The Struggle for Hand Hygiene: Ignored /Accepted from the 1850's to Current	
Q&A Report:	
"Questions Asked"	***Questions Answered (#)***
Does the benzalkonium chloride residual concern translate to rinse off applications (antibac hand wash)?	***The ANSWER: is yes – The Final rule for rinse off antiseptics was published a couple of years ago – I have attached the FDA guidelines for you to read. – 19 active ingredients were found to be ineligible and require to go through an NDA for approval. The decision on three ingredients, benzalkonium chloride, benzethenium chloride, and chloroxylenol, was deferred to allow collection of further information to allow a final decision.***
So are soaps better hand sanitizers for now?	***Not necessarily. The FDA final rule takes the stance that hand sanitizers should be used when handwashing facilites are not available but the CDC and WHO guidelines take the view that alcohol had sanitizers are better than handwashing with soap and water. This competition has been going on for a century and a quarter – as my webinar says. I have attached a copy of my slides with script – I hope it can be of help to you.***
Can you please provide clarity on which claim is correct: Antibacterial vs Antiseptic for Hand Sanitizers.	***The FDA regards alcohol hand rubs and hand sanitizers to be antiseptics.. See Guidelines attached. I have also attached a scripted copy of my talk.***
Dr. Lockhead, please advise the WHO on an effective Hand Sanirizer! They need to know.	***On your comment, -- I think I have the clout to tell the FDA what to do!***
What is the impact difference in two formulation difference of Ethanol vs Isopropyl Alcohol	***Both are effective at 70% or above. There continues to be debate on which is more effective. The differences in effectiveness caused by formulation differences appears to be greater than the difference between those actives.***
Can any type of inactive ingredients used in antiseptic rubs ? or is there a positive list ?	***There is no positive list. The performance of hand sanitizers can show large variability with formulation at the same actives level. That is one of the reasons that the FDA is requesting further testing before they approve hand rub antiseotics."***

Can you talk more in detail about the proper choice of polymer used in a alcohol rub?	***The original concept, that arose from a conversation at an SCC lake Erie Chapter meeting between me and Eleanor Fendler of GOJO Industries, was that the product had to be a clear gel with the consistency of a lotion, that shear-thinned for application, then collapsed on contact with the hands to release the alcohol to get into all the 'nooks and crannies' of the hand. We developed Acrylates/C10-30Alkyl Acrylate copolymer to show such 'quick-break' technology and we also showed that it could be done by thickening hydro-alcoholic systems with an appropriate Carbomer with an appropriate amine neutralizer . I prepared a short video to demonstrate the release of alcohol: at https://spark.adobe.com/video/XvyTzaDX0UiNp or https://youtu.be/E9uPKaJOk5E.***
Why is the CHG based Handrub are not intended to consumer use?	***Avagard contains 1% CHG and 61% ethyl alcohol. This product was approved as described in and NDA as a pre-surgical scrub or a hand rub for use by healthcare workers and the NDA did not request use by consumers. . The final rule for antiseptic hand rubs for consumers lists CHG on the ineligible list, which means that it could only be used for the purpose as an antiseptic hand rub by consumers if it successfully made its way through a new NDA which was approved for the purpose of an antiseptic handrub for consumers.***
From Dr. Jose Martinez Santiago at The Formulation Studio (London): What would the formulation approach be for an antibacterial product in an emulsion format? This would be containing emollients to help protect the skin barrier.	***Making an emulsion might be one approach. However, the presence of emollients (organic compounds) would compromise the efficacy of the antimicrobial effectiveness. Therefore, each formulation would have to be tested for effectiveness against an array of microbes – and to meet the requirements of the FDA, clinical studies would be required to demonstrate effectiveness and safety.***
From Dr. Jose Martinez Santiago at The Formulation Studio (London): How the benzalkonium chloride to compare to the alcohols both in performance and safety?	***Benzalkonium chloride has been used for a long time as an antiseptic. However, in a hand rub, Benzalkonium chloride can leave residuals that could result in the emergence of resistant and tolerant organisms. Moreover, any formulation containing benzalkonium chloride and making antiseptic or antimicrobial claims will have to conform with the FDA's new rule for such OTC products and demonstrate safety and effectiveness by clinical testing. I have attached a recent mnireview on the subject that may interest you.***

From Dr. Jose Martinez Santiago at The Formulation Studio (London): What is the holy grail for hand sanitisers today? What is the future of hand sanitization?	***It is desirable to create hand sanitizers that are effective to destroy pathogens on the hands without any long term effects on the skin microbiome or the skin barrier properties. It is also desirable to create hand sanitizers in which the antimicrobial actives do not pose the threat of causing the emergence of resistant or tolerant strains of pathogens. I hope the COVI-19 experience will draw attention to the existing need for hygiene and particularly hand hygiene.. In the USA , more than 750,000 people die each year from sepsis and more than 250,000 die from hospital-acquired infections.. Many of these result from poor hand hygiene. Going forward, we should appreciate the perils of lack of hand-sanitization. I hope sanitizers have a good future – the alternative is grim!***
What is the preferred effective concentration of alcohol in a gel sanitizer formula?	***It is generally accepted that at least 60% alcohol is required for a hand sanitizer to be effective but there is literature that indicates that 70% alcohol is preferred. Above 60% alcohol, the effectiveness appears to depend on the formulation rather than the alcohol concentration. Purell uses Carbomer as thickener and Germ-X uses acrylates/C10-30 alkyl acrylate crosspolymer. Both these thickeners are stimulated to collapse and release alcohol on contact with salt on the hands. I believe that the release of alcohol by the formula is a factor in the formulation dependence. I made a short video to demonstrate the effect and it is available at https://youtu.be/E9uPKaJOk5E.***
How much surfactant would be sufficient to give better spreading of the alcohol?	***I believe that the release of the alcohol form the gel on contact with the hands is the primary factor. Spreading might be enhanced or it may not by small amounts of surfactant. If the surfactant preferentially lowered the hand/alcohol interfacial tension, then spreading would be favored but if the surfactant preferentially lowered the air/alcohol interfacial tension, then spreading would be inhibited. Of course most surfactants will go to both interfaces and the result on spreading will be a balance of the resultant interfacial tensions. Also, if the surfactant formed viscous or elastic mesomorphic phases as the alcohol evaporated, then that would slow the spread and could prevent the alcohol penetrating the wrinkles, crevices, nooks and crannies in the hand where bacterial colonies may linger. Vi=Jon's patent from 2019 includes certain surfactants which they claim provides an increase in effectiveness.***

Gojo/Purell had a commercial aniti-viral formula only available in Europe or on cruise ships. FDA wouldnt approve it here in the US. Haas that changed or will it? Is it necessary?	***FDA didn't approve it because GOJO had not provided sufficient data to demonstrate effectiveness against norovirus. From the FDA letter to GOJO that still appears to be the case. Doig the clinicals to support the claim will be a judgement call for GOJO – because they do not have IP protection – which means that they would pay for the clinical studies but once approved, any generic company could enter for the price of an ANDA. I have attached a copy of the FDA letter.***
What would be the function of the small amount of hydrogen peroxide in the WHO handrub formulations?	***I am perplexed as to why a formulator would combine ethanol, glycerin and hydrogen peroxide because the peroxide would soon disappear by reacting with the organics to form ethers… and this would reduce the antimicrobial effectiveness of both the hydrogen peroxide and the ethanol. I don't know who created the WHO formula but I feel that we could easily improve it.***