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THE EFFECT OF THE OMNIBUS BUDGET RECONCILIATION ACT OF 1980 ON COST ISSUES RELATED TO THE PROCUREMENT OF PHARMACEUTICALS

William Bilotti
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OBRA '90 AND DRUG BID PRICES

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE

REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

IN

PHARMACY ADMINISTRATION

UNIVERSITY OF RHODE ISLAND

1993

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THE EFFECT OF THE OMNIBUS

BUDGET RECONCILIATION ACT

OF 1980

ON COST ISSUES RELATED TO

THE PROCUREMENT OF

PHARMACEUTICALS

BY

WILLIAM BILOTTI

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IN

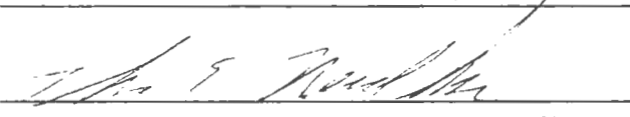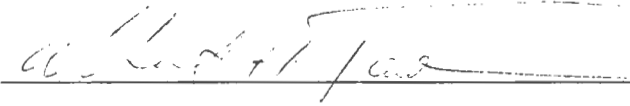PHARMACY ADMINISTRATION

UNIVERSITY OF RHODE ISLAND

1993

MASTER OF SCIENCE THESIS

OF

WILLIAM N. BILOTTI

APPROVED:

    Thesis Committee

       Major Professor _____

_____

_____

_____
DEAN OF THE GRADUATE SCHOOL

UNIVERSITY OF RHODE ISLAND

1993

ABSTRACT

In 1990 the Omnibus Budget Reconciliation Act (OBRA
'90) became law (P.L. 101-508). Language in this statute
requires that drug manufacturers provide rebates to each
state Medicaid program (See Appendix 3) for prescription
drugs purchased through the program. Rebates are calculated
by a formula, but in general are written to reduce drug
acquisition costs of 15% below wholesale acquisition cost,
that is, 15% below the prices paid by wholesalers to the
manufacturers for drugs distributed to the retail class of
trade. These discounts only apply to the prescription drug
coverage portion of the Medicaid[1] program. Though intended
to secure low prices for prescription drugs purchased
through the federal Medicaid program, it was hypothesized as
a basis for this project that OBRA '90 mandated discounts
would result in a cost shifting and increased prices paid by
other market segments, and, that by reducing manufacturer
profits, would reduce funding for manufacturer sponsored
pharmaceutical research.

To explore these hypotheses a population was defined
and a structured, closed end, opinion questionnaire was
devised. A list of qualified bidders for the State of Rhode
Island annual drug bids was selected. This list comprised
an entire universe of manufacturers who are involved in
competitive bidding on the state contracts. The list of 89
vendors, though small in absolute terms, does cover the

available pharmaceutical market as defined by the needs of those patients served by various facilities associated with the State of Rhode Island.

Respondents at central bid addresses were asked to complete anonymous questionnaires. Questionnaire design concentrated on brevity, ease of answer, and on not inducing bias. The only incentive offered to completing the questionnaire was a copy of the results.

It was found that opinions expressed in the questionnaire supported the hypothesis that OBRA '90 would add upward pressure to drug prices in general. Responses suggest that OBRA '90 will have the effect of decreasing manufacturer profit, increasing costs to buyers other than Medicaid, and decreasing respondents ability to offer low prices in competitive bids for both innovator and generic drugs. Within study limitations, modest support was found for the hypothesis that lower manufacturer profits meant less funding for research.

ACKNOWLEDGEMENTS

I wish to express my gratitude to the faculty and to the members of my thesis committee for their time and effort on behalf of this project. In particular, a special thank you to Dr. Albert J. Della Bitta for sharing his knowledge of questionnaire design, and a special thank you to Dr. Norman A. Campbell, major professor, for contributing enormous amounts of time, guidance and encouragement.

DEDICATION

For Matthew and Alexander

PREFACE

In the Spring of 1990, Senator David Pryor sponsored the "Pharmaceutical Access and Prudent Purchasing Act" and the Medicaid Anti-discriminatory Drug Act." In the House of Representatives, Ron Wyden and Jim Cooper sponsored the "Medicaid Prescription Drug Fair Access and Pricing Act". These measures contain some provisions designed to secure for Medicaid some of the discounts on prescription drugs available to other buyers. Significant portions of these three bills were incorporated into the "Omnibus Budget Reconciliation Act of 1990" (OBRA '90). On November 5, 1990, OBRA '90 was signed into law.[2]

Anecdotally, there exists a wide disparity in pharmaceutical pricing offered to the various groups of purchasers considered in this questionnaire. Historically, the Veterans Administration depot pricing has been reputed to be the recipient of the lowest prices and the price paid by the independent pharmacy the highest, while all the other groups have fallen somewhere in between. While the pharmaceutical buyer for the State of Rhode Island, an attempt was made to obtain a list of prices offered to the Veterans Administration to use as a benchmark in gauging the success of Rhode Island's procurement efforts. No one reached at the Veterans Administration would agree to provide these data.

While not supported by specific data, it is a long-

standing complaint among pharmacists that large price disparities in drug purchasing exist. As an extreme example, at one time the General Hospital, State of Rhode Island, was paying one cent each for nitroglycerine patches while the Average Wholesale Price[3] to pharmacies in the same community was one dollar each.[4] In 1990, primarily due to Senator David Pryor, the U.S. Senate became aware that while one U.S. Government agency, the Veterans Administration, was buying pharmaceuticals at bargain prices, another branch of Government, the Health Care Financing Administration for Medicaid, was paying approximately the same price as retail pharmacies, i.e., the highest.[5] The Senate, in an effort to reduce the dollar outlay for Medicaid patients, included certain provisions in OBRA '90 aimed at reducing the prices of drugs to Medicaid.

Language provisions pertinent to this thesis mandate an increasing schedule of rebates (Appendix 3) that will be returned to the Medicaid Program by the manufacturers. The Act benefits only the Medicaid Program expenditures and does not address other markets.

The goal of this research is to explore the effect of OBRA '90 mandated rebates on purchasers other than Medicaid by sending a brief questionnaire to companies active in the annual State of Rhode Island pharmaceutical bid. The questionnaire was sent to the central bid addresses of all vendors on the State of Rhode Island pharmaceutical bid

list.

The questionnaire was composed of 12 questions and four additional classification questions. The classification questions were designed to identify the type of business of the respondents. Classification separated "brand name, innovator" manufacturers from generic manufacturers and "other" businesses. Classification was necessary because OBRA '90 mandates different rebate treatments between generic and innovator manufacturers. Because nonmanufacturers were not specifically addressed by OBRA '90, they will be impacted differently, possibly only peripherally. Classification, then, allowed assessment of respondents market position when considering their answers.

Responses were analyzed to study bidders opinions on the impact of OBRA '90 on their activities. Questions were designed to explore certain possible areas of OBRA '90 impact thought to be relevant to their daily business routine, that is, the sale of pharmaceuticals, and, particularly, sales by competitive bidding. Essentially, the information sought was: What will be the effect on drug prices in market segments other than Medicaid? Will mandated discounts be a disincentive to manufacturers to provide special pricing to buying groups and institutions? If profit margins are reduced, will funding for new drug research decline?

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ISSUES AND HYPOTHESES

ISSUES:

The passage of the OBRA '90 budget legislation included provisions designed to reduce the cost of prescription medication to Medicaid (see also, Introduction). The Act mandates that rebates (Appendix 3) shall be made to Medicaid ultimately amounting to as much as 15% of the "Average Manufacturers Price" (AMP). AMP is "the average price paid by wholesalers for drugs distributed to the retail class of trade." Should a manufacturer offer "any buyer" a lower price than can be had with the rebate schedule, the Act requires that Medicaid receive additional rebates to equal that lower price. This is referred to as the "best price" and is defined by OBRA '90 as ". . . the lowest price paid by any purchaser (exclusive of depot prices and single award contract prices as defined by an federal agency) . . . exclusive of nominal prices."

In the literature reviewed, the OBRA '90 mandated Medicaid rebates appear to be unprecedented. In effect, the federal government has dictated pricing methods to private manufacturers where previously pricing had been dictated by market considerations. While evidence is available that various groups have been able to negotiate prices in the past, this has been through bargaining power:

> "The characteristic of competitive market conditions was found to significantly influence lowering of prices offered to purchasing groups."6

Also it is known that prices do vary:

> ". . . a major limitation of earlier drug pricing
> studies was that the data were obtained from published
> price lists, which do not reflect the actual prices
> paid. This finding is similar to the conclusion
> reached by Stigler and Kindhl on the basis of their
> study of several industrial markets. They found that
> published price lists tend to be rigid and do not
> accurately reflect the behavior of actual transaction
> prices. For nationally sold products, actual
> transaction prices tend to be lower and display a much
> more flexible behavior pattern than catalog prices."[7]

The OBRA '90 rebates caused much speculation that a

cost shifting would be felt by non-Medicaid purchasers, as

manufacturers conceivably sought to recapture lost profit

margin:

> "Pharmaceutical manufacturers are said to be raising
> prices to other purchasers, including other government
> agencies, to recover the discounts being offered to
> Medicaid."[8]

Indeed, almost as soon as OBRA '90 was passed, concerns

about price increases to non-Medicaid purchasers began to

appear in the media. The September, 1990, issue of The

Consultant Pharmacist warned.

> ". . . economic realities suggest there is a strong
> likelihood that major manufacturers will shift costs to
> private payers as a result of the proposal's
> implementation. . ."[9]

And, as early as January 14, 1991, Senator David Pryor is
reported as writing that there are:

> ". . . numerous confirmed reports that some drug
> manufacturers are in the process of reducing discounts
> . . . breaking long-term contracts, and refusing to
> negotiate in good faith over price."[10]

While there was much conjecture about OBRA '90's effect

on pricing, the literature search uncovered no systematic

research on the topic except for an informal anecdotal

survey conducted by the American Society of Hospital

Pharmacists that,

> ". . . according to ASHP (American Society of Hospital
> Pharmacists) . . . (their survey) . . . confirms what
> it predicted last year, that the law would have the
> unintended effect of raising drug costs to hospitals,
> HMO's, and community health centers."[11]

While the most numerous objections found were from the

ranks of various pharmaceutical market segments, the

objections of pharmaceutical manufacturers were also in

evidence. These generally predicted loss of research monies

available to develop new pharmaceuticals. Such as:

> ". . . insurers attempts to contain health care costs
> by controlling pharmaceutical expenditures may decrease
> incentives to pursue innovation in drug development,
> and discourage investment in pharmaceutical
> R & D . . ."[12]

And this, from the Pharmaceutical Manufacturers Association:

> "The research-based pharmaceutical industry invests 17
> percent of sales in R & D . . . this commitment to
> research will result in future breakthrough drugs . . .
> the proposals advanced by Senator David Pryor would
> clearly dampen the incentives to innovate . . ."[13]

Problem:

That the federal government should mandate prices and

rebates from private manufacturers is a significant

departure from the usual sense of a free market economy,

where prices are based on competition. As such, one wonders

about the impact of OBRA '90 on a highly competitive

procedure such as the bid process. Sentiments reported in

the media (above) predicted that forced rebates to one

particular market segment, Medicaid, would affect the prices

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available to other purchasers. The issues are:

> The existence of the "best price" language may limit manufacturers' ability to offer any buyer a lower price than Medicaid.

> Buyers, such as institutions and other competitive bidders, who previously obtained deep discount may be unable to maintain them as manufacturers seek to avoid the additional "best price" rebates such discounts would trigger.

> On the manufacturing side, rebates may reduce profits which some have said may lead to a reduction in research funding for new drug products.

HYPOTHESES:

This work seeks to explore the impact of OBRA '90 rebates on pharmaceutical pricing and particularly its effect on competitive bidding for pharmaceuticals in Rhode Island. An anonymous mail questionnaire (see Methodology, Exhibits) was developed to solicit opinion from business insiders (see Methodology) regarding OBRA '90's effects. Responses were analyzed to sustain or refute the following hypotheses.

Hypotheses:

> H1. That most manufacturers on the State of Rhode Island bid list are familiar with the OBRA '90 mandated Medicaid rebate requirements.

> H2. That most manufacturers are participating in the OBRA '90 mandated Medicaid rebates.

> H3. That most manufacturers will continue to participate or will begin to participate in the OBRA '90 mandated Medicaid rebates in the near term (one year).

> H4. That a majority of manufacturers will expect to lose some Gross Profit margin as a result of furnishing Medicaid rebates to each state Medicaid plan.

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H5. That a reduction in profits because of the OBRA '90 mandated Medicaid rebates will be perceived as causing a reduction in funds available to support research.

H6. That the following effects will occur in drug bid acquisitions:

> H6a: That OBRA '90 mandated rebates to one segment of the pharmaceutical market will have the unwanted effect of exerting an upward influence on prices available to buyers other than Medicaid.

> H6b: That all purchasers do not necessarily pay the same price for pharmaceuticals.

> H6c: That OBRA '90 will not cause all purchasers to receive the same price.

> H6d: That while a "best price" will be known and established in order to calculate the Medicaid rebate amounts, it will not be made generally available to buyers to serve as a reference tool or benchmark against which they might judge the success of their acquisitions.

> H6e: That OBRA '90 will diminish manufacturers ability to offer low bid prices on innovator drugs to competitive bid acquisitions.

> H6f: That OBRA '90 will diminish manufacturers ability to offer low bid prices on generic drugs to competitive bid acquisitions.

> H6g: That if a competitive procurement group's acquisition can become classified as an "exempt award" and, therefore, not a factor to be considered in the Medicaid "best price" rebate calculations, this will result in lower prices being offered.

METHODOLOGY

Development of the Questionnaire:

A copy of the legislation was obtained and reviewed. Based on this and preliminary literature research, questions were developed, refined and formatted into a survey.

Survey Design:

A structured, undisguised survey design was chosen for ease of tabulation. Survey scale was selected as a five point scale. This allowed respondents to select a "degree" of response instead of simply an affirmative, negative or "don't know." As percentages were to be calculated on the basis of total surveys returned this effectively proportioned "no answer" responses among the fixed alternatives. Therefore, "no answer" responses would be tabulated and reported separately so that they could be "distributed by the reader," if desired, which more completely disclosed the results. Structured items on the questionnaire were precoded for ease of tabulation. The necessity of quoting the actual wording used in the OBRA '90 regulations for the sake of clarity caused some questions to be lengthy. Since three pages was the practical limit to the questionnaire because of postage considerations and the desire to improve response by making the survey as brief as

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possible, the number of questions included was sixteen. These were composed of twelve research questions and four classification questions, an optional job description question and a suitable space for respondent's address, should he/she request a copy of the results.

Of the research questions, questions one through three were designed to ease respondents into the subject matter. These questions are easy to answer and nonthreatening; sensitive issues are best reserved for later in the work.[14] These questions also establish that the respondent is knowledgeable in the area being studied and that OBRA '90 mandated rebates will have some effect on his/her company in the near term. Questions four and five explore the financial impact of OBRA '90 on respondents' firm. Question number seven attempts to establish that different purchasers receive different prices for pharmaceuticals while question number eight asks if the OBRA '90 regulations will encourage their company to charge all purchasers the same price. Question number nine asks if respondents will publish the "best price" as defined by OBRA '90 in a generally available location. Questions ten, eleven and twelve explore respondents' opinion of the impact of OBRA '90 on special pricing their companies make available to competitive procurement groups.

The classification questions, thirteen through sixteen, were included to determine the type of business of respondent. This was needed because OBRA '90 mandated

rebates were written to affect manufacturers and among manufacturers the law treats innovator and generic manufacturers differently. Thus, the type of respondent's business was useful in evaluating their response.

One unnumbered open-ended question was included on a strictly optional basis asking respondents for their job title. Answers were wanted to establish that no particular position was overly represented, for instance, that responses were not limited to presidents of corporations (see results). Because it was felt more important to maximize response to the questionnaire by preserving anonymity, the question was made optional.

It was hoped that copies of results offered to an audience that had a significant interest in this topic might act as incentive to increase participation and accuracy of results. In theory, those that wished to view the results would exercise more care in filling out the questionnaire as well as respond in a more timely fashion. Special effort was taken to promise confidentiality to participants so that responses would be unguarded and anonymity protecting against possible job conflict. Further, confidentiality was ensured by using an "unkeyed" questionnaire and the promise of no hidden identifiers to the recipients. This necessitated assigning key numbers to all returns before tabulation.

Several staff members of the Department of Pharmacy Practice were chosen as a pretest audience for the

questionnaire. While this might seem a biased testing group, this selection was needed because the subject matter of the questionnaire requires some understanding of the pharmaceutical industry, pharmaceutical procurement and topics relevant to it.

Population Sampled:

A duplicate of the current bid list for the State of Rhode Island annual sealed drug bids was obtained. This list was selected because it is composed of vendors known to be active in bid acquisitions in Rhode Island. It has been updated to reflect recent takeovers and mergers within the drug industry. This list is excellent for this research application because it will direct surveys to those central addresses where bid/contract decisions are actually made. At these locations the cover letter was addressed to the Director of Professional Relations. In the event that the addressee felt unable or unqualified to answer, it was requested that the survey be forwarded to an individual with the appropriate authority and expertise who would answer.

Individuals at these addresses are able to extend special competitive pricing to, and enter into binding contracts with, pharmaceutical buyers. It can be reasoned that individuals empowered to set prices for a given corporation occupy responsible positions within that corporation and may be considered "key man" individuals. As such, they would have at least the required inside knowledge

to field any technical questions of the general nature posed by this questionnaire regarding profits and policies. In addition, the questionnaire was carefully designed not to require highly specific sensitive data about pricing and profits that might be restricted to those at the highest corporate levels only.

While it may be argued that bias is introduced by this list, it is instead the most appropriate list to the research as it consists of manufacturers who actively bid on drug contracts and the focus of this research is the impact of the OBRA '90 legislation on this type of procurement. Furthermore, the list contains only 89 vendors, and is, therefore, of convenient size while comprising the entire universe of bidders on these Rhode Island pharmaceutical contracts. Selection of this list also eliminates the need to select a suitable sample size as the entire universe can be polled.

Non-Response Bias:

A Response Rate of 28/89, or 31% was achieved. No statistical adjustment was made for nonresponse. As with all surveys the possibility of bias caused by nonresponse, failure to obtain information from some elements of the population that were selected and designated for the sample, must be acknowledged. Regrettably, available resources allowed only one wave of questionnaire distribution and a single follow-up and no monetary incentive. Also, callbacks

were not possible because of the anonymous nature of the questionnaire. No attempt was made to adjust for nonresponse bias in the small population sampled; rather, efforts centered on minimizing possible bias by maximizing response.

It was possible to employ two strategies[15] to reduce nonresponse: general methods designed to increase initial response rate and a follow-up letter to obtain additional response. Steps to maximize initial response used were:

- an "appeal" for response in a carefully composed cover letter;

- the promise of anonymity;

- questions designed not to probe sensitive areas because, "non response tends to increase with the sensitivity of the information being sought.";[16]

- questions designed not to require such technical or specialized knowledge as only a few respondents might possess;

- the promise and appearance of brevity in questionnaire design;

- the offer of a copy of the results to respondents;

- "don't know" and no answers reported separately because they ". . . can be treated as separate categories when reporting the results . . . in many ways this is the best strategy . . ."[17]

While every effort was made to maximize response by incorporating basic tenets of questionnaire and cover letter design, some nonresponse bias must be assumed in any survey. Nonresponse bias may be mitigated somewhat in this work because an entire universe was sampled and the population selected was not a random population. The more

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homogeneous the sample (i.e., the fewer conceivable subgroups it contains) the less the need for a high percentage of response.[18] The sampling frame composed the entire list of bidders on the State of Rhode Island Pharmaceutical Bids. Bidders on this list must submit an acceptable qualification questionnaire to the Division of Purchasing before inclusion. Thus, it can be argued, that nonresponders are less likely to differ from responders than if the questionnaire was sent to a more random population.

Timeframe:

A first mailing was sent out on June 1, 1992. A follow-up letter was sent out on June 4, 1992. Keyed questionnaires contain hidden codes of various types that allow researchers to know which addressee has responded. Because this survey was unkeyed to guarantee anonymity, the follow-up letter was sent to the entire universe and took the caution of expressing appreciation in case the recipient had already answered. As it is customary to receive 90% of all responses within three weeks,[19] this survey was closed on June 30, 1992.

Selection of Respondent Groups:

Classification questions at the end of the survey allow the responses to be grouped among nonmanufacturers, manufacturers of innovator prescription drugs and manufacturers of generic drugs. An open ended job

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classification section was included to ensure that responders represented a broad group of individuals and that no one group was overly represented. For reasons of confidentiality, this section was indicated as "strictly optional." It was considered more important to do everything possible to maximize response by not compromising anonymity than to have 100% response to this question.

Sixteen of twenty-eight respondents chose to answer the optional classification question. Responses were broken down as follows:

Sales or Marketing Manager....................2

Contract Manager..............................1

Vice President................................2

Manager (unspecified).........................4

Director of Professional Relations,
Information, Public Information,
Liaison, etc..................................3

Marketing Staff...............................1

President.....................................1

Director (unspecified)........................1

Medicaid Rebate Analyst.......................1

No Answer.....................................12

Survey Returns:

Returns were collected in the Department of Pharmacy Practice, Fogarty Hall, University of Rhode Island. A count of envelopes returned per day was kept for reference. Returns were then placed in large envelopes separated by day

of receipt and held for analysis.

There were no "undeliverable" returned by the Post Office. This reflects well on the accuracy and currency of the list selected. One envelope was received in error: it was a return to another survey. Apart from that there were four surveys considered unusable because respondents indicated they were unfamiliar with OBRA '90 rebates, there were no blank returns and no refusals.

Envelopes were opened carefully by hand. Each envelope and survey was then keyed alike. Keying ensures that recon-struction of respondents complete package is available should the editing procedure raise any questions that need to be answered. It also preserved data in useable form should it need revisiting for any purpose. This keying was necessary as the survey was conducted with a promise of strict dentiality. Respondents were promised no hidden identifiers were included, as in fact, none were. So keying had to be accomplished as a separate process after return. At this time postmarks appearing on the envelopes were recorded on the corresponding survey. Collecting these postmarks, then, was an exercise in proper procedure and to verify that the location of responders was not limited to any particular region or locale. Variety of postmarks was satisfactory. However, the U.S. Post Office did not post mark all envelopes. While postmarks have some uses in mail surveys, none will be made for the purpose of this analysis for reasons of confidentiality.

The completed questionnaires were then edited to improve the accuracy and clarity of answers and help eliminate inconsistencies and obvious wrong or ambiguous replies. For instance, if a respondent in an auto owners survey answers that he does not have a car but then in subsequent questions goes on to describe its color, insurance, number of miles driven, monthly payment, pride of ownership, etc., then a researcher can justify recording the respondent as an owner. In this case the editor would reason that respondent checked "do not own car" by error because that answer would be inconsistent with data collected in following questions. This editing reduces any imperfections to a minimum and ensures the fullest possible use of the survey returns. As the questionnaires returned were very well completed the amount of editing required was negligible.

Hypotheses:

The research attempted to explore the following hypotheses:

H1. That most manufacturers on the State of Rhode Island bid list are familiar with the OBRA '90 mandated Medicaid rebate requirements.

H2. That most manufacturers are participating in the OBRA '90 mandated Medicaid rebates.

H3. That most manufacturers will continue to participate or will begin to participate in the OBRA '90 mandated Medicaid rebates in the near term (one year).

H4. That a majority of manufacturers will expect to lose some Gross Profit margin as a result of furnishing Medicaid rebates to each state Medicaid plan.

H5. That a reduction in profits because of the OBRA '90 mandated Medicaid rebates will be perceived as causing a reduction in funds available to support research.

H6. That the following effects will occur in drug bid acquisitions:

H6a: That OBRA '90 mandated rebates to one segment of the pharmaceutical market are likely to have the effect of exerting an upward influence on prices available to buyers other than Medicaid.

H6b: That all purchasers do not necessarily pay the same price for pharmaceuticals.

H6c: That OBRA '90 will not cause all purchasers to receive the same price.

H6d: That while a "best price" will be known and established in order to calculate the Medicaid rebate amounts, it will not be made generally available to buyers to serve as a reference tool or benchmark against which they might judge the success of their acquisitions.

H6e: That OBRA '90 will diminish manufacturers ability to offer low bid prices on innovator drugs to competitive bid acquisitions.

H6f: That OBRA '90 will diminish manufacturers ability to offer low bid prices on generic drugs to competitive bid acquisitions.

H6g: That if a competitive procurement group's acquisition can become classified as an "exempt award" and, therefore, not a factor to be considered in the Medicaid "best price" rebate calculations, this will result in lower prices being offered.

Analysis:

Respondents were classified according to their answers to classification questions thirteen through sixteen. Then, questionnaire responses were tabulated by taking the total number of responses for each fixed alternative for each question. Responses were then cross-tabulated by respondent

group as each identified themselves in the classification questions. Finally, responses were cross-tabulated both as a percentage within class and as a total response among all classifications in order to provide an overall sense of response to each question. Results are reported later in this work.

Statistical Tests:

Regrettably, testing must be done in the aggregate, as response was not sufficient to test the cross tabs.

There are two statistical tests appropriate to this work; they are the Binomial Sign Test of a proportion and the Chi Square "goodness of fit" test. These tests are appropriate to these data characteristics of small sample size, nonrandom population and discrete values. These tests are robust, distribution free nonparametric tests, as such, it is not necessary to assume a normal distribution of the sample population.

The Binomial Test:

The binomial formula:

$$p(x) = \binom{n}{x} p^x (1-p)^{n-x}$$

is used where p (probability) = .5, indicating a random binomial distribution, and n = trials and a significance level, alpha, as close as possible to .05 is used to test the hypothesis. Because the binomial distribution is a discrete, noncontinuous distribution, a rejection region is

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found giving the significance level closest to .05 (5%
significance level). If the value of the test statistic
falls in the rejection region the Null Hypothesis is
rejected, the Alternate Hypothesis is accepted and,
therefore, statistical significance is accepted.

Null Hypothesis: The distribution of responses observed is
a random distribution.

Alternate Hypothesis: A statistically significant
preference is exhibited by the responses.

Chi Square "goodness of fit" Test:

This test requires two assumptions:

1. All expected frequencies are at least one.

2. At most, 20% of the expected frequencies are less
than 5.

Formula:

Chi Square = Sigma (O-E)(O-E)/E

Where O represents the observed frequency and E represents
the expected frequency. Expected frequency is calculated.

Expected Frequency = np

where n is the number of trials and p is the probability for
the category and at a 5% significance level (alpha = .05)
and degrees of freedom (df) = k-1 where k is the number of
categories. Using the df at alpha = .05 a critical value is
obtained. If the value of the test statistic calculated
(Chi Square) is less than the critical value, do not reject

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the Null Hypothesis. If Chi Square is greater than the value of the test statistic, accept the Alternate Hypothesis.

Null Hypothesis: The distribution of responses is random.

Alternative Hypothesis: A statistically significant preference is exhibited by the responses.

RESULTS AND DISCUSSION

Classification:

Respondents were classified in three categories
according to their answers to questions 13, 14 15 and 16.
For the purposes of this research the categories were
defined as follows:

Innovator Manufacturer: a company that manufactures or
markets a prescription drug whose original patent rights are
still in force. Such a drug may not be manufactured without
permission of the patent holder by submission to the Food
and Drug Administration (FDA) of a proper Abbreviated New
Drug Application (ANDA).

Generic Manufacturer: a company that manufactures generic
drugs but does not presently manufacture or market any
innovator drugs.

> Generic Drug: multi-source drugs whose exclusive
> patent rights have expired and with proper application
> to the FDA may be made by various pharmaceutical
> manufacturers. Also called "noninnovator multiple
> source drugs".

"Other": Companies qualified on the bid list but
identifying themselves through classification questions as
not being manufacturers. Possible examples include
wholesalers, repackagers, distributors, etc.

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CHART THIRTEEN
Classification of respondents

innovator mfr
62.5%

other
20.8%
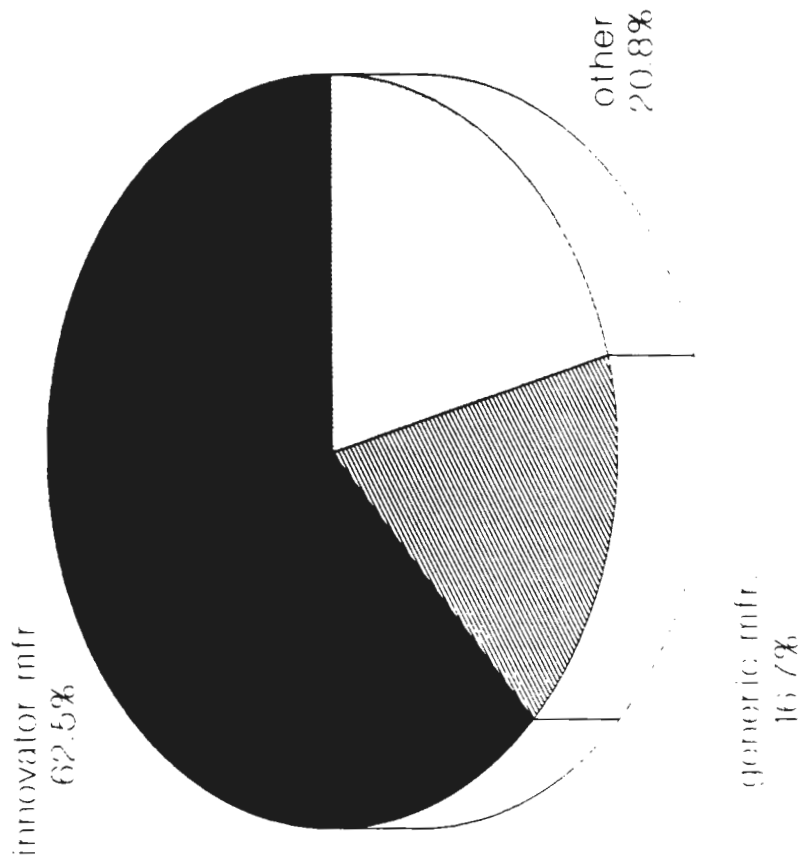
generic mfr
16.7%

Results of Classification of Respondents:

           innovator manufacturers: 15   (62.5%)

           generic manufacturers: 4   (16.7%)

           "other":   5   (20.8%)

For the purposes of this research, respondents were classified as innovator manufacturers if they responded to classification questions by indicating that they were manufacturers who marketed at least one drug protected by exclusive patent either through their own discovery and/or by license agreement. Manufacturers were classified as generic if they indicated that they were manufacturers and did not have any drugs protected by exclusive patent. "Others" were respondents whose classification questions indicated that they were neither innovator manufacturers nor generic manufacturers, but were qualified on the bid list.

Question #1:   Base = 24

1. Are you familiar with the Medicaid rebate requirements mandated by the OBRA '90, sometimes referred to as the Medicaid Prudent Purchaser Requirement?

    1. ( )yes   2. ( )no   3. ( )not sure

CHART ONE
Familiarity with OBRA-90 rebates?
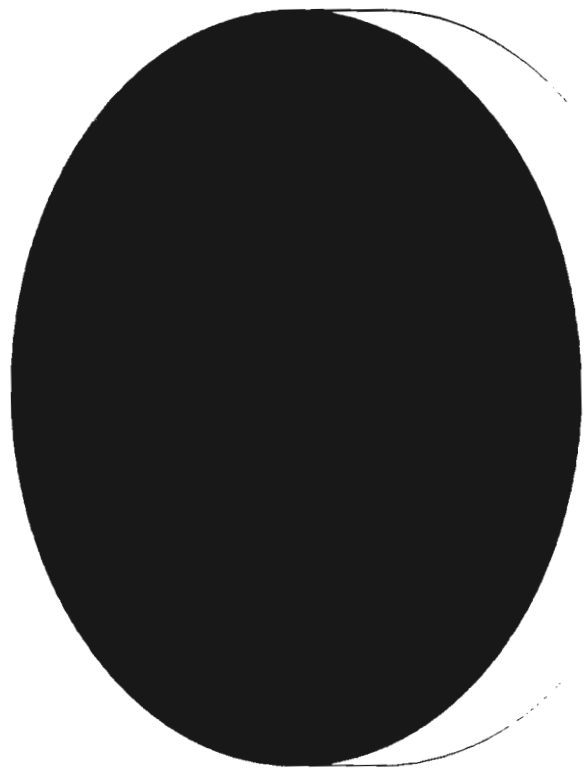
YES
100.0%

Results:

Table One

	INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS: #	#	(%)	#	(%)	#	(%)	#	(%)
(1)	15	(93.8)	4	(100)	5	(62.5)	24	(85.7)
(2)	0		0		0		0	
(3)	0		0		0		0	

no answer = 0

Statistical Tests:

A Binomial Sign Test was conducted with n trials = 24. At an alpha value of .032, x = 17, since observed x's = 24, the Null is rejected. The responses exhibit a statistically significant preference.

The results are statistically significant at an alpha value of .000.

Fully 100% of respondents included in the analysis indicated that they were aware of the OBRA '90 provisions. All classes of respondents indicated an awareness of the Act. This is encouraging because it indicates that a knowledgeable audience has been reached. These results concur with Hypothesis 1:

   ---That most manufacturers on the State of
      Rhode Island bid list are familiar with the
      OBRA '90 mandated Medicaid rebate requirements.
From the literature search it was expected that bidders

CHART TWO
Are you currently participating?

no
8.3%

yes
91.7%
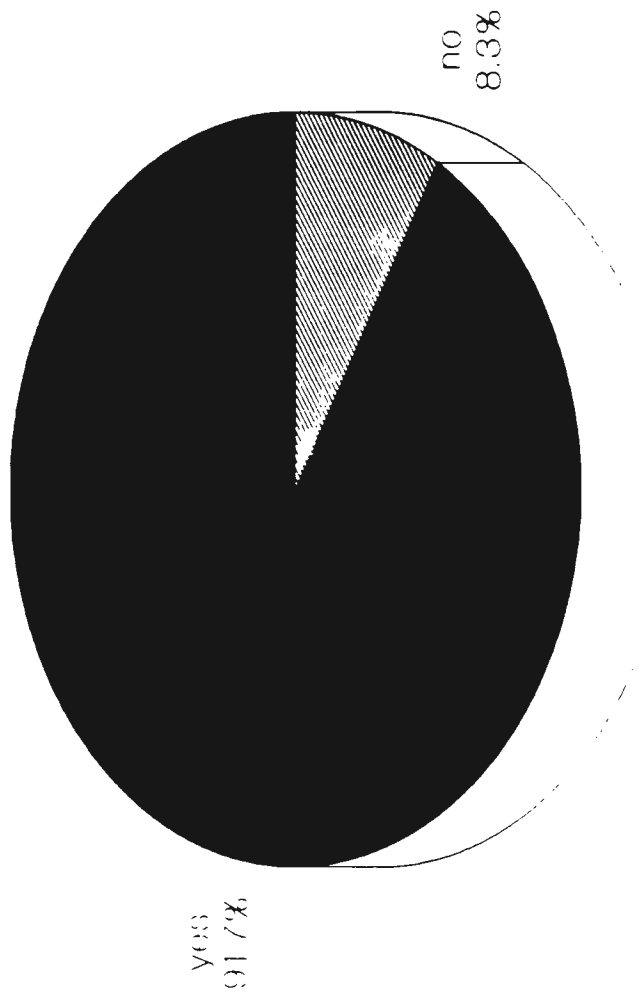
would be aware of the OBRA '90 provisions: Various hypotheses explored in this work, if supported, will show an effect upon bidders' daily pricing activities. In addition, the potential market is large as the purchases funded by Medicaid are estimated to be 10%[20] of the annual pharmaceutical market. Also, trade print media has been active in the discussion of OBRA, its controversies and repercussions in the marketplace.

Question #2:   Base = 24

2. Does your company participate in the Medicaid rebate program?

    1. ( )yes   2. ( )no   3. ( )not sure

Results:

Table Two:

	INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS: #	#	(%)	#	(%)	#	(%)	#	(%)
(1)	14	(93.3)	4	(100)	4	(80)	22	(91.7)
(2)	1	(6.7)	0		1	(20)	2	(8.3)
(3)	0		0		0		0	

no answer = 0

Statistical Tests:

A Binomial Sign Test was conducted with n trials = 24. At a p value of .032, x = 17. Since observed x's = 22 the Null is rejected. The responses exhibit a statistically

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significant preference.

At a p level of .000 the results are statistically significant.

An 91.7% of respondents indicated that they currently participated in the Medicaid rebate program. Among those who identified themselves as manufacturers, 93.3% of innovators and 100% of generic manufacturers said they participated.

A majority, 80% of other category respondents also said they were participants. Only 8.3% of respondents overall said that they did not participate in the OBRA '90 mandated Medicaid rebates. The majority response supports the Hypothesis #2:

    ---That most manufacturers are participating in

       the OBRA '90 mandated Medicaid rebates.

One can reason that of the 20% of other respondents some are likely to occupy market segments that are not affected by the OBRA '90 legislation since they are not manufacturers according to their responses to the classification questions. These individuals might be wholesalers, distributors, etc., who are entitled to be on the bid list but are not manufacturers. This can be further supported by the fact that classification questions showed that 20.8% of questionnaire respondents indicated that their company was not a manufacturer of pharmaceuticals.

Discussion of Results, Questions One and Two:

Questions one and two were designed to ease respondents into the topic of OBRA '90 rebates by asking nonthreatening, inoffensive questions in brief, straight-forward language. This is highly recommended as a basic tenet of questionnaire design by Churchill.[21] Innocuous, nonthreatening questions placed at the beginning of questionnaires draw the respondent in and convince him/her that involvement will be brief and painless. In theory, questions to be asked later include those of more emotional or confidential issues because the respondent is less likely to become annoyed with sensitive issues and discard the questionnaire after some time has been invested in answering the earlier questions.

In editing the answers to question number one, four respondents indicated they were unaware of the OBRA '90 mandated Medicaid rebate requirements. These returns were removed from the analysis of results. Tabulations for question number two showed a very high rate of participation among respondents overall at 91.7% and numbers in the affirmative were (93.3% and 100%) among those classified as innovator and generic manufacturers respectively.

High percentages of awareness and participation in the OBRA '90 mandated rebates are consistent with the nature of the list. The list used was composed of active bidders on the Rhode Island Pharmaceutical contracts, a sealed bid format. The list is continuously updated. The edition of the list used was accurate to March 10, 1992. Active

CHART THREE
How likely to continue?

very likely 79.2%

very unlikely 4.2%

not sure 8.3%

likely 8.3%
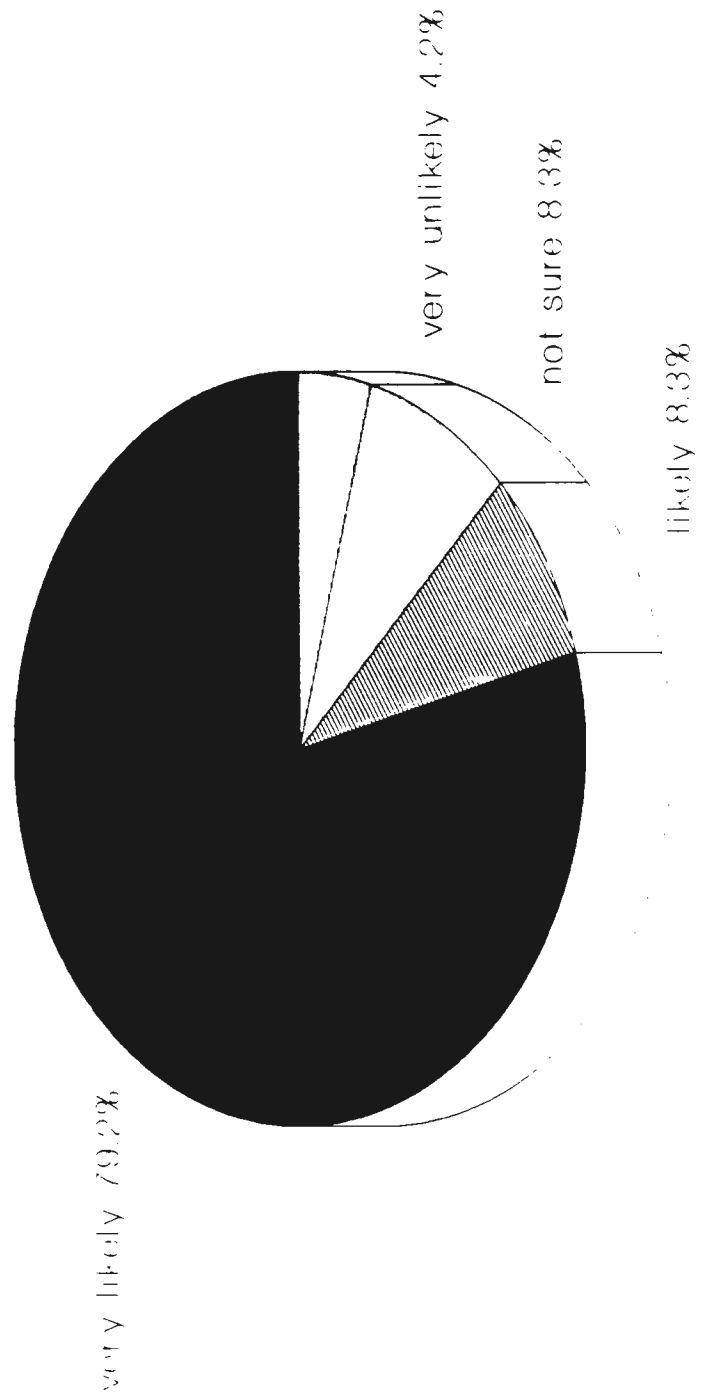
bidders could be expected to have knowledge and participate in the Medicaid rebates because Medicaid accounts for approximately 10% of drug purchases nationwide[22] and because, as hypothesized elsewhere in this work, the OBRA '90 rebates will affect prices available to non-Medicaid purchasers. Vendors in such a price aggressive arena as submitting sealed bids would likely be aware of the forces that impact their ability to price competitively. The OBRA '90 rebates are a significant and much publicized development in the media.

Question #3:   Base = 24

3. How likely is your company to begin and/or continue participation within one year?

    1. ( )very likely   4. ( )unlikely
    2. ( )likely   5. ( )very unlikely
    3. ( )not sure

Results:

Table Three:

	INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS: #	#	(%)	#	(%)	#	(%)	#	(%)
(1)	14	(93.3)	3	(75)	2	(40)	19	(79.2)
(2)	0		1	(25)	1	(20)	2	(8.3)
(3)	1	(6.7)	0		1	(20)	2	(8.3)
(4)	0		0		0		0	
(5)	0		0		1	(20)	1	(4.2)

no answer = 0

Statistical Tests:

A Chi Square "goodness of fit" test is performed (see also, Methodology) for the following hypotheses:

Null Hypothesis: the responses equal random distribution.

Alternate Hypothesis: the responses differ from random in a statistically significant fashion.

Chi Square is calculated:

Chi Square = Sigma (O-E)(O-E)/E

where E = np and degrees of freedom (df) is equal to k-1 and a significance level of 5% is used (alpha = .05).

The value of the test statistic calculated as above for question number three is 53.06. The critical value of Chi Square (.05) with df = 4 is 9.488. The value of the test statistic is greater than the critical value; therefore, the Alternate Hypothesis is accepted. The responses exhibit a statistically significant difference from random.

A total of 79.2% of respondents indicated that they were very likely to begin and/or continue participation in the program of Medicaid rebates. Combined affirmative response, those selecting either likely or very likely, was 87.5%. Previously in question number two, 91.7% of respondents said their company was participating in the Medicaid rebate program at the time of the questionnaire. Question number three finds a possible (small) reduction in participation with 87.5% of respondents answering that their company will begin and/or continue participation. In raw

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scores this represents only one less response in the affirmative. The majority response of 87.5% supported hypotheses H2 and H3:

H2. ---That most manufacturers are participating in the OBRA '90 mandated Medicaid rebates.

H3. ---That most manufacturers will continue to participate or will begin to participate in the OBRA '90 mandated Medicaid rebates in the near term (one year).

Discussion:

Only 4.2% of respondents were willing to say that they were unlikely or very unlikely to begin and/or continue participation. The two responses to this question in the "unsure" category (when added to the large number of affirmative responses) show that the level of participation is likely to continue to be high. Furthermore, once committed to participate in the rebate program a company is likely to continue participation because the Medicaid purchases are substantial, amounting to 10% of all pharmaceuticals purchased annually in the United States[23] and a company is unlikely to ignore such a large market segment.

The literature search led one to believe that a large percentage of respondents would continue or begin the rebate program and, in fact, 87.5% intend to do so. As mentioned previously, the size of the Medicaid market makes it

important to people in the business of selling

pharmaceuticals. In addition, manufacturers who participate

in the rebate program have all their drug products covered

by Medicaid and drugs that are new to the market will be

covered immediately and not have to wait until each state

accepts a particular drug into its Medicaid program. As

reported by Coster:

> "Drug manufacturers have significant incentives to
> participate in the Medicaid rebate program since there
> will be no federal matching funds available for the
> drugs of those manufacturers that have not entered into
> a rebate agreement. However, manufacturers that have
> rebate agreements in effect will have their products
> covered by the state Medicaid programs. This is a
> significant victory for all the drug companies since
> many states do not cover all the drug products of all
> manufacturers due to cost and patient care reasons. In
> addition, there is usually a significant time lag
> between the markets of a new drug and acceptance by a
> state Medicaid program. Now, all new drugs will have
> to be covered immediately by a state Medicaid program
> for a period of not less than six months after
> approval. All these benefits will have significant
> "spill-over" effects on prescribing of a company's
> products by physicians in other sectors of the
> ambulatory care market."[24]

Clearly, Coster makes a strong argument that it is in

manufacturers own best interests to participate.

Of respondents who said their company did not

participate, those companies may be nonparticipating

because their involvement in the pharmaceutical industry

may be as other than a manufacturer. Responders who were

unsure or (very) unlikely to participate were composed

mostly (66.7%) of those classified as other than a generic

or innovator manufacturer. While most respondents from

the selected universe sold pharmaceuticals that they

manufactured, the list is not restricted to manufacturing.
Other business entities that sell pharmaceuticals such as
wholesalers or repackers, to name but two possibilities, may
qualify for the list and can and do win bid acquisitions.
Not being manufacturers they would not participate as a
matter of course in the Medicaid rebate program.

Assessing question number three using just respondents
who classified themselves as generic or innovator
manufacturers, lends a much stronger impression of majority
response. Responses for innovator and generic manufacturers
were 93.3% and 100% respectively that their companies would
continue and/or begin Medicaid rebates.

Clearly, most participants in the Medicaid rebates
expect to continue, and as show in question two, most are
participating now. Thus, with continuing industry
participation, factors that this research show as likely to
be a result of changes instigated by OBRA '90 are likely to
remain factors in the marketplace in the near term.

Question #4:   Base = 24

4. What effect, if any, do you think the Medicaid rebates
will have on the Gross Profit margin of your company's
pharmaceutical line?

    1. ( )strong increase   4. ( )some decrease
    2. ( )some increase   5. ( )strong decrease
    3. ( )no effect

If you answered 1, 2 or 3, please go to question number 6.

CHART FOUR
Effect of rebates on gross profit?

some decrease
70.8%

no effect
4.2%

some increase
4.2%

strong decrease
16.7%
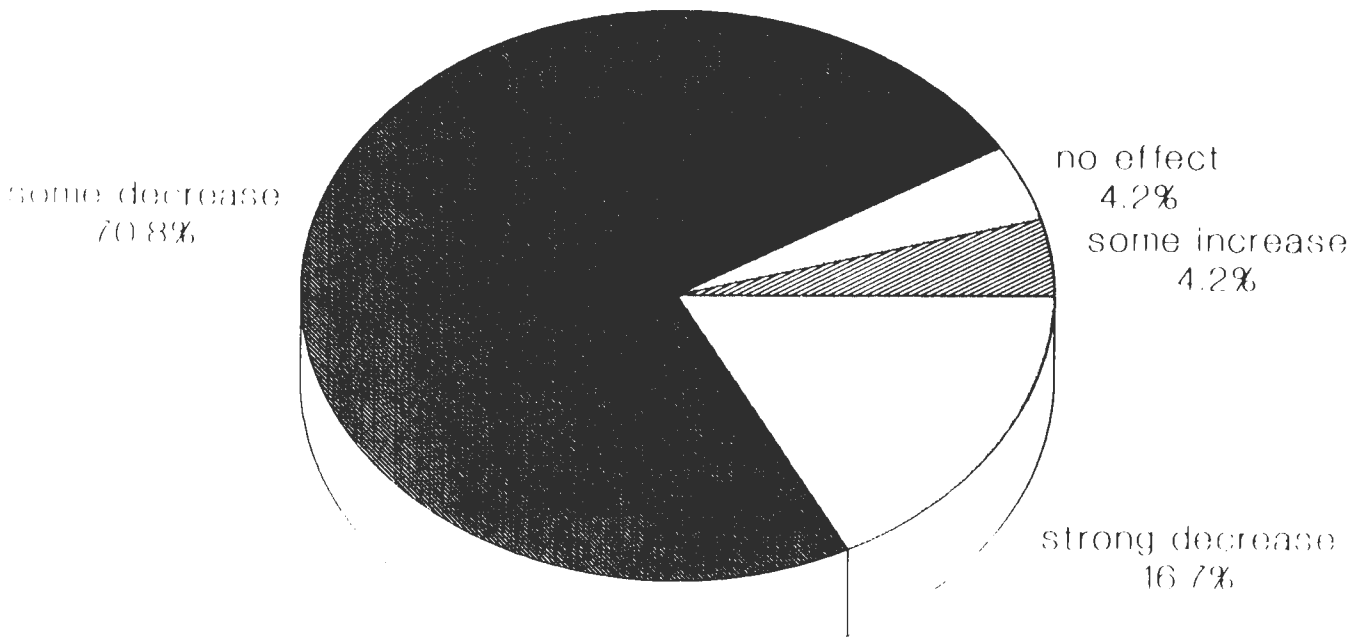
Results:

Table Four

	INNOVATOR MFR.		GENERIC MFR.	"OTHER"	TOTAL
ANS: #	#	(%)	# (%)	# (%)	# (%)
(1)	0		0	0	0
(2)	0		1 (25)	0	1 (4.2)
(3)	0		1 (25)	0	1 (4.2)
(4)	13	(86.7)	1 (25)	3 (60)	17 (70.8)
(5)	1	(6.7)	1 (25)	2 (40)	4 (16.7)

no answer = 1

Statistical Tests:

A Chi Square "goodness of fit" test is performed (see also, Methodology) for the following hypotheses:

Null Hypothesis: the responses equal random distribution.

Alternate Hypothesis: the responses differ from random in a statistically significant fashion.

Chi Square is calculated:

Chi Square = Sigma (O-E)(O-E)/E

where E = np and degrees of freedom (df) is equal to k-1 and a significance level of 5% is used (alpha = .05).

The value of the test statistic for question number four as calculated above with n = 24 and p (probability) = 0.2 is 41.8. The critical value of Chi Square (.05) with df = 4 is 9.488. Since the value of the test statistic is greater than the critical value the Alternate Hypothesis is

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accepted: the responses exhibit a statistically significant preference.

87.5% of respondents predicted their company would experience at least some decrease in Gross Profit margin in their pharmaceutical line. Of the responders, 4 or 16.7%, characterized the expected decrease as a strong decrease in profit. These results support the Hypothesis H4:

    ---That a majority of manufacturers will expect to
        lose some Gross Profit margin as a result of
        furnishing Medicaid rebates to each state Medicaid
        plan.

Discussion:

This question branched respondents. Those who expected decreases were directed to question number five. Others who did not expect a decrease were directed to question number six because if respondent did not expect a profit decrease then question number five, concerning methods anticipated of recovering profit loss, becomes irrelevant.

For 1992, OBRA '90 requires that manufacturers give Medicaid a minimum rebate of 12.5% (see Appendix 3) of the Average Manufacturers Price (AMP) or their "best price" to any purchaser as defined by OBRA '90, subject to a cap of 50% of the AMP. Estimates are that . . . "Medicaid's new prudent purchasing legislation is expected to save federal and state taxpayers from two to three point four billion dollars over five years."[25] Because of the dollars

involved, it is expected that this program will have a discernible effect on a company's gross profit, and that a majority of respondents' opinions indicate that they expected at least some decrease in gross profit. Responses by category were: innovator manufacturers, 93.4%, some measure of decrease; generic manufacturers, 50%, some measure of decrease; and, "other", 100%, at least some decrease.

Clearly, this response supports this hypothesis. To have billions of dollars removed by government fiat from an industry should have some impact on profits. And, in fact, the anticipated dollar rebates for 1991 will exceed the estimates according to a report in The Pipeline, "Prescription drug expenditures for the 1991 Medicaid program totaled $5.3 billion or $0.6 billion more than the $4.7 billion that . . . (was) . . . predicted for FY 1991.[26] As Medicaid's total expenditure rises, the amount of funds generated by the minimum 12.5% rebate rises.

A small number of respondents (4.2%) indicated that they Medicaid rebates would have no effect on their company's gross profit. An equal number (4.2%) predicted that their company would experience some increase in profits.

An increase in profits is possible in some cases because, although it seems obvious that the siphoning off of funds in the form of Medicaid rebates would always decrease the gross profit, there are some scenarios where a profit

increase is possible. For instance, as a compromise with manufacturers, those who choose to participate in the Medicaid rebate program will benefit from the fact ". . . (that) . . . now all drugs will have to be covered immediately by a state Medicaid program . . ."[27] If a manufacturer had some profitable drugs that were previously excluded from Medicaid, their inclusion now might result in an overall financial benefit. Another area of possible new profit is to manufacturers who have recently introduced or are about to introduce new drugs. Since OBRA '90 mandates that participating manufacturers shall have all drugs included for Medicaid coverage immediately upon introduction to the general market, and state Medicaid approval can take some time before a new entity is accepted for coverage, then immediate coverage could present a new profit opportunity. It is reasonable to accept the possibility that a small percentage of respondents is anticipating increased profit as a result of this law.

Question #5:   Base = 19

5. Which of these strategies is your company most likely to employ, other than price increases, to recover any profit margins that might be reduced by supplying rebates to State Medicaid programs?

        1. ( )cut advertising   4. ( )reduce research
        2. ( )expand markets   expenditure
        3. ( )cut mfr. costs   5. ( )other

CHART FIVE
Which strategy most likely to recover $?

expand markets
42.1%

cut advertising
21.1%

cut mfr. costs
10.5%

reduce research $
21.1%
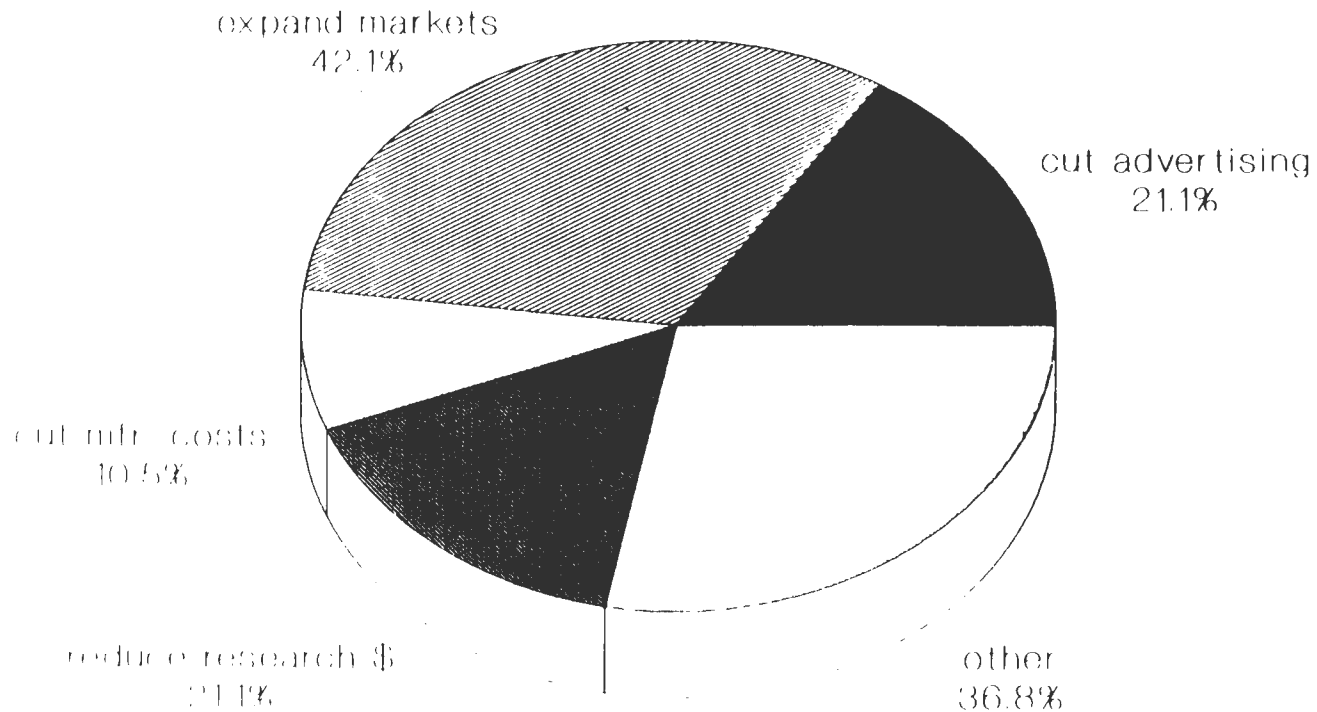
other
36.8%

Results:

Table Five

		INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS:	#	#	(%)	#	(%)	#	(%)	#	(%)
(1)		4	(26.7)	0		0		4	(21)
(2)		5	(33.3)	1	(25)	2	(40)	8	(42.1)
(3)		1	(6.7)	1	(25)	0		2	(10.5)
(4)		3	(20)	0		1	(20)	4	(21)
(5)		6	(40)	0		1	(20)	7	(36.8)

no answer = 6

Note: total may add to more than 100% because of multiple
       mentions.

Statistical Tests:

Chi Square "goodness of fit test":

Question number five requires a Chi Square test.
Regrettably, because of multiple responses this cannot be
done with the data available. Re-tabbing the questionnaires
to eliminate multiple results in 16 useable responses, which
gives an expected frequency of 3.2 per cell. Since it is
necessary to assume at least five responses per cell to
perform the Chi Square "goodness of fit test", the test
statistic would be highly unreliable. That the Chi test
cannot be done because this necessary assumption cannot be
met, does not mean that the results are insignificant;
rather, it means that they cannot be adequately tested.
Statistical inferences regarding the population may not be

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drawn from these results; what follows is a report of responses.

Question number five was asked only of those respondents who indicated in question number four that they expected their company to experience some measure of Gross Profit margin decrease because of the mandated Medicaid rebates. The remaining 79.2% of the respondents, therefore, completed question number five.

The most frequent response to this question was expansion of markets at 42.1%, followed closely by "other" at 36.8%. While 21% of the respondents felt that their company would cut advertising, an equal number, 21%, said their company would reduce research expenditure. The option with the lowest response was to cut manufacturing costs (10.5%).

In summary, 21% of all those polled supported Hypothesis H5:

> ---That a reduction in profits because of the OBRA '90 mandated Medicaid rebates will cause a reduction in funds available to support research.

Discussion:

The responses to question number five were too few to support statistical analysis. It may be of interest, however, to examine the proportions of responses in relation

to opinions expressed in the literature. Published
sentiments implied that research expenditures were huge and
that a reduction in revenues caused by the OBRA '90 rebates
would have the effect of diminishing funds available for
research:

> ". . . the Pharmaceutical Manufacturers Association
> (PMA) estimates that in 1992, $10.9 billion will be
> invested in R & D which would be 13.5% more than the
> 1991 expenditure of $9.6 billion. The industry's
> investment in R & D has been increasing at a greater
> rate than its sales . . . but the number of new
> chemical entities developed through the years has
> been decreasing due to the increased cost of
> research."[28]

and:

> ". . . the pharmaceutical industry invests the
> highest percentage of annual sales in R & D
> compared to other research-intensive industries."[29]

One reason that if all innovator manufacturers on
the mailing list responded, there would be a greater
percentage of responses predicting an impact on research
and development dollars available in the future. If
innovator manufacturers are more likely to have research
facilities than other classes of respondents, it is
possible that the effect on research programs is greater
than the survey results suggest since only 62.5% of
respondents classified themselves as innovator
manufacturers.

Question number five was designed to ask about price
increases without introducing bias by being inflammatory
and to see if anticipated gross profit loss would affect

research funding. It was felt that directly asking
respondents if they were going to "raise prices to everyone
else" would sensitize the issue. Such price questions to an
industry that is currently receiving unfavorable accounts in
the media about prices would likely be inflammatory.
Instead, respondents were asked if they were contemplating
other strategies to recoup lost profit margins due to
Medicaid rebates. "Reduce research expenditure" was one of
the closed end choices.

It was anticipated that a significant number of
respondents would feel that research funding would be
diminished as one of the historic reasons cited for high
prescription drug prices is the claimed enormous cost of
funding drug research, profits must be generated to pay
research and development costs (reputedly 230 million
dollars per drug, see below). As Gerald J. Mossinghoff
(President of the Pharmaceutical Manufacturers Association)
has stated:

> "The research-based pharmaceutical industry invests
> 17% of sales in R & D . . . this commitment to
> research will result in future breakthrough drugs
> . . .the proposals advanced by Senator David Pryor
> would clearly dampen the incentives to innovate
> . . ."[30]

Because it is a prestige issue, and, therefore,
possibly sensitizing to respondents, no classification
questions were included in the questionnaire regarding
research facilities. Therefore, it is not possible to

tabulate responses according to size and success of research facilities. If a 100% response to the questionnaire was received and all innovator manufacturers were tabulated separately, such a tabulation might allow more accurate conclusions about the impact of OBRA '90 on research and development dollars.

While one cannot make inferences on the basis of 15 respondents, that any innovator manufacturers would expect to reduce research dollars is worthy of note. The cost of developing a new pharmaceutical and bringing it to market is large,

> ". . . R & D spending has continued to increase until it now costs approximately $230 million to develop a product to the point of submitting an N.D.A. . . ."[31]

An 20% of innovator respondents indicated that there will be some reduction in funds available to support research as a result of the OBRA '90 mandated Medicaid rebates. Historically, innovator manufacturers, with their generous research and development budgets have been responsible for most of the breakthroughs in new pharmaceuticals and families of new pharmaceutical entities.
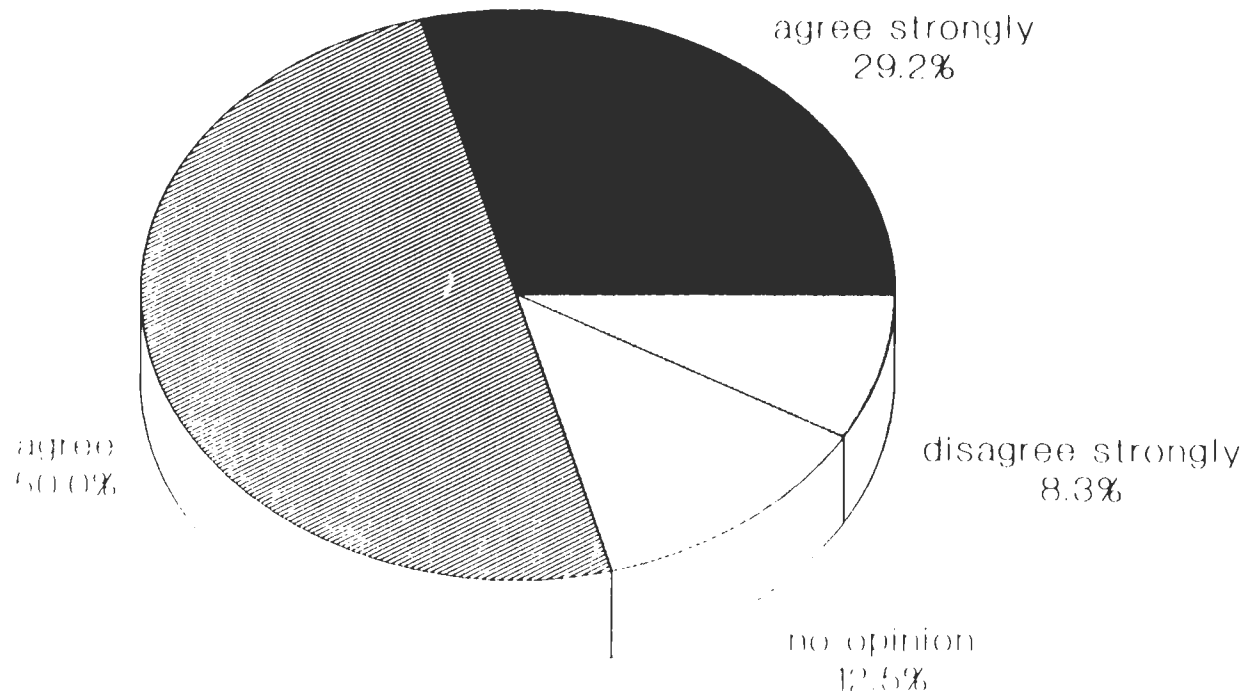
Question #6:   Base = 24

6. Some purchasers believe that mandated discounts to Medicaid have exerted upward pressure on the prices of pharmaceuticals available to the public through channels other than Medicaid; what is your opinion?

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CHART SIX
Have rebates increased costs to buyers?

agree strongly
29.2%

disagree strongly
8.3%

agree
50.0%

no opinion
12.5%

1. ( )agree strongly   4. ( )disagree
2. ( )agree   5. ( )disagree strongly
3. ( )no opinion

Results:

Table Six

	INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS: #	#	(%)	#	(%)	#	(%)	#	(%)
(1)	5	(33.3)	1	(25)	1	(20)	7	(29.2)
(2)	7	(46.7)	2	(50)	3	(60)	12	(50)
(3)	1	(6.7)	1	(25)	1	(20)	3	(12.5)
(4)	0		0		0		0	
(5)	2	(13.3)	0		0		2	(8.3)

no answer = 0

Statistical Tests:

A Chi Square "goodness of fit" test is performed (see also, Methodology) for the following hypotheses:

Null Hypothesis: the responses equal random distribution.

Alternate Hypothesis: the responses differ from random in a statistically significant fashion.

Chi Square is calculated:

Chi Square = Sigma (O-E)(O-E)/E

where E = np and degrees of freedom (df) is equal to k-1 and a significance level of 5% is used (alpha = .05). The value of the test statistic calculated as above for question number six with n = 24 and (probability) p = 0.2 is 20.28.

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The critical value of Chi Square (.05) with df = 4 is 9.488. Since the value of the test statistic is greater than the critical value, the Alternate Hypothesis is accepted: the responses exhibit a statistically significant preference.

An 79.2% of all respondents felt that mandated Medicaid discounts have exerted upward pressure on prices (50% agree; 29.2% agree strongly). Thus, a majority support the Hypothesis H6A:

> ---That the OBRA '90 mandated rebates to one segment
> of the pharmaceutical market will have the effect
> of exerting an upward influence on prices available
> to buyers other than Medicaid.

Conversely, only 8.3% of respondents took the opposite view and disagreed (strongly) that the mandated Medicaid rebates have exerted upward pressure on prices available to other market segments. Only 12.5% selected no opinion on this question.

Discussion:

In interpreting the significance of the response to this question, it must be acknowledged as a source of bias that manufacturers might find it convenient to blame the government regulations for some of the major price increases described in the media.

A counter argument to this bias is to note that the only two responses that disagreed (disagree strongly) with the notion that Medicaid rebates exerted upward pressure on

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pharmaceutical prices were from the innovator group. These responses are significant because they are contrary to the standard "party line" which seeks to avoid blame for price increases. This dissent, then, tends to support the premise that respondents' answers are unbiased in that respondents seem to answer with their own opinion rather than an association public relations line.

Respondents clearly feel that upward pressure on their drug prices has been exerted by the OBRA '90 mandated Medicaid rebates and this agrees with published comments. This finding was in keeping with the hypothesis that artificial downward pressure on prices to a particular segment would result in compensating upward pressures to other segments or a "cost shifting." It can be reasoned that manufacturers would not willingly become less price competitive in the absence of upward pressure provided by OBRA '90.

Did the OBRA '90 mandated rebates cause price increase to other buyers? Many anecdotal reports of drug price increases of up to three times the rate of inflation and caused by the OBRA '90 mandated rebates have appeared in the professional print media. For instance, "according to ASHP (American Society of Hospital Pharmacists) . . . (their survey) . . . confirms what it predicted last year, that the law would have the unintended effect of raising drug costs to hospitals, HMO's, and community health centers."[32] The ASHP says their poll has received reports of hospitals and

nonprofit organizations experiencing major price increases.

The many articles suggest a consensus that the Medicaid

rebates have sparked, either fairly or unfairly, large price

hikes in bid and contract purchasing. Senator David Pryor

has characterized the situation as, ". . . numerous

confirmed reports that some drug manufacturers are in the

process of reducing discounts . . . breaking long term

contracts, and refusing to negotiate in good faith over

price".[33] Of course, reducing or eliminating deep discounts

historically available to competitive procurement has the

same effect as raising the price to those purchasers. If

one customarily receives a 40% discount and suddenly is

given only a 15% discount on drug purchases, that would

cause a significant increase in drug acquisition cost.

The upward pressure of mandated Medicaid rebates has

been reasoned and articulated as follows by Cano:

> . . . "Economic realities suggest there is a strong
> likelihood that major manufacturers will shift costs
> to private payers as a result of the proposal's
> implementation."[34]

Another source that continues in this vein is a report

of topics discussed at the American Pharmaceutical

Association (APhA) annual meeting. The report said:

> . . . "Pharmaceutical manufacturers are said to be
> raising prices to other purchasers, including other
> government agencies, to recover the discounts being
> offered to Medicaid."[35]

Because of published statements such as these, it is

expected that the majority of responses would blame the OBRA

'90 rebates at least somewhat for these reported price

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hikes. In conformance with this, 79.2% of respondents

agreed or agreed strongly that mandated Medicaid discounts

have exerted upward pressure on prices. Only 8.3% of the

respondents opposed, indicating they did not believe the

OBRA '90 rebates exerted upward pressure on pharmaceutical

prices available to the public through channels other than

Medicaid. On this issue, 12.5% expressed no opinion at the

time of the questionnaire.

Provision of the mandated Medicaid discounts will cause

manufacturers to raise prices in other market segments.

This upward pressure will also affect group bid

acquisitions; and questions ten and eleven will examine this

issue specifically.

Question #7:   Base = 24

7. Which of the following drug purchasers, in general,

currently receives your lowest price for your single and/or

multiple source innovator drugs?   (Check one).

```
1.  ( )Medicaid          6.   ( )Veterans Administration
2.  ( )hospital          7.   ( )chain pharmacy
3.  ( )Ind. pharmacy     8.   ( )wholesaler
4.  ( )State Govt.       9.   ( )none of these
5.  ( )buying group      10.  ( )all buyers/same price--
                              Go To Question #9.
```

CHART SEVEN
Which buyer receives your lowest price?

Veterans Adm
50.0%

none of these
4.2%
state government
4.2%

Hospital
4.2%

wholesaler
8.3%

All buyers/same $
12.5%

Medicaid
16.7%

buying group
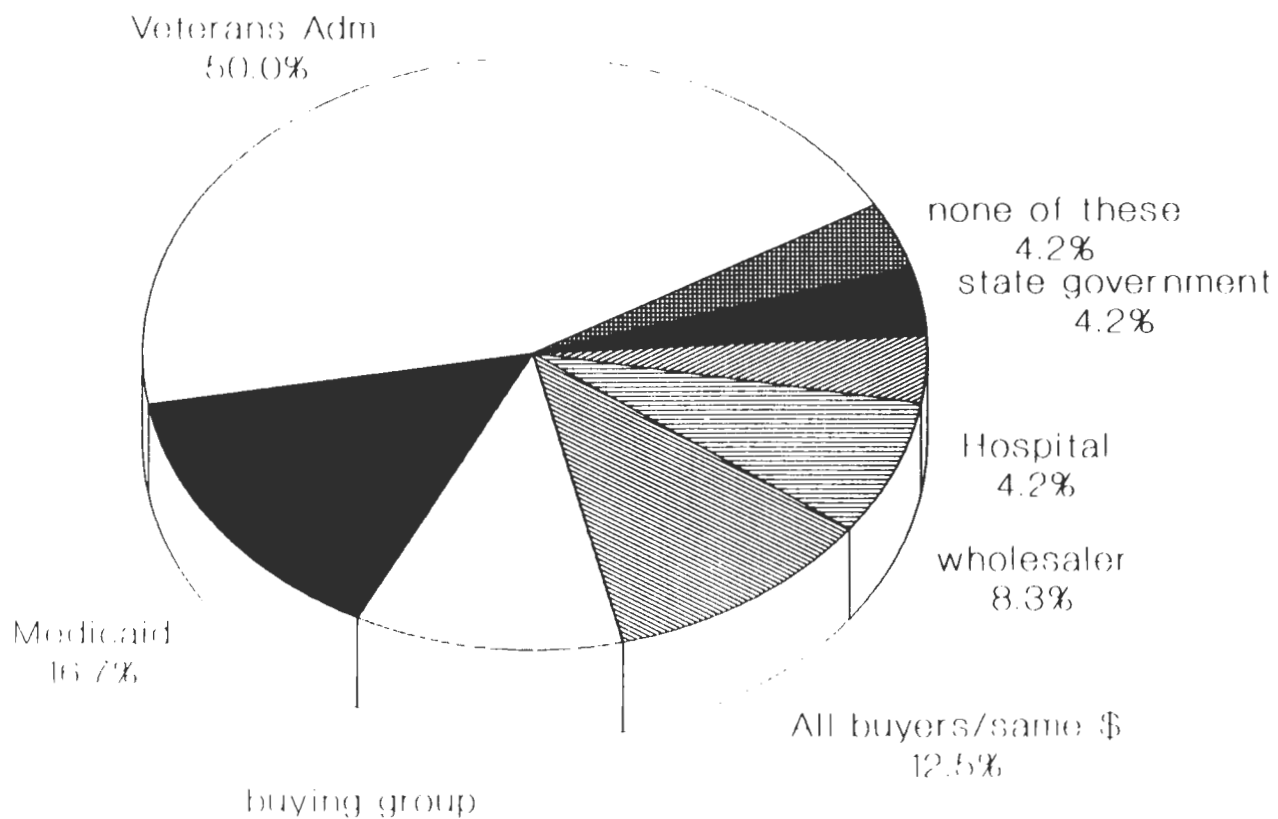
(may total > 100%)

Results:

Table Seven

	INNOVATOR MFR.		GENERIC MR.		"OTHER"		TOTAL	
ANS: #	#	(%)	#	(%)	#	(%)	#	(%)
(1)	2	(13.3)	0		2	(40)	4	(16.7)
(2)	1	(6.7)	0		0		1	(4.2)
(3)	0		0		0		0	
(4)	0		1	(25)	0		1	(4.2)
(5)	2	(13.3)	1	(25)	0		3	(12.5)
(6)	9	(60)	1	(25)	2	(40)	12	(50)
(7)	0		0		0		0	
(8)	1	(6.7)	1	(25)	0		2	(8.3)
(9)	1	(6.7)	0		0		1	(4.2)
(10)	1	(6.7)	1	(25)	1	(20)	3	(12.5)

no answer = 0
double mentions = 1*
triple mentions = 1*

*NOTE: some totals may equal more than 100% because of
         multiple mentions.

Statistical Test:

This question is tested in the binomial form, do you charge all purchasers the same price?

A Binomial Sign Test was conducted with n trials = 24. At an alpha value of .032, x = 17.   Since observed x's = 21, the null is rejected.   The responses exhibit a statistically significant preference.

The results are significant at an alpha value of .0001.

Discussion:

Question number seven was designed to test Hypothesis H6B:

---That all purchasers do not necessarily pay the same price for pharmaceuticals.

The wide variations in response support the premise that prices do vary among purchasers because many different respondents indicated many different groups of purchasers as recipients of their lowest price.

The Veterans Administration was the price winner, having been mentioned as receiving the lowest price 50% of the time. Interestingly, 12.5% of the respondents said all their customers received the same price. This was unexpected as conventional wisdom accepts for granted that different purchasers arrange unique pricing according to competitive arrangements and bargaining ability: ". . . The characteristic of competitive market conditions was found to significantly influence lowering of prices offered to purchasing groups."[36] These respondents were excused from question number eight.

Medicaid was selected as low price by 16.7% of the respondents. It is impossible to know if that were true for those respondents before the OBRA '90 act took effect. However, since Senator David H. Pryor has maintained that legislation creating the OBRA '90 rebates was necessary

because ". . . Medicaid . . . (is) . . . charged the highest prices . . ."[37] The argument can be made that this is the effect of the OBRA '90 mandated rebates. At the time of questionnaire response, OBRA '90 mandated rebates had already become active. OBRA '90 reserves to Medicaid the "best price." Medicaid and Veterans Administration are not mutually exclusive choices for low price because Veterans Administration depot[38] pricing is exempt from the "best price" calculations and, therefore, a manufacturer can give the depot a lower price than Medicaid and still give Medicaid its OBRA '90-defined "best price".

Buying groups, companies like Vector, whose business it is to negotiate (low) contract pricing with manufacturers for clients such as hospitals, were selected by respondents as receiving the lowest price 12.5% of the time while State Government, wholesalers, and "none of these" were each selected by 4.2% of respondents. Hospitals were said to receive the lowest price from just 4.2% of respondents also. No respondents said that either independent pharmacies or chain pharmacies received their lowest price.

Question seven demonstrates that different segments of the marketplace do receive different pricing for pharmaceuticals and is appropriate to this work since this thesis is in large part dedicated to exploring the effect of the OBRA '90 mandated Medicaid rebates on market segments other than Medicaid in general and in particular the market segment of pharmaceutical purchasing that is competitive bid

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purchasing. In fact, different segments of the marketplace receive very different prices.

The following attempts a brief explanation of some aspects of pharmaceutical pricing. Most people who think of pharmaceuticals envision a neighborhood drug store. Such drug stores acquire their pharmaceuticals from a wholesaler. They are charged a "wholesale price"; perhaps they receive an additional discount from this price also, individual arrangements vary greatly. The wholesalers buy their pharmaceuticals from a manufacturer; they pay less than "wholesale." The price wholesalers are charged, their acquisition cost, is defined by OBRA '90 as the "Average Manufacturers Price" (AMP). Most of the other drug buyers listed in question number seven employ various strategies in an attempt to pay as little as possible for their pharmaceuticals. The mechanism most of these purchasers employ to obtain better pricing, sometimes on their own behalf and sometimes through buying services, is the competitive bid. Bids solicit price offers from manufacturers using the force of competition to apply as much leverage as possible in order to obtain better prices. Some purchasers are more successful in obtaining low prices than others. This is a result of many factors, even the type of purchaser, that is, hospital, nonprofit hospital, charitable hospital, institution, charitable institution, and so forth. Some other more familiar factors might include dollar volume, length of contract, return policy,

etc., to name but a few variables. In general, one can say

the more competition created for the available dollars, the

lower the prices, as found by Raehtz et al.:

> "The characteristic of competitive market conditions
> was found to significantly influence lowering of prices
> offered to purchasing groups."[39]

Among all these purchasers, the Veterans Administration

depot prices are reputed to be the lowest. In fact, OBRA

'90 exempts the Veterans Administration acquisitions for the

following reason:

> ". . . the Federal government depot . . . (low) . . .
> prices reflect the manufacturer's costs of delivering
> the product in bulk to a provider, without packaging
> costs."[40]

In line with such statements, the Veterans

Administration was selected most frequently, 50% of the

time, as receiving a respondent's lowest price. Observing

the results in just innovator manufacturers the percentage

extending their lowest price to the Veterans Administration

was 60%.

In all, respondents made selections in eight separate

categories. This is evidence that prices vary widely among

various market segments. This supports the hypothesis that

all purchasers do not necessarily pay the same price for

pharmaceuticals.

Worthy of note is the result that the only two

categories that did not receive anyone's lowest price were

independent pharmacies and chain pharmacies. Those units

most familiar to the average consumer do not receive

CHART EIGHT
Is OBRA incentive to "one price" all?

not sure
9.5%

likely
14.3%

very likely
4.8%

unlikely
38.1%

very unlikely
33.3%
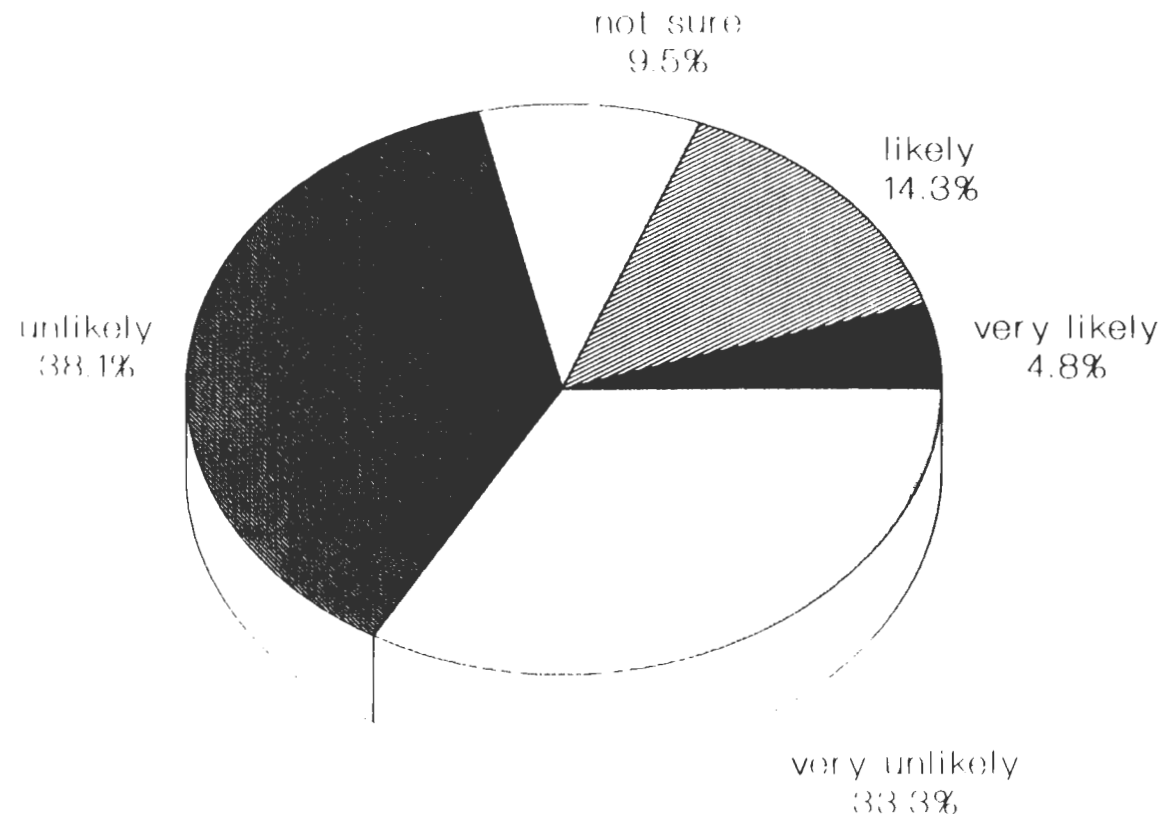
anyone's lowest price. Additional evidence that prices vary among purchasers is that pharmacy organizations have long recognized these price variations and discussed this pricing as a central topic to their business even to the point of mobilizing to affect some change. The National Association of Retail Druggists (NARD) has introduced a resolution to demand equal access to pricing for retail pharmacies and describes the existence of "multitier pricing" as . . . "the source of most of independent pharmacies problems."[41]

Question #8:   Base = 21

8. If you did not check "same price", how likely do you think that the OBRA legislation will provide an incentive to your company to offer the same price to all these purchasers?

    1. ( )very likely   4. ( )unlikely
    2. ( )likely   5. ( )very unlikely
    3. ( )not sure

Results:

Table Eight:

ANS: #	INNOVATOR MFR. # (%)	GENERIC MFR. # (%)	"OTHER" # (%)	TOTAL # (%)
(1)	1 (6.7)	0	0	1 (4.8)
(2)	2 (13.3)	1 (25)	0	3 (14.3)
(3)	1 (6.7)	1 (25)	0	2 (9.5)
(4)	6 (40)	0	2 (37.5)	8 (38)
(5)	4 (26.7)	1 (25)	2 (25)	7 (33.3)

no answer = 1

Statistical Test:

The Binomial Sign Test is used, "unsure" and no answers are eliminated, therefore n = 19. The alpha value at 5% significance is .031 for x = 14. Since the observed x's = 15, the Null is rejected. A statistically significant preference is shown by the data.

The results are significant at an alpha value of .007.

Question number eight was asked of 21 eligible respondents. The largest group of respondents, 38%, thought the OBRA '90 legislation was unlikely to provide an incentive to charge all purchasers the same price and an additional 33.3% thought that it was very unlikely. That is, a better than two-thirds majority (71.3%) support the Hypothesis H6C:

> ---That OBRA '90 will not cause all purchasers to
>   receive the same price.

Only 19.1% of responders answered that the OBRA '90 legislation would likely or very likely provide an incentive to charge all purchasers the same price. Nine point five percent (9.5%) of respondents stated they were unsure.

Discussion:

As of the date of response, the answers suggest that there will be no mass move to single pricing as a result of OBRA '90. If single pricing became the norm, medical buyers would save effort and overhead involved in price negotiations. The response suggests that medical buyers

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will still have to spend a great deal of effort, as well as overhead dollars, making sure their clients/employers receive the best price available to their market segment. This means that later discussions in this work of OBRA '90's effect on bid purchasing will remain relevant at least in the near term.

Seventy-one point three percent (71.3%) of respondents at the time of the questionnaire thought that the OBRA '90 was unlikely or very unlikely to provide an incentive to charge all purchasers the same price. This might be expected as OBRA '90 was never meant to encourage uniform pricing. OBRA '90's purpose was to secure discounts on pharmaceutical pricing for the Medicaid program.

The 12.5% of respondents to question seven who said they charged all buyers the same price were directed to skip this question.

A minority of respondents (19.1%) thought OBRA would provide an incentive to charge all purchasers the same price. This sentiment has some support in the professional media. At the Northeast Pharmaceutical Conference, the Vice President of Glaxo, the second largest manufacturer in sales of pharmaceuticals, predicted the gap between the lowest and the highest pharmaceutical prices will narrow as a result of the Omnibus Budget Reconciliation Act, "We have to lower the high price as well as raise the low price.[42]

Even if prices do get closer, however, they may not necessarily become the same for all market segments. This

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is supported by the questionnaire results. The continued existence of varied pricing means that pharmaceutical buyers will probably still rely on the bid system to obtain low prices through competition. As Lindsay has said regarding competition:

> "The available data indicate that there is much greater price flexibility and price competition in the pharmaceutical industry than has generally been assumed. Competition in prices between several sets of competing drugs has produced a downward trend in prices, relative to other consumer products."[43]

To ensure this competition, bid instruments will still be a valuable tool in market segments that previously relied on competitive bid acquisitions.

Question #9:   Base = 24

9. As the legislation requires a 12.5% discount from AMP or a "manufacturers best price," how likely is your company to publish these Medicaid prices, for example, in the company catalog, the REDBOOK, etc., so that other groups may use them as a reference?

1. ( )very likely   4. ( )unlikely
2. ( )somewhat likely   5. ( )very unlikely
3. ( )not sure

CHART NINE
Will "best prices" be published?

unlikely
29.2%

not sure
8.3%

very likely
4.2%

very unlikely
54.2%
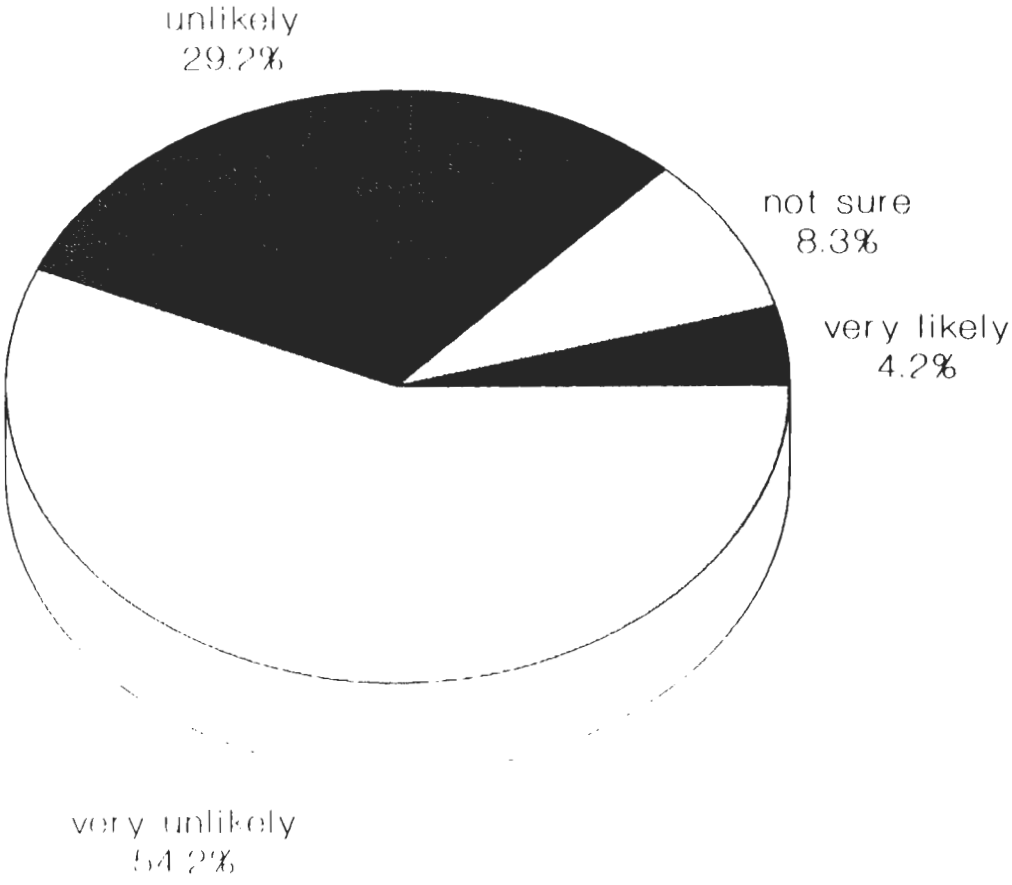
not answering • 1

Results:

Table Nine:

	INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS: #	#	(%)	#	(%)	#	(%)	#	(%)
(1)	0		1	(25)	0		1	(4.2)
(2)	0		0		0		0	
(3)	2	(13.3)	0		0		2	(8.3)
(4)	1	(6.7)	3	(75)	3	(60)	7	(29.2)
(5)	11	(73.3)	0		2	(40)	13	(54.2)

no answer = 1

Statistical Tests:

A Chi Square "goodness of fit" test is performed (see also, Methodology) for the following hypotheses:

Null Hypothesis: the responses equal random distribution.

Alternate Hypothesis: the responses differ from random in a statistically significant fashion.

Chi Square is calculated:

Chi Square = Sigma (O-E)(O-E)/E

where E = np and degrees of freedom (df) is equal to k-1 and a significance level of 5% is used (alpha = .05). The test statistic for question number nine is calculated as above with n = 23 and (probability) p = 0.2. The value of the test statistic is 20.6. The critical value of Chi Square (.05) with df = 4 is 9.488. Since the value of the test statistic is greater than the critical value, the Alternate

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Hypothesis is accepted: the responses exhibit a statistically significant preference.

A majority (83.4%) of respondents said their company was unlikely or very unlikely to publish their Medicaid prices. This majority supports the Hypothesis H6D:

> ---That while a "best price" will be known and established in order to calculate the Medicaid rebate amounts, it will not be made generally available to buyers to serve as a reference tool or benchmark against which they might judge the success of their acquisitions.

Of the 83.4% who responded in this fashion, fully 54.2% of the total respondents qualified their answer as very unlikely that their company would publish the prices. Only one respondent to the questionnaire thought that his company would publish the prices, while 8.3% of respondents were unsure.

Discussion:

It is easily understood on the basis of competition that manufacturers would prefer their prices to remain confidential. However, it removes the potential of, for instance, the State of Rhode Island accepting the U.S. Government price or that price plus a negotiated or bid "markup" as the contract price for the manufacturers pharmaceuticals. Accepting such a "Government Price" would save much work and expense by circumventing the formal bid

process. One of the elements needed to do this is, according to Rhode Island State Purchasing practices, a satisfactory industry-wide verifiable price listing to be used as baseline. Perhaps, if it were widely available, the Medicaid "best price" could be that missing element.

Historically, such information has been closely held by manufacturers even when testifying before Senate subcommittees. In an interview published in February 1990, Senator David H. Pryor enters into a discussion of the price of pharmaceuticals, especially as it relates to Medicaid pricing, and the reluctance of the drug industry to testify before Pryor's committee regarding price, profits, cost of development, etc. An especially contentious issue between Pryor and the drug companies is the appearance of what is described as ever escalating drug prices and the refusal of manufacturers to surrender their records to justify their need to charge higher prices.[44] Viewed in this light, it is surprising that any respondents would think that their company would publish sensitive price data.

Respondents who answered unsure may be reflecting the opinion that with the federal government involvement through OBRA '90 that confidentiality might be impossible. For instance, though it does not state that pricing data will be disclosed, the OBRA legislation does provide:

> ". . . That a report on pricing for prescription drugs purchased by the Department of Veterans Affairs, other federal programs, community and hospital pharmacies, and other purchasing groups and managed care plans will be submitted to several designated congressional

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committees."[45]

This misunderstanding, if indeed present, might have been
eliminated if the question had asked respondents to state
their company's preference regarding the publication of
prices. For example, "does you company favor publishing
these Medicaid prices and/or unit rebates, total rebates,
etc:", the response might have been closer to a unanimous
negative.

The 83.4% response is supportive of the hypothesis and
could possibly even understate respondents' desire to keep
price information confidential. The response also
illustrates, it is highly unlikely that pharmaceutical
buyers will be able to employ any shortcuts in their bid
acquisitions such as may have been provided by the
publication of the prices supplies to Medicaid.
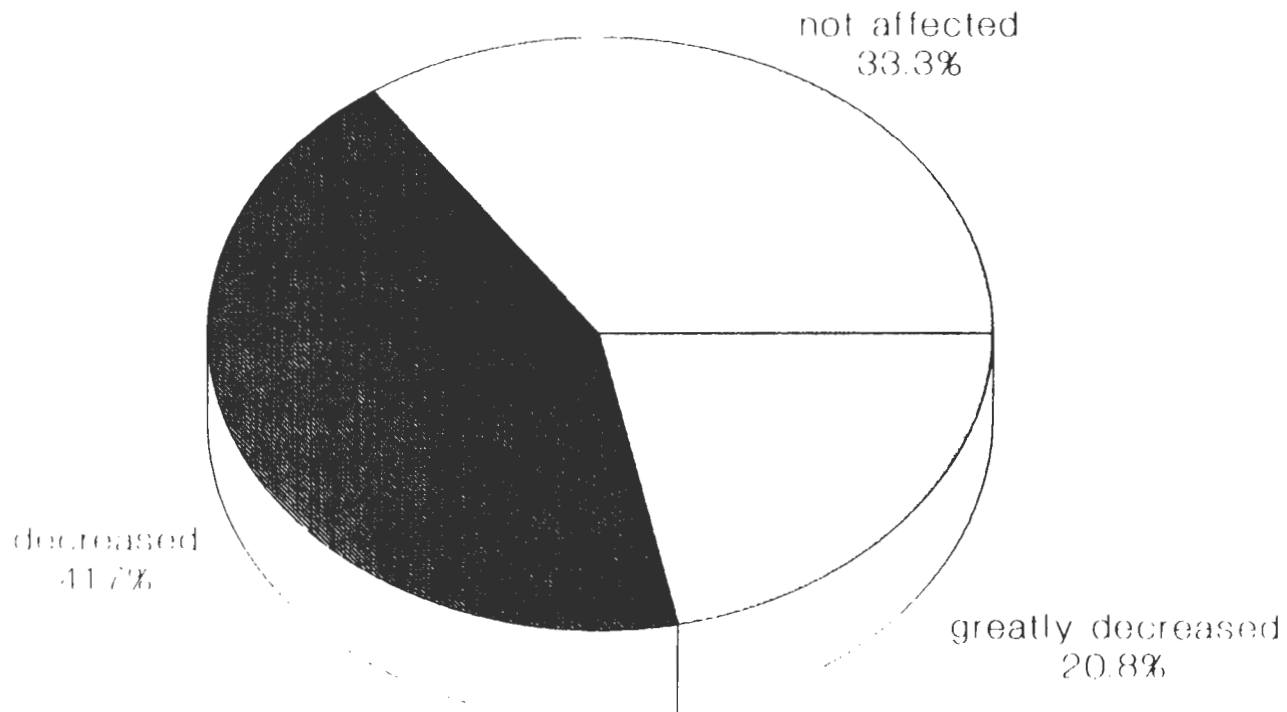

Question #10:   Base = 24

***Many segments of the pharmaceutical market practice
competitive procurement, that is, sealed bids, contract
purchasing, buying groups and so forth. The following
questions are designed to assess how this legislation will
impact the prices your company will offer to these groups.

10. Because of the OBRA '90 legislation, my company's
ability to extend special pricing to competitive procurement
groups for single and/or multi-sourced innovator drugs will
be . . .

CHART TEN
Ability to price low innovator drugs?

not affected
33.3%

greatly decreased
20.8%

decreased
41.7%

not answering ▪ 1

```
1.  (  )greatly increased        4.  (  )decreased
2.  (  )increased                5.  (  )greatly decreased
3.  (  )not affected
```

Results:

Table Ten:

		INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS:	#	#	(%)	#	(%)	#	(%)	#	(%)
(1)		0		0		0		0	
(2)		0		0		0		0	
(3)		5	(33.3)	2	(50)	1	(20)	8	(33.3)
(4)		6	(40)	0		4	(80)	10	(41.7)
(5)		3	(20)	2	(50)	0		5	(20.8)

no answer = 1

Statistical Tests:

A Chi Square "goodness of fit" test is performed (see also, Methodology) for the following hypotheses:

Null Hypothesis: the responses equal random distribution.

Alternate Hypothesis: the responses differ from random in a statistically significant fashion.

Chi Square is calculated:

Chi Square = Sigma (O-E)(O-E)/E

where E = np and degrees of freedom (df) is equal to k-1 and a significance level of 5% is used (alpha = .05). The value of the test statistic calculated as above with n = 23 and (probability) p = 0.2 is 18.07%. The critical value of Chi

Square (.05) with df = 4 is 9.488. Since the value of the
test statistic is greater than the critical value, the
Alternate Hypothesis is accepted: the responses exhibit a
statistically significant preference.

Most (62.5%) of respondents through their company's
ability to extend special pricing to competitive procurement
groups for innovator drugs would be either decreased or
greatly decreased by OBRA '90. The majority, then, support
the Hypothesis H6A:

---That OBRA '90 mandated rebates to one segment of
the pharmaceutical market will have the effect of
exerting an upward influence on prices available
to buyers other than Medicaid.

Thirty-three point three percent (33.3%) thought this
ability would not be affected, while 4.2% did not answer.

Discussion:

It was anticipated that a very large number of
respondents would indicate that OBRA '90 mandated discounts
to Medicaid would cause price increases to other buyers
because Medicaid comprises 10% of the pharmaceutical market
in the United States and this is a significant market
portion.

As OBRA '90 reserves to Medicaid a substantial rebate
from the Average Manufacturers Price (AMP) or the
manufacturers "best price," whichever is less, the incentive
will be for manufacturers to stop offering deep discounts

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because:

> "Medicaid accounts for a sizeable chunk--perhaps 10% on average--of their revenues. Now that Medicaid will be entitled to considerable rebates and eventually to the "best price" available to other buyers, it's only sensible for producers to protect their interests by raising prices . . ."[46]

Also, it is reasoned that forced discounts to Medicaid will exert upward pressure on prices available to other market segments as manufacturers attempt to maintain profitability despite significant revenues being consumed by rebates. (. . . an estimated 3.4 billion dollars over five years . . .)[47]

While 62.5% is not as large a majority as might have been expected, in light of such statements, it is still a considerable majority. Answers here may be skewed by the actual products of each manufacturer and by complex marketing decisions made at each corporate headquarters. A manufacturer with several innovator drugs, unique to their market niche, would be less affected by OBRA '90 because such a product line does not sell strictly on the basis of price and the manufacturer is under less price competitive pressure. That is, when a therapeutically unique drug (not substitutable) is indicated because of clinical considerations, for example, potency, lack of side effects, compatibility, etc., price is removed as a consideration from prescribing and purchasing. A manufacturer who enjoys such a technologically superior product line is less inclined to discount to various purchasers and would likely

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be less affected by the need to provide bids to purchasing groups who are looking for the lowest prices.

There is another area of consideration that may have lowered the majority percentage. Those respondents, (12.5%), to question number seven who said their company charged all buyers the same price. If, for any reason, a manufacturer gives little or no discount to states, hospitals, bid groups, etc., in the first place, then the OBRA '90's effect on a manufacturers group procurement policies would be diminished. In the case of these vendors who stated they charged everyone the same price, OBRA '90 could be expected to affect their bidding performance only minimally. Their answers, if consistent, may account for some of the 33.3% who maintained that their ability to extend special pricing to competitive bid groups would be unaffected. This fact tends to understate the majority support of this hypothesis (6A).

How do OBRA '90 rebates influence bid prices? The mechanics of this effect may be as follows. Before OBRA '90, a manufacturer in a competitive situation, a bid for instance, could charge whatever (low) price it chose. If it wished to pursue business in a certain sector, a teaching hospital, for example, it might set a very low price, perhaps even below cost. OBRA '90, by requiring manufacturers to rebate a percentage of AMP or extend the manufacturers "best price" to Medicaid, whichever is lower, discourages deep discounts. A manufacturer who captures

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some business by entering a low bid to a competitive purchasing market segment may have to reduce its Medicaid price below what would have been the discounted AMP amount. Then, it can be reasoned, OBRA '90's "best price" to Medicaid bars nongovernment and nonexempt buyers from receiving a price that is lower. The majority of respondents, which may in fact be understated, have answered that OBRA '90 has diminished their ability to extend special pricing to competitive procurement groups.

Questions ten and eleven were asked of the entire sample. Those answering that they charged all buyers the same price in question seven, 12.5%, could have answered accurately that OBRA '90 would have no effect on their ability to extend special pricing as they apparently do not pursue this kind of business. While it is appropriate to include these respondents to study if their ability would change, their inclusion in this analysis also lowers the number who said OBRA '90 would affect their ability to extend special pricing.

In addition, some of those respondents who have been classified as other than innovator or generic manufacturer may be wholesalers, or unit dose distributors, or businesses who may not be involved in competitive bid processes. Wholesalers, while they may be active bidders, are unaffected by legislation that requires rebates from manufacturers and would accurately describe themselves as unaffected.

In question two, it was seen that 8.3% of all respondents did not participate in the rebate program. Non-participants in the rebate program would also be unaffected by OBRA '90.

Another factor that lowers the majority result is the manufacturers product line. Question ten relates specifically to innovator drugs. Any respondents who market drugs, but not innovator drugs, that is, a generic manufacturer, would appropriately respond that they were not affected.

Finally, it is important to note that **no one** said they expected the OBRA '90 legislation to allow increased ability to extend special pricing.

For all these reasons then, the 62.5% response that expected a decrease in the ability to extend special pricing adequately supports the hypothesis that purveyors of innovator drugs are less able to extend special prices to competitive procurement groups because of OBRA '90 legislation.
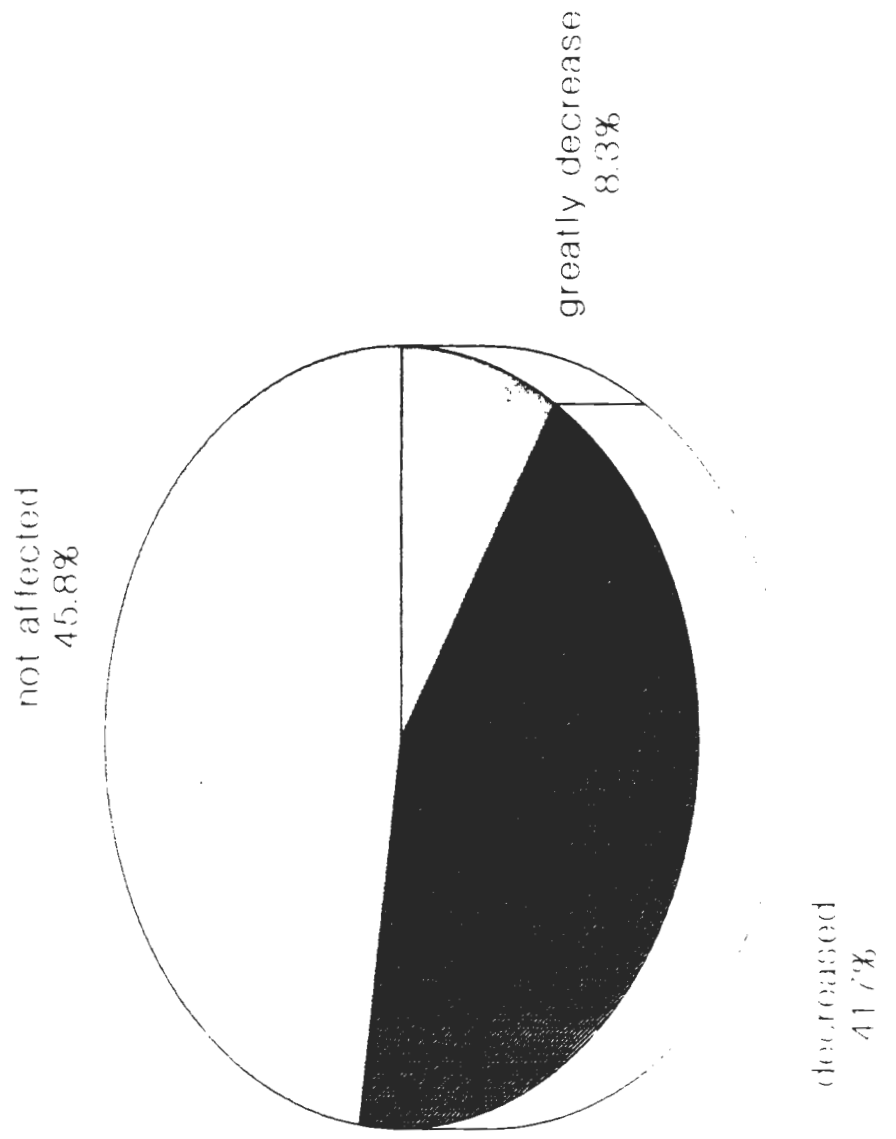
Question #11:   Base = 24

11. Because of the OBRA legislation, my company's ability to extend special pricing to competitive procurement groups for generic drugs (multi-sourced, non-innovator) will be . . .

CHART ELEVEN
Ability to low price generics?

not affected
45.8%

greatly decrease
8.3%

decreased
41.7%

not answering = 1

1. ( )greatly increased   4. ( )decreased
2. ( )increased   5. ( )greatly decreased
3. ( ) not affected

Results:

Table Eleven:

		INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS:	#	#	(%)	#	(%)	#	(%)	#	(%)
(1)		0		0		0		0	
(2)		0		0		0		0	
(3)		7	(46.7)	2	(50)	2	(40)	11	(45.8)
(4)		5	(33.3)	2	(50)	3	(60)	10	(41.7)
(5)		2	(13.3)	0		0		2	(8.3)

no answer = 1

Statistical Tests:

A Chi Square "goodness of fit" test is performed (see also, Methodology) for the following hypotheses:

Null Hypothesis: the responses equal random distribution.

Alternate Hypothesis: the responses differ from random in a statistically significant fashion.

Chi Square is calculated:

Chi Square = Sigma (O-E)(O-E)/E

where E = np and degrees of freedom (df) is equal to k-1 and a significance level of 5% is used (alpha = .05). The value of the test statistic calculated as above with n = 23 and (probability) p = 0.2 is 25.91. The critical value of Chi

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Square (.05) with df = 4 is 9.488. Since the value of the test statistic is greater than the critical value, the Alternate Hypothesis is accepted: the responses exhibit a statistically significant preference.

At the time of questionnaire response, 45.8% of those responding said that their ability would not be affected while 50% thought their ability would be either decreased or greatly decreased. For generic drugs then, exactly one half of respondents support the hypothesis H6A:

> ---That OBRA '90 mandated rebates to one segment
> of the pharmaceutical market will have the
> unwanted effect of exerting an upward influence
> on prices available to buyers other than
> Medicaid.

Discussion:

Question eleven was asked of the entire sample. There are some factors, discussed previously in question ten, which may have affected respondents answers so as to understate the support for the hypothesis. Factors that may have increased the number of respondents selecting unaffected are:

> The entire sample was polled and this included respondents who answered that they charged all buyers the same price in question seven.

> Some respondents classified as other may not be manufacturers and thus not affected by OBRA '90.

> Some responders may not supply special discounts to bid acquisitions anyway.

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Those respondents in question two (8.3%) who said they did not participate in the rebate program would be unaffected.

The percentage of respondents selecting unaffected is 45.8%. Some of this considerable number may have been due to respondents who thought their ability to bid generic drug prices would be unaffected because of internal policy adjustments made in direct response to the OBRA '90 mandated rebate provisions. January 1991 was the effective date of the OBRA '90 regulations. Generic companies were required by the provisions of OBRA '90 to rebate to Medicaid sufficient funds to result in a discount equivalent to 10% below the AMP, that is, 10% below what wholesalers pay for drugs when they purchase them direct from the manufacturer for resale to retailers. The generic OBRA '90 rebate probably served as incentive to manufacturers of generic drugs to restructure their pricing strategies. Severe discounts may have been curtailed or eliminated. Thus, respondents may have been influenced by the time of questionnaire response, June 1992. Having previously made what adjustments were possible, respondents might have been influenced to answer that their ability would be unaffected (future tense) as they answered the questionnaire in June 1992, meaning, in fact, since they had adjusted in calendar 1991 there would be no additional effect. This could have been eliminated if different verb tense had been used in the question: . . . "My company's ability to extend special pricing to competitive procurement groups has been . . ."

This might have eliminated any possible confusion for those responding.

Those who felt their ability to extend special pricing would be decreased or greatly decreased comprised 50% of the responses. These responses may be understated by the inclusions of those companies who charge all buyers the same price as discussed in the previous question. As hypothesized, a forced discount to below wholesale prices for Medicaid customers plus the potential for being forced to supply at the "best price" level would disincline manufacturers from bidding at price levels below that obtained for Medicaid by calculating a fixed reduction from wholesale acquisition cost. Because if they did price below those levels, "best price" requirements would force them to match that price for Medicaid purchasers up to specified OBRA '90 limits. For example, if a generic manufacturer bids a drug to the State of Rhode Island at a price of $10.00, and the discounted price to Medicaid is $11.00, the manufacturer must then make an additional rebate to Medicaid of $1.00 for each unit. The extra $1.00 would be provided for each unit Medicaid purchased in each state. Importantly, while the State of Rhode Island may have purchased 100 units, Medicaid, in each state, may have purchased thousands and must receive a rebate for each unit. It is conceivable in this way that a manufacturer could end up rebating many more dollars to Medicaid than it profited by its sales to the State of Rhode Island, amounting to

actually losing money. Then it can be understood how important it would be for a manufacturer not to sell at too low a price to anyone but Medicaid. This, in effect, creates an artificial floor to bid prices because manufacturers who price below this floor risk triggering the "best price" mechanism of OBRA '90. Large discounts, historically available, cannot penetrate this floor without causing potentially serious financial repercussions for the manufacturer.

The numbers claiming that their ability would be unaffected (45.8%) is greater than the number claiming no effect in question ten (33.3%). This may be a sign of an obvious phenomenon, that generic drugs are more price competitive than innovator drugs. For example, if 100 manufacturers produce an acceptable quality Penicillin G and many competitive procurers poll many vendors, the winning price is likely to be very low as manufacturers compete in this example strictly by price. Theoretically, the low price vendor will win the bid. Wholesale prices will also be low due to market pressure as wholesalers may choose one, two or several vendors' Penicillin G to inventory, but not all. In this case wholesalers may exert downward pressure on prices just as effectively as a competitive procurer can with a bid instrument. (Recall that the AMP is defined by OBRA '90 as the price manufacturers charge wholesalers.) So, if one accepts this idea of a very narrow trading range, one can see that many multi-source products may have been in

no danger of breaking through that "best price" floor. Those responders who favor this view of the generic market could be more likely to respond in the not affected category. That the generic drugs are considered more price competitive can be seen in the OBRA '90 legislation which requires smaller rebates on generic drugs than on brand name innovator drugs (see Appendix 3).

Those who felt their ability to extend special pricing would be decreased or greatly decreased comprised 50% of the survey. These responses were the expected majority. Forced discounts to below wholesale prices for Medicaid customers plus the potential for being forced to supply at the "best price" level should disincline manufacturers from bidding at price levels below that obtained for Medicaid. It was reasoned that many respondents aware of this potential would say that their ability to price (low) to competitive procurement would be decreased in some degree. The existence of this "price floor" will affect the success of competitive bid acquisitions in achieving low prices for pharmaceuticals.

Question #12:   Base = 24
12. OBRA '90 specifies that "single contract awards" and "exempt awards" will not affect Medicaid rebate calculations. Assume a bid group can qualify their acquisitions as such. How likely is the group to obtain better pricing from your company if the prices you offer are

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CHART TWELVE
If bidder exempt, will price be less?

somewhat likely
12.5%

very likely
16.7%

very unlikely
4.2%

unsure
50.0%
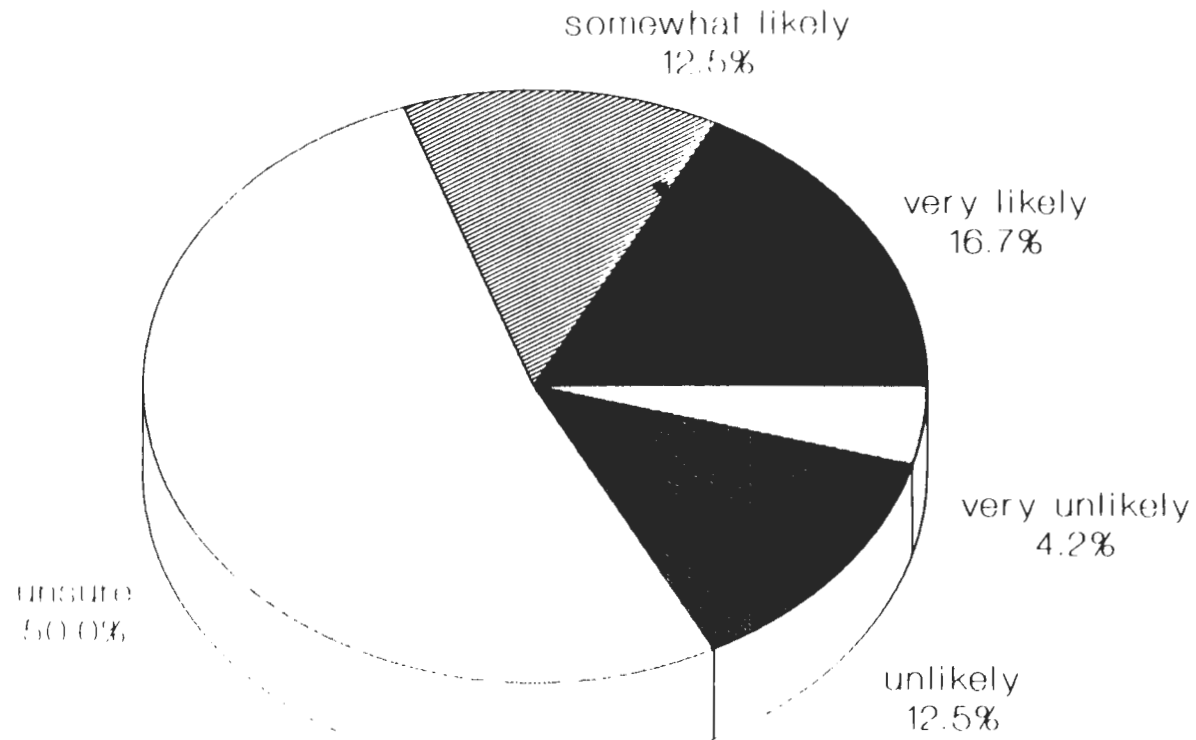
unlikely
12.5%

not answering • 1

exempt from these calculations?

1. ( )very likely   4. ( )unlikely
2. ( )somewhat likely   5. ( )very unlikely
3. ( )unsure

Results:

Table Twelve

	INNOVATOR MFR.		GENERIC MFR.		"OTHER"		TOTAL	
ANS: #	#	(%)	#	(%)	#	(%)	#	(%)
(1)	3	(20)	1	(25)	0		4	(16.7)
(2)	2	(13.3)	1	(25)	0		3	(12.5)
(3)	8	(53.3)	1	(25)	3	(60)	12	(50)
(4)	0		1	(25)	2	(40)	3	(12.5)
(5)	1	(6.7)	0		0		1	(4.2)

no answer = 1

Statistical Tests:

The question is tested with a Chi Square "goodness of fit" test. The hypotheses tested are:

Null Hypothesis: the responses are a random distribution.

Alternate Hypothesis: the responses exhibit a statistically significant preference.

$$\text{Chi Square} = \text{Sigma } (O-E)^2/E$$

The critical value of Chi Square at a 5% significance level and degrees of freedom equal to 4 is 9.488. The value of the test statistic calculated as above with n = 23 and (probability) p = 0.2 is 15.89.

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Since the value of the test statistic falls in the rejection region (Chi > 9.488) and the null is rejected. The alternate is accepted; the results are statistically significant.

More than one quarter (29.2%) of respondents thought it likely or somewhat likely that a bid group's acquisition, if qualified as exempt, would result in lower prices. This was a lower number than the media reports led one to suspect would answer in the affirmative. As hypothesis H6G states:

> ---That if a competitive procurement group's acquisition can become classified as an "exempt award" and, therefore, not a factor to be considered in the Medicaid "best price" rebate calculations, this will result in lower prices being offered.

Discussion:

The reasons why an exempt bid might win lower prices are as discussed earlier, recall the "best price" and price floor mechanisms. Before OBRA '90, manufacturers could price their pharmaceuticals at whatever (low) level they chose. If manufacturers really wanted to win a particular bid, for example, for reasons of prestige or market penetration in a particular area, or any reason, prices even below cost could be offered. Now OBRA '90 mandates that Medicaid shall have access to rebates calculated from the Average Manufacturers Price (AMP) or, if lower, shall receive the manufacturers "best price" which OBRA defines as:

". . . The lowest price aid by any purchaser (exclusive of depot prices and single award contract prices as defined by any federal agency) . . . exclusive of nominal prices . . ."

The "best price" scenario is well illustrated by Myers:[48]

"Consider a company that sells a product at an average manufacturer's price (AMP) of $50.00, but gives a special price to $5.00 (best price) to hospitals or other preferred buyers. Assume these prices do not change through 1993. In 1991 this firm will have to provide Medicaid a rebate of $12.50 per unit (25% of AMP); in 1992 the rebate will increase to $25.00 (50% of AMP). . . . After 1992, however, the cap is removed, and beginning in 1993 the rebate would be $45.00 per unit. . . . To avoid paying such a high rebate a firm may try to raise its prices in the preferred markets. The closer the best price in the preferred markets comes to the AMP, the lower the firm's rebate . . . (to Medicaid) . . . will be."

Because the manufacturer offered this hospital (example above) a lower price than the AMP, OBRA '90 mandates that an extra rebate must be made to each state Medicaid agency as calculated above.

On the other hand, the 29.2% of respondents who thought exempt bids would receive lower prices compares well to question seven regarding the Veterans Administration pricing. There, 50% of respondents said the Veterans Administration received their lowest price for pharmaceuticals. Veterans pricing is specifically exempted from the "best price" mechanism. Selection of the Veterans Administration in question number seven shows it is possible for one purchaser to receive a lower price than other market segments. Most of those other segments listed in question number seven do not have the "best price" exemption.

Admittedly, it does not prove that the reason the Veterans Administration obtained the lowest prices was because of the "best price" exemption. Literature quoted earlier leads one to believe that the combination of competition and the low cost of the depot system of distribution have been the historic reasons the Veterans Administration has secured low cost. Nevertheless, what the literature and the questionnaire responses do show is that manufacturers can continue to offer the VA low prices by virtue of its exemption without incurring rebate penalties under OBRA '90's "best price" provisions.

Some bias is included in this question by surveying those respondents who either do not participate in the Medicaid rebates or who indicated that they charge all buyers the same price. These responders would be expected to answer that exemption would not affect their bid prices.

Another issue might have been the perceived threat of the question. Respondents might have worried that bid groups might incorrectly identify themselves as exempt. Then having given those groups lower prices, perhaps depot pricing, the company would be obligated to give extra rebates to Medicaid because of the "best price" mechanism.

Examining responses further, one notices the large number of "unsure" answers. A total of 50% answered that they were unsure that an exempt bid would result in lower prices. Those respondents who selected unsure may have done so, in part, because they knew there is no specific method

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in the OBRA '90 regulations that explained how an organization other than a federal agency may qualify itself as "exempt" and, therefore, not affecting the Medicaid rebate calculations.

Positive responses would have been higher than 29.2% and unsure responses fewer if the question could have used specific OBRA '90 language that qualified a group as exempt in question twelve such as: "assume a bid group qualifies as exempt as established by paragraph 15 . . ." Since exempt is undefined, many might have selected "unsure" because they felt more information was needed. They might have been concerned that such exempt acquisition by non-Federal purchasers was impossible.

Another possible factor is that the question asks how likely respondent's company is to offer lower pricing. Responders may have felt that elimination of the "best price" mechanism as a factor would potentially allow lower prices; however, they may have been unsure their company would lower its prices regardless.

Finally, perhaps such a theoretical question was not answerable without a full understanding of corporate position on the matter and corporate position on such matters may not exist. Responders may have considered themselves too low on the corporate ladder to speak on policy issues not yet formed.

In summary, among those who expressed an opinion, as opposed to "unsure", responses were almost 3:1 that

exemption would allow lower prices (29.2% vs. 8.4%). Only 29.2% of respondents support the hypothesis that exemption from the "best price" mechanism would result in lower bid acquisition prices for pharmaceuticals.

CONCLUSION

A majority of respondents on the Rhode Island
pharmaceutical bid list are and will continue to be
participants in the OBRA '90 mandated Medicaid rebates.
Because of the nature of the population sampled, a list of
bidders in the State of Rhode Island, readers are cautioned
that the researcher cannot infer that these conclusions are
valid on a national basis. Any extrapolations to the
national scene are solely at the discretion of the reader.
Literature surveyed indicates that it is in these vendors'
self-interest to participate because participation allows
eligibility of full product line to Medicaid coverage. The
Medicaid market accounts for 10% of the dollar volume spent
on prescription drugs in the United States. Participation
in the rebates, while providing substantial savings to
Medicaid's drug bill, is expected to result in the loss of
at least some gross profit to a majority of respondents.
When respondents were asked how such a loss in gross profit
would be replaced, responses varied widely. Public
statements of manufacturer spokespersons to the contrary,
the majority of respondents did not predict that loss of
gross profit would result in a reduction of research
expenditure; however, it was not possible to test these
responses for statistical significance. Unfortunately, the
study was not able to determine pre-OBRA '90 research
activity because of space and content considerations, that

is, to be effective the questionnaire could not be overly long. Paramount design considerations were for a brief, easy, nonthreatening questionnaire to maximize response. Therefore, requests for information that could be considered confidential or sensitive were avoided. Therefore, the data are not sufficient to allow stratifying respondents according to extent of pre-OBRA '90 research activity.

Regarding drug bid acquisition effects, findings support the hypothesis that OBRA '90 rebates will result in higher prices to those buyers other than Medicaid. Buyers employing competitive acquisitions, sometimes referred to as "preferred" buyers, will probably find that their customary large discounts have been curtailed as a side effect of OBRA '90's best price mechanism. Pricing will still vary customer by customer as the majority of respondents did not predict any incentive to convert to uniform pricing. In addition, most respondents said that buyers will not be provided with published best prices by their company. This would have been useful information for pharmaceutical buyers to gauge the success of their competitive acquisitions. Hence, buyers with no uniform pricing and no published knowledge of "best price," will still labor to conduct competitive bids, but results (low prices) may be less rewarding than before OBRA '90. This will likely be the result of two factors: one, the upward pressure on product line prices in general, caused by an estimated $4.2 billion

dollars of Medicaid rebates over five years, and two, the effect of the OBRA best price mechanism which will tend to limit previously available deep discounts.

Recently, certain purchasers who find themselves disadvantaged by the OBRA '90 best price mechanism are requesting its repeal and some are seeking exemption from the best price calculations in the hope of obtaining better pricing. An amendment to a separate Veterans Administration law engineered by Senator Mikulski (D-MD):

> ". . . Has exempted V A (Veterans Administration) drug discounts for six months from use in calculating Medicaid "best price" available rebates. The intent of the amendment was to encourage manufacturers to increase discounts to V A by taking V A pricing out of the Medicaid rebate equation."[49] (Note: these would be acquisitions other than the depot purchases which are already exempt, see reference to FSS below.)

And V A Secretary Anthony Principi said he is:

> ". . . Pleased with the compromise that would provide a permanent exemption of the FSS (Federal Supply Schedule) from best price calculations . . ."[50]

Also, in response to Congressional efforts by certain groups to eliminate the best price mechanism of OBRA '90:

> "Chairman Henry D. Waxman . . . (House Energy and Commerce Subcommittee on Health and the Environment) . . . has introduced an amendment that would retain the current 'best price' method of calculating rebates from drug manufacturers to state Medicaid programs through fiscal year 1994, and exclude certain purchasers, including the Department of Veterans Affairs (DVA) and the Indian Health Service, from the calculation of 'best price'."[51]

The possibility (question number twelve) of using an exempt status from best price calculations to achieve lower bid prices was also explored. Results were inconclusive at

the time of questionnaire response with the majority of respondents saying they were unsure that exemption from best price calculations would result in lower prices. However, those respondents expressing an opinion numbered approximately 3:1 in the affirmative that exempt bids would achieve lower prices by reason of their exempt status. While support for the hypothesis that exemption from best price mechanisms would lower bid prices was inconclusive, the actions of various drug procurement groups to remove themselves from the mechanism do support this hypothesis. As mentioned above, some preferred purchasers and some departments of the Federal government are actively seeking legislative relief from the OBRA '90 best price side effects in an effort to lower their drug acquisition cost.

ENDNOTES

[1]Note: Medicaid (Title 19 of the Federal Social Security Act) is a program of national health assistance, funded by the Federal government and the states, for low-income individuals and families who are aged, blind or disabled, or members of families with dependent children.

[2]Public Law 101-508.

[3]Note: The Average Wholesale Price is an average of prices charged by representative wholesalers located in different areas of the country which are then published in various pharmacy trade publications.

[4]William N. Bilotti, anecdotal by the author while on staff at General Hospital, Rhode Island Medical Center, Cranston, RI.

[5]Carmella Bocchino, "An Interview With Senator David H. Pryor," Nursing Economic$, Vol. 8, No. 1 (January/February): 11.

[6]Raehtz, Todd R., et al., "Factors Influencing Prices Offered to Pharmaceutical Purchasing Groups," American Journal of Hospital Pharmacy, 44 (September 1987): 2075.

[7]Cotton M. Lindsay, The Pharmaceutical Industry, (New York: John Wiley and Sons, 1978), 33.

[8]Sandra M. Rifkin, ed., "Pharmacies Applaud Pryor Bill," American Druggist, Vol. 203 (May 1991): 23.

[9]Paul Cano, "Pryor Bill Spurs Medicaid Cost Containment Efforts," The Consultant Pharmacist, 5 (September 1990): 492.

[10]Anon, "Drug Companies Are Cutting Discounts to Hospitals, HMO's Says Pryor," American Society of Hospital Pharmacists Newsletter, Vol. 24 (February 1991): 2.

[11]Sandra M. Rifkin, ed., "Hospital Drug Prices Shoot Up," American Druggist, Vol. 203 (May 1991): 14.

[12]The American Biotechnology Association, "Are Cost Control Policies Too Restrictive?" Healthspan, Vol. 7 (June 1990): 6.

[13]Gerald J. Mossinghoff, "Just Take Two of These," <u>Providence Journal/Bulletin</u>, 19 October 1991.

[14]Gilbert Churchill, <u>Marketing Research</u>, (New York: CBS College Publishing, 1983): 283.

[15]Gilbert A. Churchill, Jr., <u>Marketing Research</u>, (New York: CBS College Publishing, 1983), 511.

[16]Ibid., Churchill, 510.

[17]Ibid., Churchill, 515.

[18]Paul Erdos, <u>Professional Mail Surveys</u>, (New York: McGraw Hill Book Company, 1970), 146.

[19]Paul Erdos, <u>Professional Mail Surveys</u>, (New York: McGraw Hill Book Company, 1970), Chapter 14.

[20]Sandra M. Rifkin, ed., "Medicaid Rebate Law Roils the Marketplace," <u>American Druggist</u>, Vol. 203, No. 4 (April 1991): 16.

[21]Gilbert A. Churchill, <u>Marketing Research</u>, (New York: CBS College Publishing, 1983), 217-312.

[22]Sandra M. Rifkin, ed., "Medicaid Rebate Law Roils the Marketplace," <u>American Druggist</u>, Vol. 203, No. 4 (April 1991): 14.

[23]Ibid., p. 16.

[24]John M. Coster, "The Pryor Bill: A Watershed Event for Pharmacy," <u>U.S. Pharmacist</u>, Vol. 16, No. 1 (January 1991): 58.

[25]John M. Coster, "The Pryor Bill: A Watershed Event for Pharmacy," <u>U.S. Pharmacist</u>, Vol. 16, No. 1 (January 1991): 56.

[26]Kurt A. Proctor, ed., "Medicaid Rebate Collections and Prescription Drug Expenditures Trends," <u>The Pipeline</u>, Vol. 4, No. 4 (July 1992): 2.

[27]John M. Coster, "The Pryor Bill: A Watershed Event for Pharmacy," <u>U.S. Pharmacist</u>, Vol. 16, No. 1 (January 1991): 58.

[28]Somnath Pal, "Drug Industry Invests $10.9 Billion in R & D." <u>U.S. Pharmacist</u>, (September 1992): 16.

[29]Sandra M. Rifkin, "A Tale of Two Studies," <u>American Druggist</u>, 205 (March 1992): 16.

[30]Gerald J. Mossinghoff, "Just Take Two of These," Providence Journal Bulletin, 19 October 1991.

[31]Harland A. Wade, "Positive and Negative Pressures Buffet Pharmaceutical Industry," Pharmacists' Financial News, Vol. 1, No. 2 (July 1992): 3.

[32]Sandra M. Rifkin, ed., "Hospital Drug Prices Shoot Up." American Druggist, Vol., 203, No. 5 (May 1991): 14.

[33]American Society of Hospital Pharmacists Newsletter, Vol. 24, No. 2 (February 1991): 2.

[34]Paul Cano, "Pryor Bill Spurs Medicaid Cost Containment Efforts," The Consultant Pharmacist, Vol. 4, No. 9 (September 1990): 492.

[35]Sandra M. Rifkin, ed., Pharmacists Applaud Pryor Bill," American Druggist, Vol. 203, No. 5 (May 1991): 23.

[36]Ibid., Raehtz, 2075.

[37]Carmella Bocchino, "An Interview with Senator M. Pryor," Nursing Economic$, Vol. 8, No. 1 (January/February): 6-12.

[38]Note: The Veterans Administration (VA) depot system purchases pharmaceuticals in bulk, depots are located regionally and the VA handles the distribution to facilities, quantities are large and manufacturers save the cost of distribution. This results in significant reduction in drug cost acquisition to the VA. Because part of the savings resulting are from the distribution system unique to the depot system, prices offered to the VA depot were specifically exempted from calculations of the "best price" by OBRA '90.

[39]Todd R. Raehtz, R. Milewski, and N. Massoud, "Factors Influencing Prices Offered to Pharmaceutical Purchasing Groups," American Journal of Hospital Pharmacy, Vol. 44 (September 1987): 2075.

[40]John M. Coster, "The Pryor Bill: A Watershed Event for Pharmacy," U.S. Pharmacist, Vol. 16, No. 1 (January 1991): 58.

[41]Robert D. Appel, ed., "Equal Access: Is Collaboration Possible?" National Association of Retail Druggists Newsletter, Vol. 112, No. 21 (November 15, 1990): 4.

[42] Sandra M. Rifkin, ed., "Northeast Pharmaceutical Conference," American Druggist, Vol. 203, No. 4 (April 1991): 16.

[43] Cotton M. Lindsay, ed., "The Pharmaceutical Industry" (New York, N.Y.: John Wiley and Sons, 1978): 34.

[44] Carmella Bocchino, "An Interview with Senator David H. Pryor," Nursing Economic$, Vol. 8, No. 1 (January/February): 6-12.

[45] Janice L. Feinberg, "OBRA '90: Remnants of the Medicaid Prudent Pharmaceutical Purchasing Act Become Law," The Consultant Pharmacist, Vol. 6, No. 1 (January 1991): 11.

[46] Sandra M. Rifkin, ed., "Medicaid Rebate Law Roils the Marketplace," American Druggist, Vol. 203, No. 4 (April 1991): 16.

[47] John M. Coster, "The Pryor Bill: A Watershed Event for Pharmacy," U.S. Pharmacist, Vol. 16, No. 1 (January 1991): 56.

[48] Maven J. Myers, "Possible Impact of the New Medicaid Rebate Law." American Druggist, Vol. 203, No. 2 (February 1991): 73.

[49] Denise Peterson, ed., "Senator Specter Drafting Veterans' Drug Pricing Bill," The Green Sheet, 18 May 1992.

[50] Denise Peterson, ed., "V A Says it is 'Quite Pleased' With Agreement to Exempt Prices From Medicaid," The Green Sheet, Vol. 41, No. 33 (August 1992): 3.

[51] Robert D. Appel, "Amendment Would Keep 1990-1995 Medicaid 'Best Price' Formula," National Association of Retail Druggists Newsletter, Vol. 114, No. 20 (May 1992): 6.

APPENDIX ONE

Definitions:

"Best Price": . . . "the lowest price paid by any purchaser
(exclusive of depot prices and single award contract prices
as defined by any federal agency) . . . exclusive of nominal
prices . . ."

"Average Manufacturers Price: ("AMP"): ". . . the average
price paid by wholesalers for drugs distributed to the
retail class of trade . . ."

Generic Drug: Multi-source drugs whose exclusive patent
rights have expired and with proper application to the FDA
may be made by various pharmaceutical manufacturers.
Also called "non-innovator multiple source drugs".

Generic Rebate Plan: For 1991 to 1993 the rebate is 10%;
for 1994 and future years the rebate will be 11%.

Innovator Drug: A drug whose exclusive patent rights have
not expired. Patent holder has rights to exclusive
manufacturer but may cross license other firms to
manufacture.

OBRA, The Omnibus Budget Reconciliation Act: Provisions of
this legislation require manufacturers to rebate certain
portions of the purchase price of pharmaceuticals to the
Medicaid Program in each state. Sometimes referred to as
the Medicaid Prudent Purchaser Requirements.

CPI-U: Consumer Price Index-all urban consumers, used to
calculate the rate of inflation for drug prices to see if an
additional rebate is required.

Additional Rebate: An extra rebate that is calculated using
CPI-U, on a drug-by-drug basis, to recover the increase in
average manufacturers prices over the rate of inflation,
with October 1, 1990, used as a baseline for AMP.

"Exempt Award": For the purposes of this research an
"exempt award" is an hypothetical price agreement between a
manufacturer and a purchaser in which the price quoted will
not affect the "best price to any purchaser" as defined by
OBRA '90. Such an award will not cause the manufacturer to
extend similar pricing to Medicaid or be used in any AMP
calculations.

APPENDIX TWO

Pharmaceutical Benefits Supplied Under State Medical
Assistance Programs:[1]

"Medicaid (Title XIX of the federal Social Security
Act) is a program of national health assistance, funded
by the federal government and the states, for
low-income individuals and families who are aged, blind
or disabled, or members of families with dependent
children."[2]

Medicaid is separate and distinct from Medicare, which

is a program of medical assistance for the elderly and

administered by the Social Security Administration (SSA).

Each state and some territories operate Medicaid

programs according to their own rules within a broad

framework of Federal guidelines.

Medicaid was enacted in the Social Security Amendments

of 1965, it replaced a system of categorical public

assistance that allowed the federal government to share with

the states the cost of maintaining certain groups and

providing for their medical treatment. Because the need for

increased Medical services created the need for increased

funding, Medicaid was created and amended to provide grants

to states to enable states to provide the necessary medical

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[1] Pharmaceutical Benefits Under State Medical Assistance
Programs, Fowler, Richard W., ed., National Pharmaceutical
Council, Reston, VA   22091 (September 1991), pp. 1-25.

[2] Ibid., pp. 1-25.

assistance and the categorical public assistance programs were ended.

Medicaid is available to all persons who are receiving payments under the Aid to Families with Dependent Children program and, with a few exceptions, to the aged, blind and disabled who receive Supplemental Security Income:

Eligibility standards must conform with Federal guidelines.

Payment for services is made directly to health care providers by the state administering agency or its representatives.

States provide their own quality control system following Federal guidelines.

In 1990, Medicaid accounted for $64.8 billion in Federal and state expenditures for medical services. Federal regulations describe a broad outline within which states may tailor their own programs. Funding is shared between states and the Federal government. The Federal government matches state health care provider reimbursements at a rate of between 50% and 83% depending on the state's per capita income. In Rhode Island the Federal Medical Assistance Percentage (FMAP) is 53.29%.

Federal law requires that all persons who qualify for Aid to Families with Dependent Children (AFDC) and most persons who qualify for Supplemental Security Income (SSI) also receive Medicaid coverage. Certain basic services are

required to be provided under the Medicaid coverage while others are included at the state's option. States may expand coverage to additional groups of people and expand the range of services offered.

Services Provided Under Medicaid:

1. Professional Services

2. Nursing Care Services

3. Nursing Home Services

4. Hospital and Clinic Services

5. Drugs, Supplies and Equipment

6. Special Services and Therapy

7. Institutional Care

8. Other

Pharmaceutical Reimbursement After OBRA 1990:

The Omnibus Budget Reconciliation Act of 1990 incorporated various measures to reduce expenditures for prescription drug products provided to Medicaid patients. Public Law 101-508 resulted from the OBRA 1990 and was enacted on November 5, 1990. Accordingly, effective January 1, 1991, pharmaceutical manufacturers must agree to provide rebates to all state Medicaid agencies in order for their products to be eligible for inclusion in Medicaid programs. (see OBRA rebate summary, Appendix 4).

APPENDIX THREE

SUMMARY OF OBRA '90 MANDATED MEDICAID REBATES[1]

As part of the Omnibus Budget Reconciliation Act of 1990, certain elements of previously submitted bills designed to reduce Federal and state outlays for prescription drug products provided to Medicaid outpatients were signed into law (Public Law 101-508). Accordingly, effective January 1991, in order for a manufacturer's drug product line to be eligible for any coverage under Medicaid, the manufacturer must provide rebates to all state Medicaid programs.

REBATE TERMS FOR SOLE SOURCE AND INNOVATOR MULTI-SOURCE PRODUCTS:

> Sole source and innovator multi-source products manufacturers are to pay the following rebates to each state Medicaid program quarterly.
>
> 1991: Whichever is greater, 12.5% of the average manufacturers price (AMP) or the difference between AMP and the best price, not to exceed 25%. That is, the amount of rebate is capped at 25% of the AMP.
>
> 1992: The same as 1991, except the cap becomes 50%. The potential rebate is increased to 50% of the difference between the AMP and the "best price".
>
> 1993: Whichever is greater, 15% of the AMP or the entire difference between AMP and the "best price", for 1993 there is no cap.
>
> 1994: The same as 1993.

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[1]William A. Zellmer, ed., "Summary of 1990 Medicaid Drug Rebate Legislation," American Journal of Hospital Pharmacy, Vol. 48 (January 1991): 114-117.

REBATE TERMS FOR GENERIC PRODUCTS:

    1991 to 1993: The rebate is 10%

    1994: The rebate is 11%.

ADDITIONAL REBATE:

    Should a manufacturer raise drug prices more than the
    rate of inflation, an additional rebate must be
    provided to Medicaid to the extent the price rise
    exceeds the Consumer Price Index.

    1991 to 1993: Additional rebate is calculated for each
    product of a manufacturer.

    1994: The additional rebate is calculated on the basis
    of the manufacturers product line.

Hypotheses:

H1. That most manufacturers on the State of Rhode Island bid list are familiar with the OBRA '90 mandated Medicaid rebate requirements.

H2. That most manufacturers are participating in the OBRA '90 mandated Medicaid rebates.

H3. That most manufacturers will continue to participate or will begin to participate in the OBRA '90 mandated Medicaid rebates in the near term (one year).

H4. That a majority of manufacturers will expect to lose some Gross Profit margin as a result of furnishing Medicaid rebates to each state Medicaid plan.

H5. That a reduction in profits because of the OBRA '90 mandated Medicaid rebates will cause a reduction in funds available to support research.

H6. That the following effects will occur in drug bid acquisitions:

H6a: That OBRA '90 mandated rebates to one segment of the pharmaceutical market will have the unwanted effect of exerting an upward influence on prices available to buyers other than Medicaid.

H6b: That all purchasers do not necessarily pay the same price for pharmaceuticals.

H6c: That OBRA '90 will not cause all purchasers to receive the same price.

H6d: That while a "best price" will be known and established in order to calculate the Medicaid rebate amounts, it will not be made generally available to buyers to serve as a reference tool or benchmark against which they might judge the success of their acquisitions.

H6e: That OBRA '90 will diminish manufacturers ability to offer low bid prices on innovator drugs to competitive bid acquisitions.

H6f: That OBRA '90 will diminish manufacturers ability to offer low bid prices on generic drugs to competitive bid acquisitions.

H6g: That if a competitive procurement group's acquisition can become classified as an "exempt award" and, therefore, not a factor to be considered in the Medicaid "best price" rebate calculations, this will result in lower prices being offered.

APPENDIX FIVE

Exhibits:

11 Ridge Road
North Scituate, RI   02857
Date...

Director of Professional Relations
-
-
-
-

Dear Colleague,

I am writing to request your help. By surveying active
bidders on the annual Pharmaceutical contracts for the State
of Rhode Island, I hope to find what effect, if any,
Federally mandated Medicaid rebates will have on the prices
paid by the State of Rhode Island and other procurement
groups.

Until recently, I was the Medical Buyer for the State
of Rhode Island and that assignment created my interest in
this topic. Presently, I am a Master of Science Degree
Candidate in the Pharmacy Administration Program at the
University of Rhode Island, College of Pharmacy, and this
work will be important to my degree research requirements.

Enclosed is a brief questionnaire that will take but a
few moments to complete and return in the stamped reply
envelope.

All replies are strictly confidential, there are no
hidden identifiers and all answers will be used only in
statistical tables.

Because the sampling group is select, your response is
very important to the success of this poll. Even if you
feel that you are not the most qualified to answer the
questions, your response is valuable because it will improve
statistical accuracy and help to minimize sample bias. If
you are still hesitant, please refer this survey to someone
in your organization who will answer.

If you are interested in receiving a report on the findings of this research, simply write your name and address at the end of the questionnaire. Or, if you prefer, request the results of the survey in a separate letter. Either way, your confidentiality will be respected.

Because this project must be closed soon, I would appreciate your prompt response. Thank you in advance for your kind assistance.

Sincerely,

William N. Bilotti, RPh.
MS Candidate

11 Ridge Road
North Scituate, RI
Date...

Address...
...
...
...
...

Dear Colleague,

Recently we mailed you a questionnaire asking for your help in an important survey.

If you have already returned the questionnaire, please consider this note a "Thank you" for your valuable help.

If you have not had a chance to do so as yet, may we ask you to return the completed form now. Your participation is vital to the success of our study.

Sincerely yours,

William N. Bilotti, RPh.
MS Candidate

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PHARMACEUTICAL PROCUREMENT SURVEY

DEFINITION OF TERMS:

"Best Price": . . ."The lowest price paid by any purchaser (exclusive of depot prices and single award contract prices as defined by any Federal agency) . . . exclusive of nominal prices . . ."

"Average Manufacturers Price", ("AMP"): . . ."The average price paid by wholesalers for drugs distributed to the retail class of trade . . ."

Generic Drug: Multi-source drugs whose exclusive patent rights have expired and with proper application to the FDA may be made by various pharmaceutical manufacturers. Also called "non-innovator multiple source drugs".

Generic Rebate Plan: For 1991 to 1993 the rebate is 10%; for 1994 and future years the rebate will be 11%.

OBRA, Omnibus Budget Reconciliation Act: Provisions of this legislation require manufacturers to rebate certain portions of the purchase price of pharmaceuticals to the Medicaid Program. sometimes referred to as the Medicaid Prudent Purchaser Requirements.

Survey Questions:

1. Are you familiar with the Medicaid rebate requirements mandated by the OBRA '90, sometimes referred to as the Medicaid Prudent Purchaser Requirements?
   1. ( )yes   2. ( )no   3. ( )not sure

2. Does your company participate in the Medicaid rebate program?
   1. ( )yes   2. ( )no   3. ( )not sure

3. How likely is your company to begin and/or continue participation within one year?
   1. ( )very likely   4. ( )unlikely
   2. ( )likely   5. ( )very unlikely
   3. ( )not sure

4. What effect, if any, do you think the Medicaid rebates will have on the Gross Profit margin of your company's pharmaceutical line?
   1. ( )strong increase   4. ( )some decrease
   2. ( )some increase   5. ( )strong decrease
   3. ( )no effect
   If you answered 1, 2 or 3, please go to question number 6.

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5. Which of these strategies is your company most likely
    to employ, other than price increases, to recover any
    profit margins that might be reduced by supplying
    rebates to State Medicaid programs?
    1. ( )cut advertising   4. ( )reduce research
    2. ( )expand markets   expenditure
    3. ( )cut mfr. costs   5. ( )other

6. Some purchasers believe that mandated discounts to
    Medicaid have exerted upward pressure on the prices of
    pharmaceuticals available to the public through
    channels other than Medicaid; what is your opinion?
    1. ( )strongly agree   4. ( )disagree
    2. ( )agree   5. ( )disagree strongly
    3. ( )no opinion

7. Which of the following drug purchasers, in general,
    currently receives your lowest price for your single
    and/or multiple source innovator drugs? (check one)
    1. ( )Medicaid   6. ( )Veterans Administration
    2. ( )hospital   7. ( )chain pharmacy
    3. ( )Ind. pharmacy   8. ( )wholesaler
    4. ( )State Govt.   9. ( )none of these
    5. ( )buying group   10. ( )all buyers/same price--
                                  --Go To Question #9.

8. If you did not check "same price", how likely do you
    think that the OBRA legislation will provide an
    incentive to your company to offer the same price to
    all these purchasers?
    1. ( )very likely   4. ( )unlikely
    2. ( )likely   5. ( )very unlikely
    3. ( )not sure

9. As the legislation requires a 12.5% discount from AMP
    or a "manufacturers best price", how likely is your
    company to publish these Medicaid prices, for example,
    in the company catalog, the REDBOOK, etc., so that
    other groups may use them as a reference?
    1. ( )very likely   4. ( )unlikely
    2. ( )somewhat likely   5. ( )very unlikely
    3. ( )not sure

***Many segments of the pharmaceutical market practice
competitive procurement, i.e., sealed buds, contract
purchasing, buying groups and so forth. The following
questions are designed to assess how this legislation will
impact the prices your company will offer to these groups.

10. Because of the OBRA legislation, my company's ability to extend special pricing to competitive procurement groups for single and/or multi-sourced innovator drugs will be...
    1. ( )greatly increased   4. ( )decreased
    2. ( )increased   5. ( )greatly decreased
    3. ( )not affected

11. Because of the OBRA legislation, my company's ability to extend special pricing to competitive procurement groups for generic drugs (multi-sourced, non-innovator) will be...
    1. ( )greatly increased   4. ( )decreased
    2. ( )increased   5. ( )greatly decreased
    3. ( )not affected

12. OBRA specifies that "single contract awards" and "exempt awards" will be affect Medicaid rebate calculations. Assume a bid group can qualify their acquisitions as such. How likely is the group to obtain better pricing from your company if the prices you offer are exempt from these calculations?
    1. ( )very likely   4. ( )unlikely
    2. ( )somewhat likely   5. ( )very unlikely
    3. ( )unsure

Please tell me about your company:

13. Is your company a manufacturer of pharmaceuticals at this time?
    1. ( )yes   3. ( )no--Skip to
    2. ( )not sure   Question #16.

14. Do you manufacture prescription pharmaceuticals?
    1. ( )yes   2. ( )no   3. ( )not sure

15. Does your company manufacture only generic drugs at this time?
    1. ( )yes   2. ( )no   3. ( )not sure

16. Do you market any prescription drugs protected by exclusive patent--either by your own discovery and/or by license agreement?
    1. ( )yes   2. ( )no   3. ( )not sure

Strictly optional:

    What is your job title? (e.g., vice president, supervisor, director, etc.):

If you would like a copy of the survey results as soon as available, fill in your name, company and address below. Or, you may request the results by sending a stamped, self-addressed envelope under separate cover.

_____

_____

_____

Please return the survey in the stamped envelope provided without delay.

THANK YOU AGAIN FOR YOUR COOPERATION.

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