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A Thesis Presented

By

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JAS

Dec. 7, 1976
# TABLE OF CONTENTS

Title - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - i
Approval - - - - - - - - - - - - - - - - - - - - - - - - - - - - ii
Acknowledgement - - - - - - - - - - - - - - - - - - - - - - iii
Table of Contents - - - - - - - - - - - - - - - - - - - - - - - - iv
Introduction - - - - - - - - - - - - - - - - - - - - - - - - - - - - v
Introduction Footnotes - - - - - - - - - - - - - - - - - - - - - - ix
Chapter I - - - - - - - - - - - - - - - - - - - - - - - - - - - - 1
Chapter II - - - - - - - - - - - - - - - - - - - - - - - - - - - 20
Chapter III - - - - - - - - - - - - - - - - - - - - - - - - - - 49
Chapter IV - Conclusion - - - - - - - - - - - - - - - - - - - 75
Footnotes: Chapter I - - - - - - - - - - - - - - - - - - - - - - 84
          Chapter II - - - - - - - - - - - - - - - - - - - - - 86
          Chapter III - - - - - - - - - - - - - - - - - - - - - 88
          Chapter IV - Conclusion - - - - - - - - - - - - - - 89
Bibliography - - - - - - - - - - - - - - - - - - - - - - - - - - 90
Appendix - Key Generic Drug Bills - - - - - - - - - - - - - 95
INTRODUCTION

On Aug. 3, 1976 the Federal Trade Commission began an investigation into whether pharmacists should be permitted to substitute less costly generic versions of prescription drugs in place of the brand name drugs called for by doctors.

The commission noted that consumers spend about $7.5 billion annually on prescription drugs purchased through retail pharmacies, of which 40 per cent are drugs marketed by more than one company. ¹

The investigation represented a triumph of hope over experience. Several times before over the past decade, the FDA, as well as other federal agencies and three Congressional committees, had tried to foster more widespread use of the less expensive generics. Each attempt ended in failure. Brand name drugs, almost always more expensive than their generic counterparts, are an integral part of the American Health Care Delivery system, a system super-resistant to change from without.

Such federal actions as the FDA's often have predecessors on the state level. This thesis is a study of the first state law aimed at encouraging the more frequent use of generic versions, passed by Massachusetts in 1970. * The law, like its federal counterparts, was a failure. But its experience is

* The official name of the law is "An Act creating a drug formulary commission in the department of public health and requiring doctors, when prescribing brand names to write the generic name of the drug." Mercifully, the name was shortened to "Generic Drug Law" or "Drug Formulary Law," in both official and popular usage.
instructive, not only about the Massachusetts state government, but about the politics of the American health industry as well.

The Massachusetts law required physicians who wrote prescriptions for brand name drugs to also include the names of the generic versions so the purchaser could decide which one to buy.

A brand name is given to a drug by the firm that creates it. The firm has a 17-year patent period to market the drug exclusively and recover its research outlay. At the end of the patent period, competing firms may make and market the drug.

Such firms usually sell the drug under its generic or chemical name, often a shorthand combination of its chemical ingredients, registered with the federal government at the start of the patent period.

Because of the market advantage in the 17-year patent period and because competing firms have little or no research investment to recover, they can offer their generic versions at lower, often drastically lower prices.

* The term generic drug is a broad one and the user may be open to criticism on those grounds. However, for the purposes of this paper, "generic drug" shall mean prescription drug products that are sold under non-brand or chemical names, and will suffice.

** Because new drugs are constantly being marketed and patents on others constantly are expiring, it is difficult to pinpoint the percentage of drugs on the market available by generic name. In 1975, Consumer Reports estimated that "about 35 per cent of drugs are no longer under patent (but) only some 10 per cent of prescriptions are written generically..." (Jan. 1975, pp. 3-6)

In 1974 a Food and Drug Administration expert told a Congressional Committee that of the 200 top drugs, which accounted for about 70 per cent of total usage, about half would be off patent by 1980. (U.S. Senate Subcommittee on Health of the Committee on Labor and Public Welfare Brand Names and Generics hearings, July 22, 1974, pp. 87-89.)
example, one prominent drug catalogue lists the price for
100 tablets of the brand name tranquilizer Miltown as $6.10,
while the same number of tablets of the generic version,
Meprobamate, is $1.00. Another catalogue lists 100 tablets
of Miltown as costing $7.70 compared to $1.15 for 100 tablets
of Meprobamate.

It was to enable the consumer to take advantage of such
price differences that State Rep. I. Edward Serlin, D-Mattapan,
filed the legislation which eventually led to the Generic Drug
Law. A high proportion of Serlin's constituents were elderly
and they would benefit most of any group if drug prices were
lowered. Where the average American spends $33 a year on
prescription drugs, those over 65 spend an average of $74 and
nearly one in five spends more than $100 annually. Although
they account for only 10 per cent of the population, those over
65 buy 25 per cent of all prescription drugs sold.

But neither Serlin's elderly constituents nor any other
Massachusetts citizens benefitted from his law. In filing his
bill, Serlin had opened a can of worms and had rekindled a
controversy over prescription drugs begun a decade before by
U.S. Sen. Estes Kefauver, D-Tenn., and which continues today.
Lobbyists for the nation's brand name drug makers and for Massa-
chusetts doctors and druggists killed the Serlin bill for two
years. When in the third year, it looked as though the tide
for passage of such a bill was becoming too great to swim
against, the lobbyists helped fashion a compromise which enabled
passage of a severely watered-down bill that proved to be
unworkable. Subsequent attempts to strengthen the law through amendments have been blocked by lobbyists in four legislative sessions.

To understand the debates and maneuverings which went on over the Massachusetts drug bill, the author feels that a familiarity with the background in the 10-year-old controversy over generics is necessary. Therefore, the first chapter of this four-chapter thesis is devoted to: 1) an examination of the largely scientific question of the equivalency of different versions of a prescription drug; and 2) a discussion of the two main participants in the debate over generics, the FDA and the prescription drug industry. This examination has the added benefit of providing a federal dimension to the Massachusetts controversy over generics.

The second and third chapters deal with the Massachusetts Generic Drug Law. The second chapter details the three year life of the bill that finally became the drug law, the lobbying for and against it and the reactions of key legislators. The third chapter follows the law's progress through its early years in the state Department of Public Health, and then examines efforts to amend and strengthen the law. The fourth chapter contains the author's conclusions.

A word about methodology: The second and third chapters, and to some extent the fourth, are based on interviews with legislators, lawyers, lobbyists, doctors and druggists who were in some way involved with the drug bill or law. Where a point of information was obtained in an interview, and where the source is apparent in the text, footnotes have been excluded.
FOOTNOTES

INTRODUCTION


3. Burack, Richard, Dr., Handbook of Prescription Drugs.

4. Ibid.


7. Interview, Serlin, op. cit.

CHAPTER I

"I do not know what we are going to do here," U. S. Sen. Edward M. Kennedy, D-Mass., said to the witness, an eminent teaching physician. "They say the (drug) standards are good enough. You say that the standards are not good enough..."

The senator, chairing a hearing of his subcommittee on Health and Labor, had run into the seemingly endless dispute over the safety of the nation's drug supply. Like other senators before him, Kennedy was attempting to settle the question of whether all marketed versions of a prescription drug are safe enough to be used interchangeably. He had received different answers from medical and pharmaceutical experts. 1

What puzzled Kennedy also puzzles laymen. Scientists have been enshrined in our society as keepers of the truth and problem solvers. Thus political sophisticates and laymen alike are often bewildered when scientific testimony appears contradictory. The scientists testify with the dogma of the laboratory, but their conclusions are filtered by economic interest and refracted by social and political value judgments.

The confusion that occurs when scientists fail to agree whether a nuclear power plant is safe, a breakfast food healthful or a food additive dangerous, is because "safe," "healthful," and "dangerous" are concepts loaded with social and political value judgments.

For years the experts have been at odds over the question of the quality of the nation's drug supply. Recent attempts
by federal health officials to implement a program encouraging
use of generics by Medicaid and Medicare patients have only
intensified the dispute. Attempts have been opposed by the
manufacturers of trade name prescription drugs, in the person
of their trade organization, the Pharmaceutical Manufacturers
Association. Its 131 member companies stand to suffer
considerable financial losses if generics are used more frequent-
ly, but the PMA insists its opposition is based mainly on the
existence of differences in therapeutic performance between some
generics and brand name drugs.

* A New York Times reporter may well have had Kennedy's
hearings and the drug question in mind when he wrote recently
about the problem of experts with conflicting views: "Whom
is the public to believe? How are the decision makers in
government and industry to sort out the conflicting testimony?
What are the facts? And what are only the opinions of scientists
speaking as citizens and not as experts?

"...the conflicting public statements of the experts
often adds to the confusion of a controversy and all but
paralyze the decision making process." From Science Considers
Its Own Court, Feb. 29, 1976, section 5, page 8.

The key issue in the dispute over drug safety, according
to two prominent pharmacologists, Wardell and Lasagna, "is how
to determine the point where accommodations are to be made
between safety and efficiency in the approval of drugs for the
market," or, in economic terms, the acceptable cost-benefit
ratio. They add, "Most of the debate... (on drug quality)...stems from disagreement as to what constitutes evidence of safety
and efficiency..."

In less exact but more philosophical fashion, Silverman
and Lee conclude: "In this less than perfect world, there
can never be absolute guarantees that all generic products
will inevitably be biologically or chemically equivalent.
There can never be guarantee of such equivalence for all
batches of the same product made by the same manufacturer.

Pills, Profits and Politics, Berkeley: 1974, University of
California Press, p. 159.
"The root of the drug quality dispute," according to a recent PMA statement, "and its relationship to the brand-generics issue, lies partly in the term bioavailability: the degree and rate of absorption of the active ingredient, which determines the amount available at the target site in the body." 3

Generics may be chemically equivalent to their brand name counterparts, the PMA argues, but still may be inferior in terms of bioavailability, and this can pose a hazard to health. Drugs with the same chemical ingredients do not always produce the same reactions in the body:

Even though two drugs made by different manufacturers contain the same active ingredients, their effects on patients may vary. Variations can occur in purity, potency, weight, disintegration time, dissolution time and stability. Nonactive ingredients such as binders, coaters, fillers and lubricants can also vary from manufacturer to manufacturer and they affect drug quality in important ways.

All of these factors, and others, determine how fast and thoroughly a drug dissolves and sends its active ingredients to a different part of the body. This is known as bioavailability. Drug products that exhibit comparable bioavailability characteristics are considered to be bioequivalent. Otherwise they are bioinequivalent and may not have the same therapeutic effect on patients. 4

A spokesman for the PMA, Richard Hamilton, elaborated: "We are not against generic drugs per se. Our member companies produce generic drugs and have an awful lot on the market. We're just worried about the source of the drug ... There was some very high quality generic drugs on the market ... It's
the potential for inequivalence." The potential for inequivalence, Hamilton, contended, is mainly with the lesser-known and smaller companies, which are not members of the PMA. They manufacture mostly generics. There are about 1200 such firms and the PMA points out that they are mostly regional and do little or no drug research or development. Further, the PMA has charged that the Food and Drug Administration cannot assure that bioinequivalent drugs are kept off the market. "... drug product formulation failures occur even among antibiotics certified as safe and effective, batch by batch, by the Food and Drug Administration, FDA has an impressive surveillance capability, but it is not adequate to assure that all manufacturers are equally competent."

Federal attempts to encourage generic prescribing are opposed by the PMA on grounds that such attempts are intrusions upon the physician's professional judgment as to the superiority of certain drug versions. "The issue is not whether doctors should be allowed to prescribe generically. They can do that now if they want," the PMA has written. "The real issue is whether they should be compelled to."

The PMA, moreover, disputes claims of consumer advocates
that there are substantial gains to be made from widespread use of generics and assert that "the consistent quality of the product is the key -- not whether it is prescribed by generic or brand name." Programs to encourage use of generics, the PMA has also warned, may have the unforeseen effect of discouraging the research and development of new drugs, performed exclusively by brand name drug makers. 7

Federal officials and consumer advocates dismiss the importance of bioequivalence in all but a few cases -- mainly those involving the seriously ill. Proponents of generics maintain that in most instances, a high degree of bioinequivalence can be tolerated. One senior official of the FDA, for instance, declared recently that "the problem of bioequivalence (of generics) is limited to a small fraction of drug products ... for the overwhelming majority of available drug products there is no evidence of a bioequivalence problem." 8 FDA Commissioner Alexander Schmidt, a physician, has said:

"As an individual, I ask for drugs by their generic name for myself and my family. As a physician, I prescribe drugs by their generic name for my patient. And as a professor of medicine, I teach my medical students to prescribe drugs by their generic name." 9

Some federal officials and consumer advocates maintain that the PMA's motive in disputing the quality of generics is
fear of economic loss.* U.S. Sen. Gaylord Nelson, D-Wisconsin, whose Subcommittee on Small Business and Monopoly has been probing the drug industry since 1966, has said:

The drug industry is fleecing the people by trying to convince them through high-powered advertising that drugs sold under brand name are somehow or other more reliable than the same drugs sold under their official (generic) name, for one-half to one-thirtieth as much. 10

Consumer advocate Ralph Nader has charged:

...the drug companies have persuaded doctors that generics are bad. Well, there's substantial evidence to prove that generics, with a very few exceptions, are just as high quality as brand products... What's disturbing is that this information isn't getting across in the billion dollars of advertising. 11

Further, federal officials point out that manufacturing and marketing practices have blurred the once-clear distinction between brand and generic. No longer is it easy to determine the source of a particular prescription drug. And Joseph Graedon wrote in "The People's Pharmacy":

There are very few companies that actually manufacture antibiotics. A relatively few firms produce the major bulk of the products and then sell them to lots of other pharmaceutical suppliers for distribution. While over 70 companies, for example, supply tetracycline as either a generic product or a brand name product, it was discovered ... that only four firms manufacture the bulk ingredient within the United States, according to the

* A very recent report of the General Accounting Office charged the FDA with failing to follow certain procedures in testing new drugs which the GAO warned could allow for less than safe drugs being put on the market. However, the GAO report also criticized the major drug manufacturers, who test the drugs, for also failing to follow procedures. (News Item U.S. Agency Finds Drug Testing Lax, New York Times, July 21, 1976, p. 1)
U.S. Tariff Commission. No more than 10 firms manufacture the final dosage form. 12

Dr. Henry Simmons, director of the FDA's Bureau of Drugs, has noted increasing instances where "the manufacturer is providing to a large number of firms the same drug, which is then marketed under a wide variety of brand and generic names." In this vein, Simmons noted:

"For years, the large brand name manufacturers have been major providers of generic drugs. Recent events indicate that more and more generics will be manufactured by traditionally brand name manufacturers... as expense involved in maintaining manufacturing facilities for a full line of drugs rises, more and more manufacturers -- large and small, generic and brand -- are selling to each other either bulk drugs or finished dosage forms."

Simmons added that "On the basis of data we have accrued to date, we cannot conclude there is a significant difference in quality between the generic and brand name product tested" in the Bureau of Drugs experiments. 13

Nevertheless, the brand-generic controversy persists. In holding hearings on drug safety, Kennedy's subcommittee was pursuing a line of inquiry begun in 1959 with the Subcommittee on Small Business and Monopoly, led by Sen. Estes Kefauver, D-Tenn. Probing pricing practices and the structure of the drug industry, the subcommittee heard testimony highly critical of
the drug industry, the price of drugs and the lack of drug standards. 14

The hearings resulted in the so-called Kefauver-Harris amendments to the Food, Drug and Cosmetics Act of 1938, which signalled the start of an era of government interest in the drug industry. * Officially known as the Drug Industry Act of 1962, the amendments for the first time required "substantial evidence" of the safety and efficacy of new drug products. The amendments also strengthened government control over drug advertising. 15

Kefauver's successor as committee chairman, Sen. Nelson, continued the inquiry into the drug industry. In 1966, Nelson, at President Lyndon B. Johnson's request, asked the Department of Health, Education and Welfare to form a task force on prescription drugs to conduct the most extensive study ever of the drug makers and the question of bioequivalence. 16

The task force study was based on surveys, advice of medical experts and potency tests of 4,600 drugs. In its initial report in 1968, the task force concluded that "lack of clinical equivalence (or bioequivalence) among chemical equivalents (generics) meeting all official standards has been grossly exaggerated as a major hazard to public health." 17

The potency tests showed that 7.8 percent of generic drugs and 8.8 percent of trade name drugs tested were unacceptable.

* It is unlikely that the legislation, the wisdom of which is still being disputed, would have passed if not for the thalidomide disaster, according to Wardell and Lasagna. "The fact that thalidomide had not been approved for U.S. marketing was somehow irrelevant," they added.

While the task force pointed out that this by no means established the superiority of generics over trade name drugs, neither did the statistics support the reverse proposition. The task force study stated:

Where low cost chemical equivalents have been employed -- in foreign drug programs, in leading American hospitals, in state welfare programs, in Veteran's Administration and Public Health Service hospitals, and in American military installations -- instances of clinical nonequivalency have seldom been reported, and few of these have had significant therapeutic consequences. 18

After the release of the task force study, the debate over drug quality seems to have abated. In 1973 it was revived when Casper Weinberger, secretary of the Department of Health, Education and Welfare, unveiled the proposed Maximum Allowable Cost Program (MAX). Under this program, to reduce drug expenses, price ceilings would be put on some of the drugs most commonly prescribed for Medicaid, Medicare and Public Health Service patients. Controls also would be put on fees reimbursing pharmacists who buy and dispense the drugs; and lists would be distributed to physicians and pharmacists of drug prices of less expensive substitutes. Projected savings of the program were $60 million of the $3 billion the government spends annually on drugs. ** 19

A key feature of MAX would be the list of maximum prices the government would reimburse pharmacists for certain drugs.

* The PMA published a critique of the task force study, entitled Brands v. Generics, in 1971.

** The AMA, PMA and National Association of Retail Druggists have all opposed MAC and have filed a suit challenging it in Federal District Court in Chicago. The suit is still pending and the program went into effect Aug. 26. News Item Gov't. Plan to Reduce the Cost of Drugs, New York Times, Aug. 23, 1976, p. 11
The task of deciding which drugs were safe enough in both brand and generic version to be included on the list fell to Kennedy's subcommittee. At its request, the U.S. Office of Technology Assessment (OTA) undertook a study of drug bioequivalence. The study concluded that the problem of bioequivalence existed with some drugs but was not a factor for most. The chairman of the OTA panel, Robert Berliner, dean of the Yale University School of Medicine, estimated that 85 to 90 per cent of chemically equivalent drugs on the market presented no therapeutic equivalence problems and could be used interchangeably on a MAX list. "Most drugs ought to be prescribed generically," he said. But the OTA study did not resolve the major question facing the Kennedy subcommittee -- whether generic versions could be used interchangeably with brand name counterparts. "The OTA report could be read as a victory for either side" in the bioequivalence debate, one Massachusetts public health official, a druggist, commented.

The debate over drug quality gives no indication of expiring. Not even the prestigious National Academy of Sciences managed to avoid the snarls of the debate. While the OTA study was proceeding, a panel of the Academy's National Research Council issued a study of the wisdom of state laws forbidding pharmacists from substituting one version of a drug for another prescribed by the physician. The panel urged the repeal of the anti-substitution laws passed in the early 1950's, when the quality of the drug supply was inferior to today's. The panel report stated that "no inherent reason exists for choosing the more expensive drug product simply because of
brand name familiarity." 23

There followed a series of vociferous complaints about the panel report from, among others, the PMA. In July, 1975, the academy issued a "clarification" of its report, stating that "it may be necessary to change, but not repeal, drug anti-substitution laws in some states to make these laws consistent with modern concepts of bioavailability of drugs and medical practice." 24 *

The panel's study had been undertaken in response to an announcement in 1971 that the American Pharmaceutical Association was reversing its stand against the repeal of anti-substitution laws as part of its demand for recognition of the professional right of the pharmacist to make decisions about prescription drugs. ** The APhA, representing about a third, or 38,000 of the nation's druggists, made the announcement in a white paper, "The Pharmacist's Role in Product Selection." In part, it stated:

Comparable drug products that meet the official standards and specifications are, for all practical purposes, therapeutically equivalent in all but a relatively few cases...

Some instances of therapeutic nonequivalence go undetected or unreported, but the generally low level of reported instances demonstrates that the problem cannot be widespread. 25

* What can only be described as a comedy of misinterpretation -- if not error -- preceded and postdated the panel's resolution. The details were recounted for Senator Nelson during his subcommittee's hearings. (U.S. Senate, Select Committee on Small Business, Subcommittee on Monopoly, Hearings on the Prescription Drug Industry parts 3 to 5, Washington: 1974, Government Printing Office, pp 1178-9 part 26).

** Skeptics, some druggists among them, suggest the APhA change of heart was due in no small part to the fact that pharmacists - with the advent of government, or third party payment for prescriptions, which was on a straight fee and not percentage basis - no longer had anything to lose financially with more widespread use of low cost generics. (Interview, Denmark, Tattlebaum)
Before issuing the paper, the APhA had been on record opposed to appeal of the anti-substitution laws, a position it shared with the PMA and AMA, and to which they still subscribe. After the paper was issued, the PMA and AMA criticized the APhA -- as did its own Academy of Pharmaceutical Sciences, which issued a dissenting report. 26

It is not unusual to find the AMA and PMA on the same side of an issue, least of all if it concerns drugs. Indeed, the AMA has even shared lobbyists with the PMA in its fight against the proposed MAC program. The arrangement came to light last year after a disgruntled AMA employee leaked a set of memos on the lobbying arrangement, and who was quickly dubbed "Sore Throat" after the unnamed news source of Watergate fame. 27 And when the AMA last year became the first organization to file suit to block the MAC program, The New York Daily News, in a commentary, noted:

What is surprising about the suit...is that it was filed by the AMA and not by the Pharmaceutical Manufacturers' Association. Logically, it should be the drug lobby, not the doctors' lobby, that would be most upset by the new regulations.

The fact that the AMA files suit underlines how closely linked are the economic well-being of the AMA and the drug industry. Much of the medical association's retirement fund is invested in the stock market, and 10 per cent of the stocks in the portfolio, representing $10 million, is invested in drug stocks.

In a typical year, the AMA also derives about 25 per cent of its operating income from drug advertising published in its journals... *

* Would drug firms use the power of advertising expenditures to attempt to influence policy? Recently the New York Times published a five-part series on medical incompetence, which included some uncomplimentary conclusions concerning drugs and their use by physicians and promotion by drug companies. Within a month, pharmaceutical concerns had cancelled advertising worth $500,000 from Modern Medicine, a magazine owned by The New York Times Company. An officer of the magazine said that those advertisers who canceled their advertisements felt that "you don't feed people who beat you." (News Item Drug Ads Dropped Over Times Series, Feb. 10, 1976, p. 27.)
Washington observers recall that the AMA often has supported the drug industry whenever legislation or regulations are impending that might fetter the industry. And as late as 1973, the last two chairmen and the vice chairman of the AMA's Council on Drugs were accusing the association of being "a captive of and beholden to the pharmaceutical industry."

The financial links between the AMA and PMA extend to individual doctors. The PMA-member firms, the nation's major drug makers, spend $1 billion annually for promotional activities aimed at convincing the nation's 200,000-odd prescribing physicians of the superiority of their products.

There is no doubting the extent or effect of this promotion: The primary sources of news about new drug products are not scientific articles, but drug salesmen and ads in medical journals.

The main methods of promotion are: 1) Visits to doctors by drug salesmen or "detail men" as they are called by their employers; 2) mailing of brochures and free samples; 3) advertising in medical journals which have no subscription costs; and 4) exhibits at medical society meetings.

These promotional methods were described more colorfully by a former medical director at Squibb, a physician, when he told the Kefauver Subcommittee of "... the trip hammer effects of weekly mailings, the regular visits by detail men, the two-page spreads, and the ads which appear six times in the same journal, not to mention the added inducement of the free cocktail party and the golf outing complete with three golf balls stamped with the name of the drug company and the doctor in contrasting colors."
One observer has estimated that it would take several mail
110 large mail trucks and 800 postmen to deliver the daily load
of drug circulars and samples to doctors if mailed to one
single city. 34

As for free samples of pharmaceuticals for doctors,
Kennedy revealed in 1974, from information supplied to him by
the 20 largest drug companies, that during the preceding year,
they gave 12.8 million gifts to members of the health care
profession, more than 45 million reminder items (calendars,
pens, etc.) and 2,062,953,486 dosage units of drug samples --
enough to give 10 dosage units to everyone in the country. 35

The ubiquitousness of this advertising was driven home
by a 35-year-old physician who told the Kennedy Subcommittee
of drug industry gifts and favors he received over the span of
his career. His testimony indicated, according to one account:

...(he) started accepting drug samples, gifts and
junkets from 'detail men' of drug houses as long ago
as 1958, when a junior student in Maryland College of
Pharmacy. He was still on the receiving end of drug
industry largesse 12 or 13 years later as a full-fledged
doctor with a medical fellowship in a big public
hospital... As told by (him and other) physicians,
pharmaceutical houses are unstinting in their solicitude
for the nation's doctors, starting at the outset of
medical school... 36

Once in practice, doctors have little time to spend
studying the developments in the pharmaceutical profession and
come to rely on the detail man for such information. The detail
man is by far the most costly promotional expense, accounting
for 70 per cent of the promotional budget. There are about
22,000 detail men and about 1,000 are employed by each of the
20 largest drug makers. 37 Surveys show that the detail man is
well-received by physicians.

However, critics say the detail man is first and foremost a salesman and his information is likely to be biased in favor of his company's particular product. One among a parade of former detail men to appear before the Kennedy Subcommittee told of the extent to which a firm will go to sell its product: "To persuade the doctor or pharmacist to use your brand or generic drug usually required some extra enticing. At Pfizer we sometimes sponsored contests and offered prizes for those who bought our generic drugs." The aforementioned former detail man displayed a catalogue used for such contests, which offered prizes for varying amounts of drugs purchased. If a physician ordered 1,000 doses of polio vaccine, for example, he got an upright freezer with a 5-cubic foot capacity; for 50 doses he received a Craig rechargeable electronic calculator; for 250 doses, a physician bag or cassette tape recorder. And detail men got similar prizes for selling certain quantities of drugs.

The nation's major drug manufacturers can easily afford the billion dollar annual outlay for promotion, which is but a tenth of the amount spent on prescription drugs in 1975. Moreover, the drug industry consistently is among the leading profit makers in American business, as the chief economist of the Federal Trade Commission pointed out for the Nelson Subcommittee:

Losses, or even low profits, are practically
unheard of among large drug companies. In this respect the drug industry is practically unique among important American industries... Large drug companies not only earn a higher return than any other of the major manufacturing industries shown, but none of the drug companies experience profit rates below 5 per cent ... No other industry matched drugs in the frequency with which companies had profit rates exceeding 15 per cent. 42

Since 1961, the subcommittee was told, the drug industry has ranked first or second among the 500 largest U.S. industrial corporations in terms of return on investors' equity:

RETURNS ON EQUITY AND ON SALES, INDUSTRY MEDIANS, 1961-71

<table>
<thead>
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<th>Year</th>
<th>Return on equity All Industry (percent)</th>
<th>Return on Sales Drug Industry (percent)</th>
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<tr>
<td>1970</td>
<td>9.5</td>
<td>15.5</td>
<td>2d</td>
</tr>
<tr>
<td>1971</td>
<td>9.1</td>
<td>15.1</td>
<td>2d</td>
</tr>
</tbody>
</table>

At the core of the pharmaceutical industry are the 131 members of the PMA, which do most of the industry's advertising, reap most of the profits and control 95 per cent of the market. They sell and produce both brand and generic name products, conduct most of the industry's research and control most of the patents. According to the 1968 drug task force study, the remaining 5 per cent of prescription drugs are manufactured "by many hundreds of companies and are sold by both trademark and generic names... They control few
drug patents, do little or no research, compete on the basis of both quality and price, conduct only minimal promotion of their products, and achieve relatively low rates of profit.\textsuperscript{45}  

The drug industry does not appear to be overly concentrated, with the top 10 firms controlling a bit over 50 per cent of the market and the top 20 controlling 70 per cent.\textsuperscript{46} But there does seem to be a pattern of domination by certain companies within a series of small markets such as antibiotics, hormones or analgesics. A summary of the Nelson Subcommittee hearings, for example, noted:

\begin{quote}
In a group of 20 such markets, the proportion of output accounted for by the leading five firms ranged from 56 per cent to 98 per cent. It is within these markets that decisions on prices are made and given such concentration ratios, we should not expect individual firms to disregard their own impact on market parameters. It is on this basis that market power has been achieved.\textsuperscript{47}
\end{quote}

The Nelson Subcommittee report strongly suggested that this market power was one cause of the large price variation among versions of drugs. In some instances, price differentials were found to be as great as several thousand per cent between competing products.\textsuperscript{48} Following is a list of the various prices of different versions of two drugs mentioned often at the Nelson Subcommittee hearings:
### Reserpine, U.S.P. (1,000 0.25mg. tablets)

<table>
<thead>
<tr>
<th>Company</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Pharmaceutical</td>
<td>$2.60</td>
</tr>
<tr>
<td>Carroll</td>
<td>1.15</td>
</tr>
<tr>
<td>CIBA (Serpasil)</td>
<td>39.50</td>
</tr>
<tr>
<td>Columbia Medical</td>
<td>1.30</td>
</tr>
<tr>
<td>Consolidated Midland</td>
<td>1.95</td>
</tr>
<tr>
<td>Corvit</td>
<td>2.50</td>
</tr>
<tr>
<td>Darby</td>
<td>0.60</td>
</tr>
<tr>
<td>Interstate Drug Exchange</td>
<td>2.80</td>
</tr>
<tr>
<td>Kasar</td>
<td>1.50</td>
</tr>
<tr>
<td>Lannett</td>
<td>9.12</td>
</tr>
<tr>
<td>Lilly (Sandril)</td>
<td>5.58</td>
</tr>
<tr>
<td>Modern Medical Supply</td>
<td>10.80</td>
</tr>
<tr>
<td>Parke, Davis (Serfin)</td>
<td>1.25</td>
</tr>
<tr>
<td>Penhurst</td>
<td>8.85</td>
</tr>
<tr>
<td>Pennex</td>
<td>2.40</td>
</tr>
<tr>
<td>Premo</td>
<td>1.40</td>
</tr>
<tr>
<td>Rondex</td>
<td>46.00</td>
</tr>
<tr>
<td>Smith Kline &amp; French (Eskaserp)</td>
<td>22.38</td>
</tr>
<tr>
<td>Stanlabs</td>
<td>2.50</td>
</tr>
<tr>
<td>Supreme</td>
<td>1.50</td>
</tr>
<tr>
<td>Upjohn (Reserpoid)</td>
<td>2.00</td>
</tr>
<tr>
<td>West-Ward</td>
<td>0.59</td>
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</table>

### Sodium Secobarbital, U.S.P. (1,000 100mg. capsules)

<table>
<thead>
<tr>
<th>Company</th>
<th>Price</th>
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<tr>
<td>Carroll</td>
<td>6.25</td>
</tr>
<tr>
<td>Columbia Medical</td>
<td>5.25</td>
</tr>
<tr>
<td>Darby</td>
<td>4.60</td>
</tr>
<tr>
<td>Interstate Drug Exchange</td>
<td>4.75</td>
</tr>
<tr>
<td>Kasar</td>
<td>5.25</td>
</tr>
<tr>
<td>Lannett</td>
<td>18.30</td>
</tr>
<tr>
<td>Lilly (Seconal)</td>
<td>6.20</td>
</tr>
<tr>
<td>Modern Medical Supply</td>
<td>4.00</td>
</tr>
<tr>
<td>Pennex</td>
<td>4.45</td>
</tr>
<tr>
<td>Premo</td>
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</tr>
<tr>
<td>Supreme</td>
<td>6.96</td>
</tr>
<tr>
<td>West-Ward</td>
<td>5.85</td>
</tr>
<tr>
<td>Wolins</td>
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The federal controversy over the Maximum Allowable Cost Program -- with consumer advocates and legislators opposed by drug makers and organized medicine -- had its antecedents on the state level.
Similar contests have been fought in various state legislatures which have considered generic drug bills to foster more widespread use of lower cost versions of prescription drugs.

The first such bill was introduced in 1967 in the Massachusetts Legislature, and the ensuing battle between interests pro and con prefigured the current fight over the federal MAX program. The struggle to pass and administer the Massachusetts Generic Drug Law is told in the following two chapters.
CHAPTER II

On Aug. 21, 1970, Senate 1367, known as the generic drug bill,* was signed by Massachusetts Gov. Francis W. Sargent. First of its kind in the nation, the law was an unorthodox attempt to cut drug costs.

This was to be accomplished through a change in the way prescriptions were written. The large majority of prescriptions were for the heavily-advertised brand name version of a drug. Under the new law, doctors were also required to write on the prescription the name of the generic version, which usually could be bought at substantial savings. The patient then could choose between brand and generic and communicate his preference to the pharmacist.

It had not been smooth sailing for the generic drug bill. Quite the contrary. It took three years for a bill to pass the General Court. And the one that passed, S1367, was considerably different than the original drug bill introduced in 1968 by Rep. I. Edward Serlin. Where the Mattapan lawmaker's bill was four-and-a-half lines, the bill Sargent signed ran to three pages.

The following legislative account of the bill is from House and Senate records:

After Serlin introduced his bill, H2265 in 1968, it was heard in March by the Social Welfare Committee, of which he was a member. The committee gave the bill a

* S1367 was officially designated "An Act Establishing A Drug Formulary Commission in the Department of Public Health and Requiring Physicians, When Prescribing Drugs By Brand Names, To Include The Generic of Chemical Names of Such Drugs." Mercifully, it was shortened in both official and popular usage to "Generic Drug Law" or "Drug Formulary Law."

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favorable report. It was reworded when it advanced to the House floor and was redesignated H4395, passed to be endorsed and sent to the Senate. The Senate substituted its own version of the bill, S1109, and sent it to the House. The House amended it to conform with the bill it originally sent to the Senate -- H4395 -- and sent it back. The Senate did not concur with the House version and a conference committee was convened to settle the differences between the branches. The committee, however, never reported to the Legislature and no further action was taken that year.

In 1969, several generic drug bills were filed in addition to Serlin's. Action on two of the bills was deferred until the following session by the Social Welfare Committee. The committee gave Serlin's bill, H421, the favorable report and sent it to the Senate as H5006. It was reported in a Ways and Means Committee study order in the Senate and was referred to the Rules Committee, where it stayed until the session ended.

Again in 1970, Serlin's bill, this time H523, was one of several drug bills before the Social Welfare Committee. Again Serlin's bill was the one reported out favorably and sent to the floor. The House changed it slightly, passed it and sent it to the Senate as H5222. The Senate Ways and Means Committee combined it with another bill and reported out the new version, S1360. On the floor the Senate rewrote it and redesignated it S1367. It was sent back and forth between branches for amendments, but it was finally passed and sent to the governor. He sent the bill back to the Legislature with a suggested amendment, which both branches concurred in. Sargent then signed the bill.

The preceding is the official accounting of the law but does not even hint at the lobbying battle fought over Serlin's bill, and which dictated the terms of S1367. A fuller account must start with Serlin, a lawyer who was elected to represent the Mattapan section of Boston in 1966.

Serlin's motivation in sponsoring the bill was of the sort that often fuels the engine of representative democracy -- a mixture of altruism and political self-interest.

His district was the once predominantly-Jewish Mattapan,
the 14th Ward of Boston, 10th Suffolk representative district. There were still signs of Jewishness evident there -- politicians, for instance, continued to flock to G and G's Kosher Restaurant on election eve. But increasing numbers of white residents were moving out of Mattapan as blacks moved in from nearby Roxbury. The result, one commentator wrote, was "the most severe example of blockbusting in Boston ..." 

The whites who remained behind in Mattapan tended to be older poorer Jews who had lived there all their lives and who either would not or could not leave. The diminishing white population and the always-volatile political situation in Mattapan made the chance of survival slim for a white legislator.

"Serlin was never strong in that district," Maurice Donahue, then-Senate president, recalled. "There were always a lot of opponents. So, if you had a big issue you would be on it and marry the issue, and the big issue in that district was anything to do with elderly citizens."

The wedding of Serlin and the generic drug issue, for all intents and purposes, took place in 1967 at Massachusetts General Hospital. That was where Serlin, being treated for lung cancer, first read about the probe of the pharmaceutical industry by the Subcommittee on AntiTrust and Monopoly, chaired by Sen. Gaylord Nelson, D-Wisconsin. Statements by Nelson and others extolling the benefits of widespread use of generics led Serlin

to wonder "why the consumer, especially the elderly consumer, was spending so much on high-priced drugs, when he could get low-cost generics."

Once out of the hospital and back in the House, Serlin filed the first of his generic drug bills, H2265. It stated:

Every registered Massachusetts physician who prescribes drugs for his patients shall in every prescription calling for drugs, use the generic name in addition to the brand name, if any.

Because the bill was so short, Serlin said, when he brought it to the House counsel to be checked, "He made fun of it." And Serlin added, "He didn't think much of it and didn't think it would go anywhere." There were those, however, who were not amused by the bill.

It would soon become clear that representatives of the medical community and pharmaceutical industry saw nothing funny about Serlin's bill. Indeed, they looked upon it as a threat, and would lobby mightily to kill it. Serlin's bill was the first of what were to be several attempts to alter the brand name prescription drug system. As such, the Serlin bill became the center of a legislative battle between lobbyists for the state's doctors and druggists, and the nation's brand name drug makers on one side, and Serlin and consumer interest groups on the other. That contest, which continues today in the State

* In proposing to give the consumer a voice in the selection of which version of a drug to buy, Serlin's bill posed a fundamental change in the American Health Care system. As John Cady, a marketing analyst, and others, pointed out, the distinguishing feature of that system has been that purchasers of health care services, do not, by and large, make purchasing decisions. Purchasing decisions are made almost exclusively by physicians not patients.
House over amendments to strengthen the Generic Drug Law, has involved dozens of lobbyists and legislators and cost a minimum of tens of thousands of dollars. On the federal level, a similar contest is being conducted and has spilled over into court -- as medical and pharmaceutical groups seek to stop the federal government from encouraging purchase of the least expensive versions of drugs under Medicare and Medicaid.

Initially Serlin did not anticipate opposition to his bill, he said, because of its purpose -- to lower the cost of drugs. But even if he had foreseen the opposition, it is doubtful that Serlin would have been anxious to enlist support. He had a reelection campaign in 1970 and the prospect of opponents to consider. The more supporters he had for his bill, the more he would have to share the credit when it passed. Further, Serlin was a loner and was not popular with the legislative leadership. Serlin, in Senate President Donahue's words, was "a solo performer rather than a team player."

Nonetheless, at the start Serlin did a good job of promoting his bill. After filing his bill in 1968, Serlin secured the endorsement of Republican Gov. John Volpe, through the simple expedient of writing him a letter. The letter could not have come at a more opportune time -- Volpe was in the middle of preparing his 1968 state of the state message, when cost cutting would have been uppermost in his mind. Volpe seized the opportunity to get behind Serlin's bill and, in the written reply, told the representative he was directing state officials to implement the use of generics wherever possible. "I believe that the legislation you have filed," the governor wrote, "is a
progressive step." 6

Serlin also managed to have his bill added to the Democratic legislative program for 1968, thus securing at least the nominal support of Senate President Donahue, Speaker of the House Robert Quinn and state Democratic chairman Lester Hyman. The appearance of the bill on the program could not hurt its chances in a legislature two-thirds Democratic. 7

Likewise, Serlin endeavored to promote his bill with legislators and the public: He printed and distributed circulars comparing the prices paid for certain drugs by brand and generic name -- carefully selected for maximum impact. "I sent it (the circular) to every radio and TV station," Serlin said. "I spoke on many TV shows. I don't think anyone could have lobbied more for their own bill. Tremendous interest was generated."

Among those whom Serlin's wave of publicity reached was Thomas Gallagher, a Boston Herald Traveller columnist who wrote on State House affairs and who would prove to be the singlemost important factor in the eventual passage of the Serlin bill. During the life of the bill, Gallagher, whose thrice-weekly column ran on the editorial page, would write nearly a dozen articles in behalf of the drug bill.

"A Dorchester legislator," he wrote in his first column on the bill on Jan. 24, 1968, "is convinced that millions can be slashed from Gov. Volpe's billion-dollar budget without any reduction in services to the people." 8 Referring to the effect of Serlin's publicity campaign Gallagher wrote on Feb. 22 that
the bill was "gathering momentum." But he wondered prophetically, "just how expensive, or well-financed, a lobbying effort will be made to kill the Serlin bill ..." \(^9\)

Before long, Gallagher would find out -- to his dismay. The lobbying against Serlin's bill began the moment after it appeared on the House calendar.

One of those who noted the bill's appearance was Dr. Robert Holland, legislative chairman of Massachusetts Medical Society, which counted about 7,000 of the state's approximately 10,000 doctors as members. * Serlin's bill was one of hundreds that Holland leafed through each year. He reduced the mass to a list of health-related measures for consideration of the MAX Committee on Legislation, which decided the stand on each. The stand on Serlin's bill was negative. "Our opposition to the bill," Holland explained, "was based on the simple premise that the doctor certainly should be getting the drug he writes the prescription for."

Another who took note of the Serlin bill was Boston Atty. Robert Sylvester, who had decided to enter the realm of State House lobbying and was shopping around for a client. "It didn't seem right to me," he said, "that a doctor would be interfered with in prescribing drugs for his patient." Sylvester was one of

* Not even the state knew how many doctors were practicing. Doctors were required to register with Massachusetts, but were not required to re-register until 1975. (Interview Public Health Commissioner, William Bicknell, Sept. 1975.)
several lawyers who became involved in lobbying -- for the first and last time -- with the generic drug issue. Through contacts in Washington, Sylvester was put in touch with Merck, Sharpe and Dohme, one of the nation's leading drug makers. Sylvester had worked in Washington in the years after World War II, on the staff of the Senate Labor Committee, whose subcommittee on health was in 1974-76 attempting to clear the way for rules encouraging use of generics in Medicaid and Medicare.

Merck's position on the drug bill, according to Edward Carroll, director of economic research, "was that a doctor should be able to specify what he wanted for his patients." Carroll, who hired Sylvester, said "only the doctor knows enough" and "the bill usurped his prerogative." Carroll said Merck also objected "because of the varieties in action among some brand and generic drugs."

Sylvester said, "In a way it (the opposition to the Serlin bill) was a fairly selfish attitude to take," because Merck had a financial interest in the continued supremacy of brand name drugs. But, he added, "Doctors are our best customers - we did not want them to be interfered with."

To assist in the lobbying, Sylvester arranged for Merck to retain Boston Attorney Paul Burns. For Burns, it was also the

* Umass. political science Prof. Harvey Friedman, a veteran observer of Boston politics, and a lawyer, says Boston lawyers take a fling at lobbying and quickly become disenchanted because it's unlike "the legal work they're trained for."
first — and last — try at State House lobbying. The Pharmaceutical Manufacturers Association, trade organization for the nation's 131 largest drug makers, retained a third lawyer—newcomer to lobby against the Serlin bill — Robert Gallagher of Worcester. Gallagher, like Sylvester, said he was hired through a contact in Washington, "a lawyer who I was in the Air Force with who knew I was practicing in Massachusetts." Gallagher represented the PMA in 1968 and 1969. The following year Boston Atty. Frank McGee represented the PMA in lobbying against the Serlin bill. McGee, unlike the other Boston lawyers, had worked previously for the PMA and for Smith, Kline and French, a leading drug maker.

There was one lobbyist who needed no introduction to Beacon Hill. Atty. Charles Dunn, a State House lobbyist for 30 years, represented the MMS and counted many a powerful legislator as friend. He would become a leader in the fight against the Serlin bill. Other key lobbyists included Attys. John Zamparelli and David Herman and Len Permit, all of the Massachusetts Pharmaceutical Society, representing the state's pharmacists.

Armed by their employers with facts and figures, this group of newcomers and veterans had a substantial impact on the Legislature. George Denmark, a pharmacist and then chairman of the Board of Trustees of the American Pharmaceutical Association, who supported generic drug bills, recalled:

The first thing they did was raise the question of the bogey man that all drugs are not equal. They created those questions in the minds of legislators. The companies had tremendous resources to barrage legislators with all sorts of information. And there didn't seem to be anyone to respond to the questions raised or to refute them.
There was no evidence of advanced planning or coordination among the lobbyists in their fight against the Serlin bill. Instead there was considerable duplication of effort, no doubt the intended effect. Still, certain lobbyists by nature and aptitude, concentrated on certain styles of lobbying.

"Most lobbyists," Associated Press Reporter David Rosen observed in a 1976 series, "report few entertainment expenses. Most appear to spend their time testifying at hearings, working with committee staffs, buttonholing legislators in hallways and meeting with legislative leaders." ¹⁰ For the most part, lobbying against the Serlin bill closely followed this pattern. Merck's Carroll seems to have done about the only socializing with legislators, on two trips he made from the firm's Westpoint, Pa. headquarters to Boston in 1969. There is one other addition to Rosen's description in the list of lobbying tactics below, the first:

1) **GRASSROOTS LOBBYING**: Laymen respect doctors, and the Massachusetts Medical Society made ample use of the aura of expertise of the physician. Many a senator and representative recalled being contacted by a doctor -- or druggist -- from his district and warned about the wound that the Serlin bill would inflict upon the practice of medicine. Sometimes the doctor in question was the legislator's personal physician. MMS lobbyists Dunn and Holland, who was in charge of urging MMS members to contact their legislators, agreed that the tactic is standard practice for the organization. Likewise, Permit urged druggist-members of the pharmaceutical society to contact
their legislators. "The strongest lobby you can get," Senate President Donahue observed, "is the family doctor. The personal relationship is very significant."

2) **Lobbying Legislators:** The leading practitioner of this type of lobbying was Dunn, well known and well liked by legislators, including some very influential ones. Donahue called Dunn "one of the most respected and honest lobbyists in the state's history." Sen. Beryl Cohen, D-Suffolk-Norfolk, and chairman of the Social Welfare Committee, said "He (Dunn) was very close to the Senate president," knew other legislative leaders and "did (lobbying) work on a personal basis." Dunn said he was "hitting everyone I could," and added, "That was my job, contacting reps, speaking to the leadership." Other lobbyists were friendly with lawmakers. And Atty. Zamparelli, who represented the pharmaceutical society, was the nephew of Rep. George Sacco, vice chairman of the powerful House Ways and Means Committee.

3) **Committee Lobbying:** The routine work of lobbying is testimony before legislative committees -- the Social Welfare and Ways and Means Committees in the case of the drug bill -- and conferring with and assisting legislative staffs in drafting bills. Most of the lobbyists fighting against the Serlin bill engaged in this type of lobbying at one time or another. Sometimes, the types of lobbying were combined as when, for example, Dunn conferred in the hallway with legislators over wording of a bill while inside the committee room, Holland testified on the bill.

So intense was the lobbying against the Serlin bill that
doctor, druggist, lawyer-lobbyist or all three could have spoken
to the same legislator about the Serlin bill. *

Now the stage is set for Serlin's bill, H2665, which made
its debut at a hearing before the Social Welfare Committee at
10 a.m. on March 26, 1968. Massachusetts uses a joint committee
system, avoiding the waste of time involved in double hearings and
separate House and Senate committee considerations of each bill. The joint standing committees, such as the Social Welfare Committee, carry out the main burden of hearing and recommending action on proposed legislation. Every joint committee has six senators and fifteen representatives and the committee's judgment is virtually the final word. More than 90 per cent of joint committee reports are accepted by the Legislature. 13

At least one member of the Social Welfare Committee was 100 per cent behind the generic bill. Serlin's membership on the committee, in fact, turned out to be a most fortunate coincidence for his bill. Serlin saw no allies in the audience during the hearing, only opposing lobbyists. But Serlin's presence on the committee provided him with a tactical advantage that offset what he lacked in allies.

* Unfortunately, the cost of this undertaking cannot be precisely determined but must be estimated based on present reported lobbying expenditures, which was not made a requirement until 1974. In 1975, two medical groups, four retail drug firms, the Massachusetts Medical Society and pharmaceutical association spent some $32,000 for lobbying on health related legislation. About $8,000 was spent by the MMS. About $13,000 was spent by the pharmaceutical association, whose lobbyist was George Sacco, Ways and Means Committee vice chairman when the Serlin bill was in the Legislature.

It should not seem surprising to find the pharmaceutical association outspending the MMS. "The pharmaceutical society was strong, stronger than the medical society," according to former Senate President Donahue. He agreed that the amount spent on lobbying in the years the Serlin bill was in the Legislature would have exceeded the $32,000 figure.
(Source of the lobbying figures is a report filed in January, 1976, by State House News Service reporter John Mello from Boston.)
A committee member sympathetic to a bill, according to David Truman in *The Governmental Process*, can "do much through his questioning to emphasize (his) views." In the same fashion, a committee member "hostile" to a viewpoint in testimony "may obscure the point by interruptions and obstructive arguments." Serlin may not have read Truman, but he knew instinctively to press his advantage: "I was able to cross-examine every lobbyist... If I wasn't on the committee there would have been no one with enough knowledge to refute the lobbyists' arguments."

The House chairman of the Social Welfare Committee was one of the Legislature's two druggists, Rep. Arnold Epstein, D-Brighton. "I had nothing against generic drugs," he said. But to avoid the appearance of conflict of interest — he owned a drug store — he refrained from voting on the bill. Instead, Epstein played the part of consultant advising fellow committee members on technical questions about drugs. However, both Serlin and Senate Committee Chairman Beryl Cohen agreed that Epstein later voted against the drug bill on the House floor.

Chairman Cohen, a liberal Democrat, supported the concept behind the Serlin bill, but "may not have been that hot for it," as Donahue noted. Later, Cohen declined the traditional task of a Senate committee chairman, of speaking for a House member's bill on the Senate floor.

The bill received a favorable report from the Social Welfare Committee, despite the lobbyists' opposition. "A committee almost always acts favorably on a member's bill," Epstein said.
Serlin's bill was sent to the House floor and read on April 29. Serlin spoke for it. He was opposed by only a few representatives, who made objections to the bill on the grounds that it interfered with a doctor's professional judgment. However, Serlin said, he easily turned aside their objections by stressing the savings in drugs costs his bill could effect. After the welfare committee hearing, Serlin had expected more opposition than he encountered on the House floor. Soon it would become evident that the lobbyists were concentrating their efforts on the 40-member Senate instead of the 240-member House. In the meantime, Serlin's bill passed the House easily.

Given the Social Welfare Committee report, the debate in the House may have been moot. Legislative debates often are. Debates, Truman wrote, "are frequently ridiculed as meaningless... it is rare that any speech ... changes a vote on a basic issue." In debate, Donahue said, "you're on the floor talking for the constituency outside." He agreed with Truman's assessment: "You very rarely change minds in debates on the floor. By the time of the debate, the battle lines have been drawn. The lobbying has been done beforehand on both sides."

The battle lines in the case of Serlin's bill had been drawn across the entranceway to the Senate chambers. On May 1, the bill crossed the line as 4395, a slightly rewritten version of Serlin's bill, changed on the House floor. The ensuing debate in the Senate over the bill seems to have been an exception to the Truman-Donahue axiom about the irrelevancy of floor debates.

The reason for this was Sen. Philip Ryan, D-Springfield,
the Legislature's other pharmacist. Unlike his House counterpart, Epstein, Ryan did not fear conflict of interest and, in fact, felt it was his responsibility to speak out against the Serlin bill. He called it "an attempt by the Legislature to impose its will on the professional judgment of the medical profession."

To speak for his bill, Serlin settled for the senator from his district, Samuel Harmon. An obliging, non-combative fellow, Harmon knew next to nothing about generic drugs. So Serlin sat next to him during the debates in the Senate, whispering advice. Several senators recalled the spectacle of Serlin whispering to Harmon in the chambers. It showed why the brash Serlin was disliked by several lawmakers.

"He was a pain-in-the-ass," Donahue said. "He was not well-liked at all. His personality and solo-flying hurt early passage (of his bill) as much as any other reason. You can't have a guy from the other chamber looking over your back." (Donahue, to his credit, did not let his opinion of Serlin interfere with his opinion of his bill. He was one of the senators who consistently voted for it.)

The outcome of the Harmon-Ryan debate was no surprise: Harmon took a beating. "Everybody jumped on me that first year," Harmon recalled. Ryan's warnings had a deep and lasting effect on several senators -- and complimented the lobbying that had obviously been done by lobbyists and individual doctors.

"A few doctors and a (county) medical society were hot against it (the Serlin bill) in my district, and I relied on medical opinion," said Sen. Steven Davenport, D-Jamaica Plain.
Likewise, Sen. George Keneally, D-Dorchester, whose district touches Serlin's, recalled, "We got tons of mail from various doctors and associations against the bill. I can remember going to a medical association meeting where they were all talking about it."

On May 28, the Senate voted to amend Serlin's bill with a provision that put the bill back in the doctor's court. The amended bill, H109, reflected the influence of Ryan and the doctors. The bill stated that a doctor was to write generic names on prescriptions only "when in his professional judgment the generic product is therapeutically equivalent to the brand name drug prescribed." 10

The amendment touched off a legislative ping-pong game:

-- On June 3, the House received the Senate bill and on a motion by Serlin, struck out the provision inserted by the Senate, restoring the bill to its original form.

-- On June 10, the bill was sent back to the Senate and Keneally prevailed upon his fellow senators to refuse to concur with the House deletion.

-- On June 18, the House approved Serlin's motion to insist on the deletion, and to request a conference committee to smooth out the differences with the Senate.

-- On June 24, the Senate voted to insist on its version of the bill and to enter into the conference committee. 20

For the Senate, three opponents to the Serlin bill, Keneally, Davenport, and Ronald MacKenzie, R-Burlington, were named by Donahue to the committee. 21

For the House, Serlin and legislators from Pittsfield and Nantucket were named to the committee. Its members could not
reach a compromise. No further action was taken on the bill in the 1968 session.

In a post-mortem, columnist Gallagher wrote that Serlin's bill had become "the target of the Massachusetts Medical Society, the retail druggists association, and the big drug companies." Then, he added: "Their well-heeled lobby delivered, and the bill went to its death in a conference committee ... (called) over an emasculating amendment." 23

Lobbyist-opponents of the bill had established a beachhead in the Senate for future fights over the Serlin bill. "We turned it around in the Senate," Merck's Sylvester said. "It would have passed but there was enough evidence (for us) to raise grave doubts about generics being equivalent and about interfering with physicians."

The lobbying over the Serlin bill had its lighter moments. One lobbyist, for instance, approached Serlin prior to a vote on his bill and -- unaware to whom he was talking -- proceeded to condemn the bill. When Serlin identified himself, "The lobbyist got red in the face and walked away," he said.

Serlin was also the target of the most bizarre of the lobbying ploys.

Following what he said was standard procedure, Dunn determined the identity of the doctor who treated Serlin for lung cancer, called him at Massachusetts General Hospital and "told him 'why the hell don't you tell this guy Serlin he's barking up the wrong tree with his bill.'" And Dunn said,
"As I recall, he did."

But Columnist Gallagher remembered it in a different fashion: "They were so desperate to get this bill killed they were using this guy's lung cancer to get him to take the heat off."

Soon after Dunn called the doctor, he opened the Herald Traveller and found on the editorial page "a Gallagher column condemning my efforts as the lowest form of lobbying."

"It was a very common form of lobbying," Dunn protested. "If we knew a representative was being treated by a doctor, I or others would call the doctor and tell him to set this guy straight."

Gallagher said, "It was in poor taste ... reprehensible. But it's the type of thing they would do in heavy lobbying. So I blasted this guy in my column."

The hue and cry over Berlin's bill, moreover, went beyond the Legislature. As the 1969 session opened, there had arisen among some legislators the feeling that public sentiment favored the Berlin bill.

The feeling was prompted by several factors.

Two leading opponents to the Berlin bill, Senators Davenport and Ryan, would not be returning to the Senate. Both were defeated in the fall elections, as had been Rep. Epstein. The defeats seem to have been attributed in part to their opposition to the drug bill. Encouraging such an interpretation was *

* Several legislators - Donahue, Epstein and Cohen - agreed it was so."
columnist Gallagher, who wrote on Oct. 9:

...there already are indications of some reassessments of position by legislators who voted against this consumer legislation during the last session.

Two druggists who helped lead the fight, against the bill ... were defeated in the September primary, as was ... Davenport who supported the crippling amendment which ultimately led to the bill's rejection.

Donahue explained this change in attitude that was taking place thusly: "You gotta' go where the votes are. You can't continue to do nice things for your family doctor or neighborhood druggist."

One indicator of this change in attitude was the increase in generic drug bills filed in the 1969 session. Serlin's was no longer the only one. Among the others was H2389, filed by Republican Reps. Winston Healy, of Charlemont and Robert Aronson of Sharon.

"It's what happens when a bill comes along and people think it will be popular," is how Healy cheerfully explained the proliferation of drug bills. "Legislators will file one and try to get the credit (if it passes). The fight is always in committee, over whose name goes on the bill that's reported out."

As for partisanship, Healy indicated, all bets were being hedged. "Aronson and I were Republicans and Serlin was a

* One indication of the public pulse as regards prescription drugs was a poll taken for the Boston Globe by Becker Research Corp. that was published April 19, 1969. Consumers were asked to rate the best and worst buys in the marketplace. The worst — prescription drugs, followed by auto insurance and auto repairs.
Democrat. I suppose we wanted our party on record as having filed such a bill."

Unfortunately for Healy, there was no question about whose name would be on the bill that emerged from the Social Welfare Committee with the favorable report. Not with Serlin sitting on the committee.

The committee held its obligatory hearing on the drug bills on Feb. 18, 1969. The makeup of the audience reflected a second factor behind the Legislature's changing attitude towards generics. Present were several backers of Serlin's bill. It had attracted the support of the liberal Americans for Democratic Action, Massachusetts Consumers Council and the Association of Massachusetts Consumers:

Dr. Leo Parnes, affiliated with Harvard University Health Services and Tufts Medical School, whose wife was ADA legislative chairman; and Dr. Richard Burack, author of the Handbook of Prescription Drugs, which argued in behalf of the use of generics.

Parnes told the Social Welfare Committee:

While the giant pharmaceutical manufacturers would like us to believe that brand name drugs are more potent, safe and effective than generics, there is nothing inherent in trade name preparations nor in the companies that produce them that guarantee such products.

The change in sentiment among legislators was noticed by some of the lobbyists opposed to the Serlin bill. Merck's Sylvester was one:

The legislators had to have something. They couldn't keep going home to their districts not being able to answer their constituents when they asked why the generic drug bill didn't pass. You can't stonewall it with consumer legislation. You can't keep defeating it.
So the Merck contingent of Sylvester, Burns and Carroll set about the task of devising a compromise.

This was a formulary, or listing of generic drugs in common use and therefore considered safe, and their brand name counterparts. Such a formulary was in use by the Department of Public Welfare in Merck's home state of Pennsylvania, as part of a program to encourage doctors to voluntarily prescribe the lowest cost version of a drug for relief recipients. * The Pennsylvania plan had encouraged Sen. Hugh Scott, D-Penn., to file a bill in the U.S. Senate to adopt it on a federal level. If the formulary provision were added to the Serlin bill, and if the requirement for doctors to prescribe generics was dropped, Carroll said, the Merck lobbyists were willing to drop their opposition.

Burns took the proposed compromise to Sen. Kenneally, who had led the Senate fight against the Serlin bill. Kenneally and Burns drafted a bill to create a committee to compile and publish the list of brand and generic names, to be called the Massachusetts Drug Formulary. The plan was to combine the formulary bill with Serlin's bill when it arrived in the Senate Ways and Means Committee, the fiscal unit in the Legislature through which virtually all bills affecting finances must pass.

Kenneally saw the formulary as "a compromise ... a way of

* During the first nine months of use, the Penn. Formulary saved $1 million or cut costs by 15.9 per cent.

(Interview, Atty. Robert Sylvester, Febr. 1976.)
getting the bill passed ... a way that people would know which generics were equivalent" and a way of getting the Legislature out of the hole it was in regarding the Serlin bill.

But not all the members of the lobby supported the formulary compromise. Several lobbyists were still against the passage of any drug bill, formulary or not. Though Merck stood behind the compromise, the MMS, pharmaceutical association and PMA stood ready, as the year before, to kill any drug bill.

Nor were the supporters of the Serlin bill enamored of the compromise. This was apparent during a July, 1969 hearing of the Ways and Means Committee on the Serlin and Kenneally bills.

Parnes warned the committee that Kenneally's bill was "a delaying tactic" and noted that there were several "high quality" formularies in print. "I hope your committee," Parnes said, "can vote favorably (on Serlin's bill) without the crippling amendment."

Opposed by elements of both sides in the generic drug dispute, the formulary compromise failed and so, for the second straight year, did Serlin's bill. It was reported out in a Senate Ways and Means Committee study and then was sent to the Rules Committee for the remainder of the 1969 session. 28

That was the last session in which Merck participated. "In 1970," Sylvester said, "we didn't want to get involved." Carroll suggested that his firm had despaired of passing a workable generic bill. Nevertheless, lobbyists for the medical society, pharmaceutical manufacturers, and Massachusetts druggists remained in the State House to fight the 1970 version of Serlin's
bill. "We were active as hell in 1970," Zamparelli of the Massachusetts Pharmaceutical Association said.

The ADA also filed a generic drug bill and this reflected a split between it and Serlin. Indeed, Dr. Burack and Atty. Nate Pavin of the Massachusetts Association of Consumers, as well as Dr. and Mrs. Parnes were dissatisfied with Serlin and his bill. Pavin said they wished to "get a stronger law through." At first, they tried to talk Serlin into strengthening his bill by shifting to the pharmacist the responsibility to provide the customer with the choice between drug versions. Pavin said:

We wanted a much stronger law, possibly one which said the generic drug would be prescribed (dispensed by the druggist) unless the doctor said otherwise.

We tried to talk to Serlin but you couldn't talk to him.

So the ADA filed its own bill which, compared to Serlin's bill, was simultaneously stronger and weaker. The ADA measure, H2037, required that drugs be prescribed by generic name, but left to the discretion of the physician whether to follow it. It stated:

Any preparation prescribed by a physician for which a generic name exists shall be prescribed by its generic name. A brand name may be added to such prescription and shall be supplied by the dispensing pharmacist when in the discretion of the prescribing physician it is required. 29

Of course, the bill had little chance of passage or even of receiving a favorable report from the Social Welfare Committee, with Serlin sitting on it. Rather, the ADA bill
is significant, if at all, for the effect it had on Serlin. With his bill in the hopper for the third time, he could not have been very happy to learn that a rival bill was being backed by representatives of several consumer-oriented organizations. This apparently made Serlin anxious about his bill and put him in a frame of mind to accept a compromise if it would ensure passage of his bill. * Thus Serlin, who had villified drug company lobbyists at the 1968 committee hearing on his bill and who, Parnes said, "was so anti-drug industry that it made it difficult for a bill to pass," subsequently agreed to the formulary compromise which Kenneally had introduced in 1969, and perhaps made other concessions. *

As if to increase Serlin's anxiety and solidify his resolve to compromise, Parnes introduced into the Social Welfare Committee hearing on the drug bills on March 14, 1970, a petition in support of the ADA bill signed by 14 Boston area doctors. 30 Nonetheless, professional courtesy, legislative-style, again prevailed. Serlin's bill, H524, received the favorable report from the committee. The bill was reworded on the House floor and sent to the Senate as H5222 31

Meanwhile, Sen. Ronald MacKenzie, R-Burlington, received a report from a committee of constituents he had convened to study the generic drug problem. A member of the conference

* Dr. Joseph Harris, an oral surgeon and investigator with the state Attorney General's office, said that Serlin told him that "sanctions were left out of the (final) bill as part of a compromise." Harris, in his investigative capacity, checked on compliance of doctors with the law. (Interview, May, 1976)
committee that negotiated over the Serlin bill in vain in 1968, MacKenzie said he often forms constituent committees to study complex problems because of the large number of professionals in his district. The committee on the drug issue, whose members included a doctor, a druggist a lawyer and an engineer, recommended a compromise similar to Kenneally's 1969 formulary bill.

MacKenzie, who said he favored the concept behind the Serlin bill, but thought it was "too simple to be safe," thereupon joined Kenneally in refiling his formulary bill. But before they introduced the bill, MacKenzie said, they determined that "Serlin would buy the idea."

The Kenneally-MacKenzie bill, S927, was sent to Senate Ways and Means with other drug-related measures, Serlin's bill included. On April 8, 1970, the committee reported out S1360, a combination of the Serlin and Kenneally-MacKenzie bills. But the bill included a sentence not present in either of its predecessors:

Drugs which are the subject matter of rights issued by the United States Patent Office and the U.S. Trade Mark Bureau are exempt from the provisions of this chapter. 33

No one interviewed for this paper could pinpoint the source of the sentence but there are strong indications it was inserted
on behalf of the lobbyists for the drug makers. * Pavin, for instance, recalled attempting to persuade Serlin to strike the sentence from his bill. However, Pavin said, "Serlin was uptight and there was some kind of deal with some of the key legislators and lobbyists to exclude patent rights in the bill."

S 1360 was sent by Ways and Means to the Committee on Bills in the Third Reading, which rewrote the bill. The sentence on patent rights was taken from the end of the bill and put in the middle of the new bill in slightly different form. It now read:

The source for (the formulary) ... shall not include drugs which are the subject matter of rights issued by the United States Patent Office or contained under the laws relating to trade names and trade marks. 35

The Senate passed S1367 and sent it to the House, which referred it to Ways and Means. On June 4, Committee Vice Chairman George Sacco proposed an amendment to S1367, striking out the phrase "or obtained under the laws relating to trade names and trade marks," from the sentence on patent rights. Sacco, an attorney and de facto chairman of the committee, could not recall the purpose or reason for the amendment. He said, as committee vice chairman, he would receive "clarifying amendments..."

* Many of those involved with the drug bill suspect that was the source. Connie Williams, Mrs. Parnes' successor at the ADA, says the sentence in question "appears in almost every bill in every state. The wording is exactly the same. It's too much of a coincidence." That view would confirm Mrs. Parnes' estimation of the drug company lobbyists' tactics: "The danger was present at all times. Some people didn't understand it, but we had to keep guarding against lobbyists who would try and interject their kind of language in redrafting the bill. They would try to change language or use stalling tactics or parliamentary maneuvers. Primarily, I think it was in the Senate."

Permit of the pharmaceutical society suggests the sentence might have originated with the PMA, which would have had an interest in protecting patent rights."
for certain bills from House counsel and I would introduce them." Or perhaps, he suggested, the amendment "may have been a compromise measure. Sometimes we did things we didn't really like to do to get it passed." 38

If the latter was the reason for the amendment, Sacco would have been the logical choice to introduce it. His nephew, Zamparelli, was one of two lobbyists for the Mass. Pharmaceutical Association, one of the chief foes of the original Serlin bill. In fact, Sacco himself went to work as a lobbyist for the association after he left the Legislature and ran unsuccessfully in 1974 for attorney general.

Sacco's amendment was adopted by Ways and Means and S1367 was enacted by both branches and sent to the governor. But his staff, apparently wary of any signs that the bill had been tampered with by opposing lobbyists, advised him to send it back to the Legislature with a suggested change. He did so and included the following explanation:

I recognize that to return the bill at this late date creates the danger that attempts will be made by vested interests to scuttle it during prorogation. I do not want this to happen. However, since the bill on my desk may be no bill at all, I feel that returning it is the only right course... The bill, as written, has a major defect which could nullify its effect. During the course of its passage, a provision was inserted which excludes from the list of drugs that may be listed in the formulary as therapeutically equivalent "drugs which are the subject matter of rights issued by the United States Patent Office." Nearly every drug, patented or not, has a trademark. Under federal law names of drugs are registered in the United States Patent Office and rights are granted for use of those names.

It is the opinion of those who have examined S1367 that the bill will be interpreted as excluding from the formulary any drug whose name is registered with the patent office for trademark purposes...
Sargent's amendment was to insert the word "patent" to precede and clarify the word "rights." Both House and Senate adopted the amendment and Sargent signed the bill on Aug. 21. 40

* * * * * * * * *

One reason the Serlin bill passed was offered by Senate Ways and Means Committee Chairman Burke. "The bill had been around for a long time. Many bills are introduced and only pass after they are filed for several sessions."

This suggests that the generic drug bill ran the legislative gamut in a manner similar to British "private member" bills.

Scores of such bills are introduced in Parliament at the end of each session and they often deal with "far-sighted proposals," according to one commentator. But, he noted, most such bills "rarely got much further than the second reading."

After a private member bill is introduced several times -- as was the case with Serlin's bill -- it "may be passed" or incorporated into the platform of one of Britain's parties. A proposal for daylight savings, for example, figured in a private member's bill for eight years before the government adopted it. 41

The passage of the drug bill, however, did not mean the end of the lobbying against it. Lobbyists managed to have a $67,000 appropriation for printing and distributing the formularies deleted from the Department of Public Health budget in July, 1971. Dr. Burack, who became chairman of the Formulary Commission, wrote in a letter to the governor urging that the appropriation
be restored. "The fine hand of the pharmaceutical interests was all too evident at the conference committee on the budget."

Likewise, the lobbyists branched out into the public health department, which was given partial responsibility for the law. It was only logical that the lobbyists would move into the department, for, as Truman noted, administration of a law "is, quite properly, an extension of the legislative process."

The law, its reception in the health department and attempts to amend it in the Legislature are the concerns of the next chapter.
CHAPTER III

The Massachusetts Generic Drug Law was, in the words of former Public Health Commissioner William Bicknell, "a typical Massachusetts law, lovely, liberal, loosely-worded, ineptly thought out and poorly written."

This was no accident. It was the result of compromise which ended several years of conflict between lobbyists for and against the bill with legislators in the middle. Under such circumstances, murky language may be the price of passage. David Truman has observed:

Where compromise in the legislative stage is the alternative to temporary failure and where the imperative to compromise is adopted by some participants as a means of avoiding the open frustration of expectations widely held in the community, the terms of legislative settlement are almost bound to be ambiguous.\(^1\)

And so it was with the Generic Drug Law, a 55-line piece of legislation that was a dozen times as long and almost that much cloudier than the original drug bill filed in 1968 by State Rep. I. Edward Serlin, D-Mattapan.

Serlin's aim was to cut prescription drug costs. The bill required doctors when writing prescriptions for brand name drugs also sold by generic name to include the name of the generic version. Generics generally were sold at much lower prices. Serlin wanted the choice between generic and brand name version -- until then in the sole provenance of the physician -- to be left up to the consumer, the person paying for the prescription.

If consumers chose the generic version, Serlin estimated,
total savings could be in the millions. But few Massachusetts laymen knew what the term "generic drug" meant, much less that it could mean lower prescription prices. Few, therefore, would have cared to know that Serlin's bill was twice killed by lobbyists for the state's doctors and druggists and the nation's drug makers. As Serlin spread the word that his bill would lower drug costs, however, and, coincidentally, as consumer consciousness arose, lawmakers felt that public sentiment was mushrooming in behalf of the Serlin bill.

By the 1970 session, lawmakers decided there was sufficient compulsion to warrant passage of a generic bill. But what they passed resembled Serlin's bill only slightly.

Several key senators -- who had been among those blocking passage of Serlin's bill -- supported a compromise to meet the objections of doctors, druggists and drug makers that some generics were inferior to brand name counterparts and thus could not be used interchangeably. The lawmakers combined Serlin's bill with another for a commission to compile a list of generic and brand name counterparts -- a formulary -- as a guide for doctors writing prescriptions. The new bill passed both houses and was signed into law on Aug. 21, 1970 by Gov. Francis W. Sargent.

Where Serlin's bill had simply required doctors to prescribe generically, the new law included that requirement as if in afterthought. Indeed, 51 of the 55 lines dealt primarily with the terms of the compromise -- the formulary. 2

There were, moreover, several loopholes in the law. For
instance, it directed that a physician "shall" include the
generic name of a drug on a prescription but failed to include
a sanction if the physician did not. Later, the Formulary
Commission drafted a position paper stating, in effect, that
"shall" really meant "should" thus allowing doctors to decide
whether to prescribe by brand name only. Thus, by adminis-
trative fiat, the law was watered down to allow doctors to
flout it at will. *

Further, the law ignored the realities of medical practices:
Time and the hectic pace of the doctor's workday were not on
the side of the law. It assumed a broad knowledge of
pharmaceutics by the average doctor. Most doctors had not
studied pharmacology since medical school and had not kept
pace with new drug developments. ³ Many were unfamiliar with
the long, hard-to-remember generic names of some drugs and
find it tiresome to consult the formulary whenever they wrote
prescriptions. ** Brand names, on the other hand, were devised
to be shorter, easier to remember, and therefore easier to
 prescribe. ⁴

Nevertheless, such ambiguities and complexities, according

* This interpretation was indicated by Andra Hotchkiss,
deputy general counsel of the Department of Public Health, in

** In a test taken last year, of how much doctors know about
prescribing antibiotics, half the 4,513 physicians around the
country who voluntarily took the 50-question multiple-choice
test achieved scores of "only 68 per cent or worse," according
to The New York Times. Doctors who had been out of medical
School longest tended to do worst on the test. News Item,
Doctors' Scores Low in Test on Use of Antibiotics, NYT Dec. 18,
1975, p. 28.
to Truman, can be "at the very heart of a successful political formula, especially where the necessity for compromise (in the Legislature) is recognized but is difficult to achieve in explicit terms." The ambiguity "postpones" the necessity for a showdown between the competing interests clashing over the apparent irreconcilable differences in the original bill.

For the formula to be successful, however, there must be "administrators willing to resolve the difficulties that were too thorny for the Legislature to solve." Massachusetts administrators wanted no part of the difficulties in implementing the drug law. Furthermore, the Legislature, having passed it, would not appropriate funds to administer the law properly. There could be only one outcome, failure of the law.

Surveys on its impact after it went into effect in early 1972, confirm the prognosis -- doctors, who had no reason to believe they would be penalized for not obeying the law, did not obey it. Most consumers, unaware of the benefits or even the existence of the law -- owing to the failure of the state to promote it -- continued to pay prices for brand name drugs exceeding the cost of generic counterparts.

All of this was in the future when, on Dec. 21, 1970, Gov. Sargent announced his appointments to the Formulary Commission. Sounding a note of optimism, he declared:

Passage of the generic drug bill signalled a new era for the Massachusetts consumer. The members I am appointing today will see to it that the bill is
implemented effectively. I shall continue to pursue whatever measures are necessary to assure that the prescribed drugs needed by the citizens of Massachusetts are available at reasonable costs.

The commissioners were all prestigious members of the medical and allied professions.

Named chairman was Dr. Richard Burack, author of "The Handbook of Prescription Drugs," advisor to the Massachusetts Consumers Council and long an advocate of generic prescribing and supporter of the Serlin bill. He was described in a press release from the governor's office as "a nationally known authority on drugs."

Appointed alternate chairman was another early supporter of the Serlin bill, Dr. Leo Parnes, affiliated with Tufts Medical Center and Harvard University Health Services, who had assisted his wife, who represented Americans for Democratic Action, in lobbying for passage of a drug bill.

Other members were:

George Denmark, a pharmacist and chairman of the Board of Trustees of the American Pharmaceutical Association, which represents a third of the nation's pharmacists. (Denmark also had supported a generic drug bill.)

Dr. Arthur Hadler, chief of medical services at the outpatient clinic, Boston Veteran's Administration Hospital.

Ms. Juanita Long, dean of Northeastern University School of Nursing.

Among those attending the swearing-in ceremony was the Commissioner of Public Health, Dr. Alfred K. Frechette. His department was to be the commission's administrative base, as
specified in the law. The commission was charged with "effectively implementing" the law, as Sargent had pointed out, but it was part-time and unpaid. Still its members were ready and anxious to get to work after they were sworn in. Frechette, one commissioner recalled, was reluctant:

He wanted to postpone the meeting. I can't recall why. But he wanted to sort of put the whole thing off. We said absolutely not, we wanted to have our first meeting. He said that was fine but I got the impression that he was in favor, now that we were sworn in, of forgetting the whole thing.

There were many reasons behind Frechette's reluctance. After a dozen years as public health commissioner, Frechette displayed the cautious and conservative traits of the long-time civil servant, as many of his co-workers testified. **

"His whole method of operation was not to antagonize anyone in the Legislature or medical community," Edward Lichtenstein, a department worker and the Formulary Commission's first administrator, said. "He didn't like to step on people's toes."

** The commissioner refused to allow his name to be used.

"Frechette, who now serves as chairman of the Cancer Cooperative Board, a private group, was appraised thusly by Springfield Daily News Editor Richard Garvey, a board member: "If I were to grade him for effectiveness of leadership, I'd give him no more than a 'C.' He allows the group to spend considerable time on trivia. He oftentimes is not up to date on matters, and so must consult with staff at meetings instead of prior thereto. He frequently does not make certain that staff has fairly adequately explored alternatives before asking the board members for a policy decision. He may have some special problems with the co-op because a few of the doctors on the policy board are highly respected professionals but it appears to me that it is Doctor Frechette's limited ability to lead rather than his lack of ability that restricts his effectiveness as chairman."
Frechette could hardly have relished the prospect of forcing the law on a resentful medical establishment. Nor was he alone in that reluctance in the department -- described as "doctor-oriented" by Serlin. "A lot of people (in the department) were embarrassed by it (the law)," Lichtenstein added.

Frechette's cautious attitude was reinforced by other factors, classic sources of bureaucratic inertia, stacking up against the law.

The department had played no part in originating the law, was not identified with its passage and so had no real stake in its success. If it had, the attitude of the department staff might have been different. Initiation of a law, Truman has observed, "implies a commitment to a particular line of policy" and there was no such commitment towards the drug law. 7

Peter Hiam, department hearings officer and later its counsel, agreed "It would have been low priority because the department hadn't filed the bill, .." Likewise, Serlin said "some people in the commissioner's office told me it would have been better if the department had had a hand in sponsoring the law."

If the fact that the department had not been involved in its origin hurt the law's chances, the Legislature's tight-fistedness killed them. It was common enough for the Legislature to pass a bill and then fail to appropriate funds for it. "The Legislature passes all sorts of bills but doesn't give the administering department the funds," Richard Fleming, legislative counsel for the health department, said. Commissioner Frechette
"In state government, nothing is easy. You don't get appropriations. You don't get the money you need."

In the case of the drug law, the Legislature could afford to be cavalier. There were no influential interest groups lobbying for the funds. Though consumerism was on the upswing, it would be a while before the appearance of consumer groups with sufficient clout to make the lawmakers think twice before refusing to fund a bill like Serlin's.

There was of course one legislator who wished for the law to succeed. But Serlin had no clout with the legislative leadership or fellow lawmakers. Even an outsider like Lichtenstein knew Serlin "wasn't popular with the leadership." His fellow legislators may have had to pass his bill because they could ill afford to kill it. But funding it when there was no pressure to was another story.

Frechette, moreover, was unwilling to divert funds from existing programs for a program to educate the public about the law. "It (the drug law) was one of 100 separate programs I administered," he said.

Yet, despite lack of funds and apparent hostility to the law in the department, there still existed a slim chance for its success. The department's Food and Drug Division employed 11

* Maurice Donahue, Senate president when the Serlin bill was introduced, and Duane Lochard, in New England State Politics, agree that Americans for Democratic Action, though vocal and long active in the Legislature, had little power for impact. Its impact would be strengthened when it allied with newer consumer groups such as Mass. Pirg in the later 1970's.
inspectors whose duties included monitoring pharmacies. Division Director George Michael pointed out that those inspectors could have been used to monitor prescriptions to determine if they were written according to law, and if they were not, to encourage pharmacists to urge doctors to follow the law.

But Frechette did not give the Food and Drug Division responsibility for the law. In the manner of bureaucracies, where personality can supersede program, Frechette and Michael, a chemist and 25-year veteran of the department, were perpetually at odds.

"Frechette always had a feud going with Michael and he wasn't going to give him any new responsibilities," Lichtenstein said. Hiam offered a similar though stronger appraisal: "He (Frechette) couldn't stand him."

Michael, for his part, wanted the law assigned to his division and says he favored it. "They didn't give it (the law) to me because I'm an unmitigated bastard. I would have enforced it."

There are many who agree with Michael's self-estimate. Harvey Friedman, a University of Massachusetts political science professor and long-time observer of Boston politics, said, "Michael's a wheeler-dealer." Associated Press reporter Steve Cohen, who covers the State House, said Michael has political enemies who "tried to get rid of him several times (from the department) and I don't know what keeps him there." Lucy Farmer, a public health department staff member, said, "Commissioners from Frechette on back had trouble with George and were wary of him and his political connections."
The record shows that in 1966 Michael was indicted on four charges of illegally selling and transporting alcoholic beverages. Frechette said the charges were politically inspired. At any rate they were never prosecuted. Other charges, of improperly inspecting chickens were considered but never lodged against Michael, according to Frechette.

Moreover, there were some questions about whether Michael would have enforced the drug law. "It's natural that Michael would have wanted to torpedo the law," according to Legislative Counsel Fleming. "He's a friend of those he's supposed to regulate." Farmer said: "George is a nice guy but people are afraid of him. He's aligned with what you might call some conservative-minded people."

In retrospect, however, even Frechette agreed that Food and Drug would have been the logical place to put the law. "That's a good question," Frechette replied when asked why Food and Drug was not so selected. "They do have inspectors and it would be ideal to check implementation of the law." Frechette said it was Dr. Burack, chairman of the Formulary Commission, "who didn't want it (the law) to get buried in Food and Drug."

Burack, according to Frechette, "wanted to run" the administration of the law. * Frechette, in this event, still had the commissioner's prerogative to choose a division in which to put the law. It stated that the commission would be in "the Department of Public Health," and no more. Thus, at least implicitly,

* Despite several letters from the author requesting an interview, Burack, who now practices medicine in Indiana, did not respond.
as commissioner, Frechette would have taken over from there. * The law was assigned to the Medical Care Division, headed by Dr. Ann Pettigrew, and was responsible for monitoring medical care facilities such as nursing homes and hospitals, and who got along with Frechette, according to Hiam and Farmer.

The key policy decisions, however, were left to the commission. It made its most fateful in mid-1971, when the formulary was being compiled. The commission drafted for inclusion in the formulary booklet a position paper entitled "The Role of the Physician in the Implementation of the Massachusetts Drug-Formulary." Therein, the commission allowed, the physician could write "no substitute" for the brand name called for on a prescription if, in his judgment, it was appropriate. Though the commission also stressed its hope that physicians would not "use this alternative method indiscriminately," that is just what happened. The interpretation was tantamount to giving physicians -- most of whom were indifferent or hostile to the law -- license to ignore it.

When Serlin heard of the commission's interpretation, he confronted the members he felt were responsible, Burack and Parnes. "I told them 'no substitution' wasn't in the law and what they were writing was their interpretation. I warned them I would stop them." Serlin later reconsidered because a fight with the

* State Sen. Beryl Cohen, who was chairman of the Public Health Committee when it considered Serlin's bill, said "The Department of Public Health would determine where it (the Serlin law) would be administered," and called Michael "politically controversial... There were efforts to keep things from him..."
commission "would only kill the chances for the law." To this
day, Serlin believes the commission's interpretation severely
undermined the law.

Like Serlin, lobbyists for the doctors, druggists and drug
makers were watching the development of the law. "The same
crew that worked it in the legislature didn't stop when it
passed a half dead bill," according to Sen. Beryl Cohen,
D-Norfolk-Suffolk, chairman of the Social Welfare Committee when
it considered the Serlin bills. "They (the lobbyists) were in
for the whole thing. That crew could have worked easier in the
Executive Department (in public health) than in the Legislature
anyway. They could have exerted more influence." The lobbyists
certainly made their presence felt. Each of three administrators
to the Formulary Commission received repeated visits from lobbyists
asking about the progress of the formulary and what drugs it
would and would not include. Lichtenstein tells of one visit:

They'd drop around once in a while. They have
different titles but they're lobbyists. They were
checking to see when it (the formulary) was going to
be published. One time a couple of them came to my
office and when I was talking to one, the other had
an attache case in front of him, on his lap. I
couldn't see what he was doing at first. He was
taking down what I said verbatim. Everything.
They didn't fool around. This was the first law of
its kind in the nation.

The present administrator to the commission, Irving Tattlebaum,

* For the most part the lobbyists were not the same who had
fought the Serlin bill in the Legislature. They were mostly
lawyers or veteran lobbyists. The lobbyists who frequented the
public health department were mostly full-time employees of the
various drug companies such as Clem Delahunt, Upjohn; Al Mercury,
Eli Lily; Fred Weeks, Sandoz; and Michael Feimal, Wyeth. They
also worked in the Legislature. (Interview, Sister Joan Davis,
March, 1975.)
a druggist, says, "I'm quite friendly with the lobbyists here. We've argued back and forth (about the law). That's part of the game."

The formulary was completed and mailed out to Massachusetts doctors and druggists in January, 1972. It took the commission, working with a druggist-consultant, until June 1971 to compile the list of 375 pharmaceutical products for the formulary, and another several months to secure funds for printing and distribution. A public hearing on the formulary was held June 30, during which Dermot Shea, executive secretary of the Consumer's Council, declared:

Surely in this day of rising medical costs the physicians of the commonwealth must be or should be interested in the use of low cost chemical equivalents to brand name drugs in order to benefit the low income consumer, the retired, and for, in fact, all consumers.

Contrary to Shea's hopeful assertion, the first of several surveys on the effect of the law - taken less than a year after the public hearing and three months after the law took effect - showed that physicians were prescribing generics no more often than before the law. Conducted during April, 1972, by Prof. Harold Silverman, chairman of the department of pharmaceutics at Massachusetts College of Pharmacy, the independent survey queried 200 doctors and druggists in the Boston area. The survey indicated that all but a few doctors were prescribing as they always had. Silverman characterized the general response of physicians as:

We are not ivory-towered scientists and we'll
prescribe as we damn well please. We will not do what some bureaucratic agency tells us. We'll treat our patients the way we want.

Parnes, alternate chairman of the commission, reacted philosophically to news of the survey. "The older doctors will never accept the law. They think it's some form of socialized medicine." Parnes also noted the inconvenience built-in to the new prescribing procedure:

Doctors have found the formulary inconvenient to carry about, bothersome to consult and at times embarrassing to use in front of patients... doctors find trade names easy to use while they find more complicated, sometimes tongue-twisting generic names difficult to remember, pronounce and spell and time-consuming to write. For example, the trade name KWELL is far easier to use than its generic name gamma benzene hexachloride and the brand name PEN-VEE K is less tricky than its generic name phenoxymenthyl pebecillin potassium. 10

Another reason that many doctors did not follow the law was the doubts they harbored about the quality of some generic drugs. Dr. John Turner, then president of Hampden County Medical Society, predicted:

I think the basic fear of doctors is the quality of the generic drugs. We have more confidence in trademark drugs, which we've dealt with for a long time. If I had a headache I wouldn't be too worried about the quality of the drug. If I had blood poisoning, I would... Doctors would have to explain their feelings to patients. You might call it enlightened self-interest. 11

There were doctors who weren't even bothering to explain their feelings to patients but were writing prescriptions as they always had. A survey of compliance with the law conducted by the prestigious medical journal - Medical Economics, found:
...many doctors are writing formulary prescriptions with brand names only -- although this violates the law. Many other doctors are consistently writing 'no substitution' on prescriptions. 12

The law was foundering but several personnel changes were being made in the public health department which would breathe life in the half-hearted administration. Frechette left the department in January, 1972 to work for a private medical program. Lichtenstein's pending request for a transfer to the epilepsy program was granted.

In May, 1972, Dr. William Bicknel was named health commissioner. Where his predecessor had displayed, at best, indifference towards the law, Bicknel was a staunch advocate. He designated Thomas Kerns, a specialist in the Medical Care Division, as the new administrator. In June, at Bicknel's behest, Kerns took the first state survey of compliance with the law. It covered five drug stores and three welfare department offices. The results were similar to the outcome of Silverman's survey. Few doctors were following the law. Less than 25 per cent of the prescriptions for drugs covered by the law included the generic name. 13

So low was the rate of compliance that the Formulary Commission decided to conduct a second survey covering a second three months of compliance under the law. If there was no increase in the rate, Parnes said, the commission would make suggestions to the governor and Legislature regarding what we feel should be done." But Parnes added his personal belief that -

* By order of the governor, the law was applied to all prescriptions in which the state paid part of the cost, a move which later led some liberals to charge that the poor were being given low quality drugs. Interview, Serlin, July 1975
"what we are going to have to do is have a major campaign to convince doctors and druggists to convince the public that generic drugs are good." 14 But without any funds, there could be no such program. With the Legislature's continued failure to authorize appropriations, there would be no funds.

Probably to no one's surprise, the results of the second survey were as dismal as those of the first. In October, 1972, the commission recommended to Bicknell that a fundamental change be made -- that the responsibility for providing the generic version of the drug be shifted in the law from the physician to the pharmacist. Bicknell concurred and asked Hiam, the department counsel, to incorporate the commission's suggestions with some of the commissioner's into a draft of a proposed amendment. Bicknell suggested: an increase in the number of commission members to seven, the additional two being non-medical members, thus opening the commission to consumer advocates; and a provision that the commission's activities be subject to the commissioner's approval, thus bringing the commission into the department. The amendment stated:

A pharmacist shall on receipt of an oral or written prescription containing the name of a drug indicated by brand or generically, dispense an equivalent generic drug listed in the formulary prepared by the drug formulary commission... which is the least expensive drug. If in the opinion of a physician an equivalent generic drug should not be dispensed, he may indicate in the manner of his choice on the prescription "Do not substitute" except that the indication shall not be pre-printed on the prescription. 15

Entitled "An Act Amending the Drug Formulary Law," the bill was introduced as H152 in January, 1973, but never went anywhere. The bill did not "receive much support and the committee (Social
Welfare Committee) was not very favorable to it," according to Lucy Farmer, Bicknell's legislative aide. "We were outweigthed by the pharmaceutical companies," she says. The lobbyists' arguments, used to oppose H182 and later bills to strengthen the drug law, had a familiar ring to them. The legislative fight over generic drugs had started again. Following is a legislative staff summary of those arguments:

- Allowing across the board substitution is anti-consumer because the legislation assumes that drugs listed in the Massachusetts Formulary are generically and therapeutically equivalent. The Massachusetts Drug Formulary is a drug list; no equivalence is assured.

- The bills which propose to amend the present Formulary assume that all drug products having the same generic name will produce an identical therapeutic effect on patients. However, significant variation has been noted in such factors as: time required to take effect, duration of effect, strength of medication actively working in the patient (bio-availability), and individual patient reaction.

- The proposition that the Food and Drug Administration can assure therapeutical equivalence among products having the same chemical composition is a matter of scientific debate. FDA is a regulatory agency and as such does not assure that products made by different companies are therapeutically equivalent.

- Amendments to the present law would seriously damage pharmacy's traditional relationship with medicine, reduce the protection now afforded to consumers from pharmaceutical products that are unsafe and ineffective, and increase the liability risks for both pharmacists and physicians.

- Legislation mandating generics is not necessary at this time as physicians are already prescribing generically approximately 10 per cent of the time, where, in their professional judgment, they feel it is safe to do so.

- Present information indicates that there are no measurable savings to consumers in the states where substitution is legal. Massachusetts DPH cannot cite any substantial savings to consumers.
- Latest consumer surveys dealing with both quality and prescription prices indicate where the average consumer understands the implications of generic substitution, he prefers to have his physician make the decision as to the choice of medicine to be dispensed.

Farmer learned a lot during the short life of H162. She quickly set to work preparing a battle plan to push through a proposed amendment for the 1974 session of the legislature. Her strategy stressed the value of gaining support, as a memo she sent to Irving Tattlebaum, the new Formulary Commission administrator indicates:

We should contact all of the following organizations for support - The Consumers Council Executive Office for Elder Affairs, Executive Office of Consumer Affairs, Legislative Council on Older Americans, Western Massachusetts Public Interest Research Group ... and any other interested groups you can suggest ...

We should prepare a letter to the Legislature along with a brief fact sheet to be distributed prior to the public hearing. The timing will be important.

We should meet with staff members of the Social Welfare Committee before the hearing.

We should prepare a fact sheet for internal use which will enumerate points against the bill that may come up and then list rebuttals.

We should think about planning for the hearings, who we might want to testify, etc., and just generally make sure our people and positions can be well coordinated and our presentation informative, professional and together.

Farmer, Bicknell, Hiam and members of the Formulary Commission subsequently met several times and produced H126, "An Act Amending the Drug Formulary Law," which was introduced in the 1974 session.
The bill was much like its predecessor of 1973. It increased the size of the commission from five to seven; required pharmacists to dispense the least expensive "reasonably available therapeutically equivalent drug unless the physician indicated on the prescription 'Do Not Substitute'; and required pharmacists to decline to prescribe a drug that, in his opinion, "was not of acceptable quality.'

The bill also included a provision that had been suggested by the commission: a $100 fine for any pharmacists who filled a prescription not written lawfully. That no one in the department or on the commission ever seriously proposed such a fine for doctors who disobeyed the law reflects the relative esteem in which the two professions are held. * It may also reflect professional sympathy on the part of the physicians on the commission and in the department.

Nonetheless, the amendment accorded the pharmacist a greater role in the prescription process than he had at the time. This no doubt was because of the influence of the commission's administrator, Tattlebaum, who was a druggist, and Denmark, a commission member and president of the Board.

* In a letter dated Nov. 20, 1973 Andra Hotchkiss, deputy general counsel of the Department of Public Health, indicated that, given the existence of the Formulary Commission position paper allowing the doctor to decide when to prescribe generically, and given the lack of sanctions for violators of the law, no prosecution would be possible.

Then-Atty. Gen. Robert Quinn and Serlin both said there were discussions about doctor-violators of the law, but punishing them was never seriously considered.

of Trustees of the American Pharmaceutical Association. (The APhA had issued a white paper in 1971 in effect advocating the use of generics as part of its demand for recognition of the druggist's role as purchasing agent for the consumer.)

Likewise, American society-at-large was becoming more consumer conscious. A good indication of this development in Massachusetts was the unusually large number of amendments to the drug law that were filed in the 1974 session. H126 was one of four aimed at strengthening the law, which once had trouble getting passed. But Ralph Nader was a household word by 1974. In that year, moreover, Nader and a coalition of consumer groups filed a bill in the Congress to create a Consumer Protection Agency to protect consumer rights on the federal level.

National attention was focused on the generic drug issue in December, 1973 when Casper Weinberger, secretary of the Department of Health, Education and Welfare, announced that the federal government would be reimbursing druggists who filled prescriptions for Medicaid and Medicare only for the lowest cost version of a drug. The cost control proposal, known as the Maximum Allowable Cost program, was estimated to have a savings potential of $50 million its first year and more later based on a $3 billion federal drug expenditure annually.

Still, Farmer and her colleagues were surprised at the enthusiasm for the generic drug issue in 1974. "The 1974 bill created the most hoopla," she says. "There hasn't been as much enthusiasm for a (generic drug) bill since."
On Feb. 26 the four proposed amendments were given a hearing before the Social Welfare Committee, whose makeup had changed considerably since the Serlin days. Legislators had retired or were defeated and were replaced, on the whole, by younger and more liberal representatives. Similarly, the audience at the hearing was of a different character than in the days when Serlin sat on the committee. Instead of being filled with lobbyists opposed to the generic drug law, the audience was filled with supporters. In the audience were representatives of the consumer oriented Massachusetts Public Interest Research Group, Americans for Democratic Action and State Sen, Alan Sisitsky, D-Springfield, a leading Senate liberal who had filed the other drug bills.

Bicknell, testifying for the department's bill, predicted that the American Medical Association would oppose the bill because of "economic interests" that bear "no relationship to the welfare of the patient."

It is still difficult to separate economic interests and professional standards. I am told that 42.8 per cent of the AMA revenue, or $13.6 million is derived from drug advertising in various journals of the American Medical Association.

Bicknell's words were not warmly received by Senate Committee Chairman Jack Backman, D-Brookline. He demanded that Bicknell back up his charges or withdraw them. But Bicknell stood fast and refused to withdraw the charge. "He (Backman) went up the wall," Bicknell says. "His reaction was very atypical. He's usually very liberal." Backman may have been angry over what he thought was the Department of Public Health's heavy-handedness.
Sister Joan Davis, a member of Backman's staff, says, "The hearing turned into a real inquisition as to why the Welfare Department hadn't been in on a lot of the negotiations for the bill, and was it trying to turn the elderly and the poor into second class citizens" by requiring state-financed health programs to use generic drugs.

Whatever the reason for Backman's hostility, it spelled doom for a stronger drug bill in 1974. The committee gave the department bill an unfavorable reading and reported out the "more innocuous" - in Sister Davis's words - ADA bill. The legislative session ended with no final action taken on it.

But towards the end of the 1974 session, House Speaker David M. Bartley, D-Holyoke, announced the creation of the Health Care Committee. It was indicative of the growing interest in health related matters. Bartley, according to Farmer,

... felt that health was certainly a coming thing. He felt there would be more and more interest in health-related issues and that there ought to be a substantive committee to deal with health care matters. It was recognized as a national trend.

Also, in late 1974, Sister Davis took a step that raised hopes anew for a stronger drug law. As she recalled:

We were faced with a situation where so-and-so said this and so-and-so said that, but never to each other, with a third person who's working on the legislation, there. That's what I decided to do. I asked the chairman (Social Welfare Committee Chairman Rep. Charles Flaherty, D-Cambridge) and he said sure, go ahead.

Sister Davis called together the drug company lobbyists and consumer representatives and held a series of meetings to forge a compromise. She succeeded:
It was a great thing to see happen. People from both sides came in and we obtained a consensus through about six or seven meetings.

The consensus was tested when the Health Care Committee held hearings on the half dozen bills filed to strengthen the drug law in the 1975 session. The bills were now all Senate rather than House-originated. "It's easier to get a bill passed through a 40-member body like the Senate than a 240-member body like the House," was the reason for the change, according to Peter Lappin, a member of the Health Care Committee.

On March 24, 1975, the committee held a hearing on the bills. Crowding the hearings were supporters and opponents of the drug law, now ostensibly brought together to band behind one bill that would emerge and become law. Gov. Michael Dukakis, who as a representative in 1970 had cast a vote for the Serlin bill, sent written testimony:

I would like to express my support for the bills before your committee that would strengthen the Generic Drug Law ... The legislation before you would further the intent of the 1970 law and deal with some of the problems that became apparent during its implementation.

... I would only add that, in addition to the potential savings for Massachusetts consumers, which have been professionally estimated to be approximately $15-20 million, the savings to the state itself in prescription costs for Medicaid patients would be in the neighborhood of $3-4 million.

The bill representing the consensus, S 1947, was indeed reported out favorably by the committee. It incorporated several changes in earlier bills filed by the public health department but being a compromise was substantially weaker. Entitled "An Act Clarifying the Generic Drug Law," it required that each
prescription contain two printed lines, "interchange permitted," and "dispense as written." One was to be signed by the physician. If neither was signed, the prescription was invalid. If interchange was permitted, the pharmacist was to fill the prescription with "a less expensive reasonably available interchange drug product as listed in the most current formulary." 27

The use of "interchange drug product" for generic drug was no idle phrasemaking. It was a deft verbal sidestep of the dispute over the quality of generic drugs, which in earlier bills, had been referred to as "equivalent." The use of that term, according to Formulary Commission administrator Tattlebaum, was "like waving a red flag in front of the drug company lobbyists."

"Interchangeable drug product" was defined in the bill as "a product containing a drug or drugs in the same amount of the same active ingredients in the same dosage form as other products with the same generic or chemical name." 28

A proposed budget for the Formulary Commission, which would be expanded from five to seven members under the bill, was drawn up by Sister Davis: Cost for the first year was estimated at $49,806. 29

As it turned out, however, there was no need to worry about funding. The compromise did not survive for long. When S 1947 was in the Ways and Means Committee, Bernashe managed to tack an amendment onto the bill which consumer supporters of a stronger drug law considered anathema. The Bernashe amendment would have delayed implementation of a stronger law, by tying
it to the list of drugs that would be covered under the federal 
MAX program proposed in 1973 by Sec. Weinberger. The list was 
not completed and, according to the ADA's Williams, was not 
expected to be completed for several years. 30

Consumer advocates saw the amendment as a sellout on the 
part of Bernashe to drug lobbyists. His amendment and S 1947 
died in Ways and Means. 31 Once again, the hopes for a stronger 
drug law had proved to be premature.

* * * * * * * * * * *

At this writing, a new amendment to strengthen the drug 
law, similar to S 1947, but sponsored by Rep. Louis Bertonazzi, 
D-Milford, was being considered by the 1976 session of the 
Legislature.

Bertonazzi said he was "pretty confident" that that the bill 
would "not be sidetracked this year."

Even if it did pass, however, that would by no means 
guarantee that the new law would be observed. As the sorry 
state of the present drug law shows, there is sometimes a great 
difference "between the reality and the pronouncement" regarding 
new laws, according to Speaker of the House David M. Bartley, 
D-Holyoke.

Bartley, who seems to have taken an attitude of benign 
eglect towards the Serlin bill said "the legislature sets the 
ideal (in legislation) and the goal of that ideal oftentimes 
takes five to seven years to be refined, to fully work."

But Bartley added that what he calls "the technological
question" regarding the drug law -- the bioequivalence issue -- "has never been answered at least to my satisfaction; is there such a thing as a true generic equivalent?"

That question will be further explored, and the author's conclusions will be presented, in the next chapter.
CHAPTER IV

CONCLUSION

The experience of the Generic Drug Law gives credence to Edgar Litt's observation that "there is little professional policy orientation in the operation of (Massachusetts) state government." ¹

Political considerations were foremost while the bill was in the Legislature for three years and later when the law was in the Department of Public Health.

This was in part because the drug issue came at a time when the state was undergoing a political transition. The years 1966-70 were years in which the state was making "the vital turn from the old ethnic to new pragmatic politics." ²

The stage had been set by economic and social changes in the 1950's and early 1960's. First, the state's economic base shifted from older industries that had thrived during the war to more modern ones such as electronics and research. That shift, in turn, attracted a new middle class work force of highly educated persons.

They settled where the industries were, often in the suburbs on land less expensive than in the central cities - on Route 128, outside Boston, for example. To these suburban settlements were added younger and more mobile urban residents who were attracted by the new industries, the distance from the cities, or both. ³

This new middle class demanded a more sophisticated leadership than did the ethnic-oriented constituency that characterized post-war Massachusetts politics. This constituency was fading with
the assimilation of the offspring of immigrant and first and second generation Americans. As the 1960's opened, Duane Lockhard wrote:

...the pull of ethnic association is on the decline. One measure is the concurrent decline of the old fashioned political boss and his kind of political machine which depended so much on the bewilderment of ethnic minorities for votes. (p. 308) 4

So much was it declining that in the 1966 and 1970 elections a "whole generation of political leaders" were replaced by legislators tending to be more "public regarding" or receptive to the social concerns that characterized the 1960's.

Such liberal legislators were in the minority during the late 1960's but managed at times to forge a working alliance with liberal-to-moderate Republican legislators and governors of that period. The result, one writer noted, was that the Legislature "rolled along like a great big liberal machine churning out social programs and plodding through thickets of obstructionist politics." 5

The Generic Drug Law, then, was among the "remarkable progressive legislation" of the time, as another writer called it. In 1970, for example, in addition to the drug law, the Legislature also passed America's first no-fault insurance law, a "bill of rights for consumers," and a consumer unit pricing law. 6

But the drug law was doomed to failure. It lacked a solid base in either the new consumer, issue-oriented politics or the old-style politics that coexisted together in the late 1960's.
State Rep. I. Edward Serlin, D-Mattapan, was of the old politics, but had few friends among his contemporaries. His independent nature, the fact, in Senate President Maurice Donahue's words, that Serlin was "a solo performer rather than a team player," alienated the practitioners of the old politics. His independent nature, however, also kept at a distance the liberal-oriented legislators and lobby groups that would have been natural supporters of his bill.

Serlin, a Jewish lawyer elected to represent an urban Jewish district, was feeling quite severely the effects of white flight from Mattapan: it was to win votes with the elderly whites who remained in his district, that he filed the generic drug bill.

The bill aimed at cutting drug costs, and he thought it would be of special benefit to the elderly. But they were virtually powerless to help him pass it.

Serlin unwittingly played the role of what Prof. James Q. Wilson has called the policy entrepreneur, "-- one who must appeal to an unorganized majority, the members of which may not expect to be substantially or directly benefitted by the law."

Serlin's independent nature contributed to this circumstance in two ways: 1) by keeping at a distance natural allies like the few existing liberal-oriented interest groups; and 2) by incurring the enmity of several key legislative leaders, at least to the point where they were inclined to accept the arguments of opposing lobbyists or were indifferent to Serlin's bill.

His failure to muster any organizational support in behalf
of his bill, Serlin later admitted, was a major mistake.
"That's one thing I would do differently if I were in the Legislature again," he said. "I would have found some organization that was interested in the bill and I would have had that organization fighting for that bill. Human nature being what it is, no one wants to help another person if the other person gets all the honor and glory."

Serlin also regrets not having realized the impact his bill would have - especially the opposition it would engender. "Sometimes you don't know if it's important. This type of bill, I should have realized, was extremely important. I should have obtained the co-sponsorship of, say, senior citizens or different consumers' groups. I didn't realize the importance of this. So, I would say to you if you're going to file legislation, I say it's wonderful to file it in your own name but you won't get lasting support unless you file it in conjunction with some supporting organization."

Support was a prerequisite for the drug bill because of the nature and extent of the lobbying against it. It was the lobbying that most set the experience of the drug law apart from other bills passed at the time.

The nature of the lobbying was rare because of the participation of doctors and druggists, who, given their position in society as professionals, were bound to have a special impact on legislators.

The other unusual circumstance was the high number of
lobbyists — more than one legislator commented on the intense efforts and number of lobbyists.

It was this size and intensity of the interest group activity, rather than the content -- the question of drug safety which the groups raised -- that was the decisive factor in blocking the Serlin bill.

No less an authority than Donahue, then president of the Senate, which twice blocked the Serlin bill, said the safety factor of generics was at best only secondary in importance.

Another striking feature of the lobbying was the easy access which the lobbyists had to the legislative policy making process. Merck lobbyist Paul Burns and Dunn, for example, were called on for advice and actually assisted in the drafting of the generic drug amendments. Such striking access was in one sense afforded by the dominance of the Democratic party in the House and Senate.

Under such conditions, as V. O. Key and others have noted, conservative interests with money to spend manage to influence government to the exclusion of other interests. Expanding on this, Duane Lockard has noted:

...in one party states it is easier for a few powerful interests to manage the government of the state without party interference since the parties are not representative of the particular elements that might pose opposition to the dominant interest groups. The parties do not represent the have-less elements for the simple reason that politically there is no necessity to do so.
Given this dominance, then, what was chiefly responsible for the drug bill's ultimate passage? Prof. Wilson wrote of his policy entrepreneur, that "Without special political circumstances -- a crisis, a scandal, extraordinary majorities ... the support of the media -- the normal barriers to legislative innovation (by the entrepreneur) may prove insuperable." Such a special political circumstance was primarily responsible for the passage of the drug bill: The support of the media in the person of Thomar Gallagher, Boston Herald Traveller columnist.

Like Serlin, his friend, and Dunn, his nemesis, Gallagher was of the old politics and was not particularly prone to support in his columns particular issues, such as the drug bill. His column was widely read in the State House and when he did take on the generic drug issue, legislators were apt to take notice.

Moreover, Gallagher created the belief among legislators that there was mushrooming public sentiment on behalf of the drug bill. Because what legislators believe is of primary importance, the fact that there was no great public support for the bill, as later indifference to the law showed, is beside the point.

Several key legislators, Speaker David Bartley and Senator Beryl Cohen among them, agree that Gallagher's columns were the key to the bill's passage. Serlin said, "Gallagher was a powerful factor. He got me going off the ground when I filed it. He was a big part, a big reason for the success, if you can call it that."
Even lobbyist Dunn gives Gallagher credit:

It (the bill) passed largely through the efforts of Gallagher. All the legislators down here are conditioned to editorials and editorial-like pieces that tout some bill or try to kill some bill. They are very influential.

This suggests that the press can play a positive and sometimes decisive role in the passage of consumer legislation. But the treatment of the law once it was passed and passed into the hands of the Department of Public Health suggests an unfortunate corollary: that the politics of administration can undo the positive work of the press -- by undermining this same consumer legislation.

The ideal administration, Max Weber has written, is bureaucracy in which considerations of emotion or sentiment are excluded and in which authority is structured in terms of impersonal positions and offices rather than specific identifiable individuals. 8

Weber of course meant this description as an ideal, and allowed for effects of informal relationships and other factors. However, the performance of the Department of Public Health regarding the drug law was the antithesis of rational bureaucratic administration. Politics not policy was the first consideration.

For example, the decision of Health Commissioner Alfred Frechette not to push for implementation of the law, and not to give this responsibility to George Michael, deputy commissioner in charge of the Food and Drug Division, was based on personal and political, not policy, considerations.

The Formulary Commission and its effects on the law
further illustrate non-policy considerations, as well as the unintended effects of legislation. The creation of the commission to compile the formulary, as Dr. Leo Parnes had feared, delayed implementation of the law for more than a year.

And the professional sympathies of the doctor-members of the commission showed up in the position paper that it drafted, stating, in effect, that doctors could depart from the lawful prescription-writing procedure if they felt they should. This and the lack of sanctions resulted in the wholesale disobedience or indifference toward the law by doctors.

In summary, the demise of the law in the health department illustrates what policy analyst Larry Wade has noted: "Neither theory nor institutions exist for the sustained protections through public controls of consumer as opposed to producer interests." The latter are well organized while the former are not. Wade further wrote:

...the impulses which lie behind reform-inspired regulations invariably lose their force -- become quiescent themselves.

...when the parties involved are, on the one hand, a well-organized and well-financed producer group with a permanent and major interest in the policy involved and, on the other, an amorphous consumer group without sufficient incentives to sustain long-term involvement with the policy, the initial purpose of the policy is apt to be subverted.

There have been isolated developments in favor of rational administration of the drug law -- the arrival in the health department of such policy-minded administrators as Commissioner William Bicknell and aide Lucy Farmer, for example. However, their arrival came after the damage had been done to the drug law.
Nevertheless, there may be a second chance. As this paper was being completed, Gov. Michael Dukakis (who, as a state representative, had voted for the original law) signed the strengthened Generic Drug Law that had been sponsored by Rep. Louis Bertonazzi, chairman of the Health Care Committee.
FOOTNOTES

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6. Interview, Dr. Leo Parnes, Formulary Commission, September, 1975
7. Op Cit PMA advertising insert, *Subject 4*
11. Interview, Medical *Economics*, April 1, 1974, vol. 51, No. 7, p. 172
15. Op cit, Silverman and Lee, p. 147
17. Ibid, p. 27
18. Ibid, p. 28
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27. New Item A.M.A. Aides Drive on Drug Cost Cut, New York Times, July 20, 1975, p. 21
30. Op cit, Consumer Reports, p. 4
31. Op cit Task Force on Prescription Drugs The Drug Makers and the Drug Distributors, background paper, p. 29
32. Ibid p. 27
33. Ibid p. 28
34. Ibid p. 28
37. Op cit, subcommittee hearings Brand and Generics, Part 5, p. 2394
38. Op cit, Task Force on Prescription Drugs, background paper, p. 29
40. Op cit, Silverman and Lee, p. 169
42. U.S. Senate Select Committee on Monopoly, Competitive Problems in the Drug Industry, Summary and Analysis, (Washington: 1972) p. 33
43. Ibid, p. 34
44. Op cit, Task Force on Prescription Drugs Report and Recommendations, p. 11
45. Ibid, p
47. Ibid
49. Ibid, p. 10
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3. Interview with Harvey Friedman, Prof. of Polical Science, University of Massachusetts, January, 1976.


5. Interview, Maurice Donahue, August, 1975.


13. Ibid., p. 66.


22. Ibid.


24. Ibid.


29. House Bill 2037.

30. Interview, Parnes, op. cit.


32. Ibid. p. 3212.

33. Senate Bill 1360.


35. Senate Bill 1367.

40. Bill History Index, 1970 session, op. cit., p. 3212.
FOOTNOTES

CHAPTER III

2. Senate Bill 1367.
4. Ibid., p. 12.
5. Truman, op. cit., p. 393.
14. Ibid.
16. Background Memo from Sister Joan Davis, Committee on Health Care, March 24, 1975.
17. House Bill 182, op. cit.
18. See discussion in Chapter I.
27. Ibid.
28. Ibid.
29. Background Memo from Sister Joan Davis, op. cit.
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INTERVIEWS


STATE SENATORS: George Kenneally of Boston, Steven Davenport of Boston, Ronald MacKenzie of Burlington, Donald Ryan of Springfield, Maurice Donahue of Holyoke, Sam Harmon of Boston, James Burke of Plymouth, Beryl Cohen of Norfolk-Suffolk and Alan Sisitsky.


LEGISLATIVE STAFF: Sister Joan Davis, Chris Reve, Stella Smith.

LOBBYISTS: Mrs. Connie Williams and Mrs. Elizabeth Parnes of Americans for Democratic Action; Charles Dunn, Robert Holland and John Noonan of the Massachusetts Medical Society; Robert Sylvester, Paul Burns and Edward Carroll of Merck, Sharpe and Dohme; Robert Gallagher of Pharmaceutical Manufacturers Association; Clement Delahunt of Upjohn; Lem Permit and John Zamparelli of the Massachusetts Pharmaceutical Society; Dermit Shea of the Massachusetts Consumers Council; and Nate Parvin of the Massachusetts Association of Consumers.


* - Denotes Republican.
By Mr. Serlin of Boston, petition of I. Edward Serlin that physicians prescribing certain drugs be required to use generic names on such prescriptions. Social Welfare.

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Sixty-eight.

AN ACT PROVIDING FOR THE USE OF GENERIC NAMES FOR PRESCRIPTION DRUGS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Every registered Massachusetts physician who prescribed 2 drugs for his patients shall in every prescription calling for 3 drugs, use the generic name in addition to the brand name 4 if any.
The committee on Bills in the Third Reading, to whom was referred the bill providing for the use of generic names for prescription drugs. (House No. 4395), report recommending that the same be amended by substituting therefor a new draft entitled "An Act providing that when a drug is prescribed by brand name its generic or chemical name shall be included in the prescription." (Senate No. 1109), and that, when so amended, the same will be correctly drawn.

For the committee,

JOHN E. HARRINGTON, Jr.
AN ACT PROVIDING THAT WHEN A DRUG IS PRESCRIBED BY BRAND NAME ITS GENERIC OR CHEMICAL NAME SHALL BE INCLUDED IN THE PRESCRIPTION.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Chapter 112 of the General Laws is hereby amended by
2 inserting after section 12B the following section:
3 Section 12C. Every physician who prescribed a drug by
4 brand name shall, in every such prescription, oral or written,
5 also included the generic name or the chemical name of such
6 drug, if any, whenever, in his opinion, such generically or
7 chemically named drug is the therapeutic or curative equiva-
8 lent of the brand named drug.
By Mr. Serlin of Boston, petition of I. Edward Serlin that physicians prescribing certain drugs be required to use generic names on such prescriptions. Social Welfare.

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Sixty-Nine.

AN ACT PROVIDING THAT WHEN A DRUG IS PRESCRIBED BY BRAND NAME ITS GENERIC OR CHEMICAL NAME SHALL BE INCLUDED IN THE PRESCRIPTION.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Chapter 112 of the General Laws is hereby amended by inserting after section 12B the following section: -

3 Section 12C. Every physician who prescribed a drug by brand name shall, in every such prescription, oral or written, also include the generic name or the chemical name of such drug.
The committee on Bills in the Third Reading, to whom was referred the Bill providing for the use of generic names for prescription drugs (House, No. 424) report recommending that the same be amended by the substitution of the accompanying bill (House, No. 5006).

For the committee,

MARY B. NEWMAN.
THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Sixty-Nine.

AN ACT PROVIDING THAT WHEN A DRUG IS PRESCRIBED BY BRAND NAME ITS GENERIC OR CHEMICAL NAME SHALL BE INCLUDED IN THE PRESCRIPTION.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Chapter 112 of the General Laws is hereby amended by
2 inserting after section 12B the following section:—
3 Section 12C. Every physician who prescribes a drug by
4 brand name shall, in every such prescription, oral or written,
5 also include the generic name or the chemical name of such
6 drug, if any.
By Mr. Healy of Charlemont, petition of Robert S. Aronson and other members of the House that provision be made for the use of generic names of drugs prescribed by physicians. Social Welfare.

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Sixty-Nine.

AN ACT PROVIDING FOR THE USE OF GENERIC DRUGS FOR PRESCRIPTION DRUGS WHEN RECOMMENDED BY THE PRESCRIBING PHYSICIAN.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same as follows:

1 Chapter 112 of the General Laws is hereby amended by 2 inserting after section 12B the following section: - 3 Section 12C. A registered physician who prescribes drugs 4 for his patients shall, in every prescription calling for a 5 drug by a brand name, indicate on the prescription whether 6 or not a generic equivalent may be substituted.
By Mr. Serlin of Boston, petition of J. Edward Serlin that physicians prescribing certain drugs be required to use generic names on such prescriptions. Social Welfare.

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Seventy.

AN ACT PROVIDING FOR THE USE OF GENERIC NAMES FOR PRESCRIPTION DRUGS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1. Every registered Massachusetts physician who prescribes 2 drugs for his patients shall in every prescription calling for 3 drugs, use the generic name in addition to the brand name if 4 any.
The committee on Bills in the Third Reading, to whom was referred the Bill providing for the use of generic names for prescription drugs (House, No. 523), report recommending that the same be amended by the substitution of the accompanying bill (House, No. 5222).

For the committee,

RAYMOND M. LaFONTAINE.
THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Seventy

AN ACT PROVIDING THAT WHEN A DRUG IS PRESCRIBED BY BRAND NAME ITS GENERIC OR CHEMICAL NAME SHALL BE INCLUDED IN THE PRESCRIPTION.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Chapter 112 of the General Laws is hereby amended by inserting after section 12B the following section: -
3 Section 12C. Every physician who prescribes a drug by brand name shall, in every such prescription, oral or written also include the generic name or the chemical name of such drug, if any.
By Mr. Kenneally, a petition of George V. Kenneally, Jr. and Ronald C. MacKenzie for legislation to establish a drug formulary in the Department of Public Health. Social Welfare.

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Seventy.

AN ACT ESTABLISHING A DRUG FORMULARY IN THE DEPARTMENT OF PUBLIC HEALTH.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Chapter 17 of the General Laws is hereby amended by
2 adding the following section under the caption DRUG
3 FORMULARY COMMITTEE:

4 Section 13. There shall be in the department a drug formu-
5 lary committee, hereinafter called the committee, to consist
6 of five members to be appointed by the governor from lists of
7 eligible names to be compiled and prepared by the commis-
8 sioner of public health, the commissioner of public welfare,
9 and the consumers' council. Members of the committee shall
10 include individuals possessing recognized competence in the
11 rendering of professional services under, or the administration
12 of, state health programs, and a majority of the members
13 shall be practicing members of the professions authorized to
14 render professional health services under state-financed
15 health programs. Each member of the committee shall serve
16 at the pleasure of the governor.
17 "The committee shall prepare a formulary of generic or
18 chemical and brand names of drugs and pharmaceuticals
19 which are considered by the committee as effective. The
20 sources for such a document shall include a list of drugs
21 most frequently prescribed by licensed physicians in Massa-
22 chusetts, the formularies of various hospitals in Massachu-
23 setts, and any additional formularies available from any
agency or department of the United States and of other states. The committee shall determine and include in its formulary, with respect to each drug, the maximum amount which will be paid under the state welfare program to vendors, the usual cost of each brand name when obtained by community pharmacists in usual quantities from the most frequently used source of supply, and an index of drug costs to community pharmacists which clearly indicates the degree of cost variation existing between listed brand names used for comparable therapeutic purposes. The committee shall provide for distribution of copies of such formulary and revisions thereto amongst physicians licensed to practice within this commonwealth and to other appropriate individuals and shall supply a copy to any person on request upon payment of cost of printing. Such formulary shall be revised from time to time, but in no event less frequently than once a year, so as to include new pertinent information on drugs approved for inclusion or drugs to be deleted and to reflect current information as to drug costs and therapeutic efficacy of drugs and pharmaceuticals."

Any person or party in interest aggrieved by a finding or report of the committee may appeal to the supreme judicial court for a review of such report or finding. For the purposes of this section, the term "brand name" shall mean the name that the manufacturer of such drug places on the container thereof at the time of packaging, and the term "generic name" shall mean the chemical or established name of such drug or pharmaceutical.
AN ACT PROVIDING FOR THE PRESCRIPTION OF DRUGS BY THEIR GENERIC NAMES.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Chapter 112 of the General Laws is hereby amended by inserting after section 12B the following section: -

Section 12C. Any preparation prescribed by a physician for which a generic name exists shall be prescribed by its generic name. A brand name may be added to such prescription and shall be supplied by the dispensing pharmacist when in the discretion of the prescribing physician it is so required.
Senate, April 8, 1970.

The committee on Ways and Means, to whom was committed the Senate Bill establishing a drug formulary in the Department of Public Health (Senate, No. 927) also based on the Senate Bill establishing the drug policy commission (Senate, No. 979), and the House Bill providing that when a drug is prescribed by brand name its generic or chemical name shall be included in the prescription (House, No. 5222), reports recommending that the bill, Senate, No. 927, same ought to pass, with an amendment, substituting a new draft entitled "An Act Establishing a Drug Formulary Committee in the Department of Public Health" (Senate, No. 1360).

For the committee,

JAMES F. BURKE.
The committee on Bills in the Third Reading, to whom was referred the bill establishing a drug formulary committee in the department of public health (Senate, No. 1360), reports recommending that the same be amended by substituting therefor a new draft entitled "An Act establishing a drug formulary commission in the department of public health and requiring physicians, when prescribing drugs by brand name, to include generic or chemical name of such drug" (Senate, No. 1367), and that, when so amended, the same be correctly drawn.

For the committee,

JOHN E. HARRINGTON, Jr.
SENATE - No. 1367

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Seventy.

AN ACT ESTABLISHING A DRUG FORMULARY COMMISSION IN THE DEPARTMENT OF PUBLIC HEALTH AND REQUIRING PHYSICIANS, WHEN PRESCRIBING DRUGS BY BRAND NAME, TO INCLUDE THE GENERIC OR CHEMICAL NAMES OF SUCH DRUGS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1. Section 1. Chapter 17 of the General Laws is hereby amended by adding the following caption and section:

   DRUG FORMULARY COMMISSION

2. Section 13. There shall be in the department a drug formulary commission, hereinafter called the commission, to consist of five members to be appointed by the governor from lists of eligible names to be compiled and prepared by the commissioner of public health, the commissioner of public welfare, and the consumers' council. Members of the commission shall be individuals possessing recognized competence in the rendering of professional services under, or the administration of, state health programs, and a majority of the members shall be practicing members of the professions authorized to render professional health services under state-financed health programs; provided, however, that not more than one member of said commission shall be a registered pharmacist.

3. Each member of the commission shall serve at the pleasure of the governor.

4. The commission shall prepare a formulary of generic or chemical, and brand names of drugs and pharmaceuticals considered by the commission as effective. The sources for such document shall include a list of drugs most frequently prescribed by licensed physicians in Massachusetts, the formularies of various hospitals in Massachusetts, and any additional formularies available from any agency or department of the United States and of other states, but shall not include
drugs which are the subject matter of rights issued by the United States Patent Office or obtained under the laws relating to trade names and trade marks. The commission shall provide for distribution of copies of such formulary and revisions thereto amongst physicians licensed to practice within the commonwealth and to other appropriate individuals, and shall supply a copy to any person on request upon payment of the cost of printing. Such formulary shall be revised from time to time, but in no event less frequently than once a year, so as to include new pertinent information on drugs approved for inclusion or drugs to be deleted and to reflect current information as to the therapeutic efficacy of drugs and pharmaceuticals.

Any person or party in interest aggrieved by a finding or report of the commission shall be entitled to a judicial review thereof as provided in section fourteen of chapter thirty A. For the purposes of this section, the term "brand name" shall mean the name that the manufacturer of such drug places on the container thereof at the time of packaging, and the term "generic name" shall mean the chemical or established name of such drug or pharmaceutical.

Section 2. Chapter 112 of the General Laws is hereby amended by inserting after section 12C the following section:

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Section 12D. Every physician who prescribes a drug listed in the formulary prepared by the drug formulary commission under section thirteen of chapter seventeen by brand name shall, in each such prescription, oral or written, also include the generic name or the chemical name of such drug, if any.
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Accompanying the twelfth recommendation of the Department of Public Health (House, No. 170). Social Welfare.

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Seventy-three.

AN ACT AMENDING THE DRUG FORMULARY LAW.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Chapter 112 of the General Laws is hereby amended by striking out section 12D and inserting therefor the following:

Section 12D. A pharmacist shall on receipt of an oral or written prescription containing the name of a drug indicated by brand or genericly, dispense an equivalent generic drug listed in the formulary prepared by the drug formulary commission under section thirteen of chapter seventeen, which is the least expensive such drug. If in the opinion of a physician an equivalent generic drug should not be dispensed, he may indicate in the manner of his choice on the prescription "Do Not Substitute" except that the indication shall not be pre-printed on a prescription.

1 SECTION 2. Section 13 of chapter 17 of the General Laws as inserted by Chapter 717 of the acts of 1970, is hereby amended by striking out the word "five" in the first sentence and substituting therefor the word: - seven.

1 SECTION 3. Said section 13 is further amended by striking out the second sentence and substituting therefor the following sentence: - Five members of the commission shall be individuals possessing recognized competence in the rendering of professional services under, or the administration of, state health programs at least one of whom shall be a registered pharmacist, and two members shall be selected from the public sector, one of whom shall represent the elderly; provided that not less than three members shall be practicing members of the professions
10 authorized to render professional health services under state-f
11 financed health programs.

1 SECTION 4. Said section 13 is further amended by adding at
2 the end of the fifth sentence thereof the following: - except
3 when such patented drugs are available from more than one
4 manufacturer.

1 SECTION 5. Said section 13 is further amended by adding at
2 the end of the second paragraph thereof, the following sen-
3 tence: - The commission shall promulgate such regulations and
4 formularies as may be necessary to carry out the purposes of the
5 formulary, with the approval of the commissioner.
The committee on Health Care, to whom was referred the petition (accompanied by bill, Senate No. 673) of Alan D. Sisitsky and Chester G. Atkins for legislation to clarify the generic drug law; so much of the recommendations of the Department of Public Health (House, No. 262) as relates to amending the drug formulary law (House, No. 263); the petition (accompanied by bill, House, No. 1111) of Michael F. Flaherty relative to amending the drug formulary law; the petition (accompanied by bill, House, No. 2099) of the Americans for Democratic Action, John G. King, Angelo M. Scaccia, Charles F. Flaherty, Jr., James Segel, Ronald A. Pina, Melvin H. King, Doris Bunte, Barney Frank, William D. Delahunt and Ann C. Gannett for legislation to promote quality medication at reasonable costs; and the petition (accompanied by bill, House, No. 3858) of Thomas G. Simons and others for legislation to clarify the generic drug law reports the accompanying bill (Senate, No. 1947).

For the Committee,

ROGER L. BERNASHE
AN ACT CLARIFYING THE GENERIC DRUG LAW.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Section 1. As used in this Act, the following words shall unless the context clearly requires otherwise, have the follow-
ing meanings:
4 "department", the department of public health.
6 "interchangeable drug product", a product containing a
7 drug or drugs in the same amounts of the same active ingredi-
ents in the same dosage form as other products with the same
8 generic or chemical name.
9 "practitioner", a physician, dentist, veterinarian, podiatrist,
10 scientific investigator or other person registered to distribute,
11 dispense conduct research with respect to, or use in teaching
12 or chemical analysis, a controlled substance in the course of
13 professional practice or research in the commonwealth;

1 Section 2. Section 13 of Chapter 17 of the General Laws, as
2 most recently amended by Section 1 of Chapter 717 of the
3 Acts of 1970, is hereby further amended by striking said sec-
4 tion, and inserting in place thereof the following new sec-
5 tion:
6 Section 13. There shall be in the department a Drug Formu-
7 lary Commission to consist of eight members appointed by the
8 Governor. Three shall be practitioners at least two of whom
9 shall be physicians. Three shall be pharmacists, possessing
10 among them experience in clinical pharmacy, clinical pharma-
11 cology, and pharmaceutical chemistry, one of whom shall have
12 had experience with retail pharmacy and one with
13 experience in pharmaceutical manufacturing but none of
14 whom may be affiliated with any manufacturer in particular.
15 Two members shall be lay persons, not involved in the delivery
16 of health care services; provided, that one of two lay appointees
17 shall, by reason of age, training, experience, and/or affiliation
represent the interests of the elderly.

Members shall serve for a term of three years, except, in the incidence of the first appointments under the provisions of this Act, three shall be appointed for a term of three years, three shall be appointed for a term of two years, and two shall be appointed for a term of one year, so that the terms of future members shall be staggered.

The Commission shall prepare a drug formulary of interchangeable drug products to be adopted by regulation by the Department of Public Health. Said formulary shall be based on assessment and evaluation of the present Massachusetts drug formulary prepared by the Drug Formulary Commission under section thirteen of chapter seventeen of the General Laws; the latest official national formulary, or any supplement to any of them, additional pertinent listings of the federal Department of Health Education and Welfare, Food and Drug Administration; other state formularies; those of foreign countries; and the formularies of various hospitals of the Commonwealth, as well as data submitted by manufacturers.

The Commission shall assess and evaluate chemical and laboratory testing data, clinical proof of bioequivalence and therapeutic equivalence where available.

Said formulary shall not include drugs which are the subject matter of patent rights issued by the United States Patent Office. It shall not include those drug products for which bioequivalence is considered essential according to findings of on-going federal testing.

Said formulary shall take effect no later than twelve months from the effective date of this Act.

Section 3. Chapter 112 of the General Laws, as most recently amended by Section 2 of Chapter 717 of the Acts of 1970, is hereby further amended by striking section 12D, and inserting in place thereof the following new sections:

Section 12D. Every prescription written in the Commonwealth by a practitioner shall be on prescription forms containing two lines for the practitioner signature. Alongside the first line shall be clearly printed the words "interchange per-
mitted"; instructing the pharmacist to use an interchangeable
drug product as listed in the formulary. Alongside the second
signature line shall be clearly printed the words "dispense as
written."
The practitioner, by placing his signature on the appropri-
ate signature line, has indicated his dispensing instructions
to the pharmacist. Failure of the practitioner to affix his
signature on one of the designated lines shall invalidate the
prescription.
In cases where an interchange is permitted, as indicated by
the prescriber's signature on the first signature line, the
pharmacist shall dispense a less expensive reasonably available
interchange drug product as listed in the most current formu-
ulary or supplement thereof. He shall also indicate on the label
the fact of interchange and the exact drug product dispensed.
In cases where the practitioner has instructed that the
pharmacist dispense as written, the pharmacist shall dispense
the exact drug product as written by the petitioner.
Proper forms for prescriptions are to be available no later
than six months from the effective date of this Act.
Section 12E. Every pharmacy shall display in a prominent
place that is in clear and unobstructed public view at or near
the place where prescriptions are dispensed, a sign in block
letters not less than one inch in height, which shall read:
"CONSULT YOUR PHYSICIAN CONCERNING THE AVAIL-
ABILITY OF THE LEAST EXPENSIVE DRUG FOR YOUR
USE — IF MEDICALLY ADVISABLE, GENERIC DRUGS
MAY BE LESS COSTLY."
Section 12F. In the event of noncompliance by a pharmacist,
the drug purchaser or consumer may inform the Secretary of
Consumer Affairs of said noncompliance, who shall refer the
matter to the Attorney General of the Commonwealth for
appropriate action.
Section 12G. The Department of Public Health in coopera-
tion with its Formulary Commission shall be responsible for
public education regarding the provisions of this Act.
Section 4. This act shall take effect upon passage.

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Seventy-Six.

AN ACT CLARIFYING THE GENERIC DRUG LAW.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION k. As used in this Act, the following words shall, unless the context clearly requires otherwise, have the following meanings:
2 "department", the department of public health.
3 "interchangeable drug product", a product containing a drug or drugs in the same amounts of the same active ingredients in the same dosage form as other products with the same generic or chemical name.
4 "practitioner", a physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth.
5 The Commission shall prepare a drug formulary of interchangeable drug products to be adopted by regulation by the Department of Public Health. Said formulary shall be based on assessment and evaluation of the present Massachusetts Drug formulary prepared by the Drug Formulary Commission under section thirteen of chapter seventeen of the General Laws; the U. S. Pharmacopeia, or any supplement to any of them, additional pertinent listings of the federal Department of Health, Education and Welfare, Food and Drug Administration; other state formularies; and the formularies of various hospitals of the Commonwealth, as well as data submitted by manufacturers. The Commission shall assess and evaluate chemical and laboratory
testing data, clinical proof of bioequivalence and therapeutic
equivalence where available.
Said formulary shall not include drugs which are the subject
matter of patent rights issued by the United States Patent Office.
It shall not include those drug products for which bioequivalence
is considered essential according to findings of on-going federal
testing.
Said formulary shall take effect no later than twelve months
from the effective date of this Act.

SECTION 2. Section 13 of Chapter 17 of the General Laws, as
most recently amended by Section 1 of Chapter 717 of the Acts of
1970, is hereby further amended by striking said section, and
inserting in place thereof the following new section:

Section 13. There shall be in the department a Drug
Formulary Commission to consist of eight members appointed by
the Governor. There shall be pharmacists, possessing among
them experience in clinical pharmacy, clinical pharmacology, and
pharmaceutical chemistry, one of whom shall have had
experience with retail pharmacy and one with experience in
pharmaceutical manufacturing but none of whom may be
affiliated with any manufacturer in particular. Two members
shall be lay persons, not involved in the delivery of health care
services; provided, that one of two lay appointees shall, by reason
of age, training, experience, and/or affiliation represent the
interests of the elderly.
Members shall serve for a term of three years, except, in the
incidence of the first appointments under the provisions of this
Act, three shall be appointed for a term of three years, three
shall be appointed for a term of two years, and two shall be ap-
pointed for a term of one year, so that the terms of future members
shall be staggered.

SECTION 3. Chapter 112 of the General Laws, as most
recently amended by Section 2 of Chapter 717 of the Acts of 1970,
is hereby further amended by striking section 12D, and inserting
in place thereof the following new sections:

Section 12D. Every prescription written in the Com-
monwealth by a practitioner shall be on prescription forms
containing two lines for the practitioner signature. Alongside
the first line shall be clearly printed the words "interchange
permitted"; instructing the pharmacist to use an interchangeable drug product as listed in the formulary. Alongside the second signature line shall be clearly printed the words "dispense as written."

The practitioner, by placing his signature on the appropriate signature line, has indicated his dispensing instructions to the pharmacist. Failure of the practitioner to affix his signature on one of the designated lines shall invalidate the prescription. In cases where an interchange is permitted, as indicated by the prescriber's signature on the first signature line, the pharmacist shall dispense a less expensive reasonably available interchange drug product as listed in the most current formulary or supplement thereof. He shall also indicate on the label the fact of interchange and the exact drug product dispensed. In cases where the practitioner has instructed that the pharmacist dispense as written, the pharmacist shall dispense the exact drug product as written by the petitioner.

Proper forms for prescriptions are to be available no later than six months from the effective date of this Act.

Section 12F. Every pharmacy shall display in a prominent place that is in clear and unobstructed public view at or near the place where prescriptions are dispensed, a sign in block letters not less than one inch in height, which shall read: "CONSULT YOUR PHYSICIAN CONCERNING THE AVAILABILITY OF THE LEAST EXPENSIVE DRUG FOR YOUR USE - IF MEDICALLY ADVISABLE, GENERIC DRUGS MAY BE LESS COSTLY."

Section 12F. In the event of noncompliance by a pharmacist, the drug purchaser or consumer may inform the Secretary of Consumer Affairs of such noncompliance, who shall refer the matter to the Attorney General of the Commonwealth for appropriate action.

Section 12G. The Department of Public Health in cooperation with its Formulary Commission shall be responsible for public education regarding the provisions of this Act.

SECTION 4. This act shall take effect upon passage.