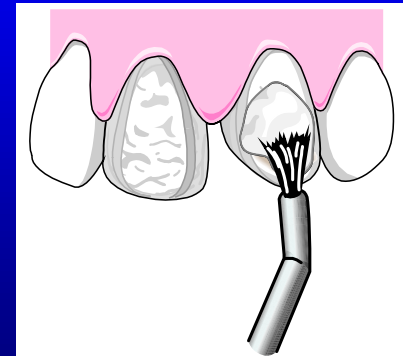


What You Need to know about Fluorides and Fluoridation!

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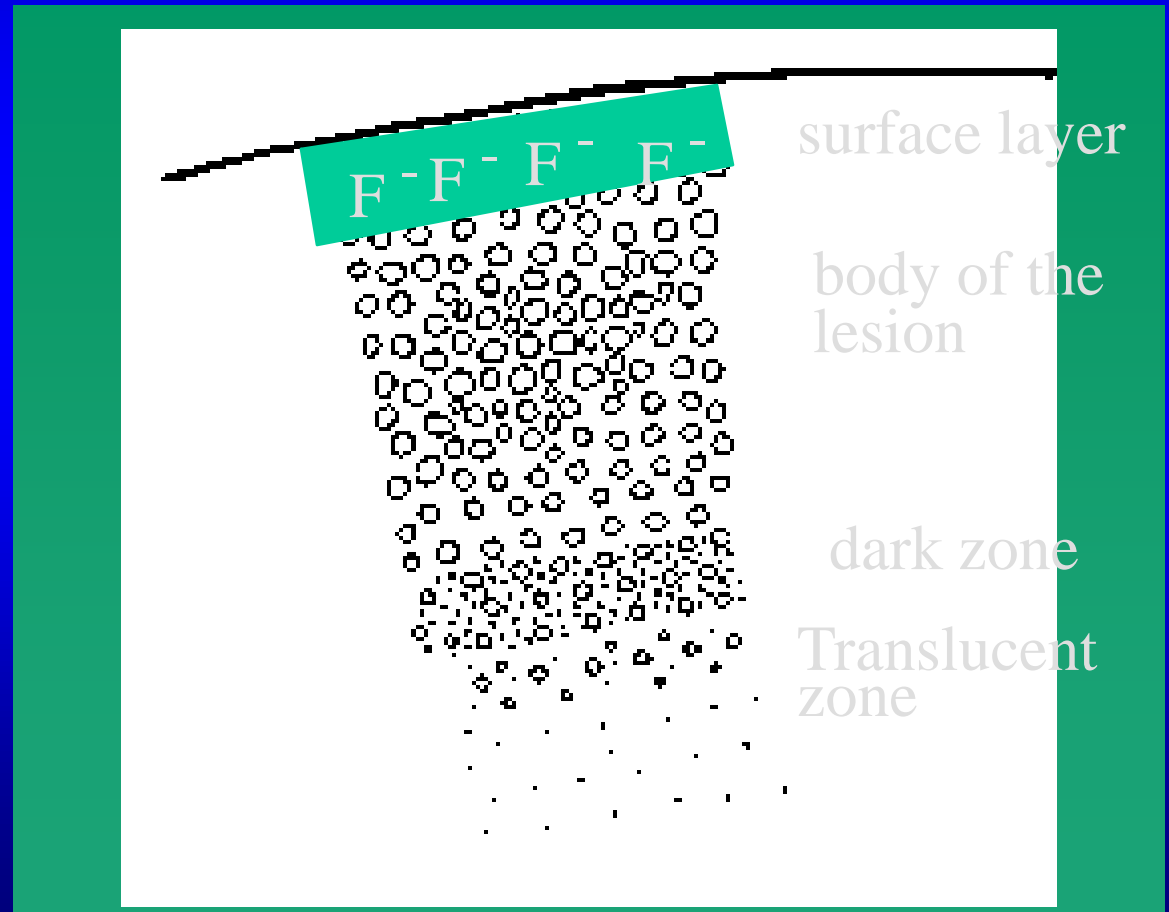
Topical Fluorides



Explosion in Product Choices...



“...F’s predominant effect is *topical*, and the effect depends on F being in the right amount in the right place at the right time.” (CDC, 2001)



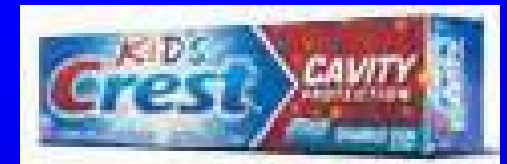
Main Fluoride Delivery Sources

– Drinking water and food

– Fluoridated products

- Water (~1 ppm)
 - Milk and Salt
- Daily Supplements

- OTC Rinses (~230 ppm)
- RX Rinses (~900 ppm)
- OTC Dentifrices (~1,100 ppm)
- RX Dentifrices and Gels (~5,000 ppm)
- In office Gels/Foams and Varnishes (~10,000 & ~22,000 ppm)



CDC Recommendations

TABLE 4. Quality of evidence, strength of recommendation, and target population of recommendation for each fluoride modality to prevent and control dental caries

Modality*	Quality of evidence (grade)	Strength of recommendation (code)	Target population†
Community water fluoridation	II-1	A	All areas
School water fluoridation	II-3	C	Rural, nonfluoridated areas
Fluoride toothpaste	I	A	All persons
Fluoride mouthrinse	I	A	High risk ¹
Fluoride supplements			
Pregnant women	I	E	None
Children aged <6 years	II-3	C	High risk
Children aged 6–16 years	I	A	High risk
Persons aged >16 years	†	C	High risk
Fluoride gel	I	A	High risk
Fluoride varnish	I	A	High risk

F toothpastes (Marinho et al., 2003)



- The regular use is associated with a clear reduction (~24%) in caries increment, which may be relatively greater with higher caries experience. (*mainly from 1000-1500 ppm*)
- A greater preventive effect was found with increased F concentration and frequency of use (*not linear; limited evidence from 5000 ppm; might be more relevant for dentin*), and with supervised brushing.
- No evidence that effect was dependent on background exposure to fluoridated water.

F Mouthrinses-History

Today we have 3 main concentrations in the US

- 100 ppm (neutral and low pH)
- 226 ppm (neutral and low pH)
- 900 ppm (neutral, Rx)

Comparison with FV:

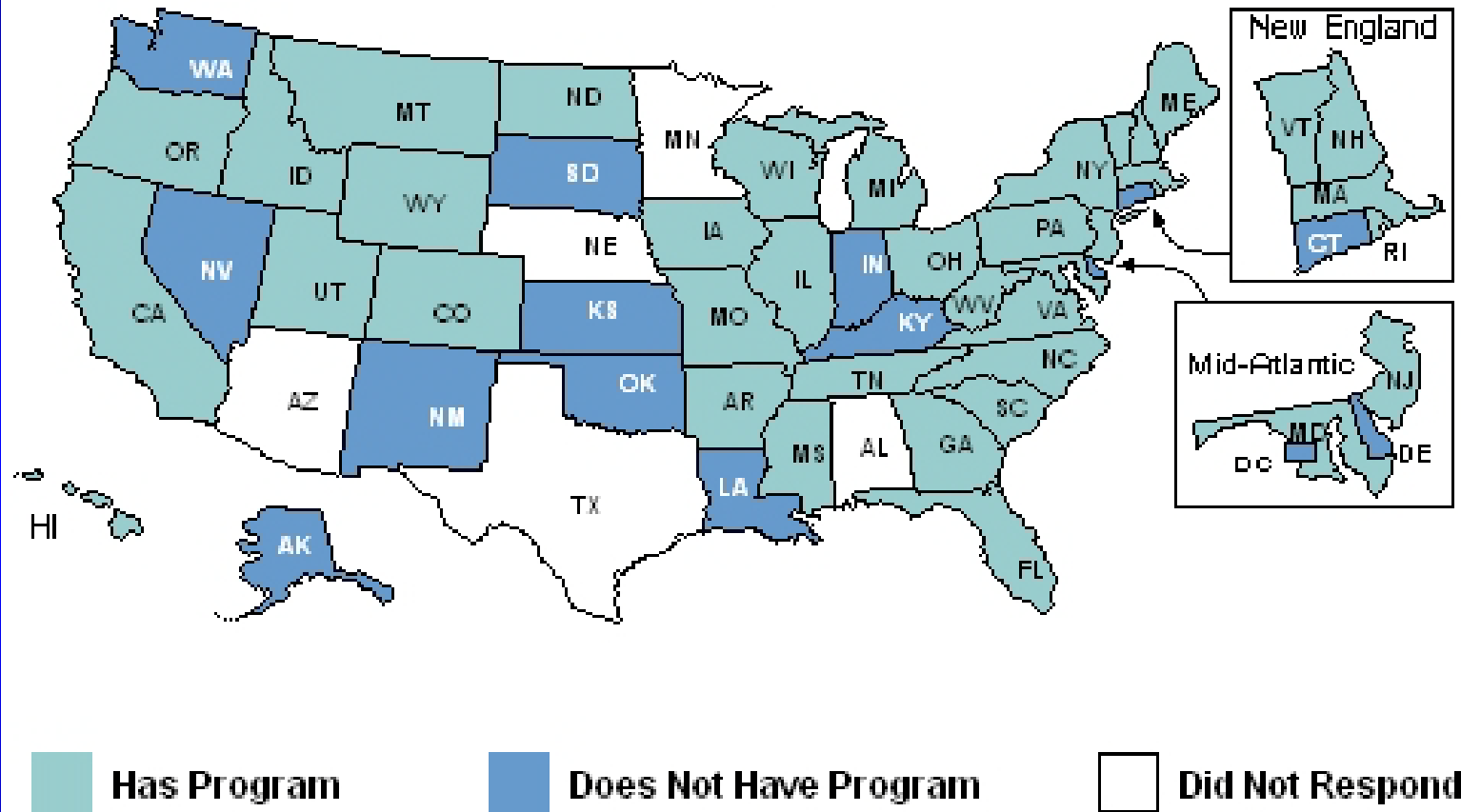
- 0.2% FMR less effective than FV (Duraphat) every 6 months - medium-risk area (Koch et al., 1979).
- FMR on the first 3 and last 3 school days every semester (1 nurse worked 4h to see 250 children) was less cost-effective than FV twice a year (2 nurses worked 4h to see 150 children) at 6-month intervals (Skold, 2005).

F Mouthrinses

- Mouthrinses and gels not appear to be more effective at reducing caries in children and adolescents than F toothpaste (Marinho et al., 2004; *The Cochrane Database of Systematic Reviews 2010*).
- The regular/supervised use of F mouthrinse (either 230 ppm 1-2x/day or 920 ppm/1x/week-0.2% NaF) by children is associated with a clear reduction (24-26%) in caries increment, regardless of fluoride background. (Marinho et al., 2003; *The Cochrane Database of Systematic Reviews, 2010*)
- Additional benefit of combining topical F products (e.g., mouthrinses) and daily F toothpaste is limited (~10%), except for at risk individuals (Marinho et al., 2004)
- “recommend that patients with fixed braces rinse daily with a 0.05% NaF mouthrinse” (Benson et al., *The Cochrane Database of Systematic Reviews 2006*)



States with Programs for Fluoride Mouthrinse 2008



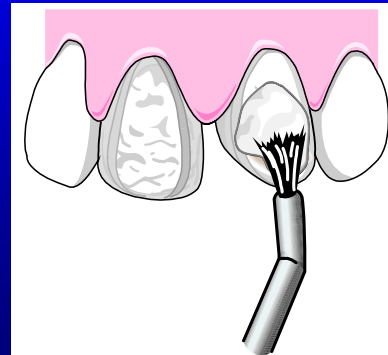
Source: The Association of State and Territorial Dental Directors and CDC Division of Oral Health's Synopses of State Dental Programs.

~32 states still reporting FMR programs

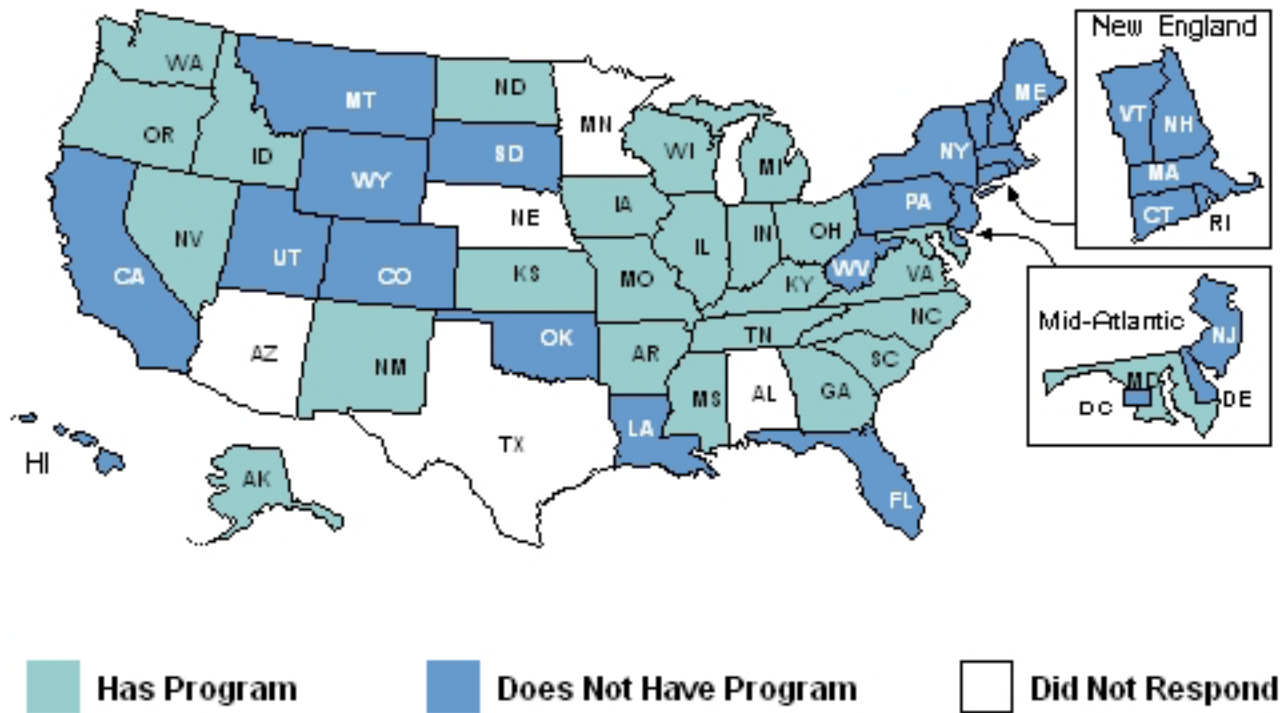
Fluoridated In-Office Products

1. ~10,000 ppm - In office Gels/Foams/Rinses (~9,000 - ~12,300 ppm)
 - a) 2% NaF (9,040 ppm)
 - » Gels, Foams, Rinses
 - b) 1.23% APF (12,300 ppm)
 - » Gels, Foams

2. ~20,000 ppm - In office Varnishes (~22,600 ppm)
 - a) Lacquers containing 5% NaF in a colophony/resin base
 - » Individual dose or 10-mL tube for multiple applications



States with Programs for Fluoride Varnish 2008



Source: The Association of State and Territorial Dental Directors and CDC Division of Oral Health's Synopses of State Dental Programs.

About 50% of states have initiated FV programs for high-risk children (in most states it must be applied by a health professional)

A bit of History of F Varnishes

- 1964 – Schmidt
 - To prolong the contact time, he incorporated NaF in a natural resin (Rosin, formerly known as colophony). Later it was registered as Duraphat®
 - Rosin is a solid form of resin obtained from pines and some other conifers. The fresh liquid resin is heated to volatilize the liquid terpene components (hydrocarbons)

A bit of History of F Varnishes

- ★ • 1960s - Duraphat®
- ★ • 1970s - Fluor Protector® (1% difluorsilane; base: polyurethane)
- ★ • 1980's - Durafluor®
- Early 1990's - Bifluorid®
- 1994- Duraphat cleared by the FDA as a class II medical device: cavity liner and for hypersensitivity
tX (some do not have approval even for this).
 - Caries prevention claim is a drug claim, therefore appropriate clinical trial evidence is needed
 - It is currently used “off label”
- 2000's Cavity Shield®, Vanish®, EnamelPro®....

Sample of FV in the US Market

All Solutions –Dentsply	Fluorilaq - Pascal
Duraphat – Colgate	Topex Durashield - Sultan
Prevident Varnish - Colgate	Dental Resources Varnish - Keystone
Flor-Opal Varnish – Ultradent	VarnishAmerica - MPL
Kolorz ClearShield – Zenith	Iris - Benco
Cavity Shield - 3M/Omnii	Massco - Eclipse
Vanish - 3M/Omnii	Duraflor Tubes & unit dose - Medicom
Enamel Pro Varnish - Premier	Halo - Medicom
Fluoridex Lasting Defense - Discus	FlouoroDose - Centrix

Most of them with no evidence at all



Easiness of Use

1. Both gels/varnish are easy to apply (varnishes easier- no trays or suction, which makes them ideal for infants/toddlers)
2. Varnish lasts 1-7 days; gels 10-15min
3. Both deposit better on demineralized surfaces (use of caries active patients or groups)

Toxicity/Undesirable Side effects

1. In office Gels/Foams/Rinses (2% NaF & 1.23% APF)
 - a) Very Safe for Adults (Fatal Acute Cases reported for Kids)
 - b) Rinses have Higher Risk
 - c) APF can damage tooth-colored restorations

2. In office Varnishes (5% NaF)
 - a) Very Safe (inadvertent ingestion is less likely)
 - b) Very small amount used (2.3-5mg)-ingestion over a long period- unlikely to contribute to fluorosis
 - c) Occasionally allergy cases have been reported to the rosin
 - d) Most Data from Duraphat

Level of Evidence-ADA Recommendations

Evidence-based Clinical Recommendations for Professionally Applied Topical Fluoride									
Risk Category	Age Category for Recall Patients								
	<6 years			6-18 years			18+ years		
	Recommendation	Grade of Evidence	Strength of Recommendation	Recommendation	Grade of Evidence	Strength of Recommendation	Recommendation	Grade of Evidence	Strength of Recommendation
Low	May not receive additional benefit from professional topical fluoride application*	1a	B	May not receive additional benefit from professional topical fluoride application *	1a	B	May not receive additional benefit from professional topical fluoride application *	IV	D
Moderate	Varnish application at 6 month interval	1a	A	Varnish application at 6 month interval	1a	A	Varnish application at 6 month interval	IV	D***
				OR Fluoride gel at 6 month interval	1a	A	OR Fluoride gel at 6 month interval	IV	D****
High	Varnish application at 6 month interval OR Varnish application at 3 month interval	1a	A	Varnish application at 6 month interval	1a	A	Varnish application at 6 month interval	IV	D***
		1a	D**	Varnish application at 3 month interval	1a	A**	Varnish application at 3 month interval	IV	D***
			OR Fluoride gel at 6 month interval	1a	A	OR Fluoride gel at 6 month interval	IV	D****	
			OR Fluoride gel at 3 month interval	IV	D****	OR Fluoride gel at 3 month interval	IV	D****	

Level of Evidence

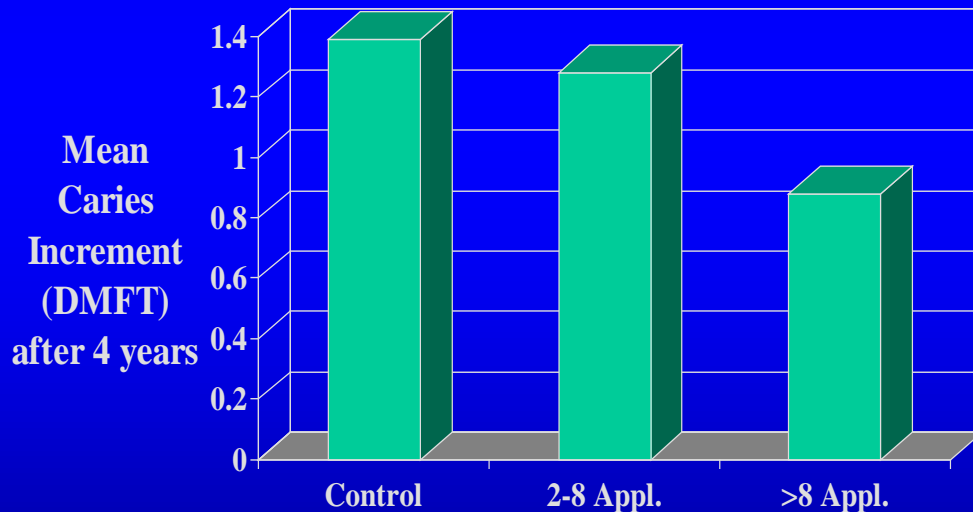
1. In office Gels/Foams/Rinses (2% NaF & 1.23% APF)
 - a) “Roughly” ~ 20% Caries Reduction in High Risk Pop
 - b) Most Evidence from Gels
 - c) Almost No Evidence for Rinses or Foams
 - d) APF likely to be more effective [gels-APF- associated with a substantial reduction (21%) in caries increment. (Marinho et al., 2001: *The Cochrane Database of Systematic Reviews*, 2006)]

2. In office Varnishes (5% NaF)
 - a) “Roughly” ~40% Caries Reduction in High Risk Pop [use 2-4 times/year, in permanent or primary teeth, is associated with a substantial (46% and 33%, respec) reduction in caries increment (Marinho et al., 2002: *The Cochrane Database of Systematic Reviews*, 2010)]
 - b) Most Evidence from Duraphat
 - c) No-limited Evidence on new ones (resin carriers)

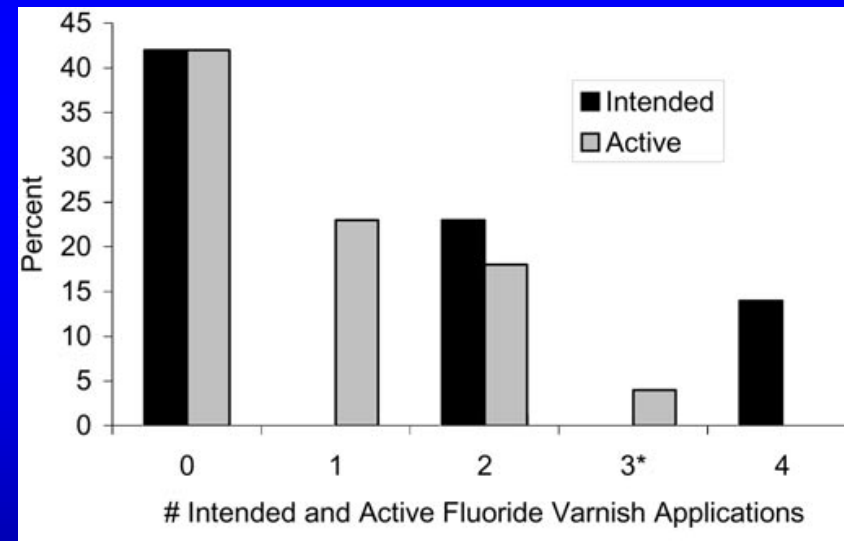
- Use in caries prevention programs for **low risk** individuals and populations, especially those that use water floss and F toothpastes, is **unlikely to be cost-effective** (Marinho et al., 2004).
- ASTDD supports FV, beginning with tooth eruption, for individuals at **moderate to high risk**. (Policy Statement, 2010)
- CDA recommends **targeting high caries risk populations (low income)** and selectively applying FV only to those **individuals who have increased risk of caries, as indicated by past or current caries** (Azarpazhooh and Main, 2008).
- The AAPD, the USDHHS Maternal and Child Health Bureau Expert Panel, and the ADA identify **low socioeconomic status (SES)** of children under 6 as a high caries risk factor an indicator for FV to reduce caries prior to onset (2007).

Varnish Effectiveness

- Effectiveness is associated with the number of applications (repeated application) *Tewari, 1990*
- Implication: < 1/year, probably waste of time



Zimmer et al., 1999



Weintraub et al., 2006

Cost-Effectiveness

1. Cost of the material for gels/varnish groups is relatively inexpensive
2. Cost of personnel to apply them (use personnel already involved in other programs)
3. Cost-effective if used in High Risk CARIIES ACTIVE patients (assess community: low SES, caries experience)

Cost-effectiveness of FV in pediatric settings during regular well-child visits at 9, 15, 24, and 36 months of age (Quiñonez et al., 2006):

- From a Medicaid's perspective, FV showed only modest improvement in outcome (2 additional months in a cavity-free state between 9-42 months of age, i.e., \$278 per case of treatment averted)...thus the program was expensive.
- Is it feasible to have pediatricians apply FV to all Medicaid children or should selected groups be targeted (need for a CRA tool)?

Are They All the Same?

We do not know!

US Regulation

- **FDA** (*medical device*)
- **ADA and ISO** (*developing standard-not for efficacy*)

Summary

- F varnish as prepared for Duraphat is clinically effective in caries management and prevention
 - Limited understanding of its MOA
- Clinical or laboratory efficacy for most of today's products is unknown
- Therefore, **program outcomes** are critical to evaluate different products/protocols for use in public health settings

Thank you...