The Addition of Vitamin D Concentrate to Milk*

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THE thought that milk should be the logical medium in which to offer " vitamin D " to infants and children is by no means new. Almost immediately after it had been clearly demonstrated that certain ultra-violet wave-lengths can confer antirachitic properties on food substances, attempts were made in Germany to put this idea into practice. The chief early obstacles in the way of successful activation of milk were the effect on taste and other properties, and the fear of toxic effects. Of late the irradiation of milk has met with a certain amount of success in some German cities. Cost has always been a consideration. The difficulties have apparently been successfully met in the work reported by Dr. George C. Supplee.

During the past years we have been engaged in the further purification and improvement of the antirachitic concentrate from cod liver oil on which we first reported in 1921; and we have recently perfected preparations of higher potency and purity which, when incorporated in milk, will not affect its taste.

For the purposes of study on a practical scale, one dairy has now been licensed to prepare such milk. The concentrate is furnished to the dairy as a " 150 D " preparation, i.e., a preparation which by line test is 150 times as strong as the standard cod liver oil according to the Steenbock line test method. This concentrate, when diluted 1 to 12,000 in milk, will give a milk which contains approximately 150 units of " vitamin D " per quart, or the equivalent of 3 teaspoonfuls of cod liver oil. The preparations furnished to the dairy are carefully standardized and assayed. The incorporation can be done either by homogenization, by partial homogenization, or by another method without homogenization. By none of these methods is there any separation of the concentrate from the cream. In the non-homogenized milk the fat globules are of the same range of size as in

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ordinary milk. The highly potent concentrate as now produced from cod liver oil is diluted down to 150 D for two reasons: to have it in conveniently dilute form for measurement, and to avoid even the remotest possibility of accidental overdosage.

The milk produced in this manner has been frequently assayed on rats for antirachitic potency and has never been found wanting. This should be so, since the concentrate is standardized and the manner of incorporating is of the simplest kind. Studies have also been made of its antirachitic effect on infants. In children receiving about 100 to 150 units daily in milk, effects recorded in the healing of rachitic bones were the same as have been frequently shown with 3 teaspoonfuls daily of cod liver oil. Both X-rays and blood phosphorus showed a return toward normal in about 2 weeks, and cases of complete healing as judged by X-ray were recorded in about 40 days.*

The " vitamin D " milk made by the addition of a concentrate has certain characteristics which may distinguish it from other " vitamin D " milks.

1. It contains the " natural vitamin D," i.e. the same antirachitic substance we have always dealt with in cod liver oil. Steenbock [1] has recently presented evidence that the product made by artificial irradiation of sterols is not the same active substance as that occurring naturally in cod liver oil.

2. The rat assay data can be directly applied to human needs, avoiding the confusion and uncertainty we encounter in irradiated products. This is important, since all methods of standardization so far proposed involve the assay by means of rats.

3. The preparation of the milk is of the simplest kind, necessitating no extra equipment and not depending on special controlled feeding of cows. The chance of error is minimal, since only a simple measurement of a standardized, previously assayed concentrate is involved.

4. The price of the milk will, to begin with, be distinctly less than the price of ordinary milk plus the price of an equivalent amount of an average good cod liver oil. One dairy has been licensed to produce this milk, and the figures for cost are actual cost to consumer including all marketing and assay costs.

These facts are presented, not so much with a view to showing any relative superiority of one " vitamin D " milk over another, but rather for the consideration of the conditions under which one or the other milk may become a practical project.

If public health measures are to be instituted by means of " vitamin D " milk, a number of questions must receive careful consideration.

1. Can a milk of sufficiently constant potency be produced regularly in a dairy? The simplicity of the process involved in the incorporation of the concentrate in milk gives us relatively high assurance that errors can be avoided.

* These studies were made on 15 rachitic infants by Dr. Donald J. Barnes at the Children's Hospital in Detroit (in press).

Assays have been carried out on a considerable number of samples made under actual production conditions. These have uniformly shown the required number of units.

2. What is the most practical number of units of "vitamin D" per quart? We tentatively suggest 150 units per quart since this corresponds to the generally accepted dose of 3 teaspoonfuls of cod liver oil for any except very young infants, who would automatically receive smaller amounts in proportion to food intake. However, the number of units per quart can be so easily adjusted that any demand for other levels can be very readily met, if necessary, even by prescription.

3. Is there any danger either to the consumer's health or otherwise in putting this "vitamin D" milk on the market? Since we are dealing with the same antirachitic principle as has been used for many years in cod liver oil, there is no reason to believe that 150 units is either too high or too low. The effectiveness of the concentrate in various species (rat, chicken and man) is entirely parallel to that of cod liver oil. The small amount of cotton seed oil used as a solvent, diluted in the milk in the ratio of 1 to 12,000, is of no consequence. The question has been raised whether the introduction of "vitamin D" milk will discourage breast feeding, but there seems to be no very positive opinion one way or another. The possibility of encouraging self-medication is no more serious than that involved in the spread of knowledge concerning the beneficial effects of sunlight.

4. What does the project involve from the standpoint of enforcement agencies? The question has been raised whether the introduction of "vitamin D" milk will not put an undue burden on the officials entrusted with the enforcement of pure food laws or necessitate the establishment of large numbers of laboratories for biological assays. A cursory survey shows that in many states there are laboratories in state institutions (state university, agricultural college or experiment station) which are carrying on work of this type, and that such laboratories are increasing in number. There should be no difficulty in selecting in each state one institution to carry on the biological assays. To such designated laboratory the enforcement officials could forward the samples as taken up and receive a report in 12 to 14 days. The cost of these assays when done regularly and in suitable numbers is not as high as is commonly thought, and could be easily defrayed by the milk organization or the producer of concentrate without any significant increase to the consumer. As far as the pure food laws and the addition of foreign material to milk are concerned we should not rely on precedent such as acidophilus milk or chocolate milk but should allow this "vitamin D" milk to stand on its own merits. If it is not a useful project it should be rejected; if it is useful, the laws can be amended. In the meantime, wherever necessary, temporary permits such as are often granted will allow a thorough trial to be made as to usefulness and practicability.

REFERENCE

1. Steenbock. *J. Biol. Chem.*, July, 1932.

NOTE: A plan of state supervision including biological assays at the State Agricultural College has in the meantime been put into effect in Michigan.