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The Economics of Dental Amalgam Regulation

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Synopsis

Objective. This article offers a practical assessment of the cost implications of an outright total ban on amalgam use as well as a partial ban in children, pregnant women and women of childbearing age. In addition, we discuss trends in amalgam use and the impact of a ban in these populations on the future utilization of broad based dental services.

Methods. We utilized the American Dental Association 2005-06 Survey of Dental Services Rendered and Dental Economics Fee Surveys for 2006 and 2007 to evaluate the current levels of amalgam and composite use and to obtain estimates of current fee levels for these procedures. We then calculate cost increases in the groups of interest for composite alternatives in the event of a ban. Population data from the US Census Bureau’s 2006 American Community Survey was used to determine the numbers of children and women of childbearing age in the United States. Finally, we estimate the average annual cost increase of dental services over the next ten years directly related to an amalgam ban in the aforementioned groups.

Results. It is estimated that the total increased expenditures for restorations during this period would be 15.4 billion in the event of a total ban and 10.3 billion with a partial ban (children under age 14 and females of childbearing age 15-44). The cost of a single composite restoration

following a total or partial ban would increase an average of 48.80 through the period ending 2016.

With the expectation that patients receive an average of two restorations per year, the total increased annual cost of care to patients in fee-for-service settings owing to a ban would be 97.60 before insurance.

Conclusions. An amalgam ban has an identifiable effect on increasing expenditures for dental care in the groups studied. However, it is our position that a ban on amalgam use would not cause a significant decline in the utilization of needed services or result in a significant increase in the incidence of untreated dental disease. While the steadily rising costs of dental care should not be ignored or minimized, the increased cost of amalgam alternatives is outweighed by their utility in potentially higher risk sub-groups of the US population.

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Dental amalgam is a mercury-containing medical device utilized over the last 175 years in the US as the primary restorative option for decayed posterior teeth. The use of amalgam mixtures for restoring teeth was first described in the Chinese materia medica of Su Kung (AD 659) and again in the medicas of the Ming period of the 16th century where its formulation is discussed: 100 parts mercury to 45 parts silver and 900 parts tin. Trituration of these ingredients produced a paste said to be as solid as silver.³ Amalgam was reintroduced to the West in France possibly as early as the middle to late 1700's. Controversy regarding the safety of mercury amalgam has haunted this common restorative material since its introduction to the dental profession in the United States in the early 1800's.

Over the last 10 years, the scientific debate over amalgam safety has intensified. Concerned health professionals, consumer activist groups and congress have applied increasing pressure on the dental profession and federal regulatory agencies to ban or restrict the use of dental amalgam owing to alleged health effects. Furthermore, concerns related to the contribution of amalgam mercury to the environment have resulted in tighter statutory limitations on mercury emissions from dental offices in the United States.

Norway has banned all mercury containing products from commerce as of January 1, 2008⁴ and Sweden and Denmark are in the process of instituting a similar ban originally scheduled for April 1, 2008. A number of remaining nations in the European Union have imposed restrictions on amalgam use in higher risk populations and a ban appears likely in the future.⁵ Moreover, FDA has recently modified its web site regarding amalgam safety to reflect newer thinking on the potential risks associated with amalgam use in sensitive subpopulations.⁶

The Food and Drug Administration, in September of 2006, held meetings regarding the potential neurological effects of dental amalgam mercury. Two advisory panels of experts were convened, the Dental Products Panel and the Peripheral and Central Nervous System Drug Advisory Panel. FDA prepared a "White Paper" and a series of related questions for the Panel's consideration.

Selected studies were submitted to the joint panels for review to determine, among other things, if FDA's position that dental amalgam remained a safe and effective material was a reasonable conclusion. The majority of panel members concluded the White Paper determination that amalgam was safe was not reasonable given the studies provided to the panel for review. Recommendations by panel members were made regarding the need to inform patients about dental amalgam's mercury content by means of labeling changes and its use restricted in pregnant women and children⁷. While these recommendations were not binding on FDA, the agency has recently decided to reconsider the issue of amalgam regulation.

The FDA on February 20, 2002 published in the Federal Register (67 FR 7620) a proposed rule entitled "Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy." At the time,

³ Malvin E. Ring, DDS, MLS, FACD; *Dentistry-an Illustrated History*, pg. 81

⁴ Norwegian Ministry of the Environment, 14 December 2007, *restrictions on the use of chemicals and other products hazardous to health and the environment*

⁵ Prof. Nairn Wilson, Dean and Head of School, King's College London Dental Institute at Guy's, King's College and St Thomas' Hospitals, London, *EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)*

⁶ <http://www.fda.gov/cdrh/consumer/amalgams.html>

⁷ <http://www.fda.gov/ohrms/dockets/ac/cdrh06.html#dentalproductspanel>

no final rule was promulgated following the end of the docket period. On April 28, 2008, the FDA reopened a 90-day docket period for this proposed rule (Docket No. FDA-2008-N-0163) and solicited public comment on a series of questions.

The purpose of this article is to address the costs of a ban on amalgam use in the US population with an emphasis on potentially vulnerable sub-groups. We also address trends in amalgam use and discuss the effect of a ban on access and utilization of dental services.

METHODS

Conceptual Considerations and Assumptions

A practical assessment of the future costs of an amalgam ban requires certain assumptions. These assumptions are stated given current knowledge but they may lack predictive validity. The degree to which a ban in selected sub-groups would affect the future costs of dental care is dependent upon a number of factors that are challenging to quantify. For example, while composites appear to be utilized in the posterior teeth around 60-70% of the time as of 2006 in general practices⁸, nearly half of all practitioners have likely abandoned the use of amalgam altogether.⁹ Costs related to the use of alternative restorative materials in practice settings that currently do not use amalgam are already factored into current pricing levels. Practices who voluntarily abandon the use of amalgam over the course of the study period further confound attempts to establish a future annual “cost” of the loss of amalgam as a restorative option owing solely to a ban.

It is also not possible to determine the number of composites that would have been done at the patient’s request or those converted to more costly procedures such as inlays, onlays or crowns whether or not a ban was imposed. Such clinical decisions hinge upon how the restorative options are presented by the dentist, the patient’s financial resources and other factors. Treatment recommendations and costs vary considerably among dentists depending upon their location, experience, training, and technical approach.

Amalgam use appears to be declining at a current annual rate of about 4%¹⁰ even in the absence of a ban but may precipitously do so in the future. The current decline is largely due to patient desires for tooth colored restorations, concerns about potential health effects and dental practices no longer offering amalgam as a restorative option. A more rapid reduction in use would occur with increased enforcement of informed consent laws at the state level and/or restrictions in use due to federal regulation.

A ban on amalgam will have different effects on matters of utilization and access depending upon the practice setting. In our view, it is more likely a ban would affect utilization of services and not

⁸ 2005-06 *Survey of Dental Services Rendered*, Table 35

⁹ http://thewealthydentist.com/survey/surveyresults/16_MercuryAmalgam_Results.htm

¹⁰ Beazoglou, et.al., *Economic Impact of Regulating the Use of Amalgam Restorations*, Public Health Reports, September-October 2007 Vol 122

necessarily access. For example, Public health clinics, Medicaid providers and the US military would not likely see a drop in utilization of services owing to a ban. In these venues, increased costs of care are borne by the taxpayer and not the patient. The primary challenge here would be the clinical conversion to amalgam alternatives. While cost increases shouldered by the taxpayer are not to be minimized, any decline in utilization of dental services would likely be limited to private, fee-for-service environments where out-of-pocket expenses are a major consideration. We are not of the opinion that access to needed dental services would be diminished by a ban.

A reduction in restorative choices directly related to a ban on amalgam would not necessarily result in a significant decrease in restorations performed. This assumption has been advanced by other investigators but is not supported by the author's (MF) anecdotal experience over nearly 30 years of clinical practice. Price elasticity factors have also been utilized in future cost determinations¹¹. When out-of-pocket expense to the consumer is involved, the case might be made that, as the price for dental care goes up, treatment could be declined or deferred. However, if patients require treatment for dental caries, they will not usually refuse or otherwise delay treatment solely on the basis that a composite of somewhat greater cost would be used as compared to an amalgam.

We conclude that a reasonable and practical approach to future cost calculations would be to first estimate the number of amalgams done in the total population and age subgroups taking into account the fee differential between amalgams and composites as well as typical annual fee increases for these procedures. Allowing for an annual "natural" decline in use of amalgam, we then can estimate the total increase in costs in the total population and selected subgroups owing specifically to a ban over the ten-year period. Our estimates do not include costs due to a supposed decline in demand for services rendered as a result of a ban.

Data Sources

We utilized the American Dental Association 2005-06 Survey of Dental Services Rendered and Dental Economics Fee Surveys for 2006 and 2007 to evaluate the current levels of amalgam and composite use and to obtain estimates of current fee levels for these procedures. While insurance claims data were available and utilized in analyses elsewhere, we found the latter sources to be reliable and concordant with insurance carrier datasets. We also utilized the US Census Bureau's 2006 American Community Survey to determine the numbers of women of childbearing age and children.

ANALYSIS and RESULTS

We first sought to ascertain the accuracy of existing data with respect to the numbers of amalgams performed in the total population as well as those performed in the subgroups of interest. In order to do this, we primarily utilized the ADA 2005-2006 Survey of Dental Services Rendered.

General practitioners who use amalgam install an average of 460 amalgams/year, Pediatric dentists 295 amalgams/year and Prosthodontists 38 amalgams/year as of 2006.¹² Based upon these estimates, in the age group 10-49, we calculated that a total of 38,261,350 amalgams were installed as of 2006 that correlates reasonably well with Beazoglou's estimate of 33,650,112 for this age group. In the age group 9 and under, similar calculations were even more closely correlated. We found that 7,850,375 amalgams were installed in this subgroup using our approach and Beazoglou 7,785,803.¹³ We concluded that the beginning point of our analysis was consistent with what other investigators have found.

¹¹ Ibid.

¹² 2005-06 *Survey of Dental Services Rendered*

¹³ Beazoglou, op.cit.

The data in Tables I-III illustrate the cost impact of a ban on the various groups studied. The effect of an average annual “natural” decline in amalgam use was estimated to be 4%. The costs of amalgam and composites (COA, COC) reflect an average annual cost increase of 4% consistent with anticipated Consumer Price Index increases for this period. The Tables also presume that any ban would not take place until at least July of 2009, the date set for FDA to issue their final rule on amalgam classification.

The number of amalgams (NOA) in women of childbearing age (15-44) beginning in 2006 was estimated to be 60% of the total number of amalgams done in males and females for that age group. This percentage was chosen since females are estimated to utilize dental services about 60% of the time.¹⁴

Table I shows that cost increases due to a total ban through the period 2016 would be 15.4 billion or 1.9 billion annual average over the study period from the date of imposition of a ban. Table II shows a ban only in children under age 14 and would cost 3.6 billion or 449 million annually. Table III illustrates that a partial ban in women age 15-44 would cost 6.7 billion or 842 million annually. If a ban was imposed upon children age 14 and under as well as women age 15-44, the total cost would be 13.9 billion or 1.3 billion annually.

The average annual increase in cost of composite restorations over the study period would be 48.80. Presuming the typical patient received two composite restorations annually, the additional average cost of treatment owing to a ban would be 97.60 before any insurance benefits were applied.

DISCUSSION

Impact of a Ban

Despite limitations in any assessment of the effects of an amalgam ban, the assumptions utilized in our analysis provide a reasonably useful and practical means of estimating the future costs of a ban in the US population.

There is a measurable effect on the cost of dental care across the spectrum of ban scenarios. There is also the common perception that composites have a shorter service life than amalgam in the posterior teeth that would add to the cost of dental care due to the need for more frequent and complex re-treatment. Traditionally, amalgams are seen as having service lives in excess of 20 years. However, amalgams often fail long before they are replaced. The current consensus among product manufacturers and dental material’s experts suggests that composite and amalgam now have comparable service lives in excess of 10 years when restorations are evaluated using standardized laboratory parameters of clinical success.¹⁵

When considered on an individual basis, we showed that the average increased cost to the consumer in a fee-for-service setting for composite would amount to just under 100.00 annually assuming two fillings a year were done. After insurance benefits were applied, the average out of pocket cost to the patient would be around 50.00 or less depending upon reimbursement levels. We find it unreasonable to conclude that an increase of this relatively small amount annually would result in a lowered utilization of dental services owing solely to a ban.

In the case of public health, Medicaid and US military clinics, we also would not expect to see a decrease in utilization and access owing strictly to a ban. It is well known in these settings that, while many patients have access to the system, a substantial number of them do not utilize the

¹⁴ Sweet, et al, *A Comparison of dental services received by Medicaid and privately insured adult populations*, JADA, Vol. 135, January 2005

¹⁵ *Statement on Posterior Resin-Based Composites*, ADA Council on Scientific Affairs; ADA Council on Dental Benefit Programs, JADA, Vol. 129, November 1998

services for which they are eligible. If patients have access but choose not to utilize the service, than that is a problem separate and distinct from any effect of an amalgam ban.

As of 2006, there were 62,305,053 women of childbearing age (15-44) in the United States. The number of children age 14 and under as of 2006 was 30,961,337. Should a ban on amalgam be imposed on these two subgroups, the total number of persons affected by a ban would be 93,266,390 or 31% of the US population as of 2006.¹⁶ We believe this percentage of the population will not have appreciably changed by July of 2009. While this is not an insignificant number, the utility of composites is likely superior in this potentially higher risk population as compared to amalgam given the comparable service lives of these products.

About 6 million women in the US become pregnant every year. Approximately 70% of these women reported receiving dental care within the previous 12 months that was generally limited to routine examination and prophylaxis¹⁷. Other treatments rendered during this time are usually limited to emergency services to include endodontics, extractions, and temporary or permanent fillings.¹⁸ Treatments of this kind are typically limited especially during the first trimester of pregnancy. Restorative care of an elective nature is not traditionally done during pregnancy no matter what the materials choices are. While this population would be well served by substantial restrictions on amalgam use, it is our opinion a ban on the product would have minimal impact on the costs of future restorative care in this subgroup.

Trajectory of the Science

The current peer reviewed science on the matter of amalgam safety appears to be at least in equipoise, i.e., any health effects of dental mercury cannot easily be substantiated or refuted. For example, in the most recent report on the Children's Amalgam Trial, a microalbuminuria (MA) was found in amalgam bearing children that is known to be a biomarker for endothelial damage, heart disease and diabetes in adults.¹⁹ In this instance, no conclusions can yet be drawn as to whether such a finding would necessarily be predictive of potential harm, but it is cause for further study. Moreover, the investigators in the CAT have been careful to make the point that, while the parameters of neurological functioning measured in the trial have thus far not demonstrated deleterious health effects, they do not rule out possible effects using other measures of analysis.²⁰

Immune sensitization to mercury, whether immediate or delayed, once thought to be less than 1%, is currently estimated to be around 6% in the general population.²¹ Given the apparent increase in sensitization to mercury and the practical difficulty at the clinical level in ascertaining who is at risk, restrictions on the further installation of amalgams in potentially vulnerable subsets of the population should be given careful consideration.

¹⁶ 2006 American Community Survey, US Census Bureau

¹⁷ *Dental Car Use Among Pregnant Women in the United States Reported in 1999 and 2002*, Preventing Chronic Disease, Public Health Research, Practice, and Policy Vol 2:No.1 January 2005

¹⁸ Michalowicz, et.al. *Examining the Safety of Dental Treatment in Pregnant Women*, JADA, Vol.139 June 2008

¹⁹ Barregard, et.al., *Renal Effects of Dental Amalgam in Children: The New England Children's Amalgam Trial*, Environmental Health Perspectives, Vol 116, No. 3, March 2008

²⁰ Bellinger, et.al., *A Dose-effect Analysis of Children's Exposure to Dental Amalgam and neuropsychological Function*, The New England Children's Amalgam Trial, JADA, Vol. 138 September 2007

²¹ J. Rodway Mackert, Testimony before Joint Panel Hearings 2006, <http://www.fda.gov/ohrms/dockets/ac/cdrh06.html#dentalproductspanel>

The trajectory of the science implicating dental mercury in health effects can be interpreted to be following that of lead.²² Advances in diagnostic technology, identification of specific mercury biomarkers, and a deepening interest in the medical and scientific communities in the health effects of mercury have contributed to this trend. Furthermore, the identification of potential health effects of mercury far below thresholds once generally recognized as safe (GRAS) are challenging classical “dose-response” toxicity models.

CONCLUSIONS

A ban on amalgam use, whether total or partial, has an identifiable effect on the cost of dental services. We estimated the average annual cost impact of a total ban to be 1.9 billion and the cost of a partial ban in women of childbearing age and children 14 and under to be 1.3 billion.

However, we are not persuaded that an increase in the cost of restorative alternatives owing to a ban would significantly reduce utilization of dental services or unduly affect issues of access to dental care. Moreover, a distinction must be made between the overall “raw” cost increases resulting from a ban and the direct cost to the consumer. It is the cost of dental services to the consumer that largely drives utilization and we believe the increased costs owing to a ban are manageable and acceptable given the increasing doubts about amalgam safety.

The effect of a partial or total ban on lower income, uninsured patients not eligible for government funded dental care is not altogether clear owing to a multitude of socioeconomic factors. The matter of dental care utilization and access in this population has been addressed elsewhere. Brown et.al. found that, while utilization rates varied across the spectrum of educational status and income level, the general trend in dental care utilization was upward even in the face of increasing costs²³. We do not conclude there is no effect but find it plausible that a ban in of itself would not necessarily reverse that trend even in lower-income, uninsured families.

We recognize there is deep division and disagreement within the dental community regarding the substance and meaning of the current science as it relates to potential health effects from dental amalgam. However, given the trajectory of the science implicating mercury in a wide variety of medical and environmental challenges, future restrictions on the use of mercury in dentistry are inevitable.

We recommend that cost increases for dental care owing to a ban or restrictions be viewed in the broader context of the “reasonable assurance of safety and effectiveness” criteria used by FDA in their regulatory determinations. If FDA believes there is risk of harm in sensitive subsets of the population that exceeds the benefit to be obtained with amalgam, then regulatory steps can be taken to reduce that risk to provide the maximum reasonable assurance of safety regardless of cost.

Our approach does not mean a ban would be moot in the face of a natural annual decline in use of amalgam or that regulation in higher risk subgroups is therefore unnecessary. Quite the contrary, if amalgam was allowed to “die a natural death”, it could take decades before its use would fall to negligible levels placing larger numbers of patients at potentially unreasonable and unnecessary risk.

Should FDA impose a ban on amalgam or restrict its use in selected subgroups, there is an obvious presumption of identifiable risks to health. We can then make the case that the overall health care expenditures necessary to deal with diseases and conditions, known or unknown, arising from the continued installation of amalgam could far exceed the relatively manageable cost increases to the consumer for the alternatives. This is not to mention the cost to the US economy of lost work time owing to concomitant illness and disability.

²² Needleman, H.L., MD, *Mercury in Dental Amalgam-A Neurotoxic Risk?*, JAMA.2006; 295:1835-1836

²³ Brown, et.al., *Dental Care Utilization: How Saturated is the Patient Market?* JADA, vol. 130, April 1999

Finally, FDA regulation alone is insufficient in addressing the multitude of complexities surrounding the continued use of a dental material that has been the mainstay of restorative dentistry for the better part of two centuries. Dental trade organizations and societies, manufacturers, licensing boards, and state legislatures are also critically important in supporting clear and enforceable guidelines for the profession regarding the installation, removal and disposal of dental amalgam consistent with the emerging science. In anticipation of restrictions imposed by FDA on amalgam use in higher risk subsets of the population, stakeholders need to find proactive ways to offer meaningful guidance on amalgam use and its alternatives for the benefit of the dental profession as well as the consumer public.

| YEAR | NOA | COA | TOTAL BAN COC | DIFF | COST > |
|------|----------|--------|---------------------|-------|-------------|
| 2006 | 52192168 | 174.93 | 214.73 | 39.80 | 0 |
| 2007 | 50104481 | 181.93 | 223.32 | 41.39 | 0 |
| 2008 | 48100302 | 189.20 | 232.25 | 43.05 | 0 |
| 7/9 | 23088145 | 196.77 | 241.54 | 44.77 | 1033646719 |
| 2010 | 44329238 | 204.64 | 251.20 | 46.56 | 2063985754 |
| 2011 | 42556068 | 212.83 | 261.25 | 48.42 | 2060683376 |
| 2012 | 40853826 | 221.34 | 271.70 | 50.36 | 2057386283 |
| 2013 | 39219673 | 230.20 | 282.57 | 52.37 | 2054094465 |
| 2014 | 37650886 | 239.40 | 293.87 | 54.47 | 2050807914 |
| 2015 | 36144850 | 248.98 | 305.63 | 56.65 | 2047526621 |
| 2016 | 34699056 | 258.94 | 317.85 | 58.91 | 2044250579 |
| | | | TOTAL | | 15412381710 |
| | | | AC | | 1926547714 |
| | | | ACF | | 48.80 |

NOA=NUMBER OF AMALGAMS
 COA=COST OF AMALGAMS
 COC=COST OF COMPOSITES
 DIFF=DIFFERENCE COC AND COA
 COST>=COST INCREASE
 AC=AVERAGE ANNUAL COST OVER 8 YEARS
 ACF=AVERAGE COST PER FILLING INCREASE

TABLE I

| BAN AGES 0-14 | | | | | |
|---------------|----------|--------|--------|-------|------------|
| YEAR | NOA | COA | COC | DIFF | COST > |
| 2006 | 12153909 | 174.93 | 214.73 | 39.80 | 0 |
| 2007 | 11667753 | 181.93 | 223.32 | 41.39 | 0 |
| 2008 | 11201043 | 189.20 | 232.25 | 43.05 | 0 |
| 7/9 | 5376500 | 196.77 | 241.54 | 44.77 | 240703704 |
| 2010 | 10322880 | 204.64 | 251.20 | 46.56 | 480637119 |
| 2011 | 9909965 | 212.83 | 261.25 | 48.42 | 479868100 |
| 2012 | 9513566 | 221.34 | 271.70 | 50.36 | 479100311 |
| 2013 | 9133024 | 230.20 | 282.57 | 52.37 | 478333751 |
| 2014 | 8767703 | 239.40 | 293.87 | 54.47 | 477568417 |
| 2015 | 8416995 | 248.98 | 305.63 | 56.65 | 476804307 |
| 2016 | 8080315 | 258.94 | 317.85 | 58.91 | 476041420 |
| | | | | TOTAL | 3589057129 |
| | | | | AC | 448632141 |
| | | | | ACF | 48.80 |

NOA=NUMBER OF AMALGAMS
 COA=COST OF AMALGAMS
 COC=COST OF COMPOSITES
 DIFF=DIFFERENCE COC AND COA
 COST>=COST INCREASE
 AC=AVERAGE COST OVER 8 YEARS
 ACF=AVERAGE COST PER FILLING INCREASE

TABLE II

| BAN AGES 15-44 | | | | | |
|----------------|----------|--------|--------|-------|------------|
| YEAR | NOA | COA | COC | DIFF | COST > |
| 2006 | 22803393 | 174.93 | 214.73 | 39.80 | 0 |
| 2007 | 21891257 | 181.93 | 223.32 | 41.39 | 0 |
| 2008 | 21015607 | 189.20 | 232.25 | 43.05 | 0 |
| 7/9 | 10087491 | 196.77 | 241.54 | 44.77 | 451612824 |
| 2010 | 19367983 | 204.64 | 251.20 | 46.56 | 901780468 |
| 2011 | 18593264 | 212.83 | 261.25 | 48.42 | 900337619 |
| 2012 | 17849533 | 221.34 | 271.70 | 50.36 | 898897079 |
| 2013 | 17135552 | 230.20 | 282.57 | 52.37 | 897458844 |
| 2014 | 16450130 | 239.40 | 293.87 | 54.47 | 896022910 |
| 2015 | 15792125 | 248.98 | 305.63 | 56.65 | 894589273 |
| 2016 | 15160440 | 258.94 | 317.85 | 58.91 | 893157930 |
| | | | | TOTAL | 6733856946 |
| | | | | AC | 841732118 |
| | | | | ACF | 48.80 |

NOA=NUMBER OF AMALGAMS
 COA=COST OF AMALGAMS
 COC=COST OF COMPOSITES
 DIFF=DIFFERENCE COC AND COA
 COST>=COST INCREASE
 AC=AVERAGE COST OVER 8 YEARS
 ACF=AVERAGE COST PER FILLING INCREASE

TABLE III

