A Glance into History

Because of the present and growing importance of the Food and Drug Administration and the publicity that it received when it celebrated its Golden Jubilee in 1956, a glance into its history will be of interest. This goes back to 1883, when that indomitable reformer, Dr. Harvey W. Wiley, was appointed chief chemist to the Department of Agriculture and embarked on a crusade for pure-food legislation. The need became apparent when the use of harmful preservatives and food adulteration, the rich harvests of the patent-medicine vendors, misleading branding, and the low standards of quality of many "ethical" medicines were revealed. What control existed was in the hands of the State Governments.

Reform by legislation takes time, and it was not until 1906 that the "Pure Food and Drugs Act," to which "Cosmetics" was later added, was passed by Congress, and was administered by Dr. Wiley until 1912. The investigative and law-enforcement functions of the Act were carried on under different organizational titles until the present name of Food and Drug Administration was provided by the Agricultural Appropriation Act of 1931. The F.D.A. was transferred from the Department of Agriculture to the Federal Security Agency in 1940, this agency becoming the Department of Health, Education and Welfare in 1953, under a Secretary with Cabinet status.

Functions of the F.D.A.

Among the functions of the Administration are the enforcement of the original Federal Food and Drugs Act, the Tea Act, the Caustic Poison Act, the Import Milk Act, and the Filled Milk Act. Its activities are "directed mainly toward promoting purity, standard potency, and truthful and informative labelling of the essential commodities covered by the provisions of these five Acts." These functions are prescribed by law, any regulations that may be imposed by the Administration on its own initiative being covered by the authority legally invested in it.

The administrative, technical, and service staff headquarters of the F.D.A. are in Washington, and it has in addition 18 district territories with chemists, inspectors, and testing laboratories. It inspects factories for raw materials used, sanitary conditions, and controls exercised in "compounding, processing, packaging, and labelling products destined for interstate shipment." Interstate commerce and the control of imports are two important factors from which the regulatory authority of the Federal Government stems. Violators are reported to the Department of Justice, but on the kindlier side the Administration also stands ready to help constructively with advice when it is sought.

By its own admission the Food and Drug Administration has been unable to discharge its duties thoroughly and effectively—it has been able to inspect each of the 1,200-odd factories only about once in five and a half years—because both funds and necessary extensions of authority have been withheld. In 1953, for instance, Congress not only reduced its appropriation but denied its request for a comprehensive factory-inspection law that would permit it to make reasonable investigations, including a look at a company's formula files.

It is hoped that the inadequacies brought to light by the Kefauver inquiry will have a salutary effect. Under

its own regulation, made effective in February, 1961, the Administration now requires that literature promoting the sale of prescription drugs must include information pertaining to "relevant hazards and conditions in which the drug should not be used."

Proposed New Measures

In July, 1960, Commissioner Larrick of F.D.A. asked for stronger regulations, especially one requiring that a new drug be barred from the market until factory inspection had confirmed the manufacturer's statement regarding the reliability of manufacturing methods, facilities, and controls. This was the request denied by Congress in 1953. Arthur S. Flemming, then Secretary of Health, Education and Welfare, went further in requesting the National Academy of Sciences to investigate the whole matter of the control of production and distribution of drugs. A committee of eight was appointed, which brought in the following recommendations "to be acted on promptly."

These provided that the F.D.A. be given statutory authority to require proof of effectiveness as well as safety of all new drugs, "to require manufacturers of new drugs to maintain records and submit reports of clinical experience and other relevant data," and to apply certification procedures to all antimicrobial agents used in prophylaxis and treatment of infectious diseases.

They endorsed the Commission's proposals "to clarify and strengthen existing inspection authority, and to require that all drugs be manufactured and packaged under adequate controls," as well as endorsing proposed amendments to present labelling requirements published by the Commissioner in the Federal Register for July 22, 1960.

They further recommended the co-ordinating of supervision of labelling, promoting, and advertising, now divided among several agencies of the Government; the maintenance of research programmes on methodology and standardization of drug testing, and the establishment of an advisory organization of scientific and technical experts.

Not least, they recommended that funds be made available for these expanded activities. It is hoped that the present Congress will take early action on the proposed measures.

TEATS

BY

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It is surprising how little guidance on the use of teats for artificial feeding of infants is offered to the medical student or even doctors and nurses whose special interests lie in the field of child care. Many paediatric textbooks deal fully with artificial milks but make slight reference to the necessary equipment for giving a bottle-feed. The result is that the practical difficulties facing a young inexperienced mother whose baby is not managing to suck successfully from a bottle may present as big a problem to her medical adviser. Hunger, vomiting, colic, and excessive crying can all be caused by faulty feeding technique and the use of

the wrong teat, whilst infection such as gastroenteritis or moniliasis may follow should cleansing and sterilization of the feeding utensils be inadequate.

An attempt has been made, therefore, to find which qualities should be present in a good teat and to observe the common faults associated with sucking from a teat.

Method

The investigation was carried out in two parts: (1) a clinical evaluation of the more commonly used types of teat; and (2) a scientific study of all readily available teats on the market.

1. An unselected group of 100 mothers attending two welfare centres in Kensington were questioned about the type of teat they used for infant feeding, the reason for their choice, how long each teat was expected to last, and what means of cleansing and sterilization were adopted. A history of vomiting, persistent crying, colic, or wind prompted more detailed questioning and an examination of the child. Where doubt existed about the cause of the symptoms a feed was supervised either at the clinic or by the health visitor in the home.

sq. cm.) pressure in a domestic pressure cooker. The results were expressed for comparative purposes as a percentage weight increase. Changes in rubber texture such as increased opacity, stickiness, and smell after the above treatments were recorded.

(b) The elasticity of the teat was calculated by measuring the static and stretched length of the diameter at the base of the teat, and for comparative results was expressed as

$$\text{stretch length} - \text{static length} \div \text{static length}$$

(c) A comparison of the flow rate through different-sized holes and different numbers of holes in various teats. The flow rate was checked at a pressure head of atmospheric +25 cm. of water. The effect on the flow rate after boiling the teat for an hour was determined.

(d) The length of the sucking-stem of the various teats was measured in centimetres.

(e) The ease of cleansing was compared. Points noted were the presence of rims and phalanges which might prove a hindrance to effective cleansing and whether or not the teat could be inverted for direct visual cleansing.

Results

The hospital, the chemist, and the advertiser are mainly responsible for the type of teat used in infant-

Types of teat (see Table).

Observations were also made on the feeding of well-established bottle-fed babies.

2. The scientific study which was undertaken by the Scientific Branch of the London County Council included a comparison of the following features in seven well-known makes of teat.

(a) The quality of the rubber as indicated by the water-absorption test. The teat was weighed and its increase in weight noted after immersion in cold water for 24 hours, boiling water for one hour, and 1% hypochlorite solution for 24 hours. Observations were made on the effect of a temperature of 120° C. for 10 minutes at 15 lb. (1.05 kg./

feeding. It is exceptional for any advice to be volunteered by the nursing staff of a maternity unit, but a mother will observe the make of teat adopted in the unit and afterwards purchase the same brand unless difficulties are encountered. The chemist's stock is variable, but at least seven different makes are readily available. Most of these are offered in varying shapes (see Fig.) with a small, medium, or large hole, or with more than one hole. The chemist bases his advice to the mother on what seems a popular sale. Financial consideration plays a very small part, as the price range between the various makes is small. Women's journals

and health magazines influence choice by the advertisements they carry, while certain manufacturers make a direct approach to mothers by sending samples of teats to the home after the announcement in the birth columns of a newspaper of the child's arrival.

Wide variations from one to six weeks were encountered when questioning mothers about the expected life of a teat. It is common for more than one teat to be in use at a time and for its effective life to be prolonged by enlarging the aperture with a red-hot darning-needle. There was a definite correlation between the life of the teat and the method of its sterilization (see below). Of the 100 mothers questioned, three placed the cleansed teat for a few moments in water that had gone off the boil, two sterilized the teat by means of a pressure-cooker, 38 boiled the teat for at least two minutes, and 57 used a hypochlorite solution for sterilization. It was not generally appreciated that the teat should be kept in a covered receptacle in the fluid in which it was sterilized until the next feed was due.

The symptoms associated with the use of the wrong teat or an inadequate understanding of how the feed should be given through a teat proved difficult to assess. This is because the most important factor of all, the adaptability of the individual baby and his power to overcome obstacles to sucking, can only be surmised. Nevertheless, supervision of a feed in cases where there was a history of crying or vomiting did achieve good results.

The commonest feeding faults encountered were:

Sucking from a teat with too small a hole or placing too much reliance on the fact that the size was bound to be adequate as it had been sold as "large" or "three-holed."

Sucking from a hole that was too large. This was not as common as the mistake above, and usually arose from the mother's attempt to increase the size of an inadequate hole by snipping off the tip of the teat with scissors.

Allowing the child to continue to suck after the hole had become occluded with undissolved particles of powdered milk. This is particularly likely to occur when reinforcing filaments in the teat structure become exposed at the rim of the hole and form a sieve which holds up solid particles that might otherwise have been sucked through.

Sucking on a teat that has poor resilience. This could be due to poor-quality rubber or to inadequate appreciation of the limited life of a teat.

Allowing the baby to suck on a flattened teat through failure to understand that a vacuum is created in the upright type of feeding-bottle as milk is sucked out, and that unless the baby releases the teat and allows air to flow freely again into the bottle the teat walls will gradually approximate. Allied to this is an unwarranted faith in the so-called "anticolic" valve of certain teats.

Failing to fill the teat with milk before inserting it into the baby's mouth.

The findings of the Scientific Branch of the London County Council are summarized in the Table. No teat was found to be ideal in all respects and some of those examined had little to recommend them. Surprising differences in size, weight, elasticity, and flow rate were noted in what purported to be batches of the same teat.

Sterilization procedures reduce the useful life of a teat. Of the available methods studied, "dry" sterilization such as occurs in a pressure-cooker caused very little deterioration of the rubber but was responsible for a rather unpleasant smell from certain teats.

Summary of Findings During Comparison of Teats

Type of Teat	Rubber Quality	Elasticity	Flow Rate	Uniformity in Size and Weight in Batches of Similar Teats	Ease with which Teats can be Cleaned
A	Good	Poor	Poor	Average	Poor
B	Poor—average	Poor—average	"	Poor	Average
C	"	"	"	Average	"
D	Poor	Poor	Good	Poor	"
E	Average	Good	Good	Good	"
F (a)	Entirely silicone	Poor	Good—excessive	Average	Poor
	teat				
F (b)	Good	Average	Poor	Good	"
G	"	Good	Good	"	Average

If hypochlorite solution is used instead, the rubber swells and tends to become opaque through absorption of water, while sterilization by boiling causes the greatest damage, for the effect of heat on the rubber is added to that of water. Sterilization will be effective only if applied to a teat that has been previously cleaned. If warm water is used instead of cold for the initial rinsing it will precipitate a film of coagulated protein from the milk on to the inner wall of the teat, and this is difficult to remove and may interfere with subsequent sterilization. In a hard-water area dissolved salts, which come out of solution when tap-water is boiled, are deposited on the teat, and from simple observation this film is difficult to differentiate from that of coagulated milk protein.

Discussion

Ardran and Kemp (1959) have shown by means of cine films that for effective sucking from a teat a baby must be able to compress the rubber between his tongue and hard palate, occlude the neck of the teat between his jaws, and eject the milk through a hole that is large enough. Should the teat walls be too rigid—and this applied to some of those we examined—it becomes more difficult to clamp the neck, and as the infant's tongue compresses the rubber against the hard palate milk rushes back into the bottle as well as forward into the child's mouth. Alternatively, a teat that is too soft will collapse too readily and make sucking difficult. The wasted effort on the baby's part can be further aggravated if the ejection hole is too small to allow milk to be expelled freely from the teat. There is a wide variation in the size of hole in different makes regardless of claims of small, medium, and large, and one teat examined had been sold without any hole. Except in the case of the teat made entirely from silicone, subsequent sterilization alters the position further, for as the rubber swells it absorbs water and tends to occlude the original hole.

Calculations by Ardran and Kemp (1959) showed that with a hole diameter of approximately 20/1,000 in. (0.51 mm.) (which corresponds roughly to a small-hole teat) a column of milk 22 cm. high will drip out of a bottle at a rate of 15 ml. a minute, while a slightly larger hole, 26/1,000 in. (0.66 mm.), speeds the rate to 28 ml. a minute. The flow rate we obtained with similar pressures in our investigations prior to sterilization of the teats varied from 0.2 to 25 ml. a minute. From this it will be seen how important it is to inspect the individual teat when a baby has difficulty in sucking. From clinical observation a flow rate of 60 drops a minute from an inverted bottle seems to be well managed in the majority of babies.

The elasticity or resilience of the rubber affects the speed at which the teat can refill, and so is one of the controlling factors in the time taken for the baby to suck his feed. It also influences the ease with which the base of the teat can be stretched over the neck of the bottle during the preparation of the feed. As the teat is usually lifted directly from the sterilizing solution it is wet and slithery, and this, combined with poor elasticity, may make for excessive handling by the mother in her attempt to attach it to the bottle. This increases the risk of infection to the child should the mother's hands not be clean, and it is not unknown for the teat to shoot completely out of her hands on to the floor and subsequently be offered to the baby without re-sterilization. Certain manufacturers have added a flange to the rim of their teat to enable the teat to be grasped more firmly, but the teat-bulb/flange junction interferes with cleansing and is in itself a possible source of infection.

It is almost impossible to invert some new teats with the little finger to perform the often-repeated advice on cleansing. To surmount this difficulty it is suggested that a glass rod should be used in place of the finger or that inversion be abandoned altogether and that the deposit lining the inner wall of the teat be removed by abrasion after dropping a little coarse salt into the bulb.

Gunther (1955) found that in 150 women the protractibility of the nipple varied from 2 to 3.75 cm. and that those women who offered a length of 2.7 cm. or over were more likely to be able to feed their babies successfully than those whose protractibility was less. This cannot be related directly to artificial feeding, where the elasticity of the teat is but one of a variable number of factors, but it was noted that in the teats investigated the actual sucking-stem lay between 2.8 and 3.1 cm. and that this range appeared to have no particular influence on sucking. Varying shapes of teat, sold with either cherry or straight top, offered no special advantage and served only to confuse the mother when making her selection.

Summary

The type of teat used is of importance in bottle-feeding. Guidance should come from the medical adviser, if necessary after observing a feed, rather than be left to sales persuasion.

A good teat should not absorb excessive amounts of water, should be resilient, should have a medium-sized hole which can be enlarged as the rubber deteriorates, and there should be no attachments in the form of anticolic valves, rims, or flanges.

Dry sterilization of teats preserves the rubber longer than wet procedures. Hypochlorite solution causes less deterioration than boiling.

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The article contains my personal opinions and conclusions, for which the Council bears no responsibility.

REFERENCES

- Ardan, G. M., and Kemp, F. H. (1959). *Acta paediat. (Uppsala)*, 48, 261.
Gunther, M. (1955). *Lancet*, 1, 575.

Nova et Vetera

REFLECTIONS ON GENIUS

In a busy professional and administrative life Sir Russell Brain finds time to instruct and delight us by his books on philosophy and on English literature. The present volume of essays¹ is at one and the same time medical, scientific, philosophical, and eminently readable. The first essay, which gives the title to the book, is abridged from the Galton lecture delivered to the Eugenics Society in 1948, and ably presents the view that genius is usually the resultant of several factors including intelligence and heredity. "It is the uniqueness of particularly favourable combinations that makes the genius."

In the essay on Swift the author gives a masterly analysis of his subject's character and illnesses which no future biographer of this unhappy and disappointed man can afford to ignore.

"The mystery about Swift is that there should ever have been any mystery about him," says Sir Russell, "for he described himself in his writings implicitly and even explicitly; he concealed nothing, and he was exactly what he appeared to be."

Swift was emotionally immature. In part he was a genius, in part he had never grown up. This explains his relations with Stella and with Esther Vanhomrigh (Vanessa). He liked feminine society; he even philandered, but he could not face marriage, except, possibly, as a nominal ceremony in order to keep Stella as his friend. Additional evidences of his immaturity are his private amusements, which, Kipling² reminded us, were "ridiculous and trivial." For instance, he would play at horses, harness his servants and drive them all over his vicarage at Laracor.

From his forty-third year Swift suffered from Ménière's syndrome, gastric disorders, and gout. Sir Russell finds he did not go mad, as is usually held. Blindness, deafness, cerebral arteriosclerosis, and melancholia were features of his declining years, while an orbital cellulitis in 1742 led to an infective intracranial complication resulting in severe motor aphasia. His death is said to have occurred after convulsions lasting 36 hours.

The author is a staunch Johnsonian, and six essays deal with different aspects of the "Great Cham of Literature": his interest in science and natural history—including his imitation of the kangaroo, an incident discreetly omitted by Boswell; his liking for Fanny Burney and Mrs. Thrale; the nature of his convulsive movements, ascribed to St. Vitus's dance but really habit spasms or tics; an account of the necropsy on Johnson, from which Sir Russell concludes that hyperpiesia and chronic heart failure, ischaemic kidneys, chronic emphysema, and cholecystitis were the chief pathological features; and "Lord Monboddie: Evolutionist and Anti-Johnsonian." There is a brief study of the poet Christopher Smart, in whom the divine spark of true poetry was only kindled in the course of an attack of insanity.

¹ *Some Reflections on Genius and Other Essays*. By Russell Brain. (Pp. 192+vii; illustrated. 30s.) London: Pitman Medical Publishing Co. Ltd. 1960.

² See "The Propagation of Knowledge" in *Debts and Credits*.