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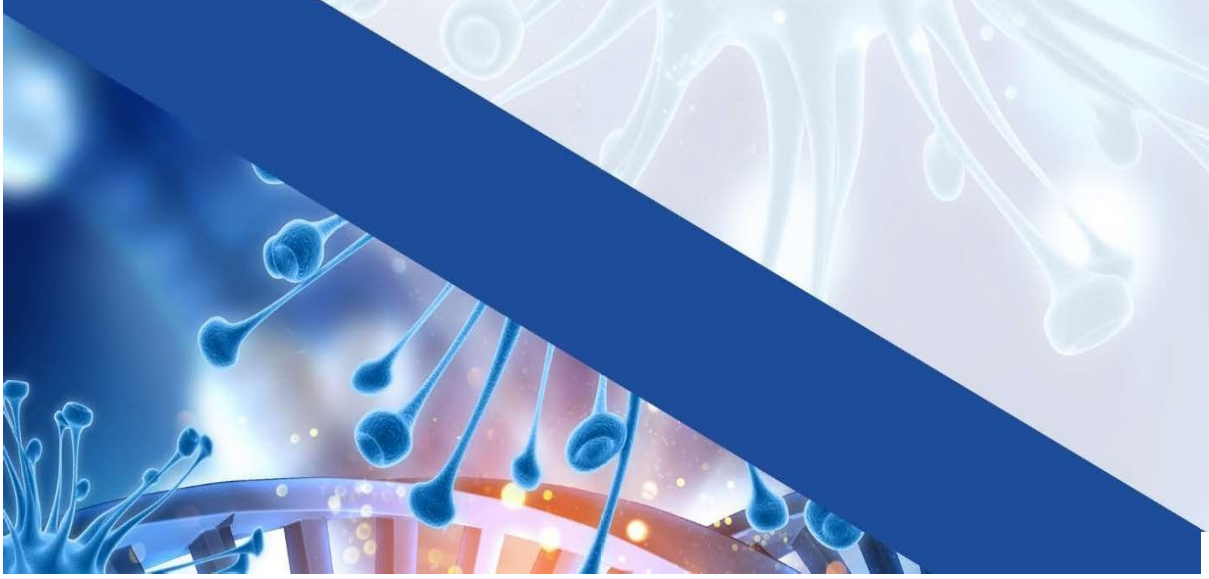

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Technical Articles

HUMAN HEALTH, NUTRACEUTICALS AND DIET REGIMEN

Dr. Mrs. Neela Manish Bhatia
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Nutraceuticals is a broad umbrella term that is used to describe any product derived from food sources with extra health benefits in addition to the basic nutritional value found in foods. Nutraceutical products can be considered non-specific biological therapies used to promote general well-being. The term "nutraceutical" combines the two words of "nutrient," which is a nourishing food component, and "pharmaceutical," which is a medical drug. The concept of "nutraceutical" arose first in the survey from U.K., Germany and France, where diet was rated higher by the consumers, then exercise or hereditary factors to achieve a good health. The name was coined in 1989 by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine, which is an American organization located in Cranford, New Jersey. According to De Felice, nutraceutical can be defined as, "a food (or a part of food) that provides medical or health benefits, including the prevention and or treatment of a disease".

The philosophy behind nutraceuticals is to focus on prevention, according to the saying by a Greek physician Hippocrates (known as the father of medicine) who said "let food be your medicine". Nutraceuticals, medicinal herbal products, and diet regimens have been shown to elicit health promoting, preventive and curative effects toward many different pathological conditions, such as cardiovascular diseases, the metabolic syndrome, and age-related frailty including cognitive decline and neurodegenerative disorders. A variety of nutraceuticals have shown potential anticancer activity via multiple pathways. Additionally, specific diet regimens such as ketogenic diet and caloric/protein restriction diet have been shown to benefit cancer patients undergoing radio- and chemotherapy and to prevent cancer cachexia.

The importance and role of basic nutrients in the growth, maintenance, and wellness of the body are well established. Food supplies energy, nutrients (fats, carbohydrates, proteins, vitamins, minerals) and non-nutrients (fiber, antioxidants, inducers of beneficial enzyme activities, prebiotics, and probiotics); and the human body is well capable of utilizing all these molecules from the food. Eating habits and trends in food production and consumption have health, environmental and social impacts.

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Diet has implications on gut health. Gut complications, such as ulcerative colitis, Crohn's disease, irritable bowel syndrome, and gluten therapy resistant celiac, result from overgrowth and imbalance of intestinal microbial flora, and are related to one's diet.

Nutraceuticals covers most of the therapeutics areas such as anti-arthritic, cold and cough, sleeping disorders, digestion and prevention of certain cancers, osteoporosis, blood pressure, cholesterol control, pain killers, depression and diabetes. Nutraceuticals can be organized in several ways depending upon its easier understanding and application, i.e. for academic instruction, clinical trial design, functional food development or dietary recommendations. Some of the most common ways of classifying nutraceuticals can be based on food sources, mechanism of action, chemical nature etc. The food sources used as nutraceuticals are all natural and can be categorized as Dietary Fibre, Probiotics, Prebiotics, Polyunsaturated fatty acids, Antioxidants, vitamins, Polyphenols, Spices etc.

More broadly, nutraceuticals can be classified in two groups potential nutraceuticals and established nutraceuticals. A potential nutraceutical could become an established one only after efficient clinical data of its health and medical benefits are obtained. It is to be noted that much of the nutraceutical products are still lays in the 'potential' category. In most countries nutraceuticals are taken as part of dietary supplements. Frequency of nutraceuticals use is 50%–70% in developed countries' population and this number is increasing by the age. Ladies use more nutraceuticals than men. From a safety point of view nutraceuticals are trusted products even if they are not approved by authorities like pharmaceutical regulators.

The importance of nutraceuticals is expanding globally in terms of scientific services, legal aspects, and marketing strategies for health promotion, reduction of disease, and health care costs. An increasing nutritional interest in promoting good health and life expectancy created a growing segment of the food industry.

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HOW PERSON GETS FAIR COMPLEXION

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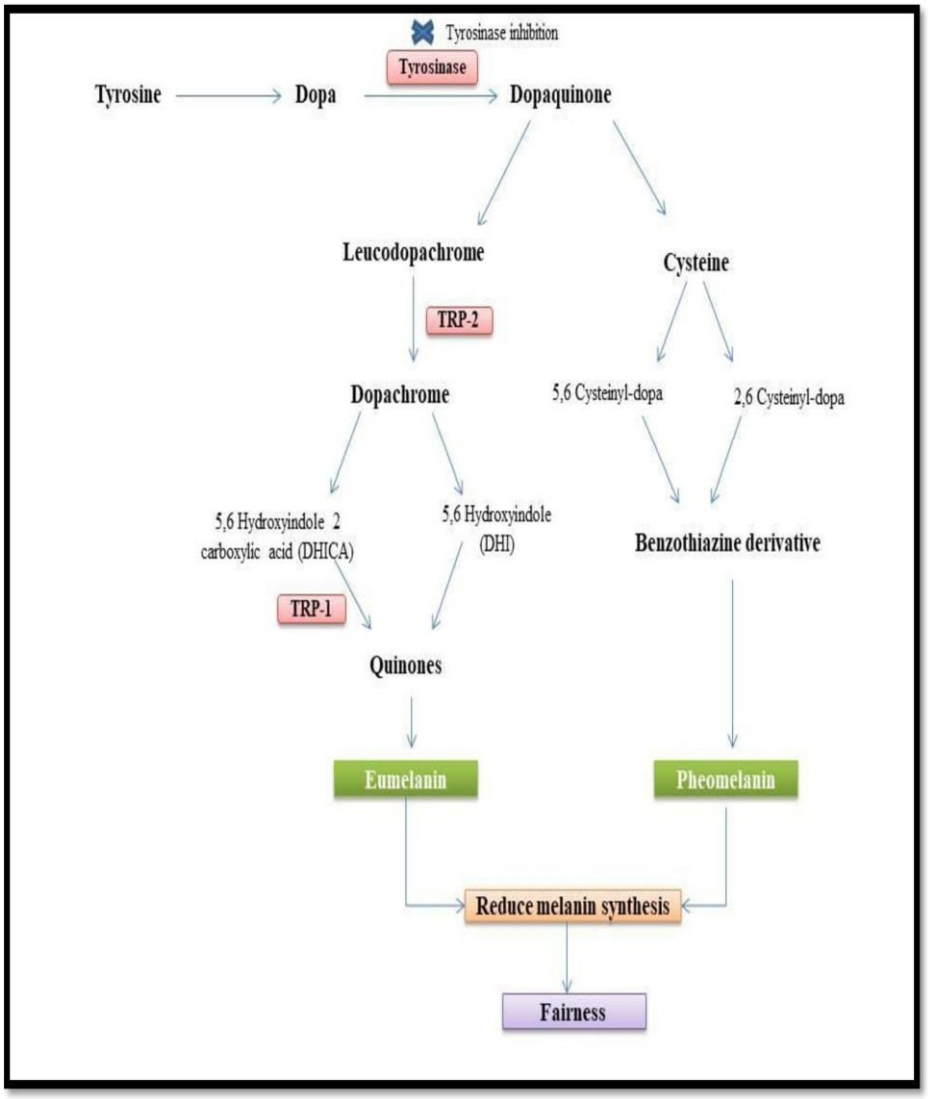

Fig: How person gets fair complexion

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DRUG REPURPOSING: FUTURE OF DRUG DISCOVERY

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Drug discovery and development is an expensive, time-consuming, and risky business. Conventional drug development strategies are drug discovery, preclinical studies, clinical trials, and post-marketing safety monitoring. Due to regulatory requirements regarding safety, efficacy, and quality in animal research and clinical trials, the time required to develop a new drug is more time consuming. In recent years, the drug repositioning strategy has gained considerable momentum with about one-third of the new drug approvals.

Drug repurposing is drug re-tasking, drug reprofiling, drug rescuing, drug recycling, drug redirection, and therapeutic switching. It can be defined as a process of identification of new pharmacological indications from old, existing, failed, investigational, already marketed, FDA approved drugs or pro-drugs, and the application of the newly developed drugs to the treatment of diseases other than the drug's original/intended therapeutic use. It involves establishing new therapeutic uses for already known drugs, including approved, discontinued, abandoned and experimental drugs.

The novel approach of drug repositioning has the potential to be employed over traditional drug discovery program by mitigating the high monetary cost, longer duration of development and increased risk of failure. It confers reduced risk of failure where a failure rate of ~45% is associated due to safety or toxicity issues in traditional drug discovery program with additional benefit of saving up to 5–7 years in average drug development time. In recent years, the drug repositioning strategy has gained considerable momentum with about one-third of the new drug approvals correspond to repurposed drugs which currently generate around 25% of the annual revenue for the pharmaceutical industry. A crucial purpose of drug repositioning is to find new drug-disease relationships. Multiple methods have been developed to achieve this goal, including computational methods, biological experimental methods, and the combination of both. With the open-source of many drug-related databases, this advancement has accelerated the development of a computational approach.

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At the same time, the mixed approach that combining biology and computational method greatly improves the efficiency of drug repositioning while reducing costs. Drug repurposing strategy should avoid hasty proof-of-concept. Instead, a detailed and comprehensive plan should be proposed, and the information obtained in the previous development cycle should be used to appropriately simplify the work.

Conclusively, drug repositioning has become a successful drug discovery strategy due to reduced costs and faster approval procedures. Many successful examples have also shown the great potential of this method in practice. With the rapid development of computing methods and data explosion, the mixed advantages of drug repositioning will become more prominent.

Reference: *https://www.nature.com/articles/nrd.2018.168*

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HYBRIDIZATION MICROARRAYS WITH IN SITU PROBE SYNTHESIS: COMBIMATRIX TECHNOLOGY

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The use of on-chip *in situ* probe synthesis provides an attractive alternative to hybridization microarrays fabricated using presynthesized oligonucleotides and their physical deposition on the substrate. Chips with *in situ* probe synthesis are much more flexible to build, and valuable in the experiments where new sequences need to be introduced frequently. A method relying on photolithography and combinatorial chemistry allowing for parallel synthesis of probes nucleotide-by-nucleotide has been developed (Fodor *et al*., 1991). The use of photolabile chemistry allows for deprotection of the linker under the UV light exposure and attachment of the nucleotide. The fabrication costs of the photolithographic mask sets are, however, fairly high. Therefore, this technology has been modified by using Digital Light Processor (DLP) to develop the Maskless Array Synthesizer (MAS), which delivers focused light beams to selected portions of the substrate, thus eliminating need for the photomask.

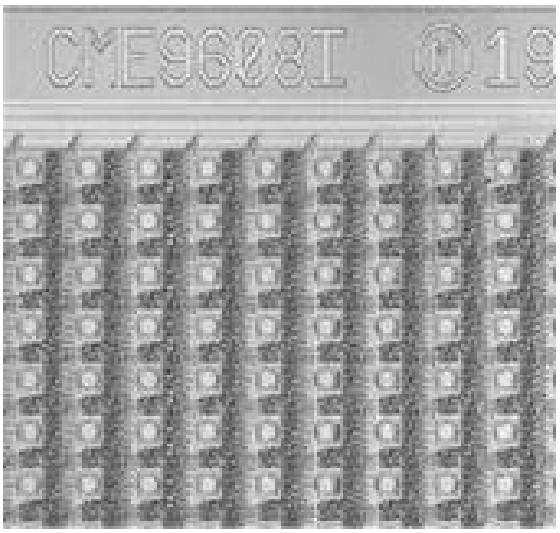

Figure 1. A section of the CombiMatrix CME9608 chip. Each of the small round disks is an electrode. Each electrode site is associated with CMOS circuitry for individually addressing and operating the electrode.

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Another step toward miniaturization of diagnostic assays can be undertaken when electrochemical synthesis of probes is implemented. CombiMatrix (http://www.combimatrix.com) introduced electrochemical *in situ* synthesis using electronic CMOS devices. These chips contain high-density arrays of individually addressable microelectrodes. A typical chip has 1,024 microelectrodes that are each 100 mm in diameter (see Fig. 1). The CombiMatrix biochips are coated with proprietary approximately 1 mm thick porous reaction layer material, which is used for immobilization and synthesis of biomolecules used for subsequent binding of target. Covalent linkage of the molecules within the porous layer is accomplished using reagents that are generated *in situ* by the microelectrodes.

Reference: *The Use of Microelectronic-Based Techniques in Molecular Diagnostic Assays Piotr Grodzinski, Paolo Fortina, in Molecular Diagnostics (Second Edition), 2010*

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WIRELESS HEALTHCARE DELIVERY: ADAPTING TO TOMMOROW'S NEEDS

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A health care system is the organization and the method by which healthcare is provided. In practice, these systems vary widely from one country to another, and not all healthcare is delivered as a way of a healthcare system. Healthcare delivery is a complex process involving all types of integrated and inter-dependent steps, each of which has the potential to fail. Failure at any point can set off a chain of events that can result in patient injury. Medication ordering, preparation, and delivery are multidisciplinary processes in their own right; but multiple checkpoints and safeguards must be placed to arrest errors before the medication reaches the patient. Just as the principal objective of a healthcare system is to improve people's health, the chief function the system needs to perform is to deliver health services. Service provision refers to the way inputs (such as money, staff, equipment, and drugs) are combined to allow the delivery of a series of health interventions. Thus, improving and scaling up service delivery depends on having key resources and on how required resources are organized and managed. Lack of managerial capacity at all levels of the healthcare system is being cited increasingly as a binding constraint to scaling up services and achieving the Millennium Development Goals.

Health processes enhanced by wireless technology

The first one, enhanced health processes, emerges from the world-wide cost crisis of health care industry. The processes have to be enhanced and wireless technology is seen one of the most promising solutions. Wireless technology brings methods to manage the processes by using locating and tracking information in addition to collection of diagnostic data unobtrusively and conveniently. Also, a unified platform supported by wireless technology could be used to enhance healthcare processes by integrating different software and hardware applications to communicate to each other.

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The following parameters are important and considered vital in regard to wireless communications and healthcare systems:

1. Collection of vital parameters from patients by wireless sensors (human monitoring)
2. Health processes enhanced by wireless technology
3. Locating and tracking of people, information, equipment and goods.
4. Integration of different software and hardware applications on the unified platform supported by wireless technology.
5. Ubiquitous healthcare services available for out-hospital and home-hospital patients.
6. User-friendly integration of mobile devices and services to the last meter wireless body area network (Bluetooth, ZigBee, Ultrawideband, etc.).

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ANALYSIS OF IMPURITIES IN PHARMACEUTICALS: A SIGNIFICANT APPROACH FROM REGULATORY PERSPECTIVE

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The pharmaceutical manufacturing of formulations revolve around quality. The assessment and quality establishment of pharmaceutical crude materials and finished products for presence of undesirable impurities is a fundamental piece of the quality improvement. From the customer's view quality means pleasant appearance, taste with good packaging. But in the case of pharmaceutical industries, quality has an entirely different perspective and it means providing drug standards conforming to a variety of regulatory conditions and establishing safety of pharmaceuticals. Thus a detailed awareness of the various types of impurities and aspects of their regulation and control, which infer quality is highly crucial. According to the International Conference on Harmonization (ICH) guidelines, impurities associated with APIs are classified in different ways like organic impurities, inorganic impurities, enantiomeric impurities and in-process production impurities. Impurities present in new drug substances used in clinical and safety trials are covered by ICH Q-3 guidelines. During the study of chemistry aspects there is strong need to classify and identify impurities, generate the report for different impurities, list various impurities present in any substances, and give a brief discussion of analytical procedures for impurity identification and detection. Study of safety aspects of impurities include reporting of those impurities which are present at a considerably lower concentration or not present at all during discovery of new drug substance. Commonly used impurity terms used to describe an impurity or impurities are intermediates, penultimate intermediate, by-product, transformation product, interaction product, related product, degradation product, foreign substance, toxic impurity, concomitant component, ordinary impurity, organic volatile impurity etc.

Since presence of these unwanted impurities, even in small amounts, may influence the efficacy and safety of the pharmaceutical products thus impurity profiling (i.e., identification and quantification of impurity in pharmaceuticals), is now receiving critical attention from regulatory authorities.

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The different pharmacopoeias like BP (British pharmacopoeias), USP (United States pharmacopoeias), IP (Indian pharmacopoeias), and others are gradually incorporating limits to the allowable levels of impurities present in active pharmaceutical ingredients (APIs) or formulations. Impurity identification and quantitation in drug discovery presents a significant analytical challenge for the detection, quantitation, and characterization of the compounds in the presence of impurities. The impurities can be identified predominantly by various like reference standard method, spectroscopic method (Ultraviolet, Infrared, Nuclear Magnetic Resonance, Mass spectrometry), various separation methods (TLC, GC, HPLC, CE and SFC), various isolation and characterization methods. Along with the routine use of authentic markers and analytical techniques, isolation and characterization of impurities are required for acquiring the data that establishes biological safety and efficacy. Various regulatory authorities like ICH, USFDA etc., have specified limits for different types of impurities in APIs.

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AN OVERVIEW OF COMBINATORIAL CHEMISTRY IN DRUG DISCOVERY AND DEVELOPMENT

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Combinatorial chemistry involves the synthesis or biosynthesis of chemical libraries which is a family of compounds having a certain base chemical structure of molecules for the purpose of biological screening, particularly for lead discovery or lead modification. Generally, these chemical libraries are prepared in a systematic and repetitive way by covalent assembly of building blocks (various reactant molecules that build up parts of the overall structure) to give a diverse array of molecules with a common scaffold (the parent structure in the family of compounds). The advantage of this methodology is that it is carried out on a solid (polymeric) support, so that isolation and purification of the product of each reaction can be performed by simple filtration and washing (with a variety of solvents) of the polymeric support to which the building blocks have been attached. Because of the insolubility of the polymer, everything not attached to the polymer is removed, which allows the use of excess reagents to drive the synthetic reactions.

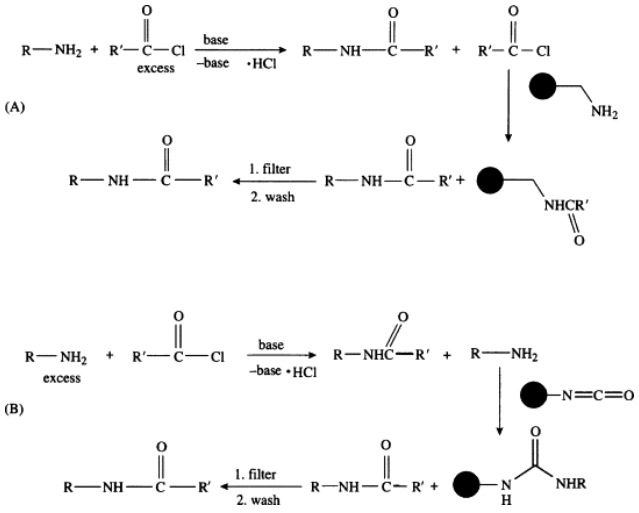

Figure: Use of polymer-bound reagents to scavenge excess reactants in a reaction

The disadvantages of this methodology are the difficulty in scaling up the reactions and the sluggishness of reactions. An alternative strategy (*covalent scavenger technology*) is to carry out the reactions in solution with excess reagent, which is then scavenged with a polymeric-supported scavenger after the reaction is completed. In this approach, filtration removes the excess reagent attached to the scavenger polymer, leaving the product in solution. Another approach is to use polymer-supported reagents with solution reactions. To avoid problems of heterogeneous polymer reactions, soluble polyethylene glycol polymers can be used.

Reference: *Drug Discovery, Design, and Development, Richard B. Silverman, in The Organic Chemistry of Drug Design and Drug Action (Second Edition), 2004*

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Sr. No.	Title	Patent Application Number	Status	Name of the Inventor/s	Month & Year
01	Analytical method for beta-secretase estimation from biological fluids	201721033863A	Published	Gaurav Gangadhar Gadgil, **Manish Sudesh Bhatia, Rakesh Pandit Dhavale**	March 2019
02	Herbal composition for transdermal delivery	201721044914	Published	**Dinanath T. Gaikwad, Namdeo R. Jadhav**	June 2019
03	Lyophilized myeloperoxidase from mammalian heart	201921023861	Published	Mr. Vaibhav Suresh Khade, **Dr. Mrs. Neela Manish Bhatia, Dr. Manish Sudesh Bhatia**	July 2019
04	Myeloperoxidase bioassay kit	201921023862	Published	**Dr. Mrs. Neela Manish Bhatia,** Mr. Vaibhav Suresh Khade, **Dr. Manish Sudesh Bhatia**	July 2019
05	Predictive computational model for selection of suitable grade of polymer for desired formulation property	201921010545	Published	Dr. Ajit S. Kulkarni, Dr. Vinod L. Gaikwad, **Dr. Manish S Bhatia,** Mr. Amit J Kasabe	Oct. 2020

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