 (494,468.39)	9.16 (8.67)	11.02	(2.79)	(X)

Note: Numbers in ( ) are unadjusted for expenditures ($) and y.

Hypothesis 9:

There was no change in expenditures per internal analgesic unit for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

The comparison of expenditures per unit for institutional Medicaid recipients between periods is presented in Table 18. Total expenditures per unit increased from 0.1375¢ to 0.1426¢ between periods. The z-value comparing the mean expenditures per unit was significant ($z = -31.29$, $p < 0.05$). Thus, hypothesis nine was rejected and there was a difference in expenditures per unit between periods. The expenditures per unit for Schedule IV and propoxyphene napsylate decreased significantly. Yet, the expenditures per unit for Schedule III, propoxyphene hydrochloride, NSAIDs, and OTCs increased significantly. Only Schedule II showed no significant change. Table 18 also shows that the number of units decreased from 3,757,858 to 3,663,385 or 2.5 percent.

Hypothesis 10:

There was no change in the number of prescriptions per internal analgesic recipient for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

A comparison of the number of prescriptions per recipient for institutional Medicaid recipients is shown in Table 19. The total number of prescriptions per recipient increased from 3.03 to 3.11 between periods. The z-value comparing the mean values was

TABLE 18

INSTITUTIONAL EXPENDITURES PER UNIT

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF UNITS	EXPENDITURES ($)	y $ EXPENDITURES PER UNIT	s $ EXPENDITURES PER UNIT	NUMBER OF UNITS	EXPENDITURES ($)	y $ EXPENDITURES PER UNIT	s $ EXPENDITURES PER UNIT		
SCHEDULE II	259,872	19,164.07	0.0737	0.1872	271,072	20,269.48 (24,903.36)	0.0735 (0.0919)	0.2054	0.37	
SCHEDULE III	196,625	30,825.32	0.1568	0.2758	208,611	45,332.10 (29,734.41)	0.2158 (0.1425)	0.2876	(66.67)	(X)
SCHEDULE IV	13,550	2,519.57	0.1859	0.2712	15,863	2,008.30 (2,480.14)	0.1250 (0.1563)	0.2536	19.78	X
PROPOXYPHENE NAPSYLATE	259,485	71,605.66	0.2760	0.2780	0	0	0	0	505.73	X
PROPOXYPHENE HYDROCHLORIDE	58,824	8,020.97	0.1364	0.2104	223,445	37,569.40 (38,415.48)	0.1668 (0.1719)	0.2517	(29.86)	(X)
NSAIDs	806,261	307,206.17	0.3810	0.2460	818,128	348,958.86 (314,881.23)	0.4168 (0.3849)	0.2986	(83.26)	(X)
OTCs	2,163,241	77,206.37	0.0357	0.0312	2,126,266	77,304.25 (84,053.77)	0.0363 (0.0395)	0.0343	(18.75)	(X)
TOTAL	3,757,858	516,548.13	0.1375	0.2158	3,663,385	531,442.39 (494,468.39)	0.1426 (0.1350)	0.2281	(31.29)	(X)

Note: Numbers in ( ) are unadjusted for expenditures ($) and y.

TABLE 19

INSTITUTIONAL PRESCRIPTIONS PER RECIPIENT

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIP-TIONS	y NUMBER OF PRESCRIP-TIONS PER RECIPIENT	s NUMBER OF PRESCRIP-TIONS PER RECIPIENT	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIP-TIONS	y NUMBER OF PRESCRIP-TIONS PER RECIPIENT	s NUMBER OF PRESCRIP-TIONS PER RECIPIENT		
SCHEDULE II	666	1,683	2.53	2.81	740	1,903	2.57	2.98	(0.26)	
SCHEDULE III	2,216	4,180	1.89	1.11	2,211	4,282	1.94	1.19	(1.44)	
SCHEDULE IV	132	313	2.37	1.45	118	268	2.27	1.58	0.52	
PROPOXYPHENE NAPSYLATE	2,621	5,771	2.20	1.03	0	0	0	0	109.35	X
PROPOXYPHENE HYDROCHLORIDE	520	1,166	2.24	1.06	2,300	5,288	2.30	1.07	(1.16)	
NSAIDs	4,981	12,992	2.61	1.09	5,184	13,713	2.64	1.12	(1.37)	
OTCs	14,270	31,385	2.20	1.25	13,873	31,585	2.28	1.32	(5.22)	(X)
TOTAL	18,968	57,490	3.03	0.41	18,325	57,039	3.11	0.10	(26.06)	(X)

significant ($z = -26.06$, $p < 0.05$). As a result, hypothesis ten was rejected and it can be concluded there was a difference in the number of prescriptions per institutional recipient between periods. All categories in the prescription mix showed some increase except for Schedule IV and propoxyphene napsylate. However, OTCs was the only category that had a significant increase and propoxyphene napsylate was the only category that had a significant decrease in the number of prescriptions per recipient.

Hypothesis 11:

There was no change in the number of units per internal analgesic recipient for institutional Medicaid recipients at the 95 percent level of confidence after propoxyphene napsylate was added to the Negative Drug List.

Table 20 shows a small difference in the number of units per institutional recipient between periods. The total number of units per recipient increased from 198.12 to 199.91 which was insignificant ($z = -0.31$, $p > 0.05$). So hypothesis 11 was not rejected and there is no significant difference in the number of units per recipient between periods. Individually, no category in the prescription mix had a significant increase or decrease except propoxyphene napsylate. The high mean and standard deviation for Schedule II as compared with other categories in the prescription mix results primarily from the large unit variance seen between Schedule II morphine injections and prescriptions for morphine oral solution.

TABLE 20

INSTITUTIONAL UNITS PER RECIPIENT

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF RECIPIENTS	NUMBER OF UNITS	y UNITS PER RECIPIENT	s UNITS PER RECIPIENT	NUMBER OF RECIPIENTS	NUMBER OF UNITS	y UNITS PER RECIPIENT	s UNITS PER RECIPIENT		
SCHEDULE II	666	259,872	390.20	1672.48	740	271,072	366.31	1262.21	0.30	
SCHEDULE III	2,216	196,625	88.73	408.31	2,211	208,611	94.35	459.54	(0.43)	
SCHEDULE IV	132	13,550	102.65	150.71	118	15,863	134.43	404.77	(0.80)	
PROPOXYPHENE NAPSYLATE	2,621	259,485	99.00	613.64	0	0	0	0	8.26	X
PROPOXYPHENE HYDROCHLORIDE	520	58,824	113.12	177.60	2,300	223,445	97.15	118.77	1.95	
NSAIDs	4,981	806,261	161.87	145.60	5,184	818,128	157.82	128.53	1.48	
OTCs	14,270	2,163,241	151.59	581.79	13,873	2,126,266	153.27	361.19	(0.29)	
TOTAL	18,968	3,757,858	198.12	651.10	18,325	3,663,385	199.91	434.44	(0.31)	

TABLE 21

INSTITUTIONAL UNITS PER PRESCRIPTION

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)				TEST STATISTIC (z) VALUE	SIGNIFICANCE
	NUMBER OF PRESCRIP-TIONS	NUMBER OF UNITS	y UNITS PER PRESCRIPTION	s UNITS PER PRESCRIPTION	NUMBER OF PRESCRIP-TIONS	NUMBER OF UNITS	y UNITS PER PRESCRIPTION	s UNITS PER PRESCRIPTION		
SCHEDULE II	1,683	259,872	154.41	490.74	1,903	271,072	142.44	360.75	0.82	
SCHEDULE III	4,180	196,625	47.04	139.86	4,282	208,611	48.72	119.96	(0.59)	
SCHEDULE IV	313	13,550	43.29	52.79	268	15,863	59.19	253.01	(1.01)	
PROPOXYPHENE NAPSYLATE	5,771	259,485	44.96	408.88	0	0	0	0	8.35	X
PROPOXYPHENE HYDROCHLORIDE	1,166	58,824	50.45	62.42	5,288	223,445	42.26	42.45	4.27	X
NSAIDs	12,992	806,261	62.06	57.17	13,713	818,128	59.66	42.41	3.88	X
OTCs	31,385	2,163,241	68.93	299.95	31,585	2,126,266	67.32	115.38	0.89	
TOTAL	57,490	3,757,858	65.36	274.80	57,039	3,663,385	64.23	118.20	0.91	

TABLE 22

PROPORTION OF PROPOXYPHENE NAPSYLATE POSSIBLY SWITCHED TO PROPOXYPHENE HYDROCHLORIDE

	NONINSTITUTIONAL				INSTITUTIONAL			
	RECIPIENTS	PRESCRIPTIONS	UNITS	EXPENDITURES ($)	RECIPIENTS	PRESCRIPTIONS	UNITS	EXPENDITURES ($)
Original Number for Propoxyphene Napsylate	5,006	9,416	409,278	105,254.14	2,621	5,771	259,485	71,605.66
Number Increase for Propoxyphene Hydrochloride	(3135 - 1031)	(6754 - 2151)	(345,769 - 111,673)	(36,795.81 - 10,816.57)	(2300 - 520)	(5288 - 1166)	(223,445 - 58,824)	(37,569.40 - 8,020.97)
	2,104	4,603	234,096	25,979.24	1,780	4,122	164,621	29,548.43
	42.0%	48.9%	57.2%	24.7%	67.9%	71.4%	63.4%	41.3%
Number of Propoxyphene Napsylate Unaccounted	2,902	4,813	175,182	79,274.90	841	1,649	94,864	42,057.20
	58.0%	51.1%	42.8%	75.3%	32.1%	28.6%	36.6%	58.7%

TABLE 23

TEST STATISTIC DATA FOR THE VARIABLES STUDIED

VARIABLES	NONINSTITUTIONAL			INSTITUTIONAL		
	MEAN BEFORE (4/84 - 6/84)	MEAN AFTER (4/85 - 6/85)	TEST STATISTIC (z) VALUE (α = 0.05)	MEAN BEFORE (4/84 - 6/84)	MEAN AFTER (4/85 - 6/85)	TEST STATISTIC (z) VALUE (α = 0.05)
Expenditures per Recipient	$24.95	$29.95 (27.48)	(21.46)	$27.23	$28.51 (26.98)	(3.68)
Expenditures per Prescription	$11.74	$13.09 (12.01)	(24.02)	$8.98	$9.16 (8.67)	(2.79)
Expenditures per Unit	$0.2338	$0.2432 (0.2330)	(59.49)	$0.1375	$0.1426 (0.1350)	(31.29)
Prescriptions per Recipient	2.12	2.29	(15.18)	3.03	3.11	(26.06)
Units per Recipient	106.70	123.24	(6.06)	198.12	199.91	(0.31)
Units per Prescription	50.21	53.86	(3.72)	65.36	64.23	0.91

Note: Numbers in ( ) are unadjusted for mean expenditures in the after period.

higher in the institutional setting. The percent change to propoxyphene hydrochloride for recipients was 67.9 versus 42.0 percent, for prescriptions was 71.4 versus 48.9 percent, for units was 63.4 versus 57.2 percent, and for expenditures was 41.3 versus 24.7 percent. The calculated chi square values for recipients prescriptions and units are 460.60, 744.58 and 2,571.91 respectively which are highly significant. Thus, hypothesis 13 was rejected and it can be concluded that there was a difference in the proportion of propoxyphene napsylate substituted to propoxyphene hydrochloride between institutional and noninstitutional Medicaid recipients.

The mean data and statistical analysis results for each of the variables studied are summarized in Table 23. In the noninstitutional population the data show expenditures per recipient increased significantly, but the number of prescriptions per recipient and units per recipient also increased significantly between periods. Moreover, as mentioned previously, the number of recipients, prescriptions, and units decreased by 14.6 percent, 8.1 percent, and 1.4 percent respectively between periods studied. Thus, the increases seen in prescriptions per recipient and units per recipient may simply be attributed to the smaller decline in the number of prescriptions and units as compared with the decline in the number of recipients.

The decline in the number of noninstitutional recipients in the prescription mix was not consistent with prescription trends in the total Medicaid population. Secondary data obtained from the Wisconsin Medical Assistance Program (WMAP) are presented in Table 24. Table 24 shows the breakdown of prescription benefits by different categories

TABLE 23

TEST STATISTIC DATA FOR THE VARIABLES STUDIED

VARIABLES	NONINSTITUTIONAL			INSTITUTIONAL		
	MEAN BEFORE (4/84 - 6/84)	MEAN AFTER (4/85 - 6/85)	TEST STATISTIC (z) VALUE (α = 0.05)	MEAN BEFORE (4/84 - 6/84)	MEAN AFTER (4/85 - 6/85)	TEST STATISTIC (z) VALUE (α = 0.05)
Expenditures per Recipient	$24.95	$29.95 (27.48)	(21.46)	$27.23	$28.51 (26.98)	(3.68)
Expenditures per Prescription	$11.74	$13.09 (12.01)	(24.02)	$8.98	$9.16 (8.67)	(2.79)
Expenditures per Unit	$0.2338	$0.2432 (0.2330)	(59.49)	$0.1375	$0.1426 (0.1350)	(31.29)
Prescriptions per Recipient	2.12	2.29	(15.18)	3.03	3.11	(26.06)
Units per Recipient	106.70	123.24	(6.06)	198.12	199.91	(0.31)
Units per Prescription	50.21	53.86	(3.72)	65.36	64.23	0.91

Note: Numbers in ( ) are unadjusted for mean expenditures in the after period.

TABLE 24

PRESCRIBED DRUG STATISTICS FOR THE WISCONSIN MEDICAID POPULATION FOR THE PERIODS STUDIED

	BEFORE (4/84 - 6/84)	AFTER (4/85 - 6/85)
A. AGED		
1. Expenditures	4,819,067.86	5,156,422.85
2. Ave. Eligible	55,141.00	55,123.33
3. Ave. Recipient	34,499.33	34,328.33
4. Percent (%) Using	62.56	62.27
5. Total Prescriptions	413,695.00	416,375.00
6. Prescriptions/Recipient	3.99	4.04
7. Cost/Prescription	11.64	12.38
B. BLIND/DISABLED		
1. Expenditures	3,622,196.02	4,213,543.70
2. Ave. Eligible	52,639.00	57,480.00
3. Ave. Recipient	24,417.33	26,250.33
4. Percent (%) Using	46.38	45.66
5. Total Prescriptions	271,384.00	289,718.00
6. Prescriptions/Recipient	3.70	3.67
7. Cost/Prescription	13.34	14.54
C. AFDC		
1. Expenditures	2,809,229.11	1,968,337.22
2. Ave. Eligible	325,917.00	333,341.66
3. Ave. Recipient	53,569.33	37,454.33
4. Percent (%) Using	16.43	11.23
5. Total Prescriptions	296,508.00	196,670.00
6. Prescriptions/Recipient	1.84	1.75
7. Cost/Prescription	9.47	10.00
D. OTHER and NON TITLE IX		
1. Expenditures	191,908.56	194,135.66
2. Ave. Eligible	5,147.00	5,327.00
3. Ave. Recipient	1,673.00	1,587.00
4. Percent (%) Using	32.50	29.78
5. Total Prescriptions	16,774.00	15,904.00
6. Prescriptions/Recipient	3.26	2.92
7. Cost/Prescription	11.44	12.21
E. TOTAL		
1. Expenditures	11,442,401.55	11,532,439.43
2. Ave. Eligible	438,757.33	451,176.66
3. Ave. Recipient	114,084.00	99,550.66
4. Percent (%) Using	26.00	22.06
5. Total Prescriptions	998,361.00	918,667.00
6. Prescriptions/Recipient	2.91	3.07
7. Cost/Prescription	11.46	12.55

of recipients for the periods studied. Expenditures were not adjusted for producer price or reimbursement changes between periods. In addition, data in the after period do not include those AFDC eligibles enrolled in HMOs. The purpose of Table 24 is to show that the largest consumers of prescription benefits (aged and blind/disabled) did not have any significant changes in the percent using or prescriptions per recipient between periods. As a result, the decline in the number of noninstitutional recipients in this study may represent recipients who elected to pay out-of-pocket cash for continued therapy or recipients who discontinued prescription treatment all together. This response might result in a cost savings to the WMAP, but represents a cost-transfer to those recipients who may be the least able to absorb these costs.

Noninstitutional expenditures examined on a per prescription basis showed a significant increase in cost. Yet, the units per prescription increased significantly. Since cost is a function of both price and quantity, the increase in expenditures per prescription may just be a reflection of the quantity increase. Noninstitutional expenditures per unit increased significantly and probably reflects the use of more expensive agents (e.g., NSAIDs) between periods.

In the institutional population the data show expenditures per recipient increased significantly, but the prescriptions per recipient increased significantly. In addition, units per recipient increased, but not to any significant degree. In contrast with the noninstitutional population, the number of recipients, prescriptions, and units showed only slight decreases of 3.4, 0.8, and 2.5 percent

respectively. This smaller drop out rate probably results from the influence of a consultant pharmacist in this setting. For example, as was shown in Table 22 above, a larger proportion of propoxyphene napsylate was switched to propoxyphene hydrochloride in the institutional population.

Institutional expenditures per prescription increased significantly, even though units per prescription declined slightly. Thus, additional expenditures were measured. Finally, institutional expenditures per unit increased significantly probably due to the use of more expensive agents (e.g., NSAIDs).

Other Findings

The findings reported in this section are not tested as formal research hypotheses. This section examines market share changes of components in the prescription mix, and estimates cost savings when propoxyphene napsylate was added to the Negative Drug List.

A comparison of market share changes for the noninstitutional prescription mix between periods is presented in Table 25. The categories that had the largest changes between time periods were propoxyphene napsylate, propoxyphene hydrochloride, and NSAIDs. Schedule II shows a slight increase and OTCs declined. The most interesting observation from Table 25 is the large disproportional increase in total expenditures for NSAIDs as compared with NSAID market share increases in recipients, prescriptions, and units. This is in contrast to the larger market share increases in recipients,

TABLE 25

MARKET SHARE CHANGES IN THE NONINSTITUTIONAL PRESCRIPTION MIX

PRESCRIPTION MIX	BEFORE (4/84 - 6/84)				AFTER (4/85 - 6/85)			
	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIPTIONS	NUMBER OF UNITS	TOTAL EXPENDITURES ($)	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIPTIONS	NUMBER OF UNITS	TOTAL* EXPENDITURES ($)
SCHEDULE II	2,158 (5.2)	4,228 (5.8)	193,505 (5.3)	43,981.06 (5.2)	2,116 (5.9)	4,560 (6.8)	301,471 (8.4)	45,512.21 (5.1)
SCHEDULE III	11,804 (28.2)	19,733 (27.1)	684,408 (18.7)	105,161.84 (12.3)	10,215 (28.7)	18,130 (27.1)	660,369 (18.3)	136,211.96 (15.2)
SCHEDULE IV	2,148 (5.1)	3,963 (5.4)	147,670 (4.0)	25,926.07 (3.0)	1,774 (5.0)	3,532 (5.3)	141,324 (3.9)	21,163.30 (2.4)
PROPOXYPHENE NAPSYLATE	5,006 (12.0)	9,416 (12.9)	409,278 (11.2)	105,254.14 (12.3)	14 (0)	17 (0)	979 (0)	266.03 (0)
PROPOXYPHENE HYDROCHLORIDE	1,031 (2.5)	2,151 (3.0)	111,673 (3.0)	10,816.57 (1.3)	3,135 (8.8)	6,754 (10.1)	345,769 (9.6)	36,795.81 (4.1)
NSAIDs	15,827 (37.8)	27,337 (37.6)	1,448,301 (39.7)	538,310.57 (63.0)	15,393 (43.2)	28,678 (42.9)	1,539,160 (42.7)	634,874.30 (70.9)
OTCs	3,838 (9.2)	5,902 (8.1)	656,701 (18.0)	24,313.04 (2.8)	2,992 (8.4)	5,192 (7.8)	612,047 (17.0)	20,357.38 (2.3)
TOTAL	[1] 34,224 / 41,812 (100.0)	72,730 (100.0)	3,651,536 (100.0)	853,763.29 (100.0)	[1] 29,220 / 35,639 (100.0)	66,863 (100.0)	3,601,119 (100.0)	894,914.96 (100.0)

[1]Numbers do not add to total because some recipients are in more than one eligibility category.

*ADJUSTED FOR PRESCRIPTION CHARGE FORMULA CHANGE AND PRODUCER PRICE INDEX CHANGES.

prescriptions, and units for propoxyphene hydrochloride, but the relative smaller increase in total expenditures. This market share increase in total expenditures for NSAIDs is probably the reason noninstitutional expenditures per unit increased significantly from the hypotheses testing.

The statistical analysis showed that the number of prescriptions per recipient increased significantly for the noninstitutional population. This might result from the prescribing of two single entity products (e.g., propoxyphene hydrochloride and acetaminophen) in lieu of Darvocet-N^{R}. However, on examination of the noninstitutional market share data, the share of OTCs declined. This decline in market share for OTCs probably shows that two single entities were not prescribed in place of Darvocet-N^{R}. More likely, with the noninstitutional population, Darvocet-N^{R} often was replaced with a single entity product such as propoxyphene hydrochloride or a NSAID. Also, as noted previously, the decline in the number of noninstitutional recipients between periods is evidence that some recipients discontinued therapy or paid for Darvocet-N^{R} out-of-pocket.

A comparison of market share changes for the institutional prescription mix between periods is presented in Table 26. The categories that had the largest changes between time periods were propoxyphene napsylate, propoxyphene hydrochloride, and NSAIDs. Schedule II showed a slight increase, and Schedule III, IV, and OTCs remained approximately constant. As with the noninstitutional population, the NSAIDs had a disproportionate increase in total

TABLE 26

MARKET SHARE CHANGES IN THE INSTITUTIONAL PRESCRIPTION MIX

PRESCRIPTION MIX	BEFORE (4/84 - 6/84) NUMBER OF RECIPIENTS	NUMBER OF PRESCRIPTIONS	NUMBER OF UNITS	TOTAL EXPENDITURES ($)	AFTER (4/85 - 6/85) NUMBER OF RECIPIENTS	NUMBER OF PRESCRIPTIONS	NUMBER OF UNITS	TOTAL* EXPENDITURES ($)
SCHEDULE II	666 (2.6)	1,683 (2.9)	259,872 (6.9)	19,164.07 (3.7)	740 (3.0)	1,903 (3.3)	271,072 (7.4)	20,269.48 (3.8)
SCHEDULE III	2,216 (8.7)	4,180 (7.3)	196,625 (5.2)	30,825.32 (6.0)	2,211 (9.0)	4,282 (7.5)	208,611 (5.7)	45,332.10 (8.5)
SCHEDULE IV	132 (0.5)	313 (0.5)	13,550 (0.4)	2,519.57 (0.5)	118 (0.5)	268 (0.5)	15,863 (0.4)	2,008.30 (0.4)
PROPOXYPHENE NAPSYLATE	2,621 (10.3)	5,771 (10.0)	259,485 (6.9)	71,605.66 (13.9)	0 (0)	0 (0)	0 (0)	0 (0)
PROPOXYPHENE HYDROCHLORIDE	520 (2.0)	1,166 (2.0)	58,824 (1.6)	8,020.97 (1.6)	2,300 (9.4)	5,288 (9.3)	223,445 (6.1)	37,569.40 (7.1)
NSAIDs	4,981 (19.6)	12,992 (22.6)	806,261 (21.4)	307,206.17 (59.5)	5,184 (21.2)	13,713 (24.0)	818,128 (22.3)	348,958.86 (65.7)
OTCs	14,270 (56.2)	31,385 (54.6)	2,163,241 (57.6)	77,206.37 (14.9)	13,873 (56.8)	31,585 (55.4)	2,126,266 (58.0)	77,304.25 (14.5)
TOTAL	[1] 18,968 / 25,406 (100.0)	57,490 (100.0)	3,757,858 (100.0)	516,548.13 (100.0)	[1] 18,325 / 24,426 (100.0)	57,039 (100.0)	3,663,385 (100.0)	531,442.39 (100.0)

[1]Numbers do not add to total because some recipients are in more than one eligibility category.

*ADJUSTED FOR PRESCRIPTION CHARGE FORMULA CHANGE AND PRODUCER PRICE INDEX CHANGES.

expenditures as compared to the increase in recipients, prescriptions, and units. The market share increase of expenditures for propoxyphene hydrochloride more closely matched the increase in recipients, prescriptions, and units. This is in contrast to the noninstitutional population, but is logical because a larger proportion of the institutional population likely was switched to propoxyphene hydrochloride and less to NSAIDs when propoxyphene napsylate was added to the Negative Drug List. However, this market share increase in total expenditures for NSAIDs is so significant due to their high costs that this is probably the reason institutional expenditures per unit increased significantly from the hypothesis testing.

The statistical analysis showed that the number of prescriptions per recipient increased significantly for the institutional population. Again, this might result from the prescribing of two single entity products (e.g., propoxyphene hydrochloride and acetaminophen) in lieu of Darvocet-N^{R}. However, an examination of the institutional market share data shows OTCs remained essentially constant. Thus, in the institutional population, Darvocet-N^{R} probably was replaced with a single entity product such as propoxyphene hydrochloride or a NSAID.

Finally, the data in Tables 25 and 26 above show interesting differences of market share in the prescription mix categories between the noninstitutional and institutional Medicaid population. In the noninstitutional population the market shares of Schedule II and IV were higher. Moreover, the market shares of Schedule III and NSAIDs were considerably higher in the noninstitutional setting. However,

the market share of OTCs in the institutional population was substantially higher. These differences of market share in the prescription mix categories between noninstitutional and institutional populations determines expenditures and potential savings when a drug like propoxyphene napsylate is added to the Negative Drug List.

The potential drug savings to the WMAP if all propoxyphene napsylate was changed to propoxyphene hydrochloride is presented in Table 27. Based upon the volume of propoxyphene napsylate used and the mean difference in cost between the napsylate and hydrochloride salts, a potential savings is projected for the number of recipients, prescriptions, and units, assuming all other categories in the prescription mix remained constant. The projected savings in the noninstitutional and institutional populations vary, but parallels the decline noted earlier in the number of recipients, prescriptions, and units between periods. The relatively constant usage in the institutional population projects to a more uniform potential savings across the variables.

The estimated savings to the WMAP from the actual increase in propoxyphene hydrochloride usage is presented in Table 28. Based upon the actual increase in propoxyphene hydrochloride between periods when propoxyphene napsylate was added to the Negative Drug List, and the mean difference in cost between the salts, an estimated savings was projected. The estimated savings in all cases is significantly less than the potential savings because, as Table 22 showed above, not all

TABLE 27

POTENTIAL SAVINGS IF ALL PROPOXYPHENE NAPSYLATE PRESCRIPTIONS WERE CHANGED TO PROPOXYPHENE HYDROCHLORIDE

VARIABLES	NONINSTITUTIONAL			INSTITUTIONAL		
	Sum total difference of propoxyphene salts between periods.	Mean difference between Propoxyphene-Propoxyphene Napsylate (1984) Hydrochloride (1985)	Potential savings	Sum total difference of propoxyphene salts between periods.	Mean difference between Propoxyphene-Propoxyphene Napsylate (1984) Hydrochloride (1985)	Potential savings
Number of Recipients	5,006	(21.02 - 11.59) $9.43	$47,206.58	2,621	(27.32 - 16.20) $11.12	$29,145.52
Number of Prescriptions	9,416	(11.18 - 5.38) $5.80	$54,612.80	5,771	(12.41 - 7.04) $5.37	$30,990.27
Number of Units	409,278	(0.2572 - 0.1052) $0.1520	$62,210.26	259,485	(0.2760 - 0.1668) $0.1092	$28,335.76

TABLE 28

ESTIMATED SAVINGS USING PROPOXYPHENE HYDROCHLORIDE VERSUS PROPOXYPHENE NAPSYLATE

VARIABLES	NONINSTITUTIONAL			INSTITUTIONAL		
	Before-After difference for propoxyphene hydrochloride	Mean difference between Propoxyphene-Propoxyphene Napsylate (1984) Hydrochloride (1985)	Estimated savings	Before-After difference for propoxyphene hydrochloride	Mean difference between Propoxyphene-Propoxyphene Napsylate (1984) Hydrochloride (1985)	Estimated savings
Number of Recipients	(3,135 - 1,031) 2,104	(21.02 - 11.59) $9.43	$19,840.72	(2,300 - 520) 1,780	(27.32 - 16.20) $11.12	$19,793.60
Number of Prescriptions	(6,754 - 2,151) 4,603	(11.18 - 5.38) $5.80	$26,697.40	(5,228 - 1,166) 4,122	(12.41 - 7.04) $5.37	$22,135.40
Number of Units	(345,769 - 111,673 234,096	(0.2572 - 0.1052) $0.1520	$35,532.59	(223,445 - 58,824) 164,621	(0.2760 - 0.1668) $0.1092	$17,976.61

napsylate was changed to hydrochloride.

From the opinions of selected physicians practicing around the Madison area and current medical knowledge, the logical substitution choice other than propoxyphene hydrochloride, with or without an OTC analgesic, would have been a NSAID. Based on market share data calculated in Tables 25 and 26 above, the proportion of propoxyphene napsylate possibly switched to propoxyphene hydrochloride or a NSAID is presented in Table 29. The data in Table 29 show that the NSAIDs probably account for a large share of the original napsylate not changed to the hydrochloride salt. This is especially true in the noninstitutional population where a smaller proportion of napsylate apparently went to the hydrochloride salt.

The large market share increases observed for NSAIDs across the variables do not parallel the increase of NSAID use in the WMAP for fiscal years 1984 and 1985. Table 30 shows that the number of prescription orders for NSAIDs increased 0.75 percent between years. In this study, the number of prescription orders for NSAIDs in the noninstitutional Medicaid population increased 4.9 percent even with a decrease in total noninstitutional prescriptions by 8.1 percent. In the institutional population, the number of prescription orders for NSAIDs increased by 5.5 percent even with a decrease in total institutional orders of 0.78 percent. Thus, the evidence suggests that a portion of propoxyphene napsylate volume was switched to NSAIDs.

In an attempt to estimate more accurately potential expenditures, the estimated savings of using propoxyphene hydrochloride must be compared with the additional expense of using NSAIDs. Table 31 was

TABLE 29

MARKET SHARE OF PROPOXYPHENE NAPSYLATE POSSIBLY SWITCHED TO NSAIDs

	NONINSTITUTIONAL				INSTITUTIONAL			
	PERCENT OF RECIPIENTS	PERCENT OF PRESCRIPTIONS	PERCENT OF UNITS	PERCENT EXPENDITURES ($)	PERCENT OF RECIPIENTS	PERCENT OF PRESCRIPTIONS	PERCENT OF UNITS	PERCENT EXPENDITURES ($)
A. Original Market Share of Propoxyphene Napsylate	12.0	12.9	11.2	12.3	10.3	10.0	6.9	13.9
B. Market Share Increase of Propoxyphene Hydrochloride Between Periods	(8.8 - 2.5) 6.3	(10.1 - 3.0) 7.1	(9.6 - 3.0) 6.6	(4.1 - 1.3) 2.8	(9.4 - 2.0) 7.4	(9.3 - 2.0) 7.3	(6.1 - 1.6) 4.5	(7.1 - 1.6) 5.5
C. Market Share of Napsylate Unaccounted (A - B)	5.7	5.8	4.6	9.5	2.9	2.7	2.4	8.4
D. Market Share Increase of NSAIDs Between Periods	(43.2 - 37.8) 5.4	(42.9 - 37.6) 5.3	(42.7 - 39.7) 3.0	(70.9 - 63.0) 7.9	(21.2 - 19.6) 1.6	(24.0 - 22.6) 1.4	(22.3 - 21.4) 0.9	(65.7 - 59.5) 6.2
E. Final Market Share of Napsylate Unaccounted (C - D)	0.3	0.5	1.6	1.6	1.3	1.3	1.5	2.2

TABLE 30

NONSTEROIDAL ANTI-INFLAMMATORY DRUG ANALYSIS FOR WISCONSIN MEDICAID

DRUG	PERIOD 1 07/83 - 06/84		MARKET SHARE % CHANGE	PERIOD 2 07/84 - 06/85		MARKET SHARE % CHANGE '85 VS. '84	PERIOD 3 07/85 - 06/86		MARKET SHARE % CHANGE '86 VS. '85
	PAID AMOUNT	PRESCRIPTION NUMBER		PAID AMOUNT	PRESCRIPTION NUMBER		PAID AMOUNT	PRESCRIPTION NUMBER	
1. ANAPROX	$80,353.83 (2.3)	4,606 (2.7)	-	$77,908.59 (2.2)	4,103 (2.4)	(0.1) / (0.3)	$77,554.89 (2.1)	3,705 (2.1)	(0.1) / (0.3)
2. CLINORIL	$421,766.00 (12.0)	16,834 (9.8)	-	$431,961.96 (12.0)	16,450 (9.5)	0 / (0.3)	$463,900.25 (12.4)	16,455 (9.5)	0.4 / 0
3. DOLOBID	$145,520.79 (4.2)	7,547 (4.4)	-	$168,930.24 (4.7)	7,876 (4.5)	0.5 / 0.1	$186,886.43 (5.0)	7,958 (4.6)	0.3 / 0.1
4. EASPRIN	$10,534.57 (0.3)	1,185 (0.7)	-	$11,346.33 (0.3)	1,156 (0.7)	0 / 0	$11,473.52 (0.3)	979 (0.6)	0 / (0.1)
5. ESGIC	$11,852.58 (0.3)	1,540 (0.9)	-	$12,502.73 (0.3)	1,537 (0.9)	0 / 0	$11,964.28 (0.3)	1,380 (0.8)	0 / (0.1)
6. FELDENE	$505,798.60 (14.4)	19,017 (11.0)	-	$646,495.92 (17.9)	22,474 (12.9)	3.5 / 1.9	$738,149.29 (19.8)	23,194 (13.4)	1.9 / 0.5
7. INDOCIN	$330,529.00 (9.4)	18,198 (10.5)	-	$276,516.75 (7.6)	14,269 (8.2)	(1.8) / (2.3)	$164,424.34 (4.4)	8,030 (4.6)	(3.2) / (3.6)
8. Indomethacin	$10.94 (0)	2 (0)	-	$43,766.97 (1.2)	3,046 (1.8)	1.2 / 1.8	$94,148.01 (2.5)	6,658 (3.8)	1.3 / 2.0
9. MECLOMEN	$49,459.32 (1.4)	2,757 (1.6)	-	$58,224.25 (1.6)	2,999 (1.7)	0.2 / 0.1	$57,270.02 (1.5)	2,614 (1.5)	(0.1) / (0.2)
10. MOTRIN	$597,221.63 (17.0)	35,839 (20.8)	-	$371,883.08 (10.3)	24,908 (14.3)	(6.7) / (6.5)	$241,758.94 (6.5)	19,450 (11.2)	(3.8) / (3.1)
11. Ibuprofen	-0-	-0-	-	-0-	-0-	0 / 0	$78,016.41 (2.1)	8,465 (4.9)	2.1 / 4.9
12. NALFON	$175,149.52 (5.0)	8,801 (5.1)	-	$160,041.34 (4.4)	7,418 (4.3)	(0.6) / (0.8)	$141,309.40 (3.8)	5,874 (3.4)	(0.6) / (0.9)
13. NAPROSYN	$684,207.09 (19.5)	24,061 (13.9)	-	$770,873.02 (21.4)	25,453 (14.6)	1.9 / 0.7	$909,804.47 (24.4)	28,147 (16.2)	3.0 / 1.6
14. ORUDIS	-0-	-0-	-	-0-	-0-	0 / 0	$6,422.51 (0.2)	253 (0.1)	0.2 / 0.1
15. PONSTEL	$16,821.68 (0.5)	1,669 (1.0)	-	$14,291.15 (0.4)	1,322 (0.8)	(0.1) / (0.2)	$9,447.60 (0.2)	786 (0.4)	(0.2) / (0.4)
16. RUFEN	$300,109.33 (8.5)	23,548 (13.6)	-	$380,518.55 (10.5)	34,433 (19.8)	2.0 / 6.2	$346,930.84 (9.3)	32,827 (18.9)	(1.2) / (0.9)
17. SUPROL	-0-	-0-	-	-0-	-0-	0 / 0	$13,225.44 (0.4)	761 (0.4)	0.4 / 0.4
18. TANDEARIL	$2,655.33 (0)	358 (0.2)	-	$1,430.77 (0)	197 (0.1)	0 / (0.1)	$580.49 (0)	57 (0)	0 / (0.1)
19. TOLECTIN	$181,154.84 (5.2)	6,555 (3.8)	-	$183,554.00 (5.1)	6,175 (3.6)	(0.1) / (0.2)	$182,120.25 (4.9)	5,648 (3.3)	(0.2) / (0.3)
TOTAL	$3,513,145.05 (100.0)	172,517 (100.0)	-	$3,610,245.65 (100.0)	173,816 (100.0)	2.76% / 0.75%	$3,735,387.38 (100.0)	173,241 (100.0)	3.47% / (0.33%)

TABLE 31

NUMBER OF RECIPIENTS, PRESCRIPTIONS AND UNITS OF PROPOXYPHENE NAPSYLATE POSSIBLY SWITCHED TO PROPOXYPHENE HYDROCHLORIDE AND NSAIDs

	NONINSTITUTIONAL[a]				INSTITUTIONAL			
	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIPTIONS	NUMBER OF UNITS	EXPENDITURES ($)	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIPTIONS	NUMBER OF UNITS	EXPENDITURES ($)
A. Original Number of Propoxyphene Napsylate	5,006	9,416	409,278	$105,254.14	2,621	5,771	259,485	$71,605.66
B. Number Increase of Propoxyphene Hydrochloride Between Periods	[1] (3629 - 1031) 2,598	(7242 - 2151) 5,091	(357,354 - 111,673) 245,681	(34,113.80 - 10,816.57) $23,297.23	(2300 - 520) 1,780	(5288 - 1166) 4,122	(223,445 - 58,824 164,621	(35,593.05 - 8,020.97) $27,572.08
C. Number of Napsylate Unaccounted (A - B)	2,408	4,325	163,597	$81,956.91	841	1,649	94,864	$44,033.58
D. Number Increase of NSAIDs Between Periods	[2] (18088 - 15827) 2,261	(31190 - 27337) 3,853	(1,557,744 - 1,448,301) 109,443	(605,813.00 - 538,310.57) $67,502.43	(5184 - 4981) 203	(13713 - 12992) 721	(818,128 - 806,261) 11,867	(339,217.57 - 307,206.17) $32,011.40
E. Final Number of Napsylate Unaccounted (C - D)	147	472	54,154	$14,454.48	638	928	82,997	$12,022.18

[a]Numbers converted to 1984 levels because the number of recipients, prescriptions and units declined significantly between periods.

[1] $\frac{1031}{2.5} = \frac{X}{8.8}$; X = 3629

[2] $\frac{15827}{37.8} = \frac{X}{43.2}$; X = 18088

constructed to determine the actual increase of propoxyphene hydrochloride and NSAIDs between periods for the different variables. In addition, the increase of propoxyphene hydrochloride and NSAIDs in the noninstitutional population were converted by proportion to 1984 usage levels so as to eliminate the actual decrease observed in the number of recipients, prescriptions, and units. Since the institutional population did not vary as substantially, no adjustments in usage were calculated.

As a result, Table 32 was constructed and it compares the savings of using propoxyphene hydrochloride to the additional expenditures of using NSAIDs. In summary, total expenditures were estimated for the noninstitutional and institutional populations after propoxyphene napsylate was added to the Negative Drug List. The data show that in the noninstitutional population the WMAP would have expended more after propoxyphene napsylate was added to the Negative Drug List as a result of the substitution of NSAIDs and assuming no decline in usage. The net savings in the institutional population were positive because a larger proportion of napsylate was switched to the hydrochloride salt and a smaller proportion was switched to NSAIDs. It is interesting to note that the estimated savings in Table 32 varies depending on the method used in calculation and the variable observed. However, in each case the savings were substantially less than one might anticipate.

Finally, a comparison of expenditures per prescription among the different NSAIDs between fiscal years is presented in Table 33. The expenditures per prescription calculated were derived from the data in

TABLE 32

ESTIMATED SAVINGS USING PROPOXYPHENE HYDROCHLORIDE VERSUS NAPSYLATE WITH THE SUBSTITUTION EFFECT

	NONINSTITUTIONAL[a]				INSTITUTIONAL			
	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIPTIONS	NUMBER OF UNITS	EXPENDITURES ($)	NUMBER OF RECIPIENTS	NUMBER OF PRESCRIPTIONS	NUMBER OF UNITS	EXPENDITURES ($)
A. Estimated savings using propoxyphene hydrochloride	[2598 x (21.02 - 11.59)]	[5091 x (11.18 - 5.38)]	[245,681 x (0.2572 - 0.1052)]	[105,254.14 - 23,297.23]	[1780 x (27.32 - 16.20)]	[4122 x (12.41 - 7.04)]	[164,621 x (0.2760 - 0.1668)]	[71,605.66 - 27,572.08]
	$24,499.14	$29,527.80	$37,343.51	$81,956.91	$19,793.60	$22,135.14	$17,976.61	$44,033.58
B. Additional expenditures using NSAIDs	[2261 x (40.17 - 11.59)]	[3853 x (21.56 - 5.38)]	[109,443 x (0.4018 - 0.1052)]		[203 x (65.78 - 16.20)]	[721 x (24.86 - 7.04)]	[11,867 x (0.4168 - 0.1668)]	
	$64,619.38	$62,341.54	$32,460.79	$67,502.43	$10,064.74	$12,848.22	$2,966.75	$32,011.40
C. Expenditures of the final unaccounted numbers	[147 x (29.95 - 11.59)]	[472 x (13.09 - 5.38)]	[54,154 x (0.2432 - 0.1052)]		[638 x (28.51 - 16.20)]	[928 x (9.16 - 7.04)]	[82,997 x (0.1426 - 0.1668)]	
	$2,698.92	$3,639.12	$7,473.25	-	$7,853.78	$1,967.36	$-2,008.53	-
D. NET SAVINGS [A - (B + C)]	($42,819.16)	($36,452.86)	($2,590.53)	$14,454.48	$1,875.08	$7,319.56	$17,018.39	$12,022.18

[a]Estimates based on 1984 usage level because the number of recipients declined significantly between periods.

TABLE 33

NONSTEROIDAL ANTI-INFLAMMATORY DRUG ANALYSIS PER PRESCRIPTION FOR WISCONSIN MEDICAID

DRUG	PERIOD 07/83 - 06/84	PERIOD 07/84 - 06/85		PERIOD 07/85 - 06/86	
	PAID AMOUNT PER PRESCRIPTION	PAID AMOUNT PER PRESCRIPTION	% CHANGE	PAID AMOUNT PER PRESCRIPTION	% CHANGE
1. ANAPROX	$17.44	$18.99	8.9%	$20.93	10.2%
2. CLINORIL	$25.05	$26.26	4.8%	$28.19	7.3%
3. DOLOBID	$19.28	$21.45	11.2%	$23.48	9.5%
4. EASPRIN	$8.89	$9.82	10.5%	$11.72	19.3%
5. ESGIC	$7.70	$8.13	5.6%	$8.67	6.6%
6. FELDENE	$26.60	$28.77	8.2%	$31.82	10.6%
7. INDOCIN	$18.16	$19.38	6.7%	$20.48	5.7%
8. Indomethacin	NONE	$14.37	(25.8%)*	$14.14	(31.0%)*
9. MECLOMEN	$17.94	$19.41	8.2%	$21.91	12.8%
10. MOTRIN	$16.66	$14.93	(10.4%)	$12.43	(16.7%)
11. Ibuprofen	NONE	NONE	-	$9.22	(25.8%)*
12. NALFON	$19.90	$21.57	8.4%	$24.06	11.5%
13. NAPROSYN	$28.44	$30.29	6.5%	$32.32	6.7%
14. ORUDIS	NONE	NONE	-	$25.38	-
15. PONSTEL	$10.08	$10.81	7.2%	$12.02	11.2%
16. RUFEN	$12.74	$11.05	(13.3%)	$10.57	(4.3%)
17. SUPROL	NONE	NONE	-	$17.38	-
18. TANDEARIL	$7.42	$7.26	(2.2%)	$10.18	40.2%
19. TOLECTIN	$27.64	$29.72	7.5%	$32.24	8.5%
TOTAL	$20.36	$20.77	2.0%	$21.56	3.8%

*COMPARED WITH BRAND NAME

Table 30 above. In this study, the mean expenditure per prescription for propoxyphene napsylate in the noninstitutional population was $11.18 (Table 11 above) and in the institutional population it was $12.41 (Table 17). From the data in Table 33 (Period 07/83 - 06/84), only 4 of 19 (21.0%) NSAIDs were less costly per prescription than propoxyphene napsylate. In addition, from the market share data in Table 30 above, the trend was towards the use of Feldene, Naprosyn, and Rufen between periods one and two. At this same time Motrin market share was decreasing, but ibuprofen still held a large share of the market. Moreover, the data in Table 33 show Naprosyn and Feldene were two of the most costly NSAIDs per prescription.

CHAPTER FIVE

SUMMARY AND CONCLUSIONS

The purpose of this study was to utilize computer reports generated by the Wisconsin Medicaid Management Information System (MMIS) to examine the effect on prescribing mix and expenditures for internal analgesics after propoxyphene napsylate was added to the Negative Drug List.

A cross-sectional descriptive survey methodology was used and primary data were obtained from computer reports generated by the Wisconsin MMIS. On February 1, 1985, propoxyphene napsylate products were added to a Negative Drug List and were no longer covered by the Wisconsin Medical Assistance Program (WMAP). In order to observe a before/after effect, quarterly data were extracted from one period before (April-June 1984) and one period after (April-June 1985) propoxyphene napsylate was added to the Negative Drug List. Also, the data were separated into institutional and noninstitutional Medicaid recipients. The data were processed in aggregate for drug analgesic entities in Schedule II, Schedule III, Schedule IV, nonsteroidal anti-inflammatory drugs (NSAIDs), and over-the-counter (OTC) analgesics. In addition, propoxyphene napsylate and propoxyphene hydrochloride were examined separately to obtain more specific information on expenditures. For noninstitutional and institutional Medicaid recipients, data for the following variables were extracted

and calculated: (1) expenditures per recipient, (2) expenditures per prescription, (3) expenditures per unit, (4) prescriptions per recipient, (5) units per recipient, and (6) units per prescription. This study did not use a sample, but used a complete census of recipients, prescriptions, and units for each component in the prescription mix. A two-tailed statistical test was used for comparing the population means.

Significant differences were found between time periods for all variables in the noninstitutional population. The mean data are summarized in Table 23 previously. The data show expenditures per recipient increased significantly, but the number of prescriptions per recipient and the units per recipient also increased. However, the actual number of recipients, prescriptions, and units declined by 14.6, 8.1, and 1.4 percent respectively. Since these same declines in usage were not observed in the overall WMAP drug benefit portion for the same time periods, it is likely that some of these recipients discontinued therapy or paid for the prescription out-of-pocket. As a result, this response may have saved the WMAP money, but represents a cost-shift to those recipients who may be the least able to absorb these costs. Moreover, expenditures examined on a per prescription and per unit basis show additional program costs, although the units per prescription increased.

Some significant differences were found between time periods for variables in the institutional population. The mean data also are summarized in Table 23 previously. The data show expenditures per recipient increased significantly, but the number of prescriptions

per recipient increased significantly and the units per recipient increased slightly. Moreover, no significant declines were observed in the actual number of institutional recipients, prescriptions, and units. Expenditures examined on a per prescription basis increased significantly, yet the units per prescription showed no significant change between time periods. In addition, expenditures per unit did increase significantly and probably reflects the use of more expensive agents (e.g., NSAIDs).

Market share changes among the different categories within the prescription mix show that a larger proportion of propoxyphene napsylate was changed to propoxyphene hydrochloride in the institutional versus the noninstitutional population after napsylate was added to the Negative Drug List. In addition, the market share data show that a substantial portion of propoxyphene napsylate probably was switched to one of the NSAIDs. This response is probably the reason expenditures per unit increased for both the noninstitutional and institutional populations. Moreover, this substitution result negatively affects the estimated savings of a Negative Drug List.

The estimated savings to the WMAP were substantially less than if all propoxyphene napsylate was changed to the hydrochloride salt. Also, the savings declined further when the additional costs of substituting NSAIDs were considered and also adjusting usage levels in the noninstitutional population to eliminate the decrease in

recipients between the periods. The analysis estimating a net savings including the adjustments just mentioned were summarized in Table 32 previously. The data show a negative net savings for the noninstitutional population and a small positive net savings for the institutional population. The savings in the institutional population resulted from the greater use of the hydrochloride salt instead of NSAIDs after propoxyphene napsylate was dropped from the program. Finally, additional evidence was shown in Tables 30 and 33 above of the greater cost per prescription for NSAIDs as compared with either propoxyphene napsylate or propoxyphene hydrochloride.

The 1980s represents a period of retrenchment in budgets for a wide variety of health and human services programs, including health care. Medicaid budgets are being stressed as never before, and it is becoming increasingly important to find ways to achieve efficiency and economy without sacrificing the quality of patient care. An amount of unnecessary prescribing (or unnecessarily costly prescribing) takes place and is reimbursed by the Medicaid system. Any method that could eliminate unnecessary costs would be an important means of improving the economic status of programs.

The data gathered during this study are not to be misconstrued as suggestive of drug misuse. The number and percentage of recipients being treated may provide patterns of medication and cost estimates, but do not necessarily reflect the quality of medical practice. The quality of medical practice cannot be determined by the number of

patients receiving a particular medication, but by the documented need for the initiation and continuation of a particular medication. The role of a Medicaid system is not to determine how many medications can be discontinued, but to aid in implementing the most rational treatment regimen. At the same time, it should not be assumed that fewer drugs always represents better care for the patient.

One aspect of increased cost is increased accessibility, which is the very reason for the creation of Medicaid programs. Therefore, the objective is to control the rate of increase in price while monitoring the quality and parameters of quantity component increases. For example, even though the data in this study showed the cost savings of reduced propoxyphene napsylate prescribing to be partially offset by additional expenditures in the use of NSAIDs, this would still be a net positive effect of the intervention, since the latter category of drugs have been documented to be more effective analgesics than propoxyphene and are much less subject to abuse and overdose. It must be remembered that dollar savings are part, but not all, of the "benefit" side of the equation in any attempt to improve the appropriateness of drug prescribing.

It is recommended that future additions to the Negative Drug List be accompanied by educational programs designed to encourage the use of less expensive, therapeutically equivalent drugs. Effective utilization review, including review of drug prescribing, and better physician access to information on drug prices may foster rational

drug therapy and reduce drug expenditures more effectively than controls imposed solely on the drug component of health care. Future research might focus on a causal research design or longitudinal study using MMIS data which would be capable of providing more convincing evidence of causal relationships than exploratory or descriptive designs used in this study.

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APPENDICES

APPENDIX A

Small Portion of Fortran Computer Program Used To Extract The Data

```
      CHARACTER*1       NAC
      CHARACTER*14      RECIP_ID, OLD_RECIP_ID
      CHARACTER*1       TDASH(132)
      CHARACTER*30      TYPE_NAME(8),PERIOD_NAME(7),INST_NAME(3)
      CHARACTER*20      ELEMENT_NAME(4,6)

      INTEGER           WTAB(6,2),DTC_CHECK_TABLE(999),
C                       MONTH_PERIOD_TABLE(12),MED_STAT_CONV_TABLE(100),
C                       TYPE_TABLE(9)

      DATA        MONTH_PERIOD_TABLE/1,1,1,2,2,2,3,3,3,4,4,4/,
C           TDASH/132*'-'/, TYPE_TABLE/9*0/,
C          TYPE_NAME/'SCHEDULE II','SCHEDULE III','SCHEDULE IV',
C            'PROPOXYPHENE NAPSYLATE','PROPOXYPHENE HYDROCHLORIDE',
C            'NSAIDs','OTC - ASPIRIN','TOTAL'/,
C          PERIOD_NAME/'4-84 TO 6-84','7-84 TO 9-84','10-84 TO 12-84',
C            '1-85 TO 3-85','4-85 TO 6-85','7-85 TO 9-85','TOTAL'/,
C          INST_NAME/'INSTITUTIONALIZED','NON-INSTITUTIONALIZED','TOTAL'/,
C            ELEMENT_NAME/'# RECIPIENTS',
C                       'TOTAL COST',
C                       'COST/RECIPIENT',
C                       'S.D. COST/RECIP',
C                       '# SCRIPTS',
C                       'TOTAL COST',
C                       'COST/SCRIPT',
C                       'S.D. COST/SCRIPT',
C                       '# UNITS',
C                       'TOTAL COST',
C                       'COST/UNIT',
C                       'S.D. COST/UNIT',
C                       '# RECIPIENTS',
C                       '# SCRIPTS',
C                       'SCRIPTS/RECIP',
C                       'S.D. SCRIPTS/RECIP',
C                       '# RECIPIENTS',
C                       '# UNITS',
C                       'UNITS/RECIP',
C                       'S.D. UNITS/RECIP',
C                       '# SCRIPTS',
C                       '# UNITS',
C                       'UNITS/SCRIPT',
C                       'S.D. UNITS/SCRIPT'/,
C            WTAB /2,1,3,2,2,1,3,3,3,1,5,5/

      OPEN(UNIT=1,FILE='[PERSON.RES.WAYNE.PROGJKNOCKE.855',
C          FORM='UNFORMATTED', STATUS='OLD',READONLY)
      OPEN(UNIT=90,RECL=340,FILE='[PERSON.RES.WAYNE.PROGJKNOCKE85.DAT',
C           STATUS='NEW')
      OPEN(UNIT=92,FILE='[PERSON.RES.WAYNE.PROGJKNOCKE_85.OUT',
```

APPENDIX B

First Notice: Non-Coverage of Propoxyphene Napsylate Products

Medical Assistance Provider Bulletin

Attention: [redacted]

Subject: HMO and General Program Policy

Date: [redacted]1984

Code: MAPB-084-030X

This Bulletin contains important information concerning the following subjects:

I. Expansion of the HMO Preferred Enrollment Initiative
II. Renewal of Non-Institutional Provider Agreements
III. Refunds for Drug Returns
IV. Assignment of Medicare Part B Benefits
V. Divestment Notice
VI. Dental Services
VII. Vision Services
VIII. Physician and Laboratory Services
IX. Prior Authorization
X. Private Insurance Crossover Claims
XI. SSOP Toll-Free Telephone

I. EXPANSION OF THE HMO PREFERRED ENROLLMENT INITIATIVE

In February, 1982 the Department of Health and Social Services received a waiver from the Federal Government which allows the Department to require Medicaid recipients to enroll in a Health Maintenance Organization (HMO), with certain provisions for disenrollment. The effort to increase enrollment of Medicaid recipients in HMOs under this waiver authority has been termed the "HMO Preferred Enrollment Initiative" (HMO PEI). The Initiative has already been implemented on a limited basis in two areas of the state: in Dane County, where recipients eligible for Aid to Families with Dependent Children (AFDC) have been enrolled in the Group Health Cooperative; and in Clark, Taylor, Wood, and Marathon Counties, where recipients eligible for AFDC have been enrolled in the Greater Marshfield Community Health Plan. The Department has provided information concerning the Initiative in previous Bulletins.

The Department plans to expand the HMO Preferred Enrollment Initiative to include enrolling recipients in Dane County and Milwaukee County into an expanded number of HMOs. Enrollment of recipients into HMOs will begin on July 1, 1984 in Dane County, and on September 1, 1984 in Milwaukee County.

Wisconsin Department of Health and Social Services, Division of Health, Bureau of Health Care Financing, Provider/Recipient Services, P.O. Box 309, Madison, Wisconsin 53701 · Telephone: (608) 266-9744

V. DIVESTMENT NOTICE

The October 7, 1983 WMAP Provider Bulletin directed all providers to post a notice attached to that bulletin regarding "Divestment"; it was titled "Important Notice". As a result of a recent court decision, that October 7, 1983 "Important Notice" on "Divestment" should be removed immediately.

VI. DENTAL SERVICES

Effective August 1, 1984, additional dental prophylaxes may be allowed, following prior authorization, not to exceed more than two (2) additional prophylaxes per year, per recipient, per dentist for procedure code 01120 (children) or not to exceed more than three (3) additional prophylaxes per year, per recipient, per dentist for procedure code 01110 (adults).

Providers must clearly describe on the prior authorization request the reason why additional prophylaxes are required (e.g., the patient is physically and/or mentally handicapped and unable to maintain oral hygiene).

VII. VISION SERVICES

Effective April 1, 1984, polycarbonate lenses (single and multi-vision) are included in the VPP contract. Prior authorization is required for the lenses; as with other materials and services requiring prior authorization, a copy of the approved prior authorization form must be sent to WOS with the order for polycarbonate lenses.

VIII. PHYSICIAN AND LABORATORY SERVICES

SMS RECOMMENDATIONS: GASTRIC BYPASS, PROPOXYPHENE NAPSYLATE

The Department has accepted the recommendations of the State Medical Society Medicaid Medical Audit Committee relative to prior authorization criteria for coverage of gastric bypass and coverage of propoxyphene napsylate products.

Effective August 1, 1984, the minimal acceptable criteria for prior authorization approval of gastric bypass will be that the recipient is at least 25 years old and weighs at least twice as much as his/her ideal weight.

Effective August 1, 1984, propoxyphene napsylate products (e.g., Darvocet-N) will no longer be covered by the Wisconsin Medical Assistance Program. Physicians wishing to obtain the analgesic properties of these products may substitute propoxyphene hydrochloride compounds or propoxyphene, which are covered by the WMAP.

LAB PANELS

The Physician Provider Handbook (K5-004, K5-005) and Laboratories, X-Ray and Radiology Provider Handbook (G2-003 through G2-005) state the policy governing reimbursement of hematology and chemistry tests and/or panels. The following claims processing policy applies to each category, with respect to non-institutional care.

Hematology tests - If individual tests are billed in addition to a CBC (e.g., CBC plus white blood cell count), only the CBC will be paid, effective for dates of service on and after August 1, 1984.

APPENDIX C

Final Notice: Non-Coverage of Propoxyphene Napsylate Products

JAN 3 0 1985

Medical Assistance Provider Bulletin

Attention: All Certified Durable Medical Equipment Suppliers and [redacted]

Subject: Rate Changes, General Program Information, and DME Additions

Date: [redacted]

Code: MAPB-085-006-I (DME)
MAPB-085-025-H (Pharmacy)

I. Calendar Year 1985 Rate Updates

DME Rate Update: Effective for dates of service on and after January 1, 1985, maximum allowable fees for durable medical equipment (DME) will be updated to reflect an overall 3% increase, as allowed by the Wisconsin State Legislature. For each covered item billed to the Wisconsin Medical Assistance Program (WMAP), a provider will be reimbursed at the lesser of the provider's usual and customary charge or the updated maximum allowable fee for the item. Providers are reminded that they are required to bill the WMAP the usual and customary charge, that being the charge billed for the service when provided to the general public.

Maximum allowable fees will remain suspended for wheelchair and orthopedic shoe related services. Providers will be informed in advance when maximum allowables are assigned to these two areas.

Professional Fee Increase - Pharmacists: Effective for dates of service on and after January 1, 1985, the traditional (non-unit dose) professional fee for legend drugs will be $3.61, and the unit dose professional fee will be $5.56. Pharmacists are reminded that all drug products must be billed to the WMAP at a charge no greater than the provider's usual and customary charge to the general public, as defined in the Pharmacy Handbook.

II. Non-Coverage of Propoxyphene Napsylate Products

~~Effective for dates of service on and after February 1, 1985, propoxyphene napsylate products (e.g., Darvocet-N) will no longer be covered by the WMAP.~~

The Medicaid Medical Audit Committee of the State Medical Society recommended that all physicians be informed that physicians wishing to obtain the analgesic properties of these products may substitute propoxyphene hydrochloride compounds of propoxyphene, which are covered by the WMAP and have comparable clinical value at much lower cost. All physicians certified to participate in the WMAP have recently been advised of this policy.

APPENDIX D

Basic Extract For The Prescription Mix

CPAS Request for Evaluation of Addition of Darvocet N to Negative Formulary

Extract

1) Claim Type 10 (drug)

2) All Med Stats except 31, 32, 38 in Milw (40) and Dane (13) Counties

3) Aggregation of data by drug groups listed below

4) Time Periods January-June 1984 and April-September 1985

5) Data elements from the following drug group include amount paid, quantity, date of service, place of service (POS 1 office/pharmacy and POS 4 or 8 Nursing home)

Propoxyphene HCl

Therapeutic Class 223-All except NDC 00002-0351-XX through 00002-0363-XX
215-NDC 00007-0474-XX

Propoxyphene Napsylate

00002-0351-XX through 00002-0363-XX

NSAIDS

Therapeutic Class 255

Indomethacin
00005-3761-XX through 00005-3762-XX
00006-0025-XX
00006-0050-XX
00006-0150-XX
00006-0693-XX

Dolobid
00006-0675-XX
00006-0697-XX

Clinoril
00006-0941-XX through 00006-0942-XX

Ibuprofin
00009-0725-XX
00009-0733-XX through 00009-0750-XX

Tanderil
000028-0024-XX

Tolectin
00045-0412-XX through 00045-0414-XX

Feldene
00069-3220-XX through 00069-3230-XX

Meclomen
00071-0268-XX through 00071-0269-XX

Easprin
00071-0490-XX

Indomethacin
00093-0585-XX through 00093-0587-XX
00172-2997-XX through 00172-2998-XX
00378-0143-XX
00378-0147-XX

Ibuprofin
00524-0039-XX
00524-0062-XX
Indomethacin
00536-3981-XX through 00536-3982-XX
Feldene
00663-3220-XX through 00663-3230-XX
Indomethacin
00677-0872-XX through 00677-0873-XX
Meclomen
00710-0268-XX through 00710-0369-XX
Nalfon
00777-0876-XX through 00777-0877-XX
00777-2159-XX
Indomethacin
00781-2325-XX
00781-2350-XX
Naprosyn
18393-0272-XX through 18393-0277-XX

Therapeutic Class 221

Ponstil
00071-0540-XX
00710-0540-XX
Naprosyn
18393-0274-XX

Therapeutic Class 225

Ibuprofin
00524-0062-XX

Therapeutic Class 247

Naproxyn
18393-0274-XX
Disalcid
00089-0148-XX through 00089-0151-XX

Therapeutic Class 249 (All NDCs)

Therapeutic Class 251 (All NDCs)

ANALGESICS

Schedule IV

Therapeutic Class 221

Esgic
00535-0011-XX
Therapeutic Class 237 (All NDCs)

Schedule III

Therapeutic Class 217 (All NDCs)

Therapeutic Class 227 (All NDCs)

Therapeutic Class 229 (All NDCs)

Therapeutic Class 245 (All NDCs)

Therapeutic Class 247

Synalgos DC
00082-4170-XX
00082-4191-XX

Banacap HC
00456-0610-XX

Schedule II

Therapeutic Class 225

Pentazocine
00024-1927-XX through 00024-1951-XX

Therapeutic Class 231 (All NDCs)

Meperidine

Therapeutic Class 233 (All NDCs)

Dihydroxycodeine

Therapeutic Class 235 (All NDCs)

Codeine

Therapeutic Class 239 (All NDCs)

Morphine

Therapeutic Class 241 (All NDCs)

Hydromorphone

Therapeutic Class 247

00002-2153-XX
00004-1910-XX through 00004-1911-XX
00056-0384-XX through 00056-0386-XX
00060-0127-XX
00590-0384-XX through 00590-0386-XX
00990-0000-02
60000-1705-20

OTC Analgesics

Therapeutic Class 999

00002-0111-XX
00002-0132-XX
00002-2005-XX through 00002-2007-XX
00003-0351-XX through 00003-0355-XX
00005-3212-XX
00007-0175-XX
00007-3824-XX through 00007-3826-XX
00031-6207-XX through 00031-6224-XX
00034-5410-XX
00043-0104-XX
00043-0104-XX
00045-0185-XX through 00045-0187-XX
00045-0449-XX
00045-0460-XX through 00045-0502-XX
00054-8008-XX through 00054-8010-XX
00056-0132-XX
00067-0135-XX through 00067-0137-XX
00071-0640-XX
00081-0210-XX
00081-0306-XX
00087-0730-XX through 00087-0733-XX
00143-2062-XX
00143-7055-XX
00149-0110-XX through 00149-0111-XX
00228-1147-XX through 00228-1151-XX
00245-0121-XX through 00245-0123-XX
00363-0440-XX
00363-5570-XX
00414-0109-XX through 00414-0328-XX
00467-0078-XX
00536-0122-XX
00573-0150-XX through 00573-0290-XX
00766-5610-XX through 00766-5611-XX
00781-6375-XX
12280-0002-XX through 11280-0521-XX
37000-0028-XX through 37000-0029-XX
49692-0901-XX through 49692-0903-XX
80000-0125-XX through 80001-5005-XX
80004-0000-XX
90001-0325-XX through 90001-0400-XX

APPENDIX E

Producer Price Index For The Net Output Of Selected Pharmaceutical Preparations For 1984 and 1985

PRODUCER PRICE INDEX FOR THE NET OUTPUT OF

SELECTED PHARMACEUTICAL PREPARATIONS: 1984

(Index Base 06/81 = 100)

PHARMACEUTICAL PREPARATIONS	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
A. PRESCRIPTION												
1. ANALGESICS	140.2	140.7	142.9	142.1	143.1	150.9	150.6	151.4	152.8	154.3	154.6	155.1
2. ANTIARTHRITICS	128.1	131.7	131.7	133.2	133.2	133.2	133.2	115.4	115.4	115.4	115.4	115.4
B. NON-PRESCRIPTION												
1. ANALGESICS, INTERNAL (except antiarthritics)	125.0	126.0	126.0	129.4	131.1	131.6	131.6	132.1	132.1	135.2	134.7	134.6

PRODUCER PRICE INDEX FOR THE NET OUTPUT OF

SELECTED PHARMACEUTICAL PREPARATIONS: 1985

(Index Base 06/81 = 100)

PHARMACEUTICAL PREPARATIONS	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
PRESCRIPTION												
1. ANALGESICS	162.1	163.4	165.8	167.5	168.6	177.0	177.0	177.8	177.6	179.1	180.1	180.1
2. ANTIARTHRITICS	115.4	119.7	119.7	121.8	121.8	114.4	114.4	114.4	114.4	117.6	117.6	117.6
NON-PRESCRIPTION												
1. ANALGESICS, INTERNAL (except antiarthritics)	139.2	139.1	139.1	139.9	140.8	143.0	148.0	147.9	147.9	147.6	147.6	147.6

APPENDIX F

Large Sample Test Of An Hypothesis Between Means

Large Sample Test Of An Hypothesis Between Means

The technique used in comparing population means is to hypothesize that there is no difference in the means of the two populations.

$$H_o: \ (\mu_1 - \mu_2) = 0$$
$$H_a: \ (\mu_1 - \mu_2) \neq 0$$

The null hypothesis is rejected when the calculated z-value is greater than the tabled z_α or $z_{\alpha/2}$ value at a specified level of confidence. The formula for calculating the z-value is:

$$z = \frac{(y_1 - y_2)}{\sqrt{\frac{(o_1)^2}{n_1} + \frac{(o_2)^2}{n_2}}}$$

Where:

y_1 = average response from population 1

y_2 = average response from population 2

For this project, the specified level of confidence is 95 percent ($\alpha = 0.05$). Thus, $\alpha/2 = 0.025$ and $z_{\alpha/2} = 1.96$. The rejection region is $z < z_{\alpha/2}$ or $z > z_{\alpha/2}$. Therefore, any z-value

greater than 1.96 or less than -1.96 will lead to rejection of the null hypothesis (no difference) and acceptance of the research hypothesis (is a difference between means).

APPENDIX G

The Chi Square (X^2) Test

The chi square test was used to determine if observed frequencies are statistically different in the institutional population from frequencies expected under the null hypothesis. The test is:

$$x^2 = \sum_{i=1}^{I} \sum_{j=1}^{J} \frac{(O_{ij} - E_{ij})^2}{E_{ij}}$$

where

O_{ij} = observed frequency for the i^{th} level of factor 1, and the j^{th} level of factor 2.

E_{ij} = expected frequency under the null hypothesis for the i^{th} level of factor 1, and the j^{th} level of factor 2.

The double summation ($\Sigma \Sigma$) directs one to sum over all cells.

The degrees of freedom (d.f.) are obtained by:

d.f. = (I - 1) (J - 1) where

I = the total number of levels of factor 1

J = the total number of levels of factor 2

In testing hypothesis 13:

Number of Recipients

	Noninstitutional	Institutional	Total
Number switched to propoxyphene hydrochloride	2,104	1,780	3,884
Number switched to "other" unaccounted	2,902	841	3,743
Total	5,006	2,621	7,627

1. The difference between the observed and the expected frequencies are calculated for each cell.
2. The difference is squared and divided by the expected frequency.
3. The quotients are summated for all cells.

$$X^2 = \frac{445^2}{2549} + \frac{445^2}{1335} + \frac{445^2}{2457} + \frac{445^2}{1286}$$

$$= 77.69 + 148.33 + 80.60 + 153.98 = 460.60$$

$$d.f. = (2 - 1)(2 - 1) = 1$$

Since the calculated X^2 of 460.60 is greater than the X^2 table value for one degree of freedom with 95 percent confidence (3.84), the null hypothesis cannot be accepted.