From: Andrew Crawford
Sent: Wednesday, September 15, 2021 2:14 PM
To: OpenMeeting
Subject: Re: Complete test line and reply with successful test run to by 7 AM September 15, 2021 (Earlier is best) - Thank you

Dear FTC,

Many thanks for the opportunity to address the Commission during today's open meeting. To complement my comments, I've attached the Consumer Privacy Framework for Health Data that I referenced in my comments. Would it be possible to include the attached in the meeting event record?

Kind regards,
Andrew

Andrew Crawford
Policy Counsel | Privacy and Data Project

On Tue, Sep 14, 2021 at 3:14 PM OpenMeeting wrote:

Good afternoon Andrew,

You are speaker #3. Here is the Zoom link for the meeting:

Public Comments Room:

Link: [redacted]

[redacted]

Thank you,

Office of Public Affairs

From: Andrew Crawford >
Sent: Tuesday, September 14, 2021 3:06 PM
To: OpenMeeting
Subject: Re: Complete test line and reply with successful test run by 7 AM September 15, 2021 (Earlier is best) - Thank you

Dear FTC,

Many thanks for the email and information. I've successfully completed the test. Please let me know if you need any additional information from me.

Thanks and I look forward to tomorrow's meeting.

Kind regards,

Andrew

Andrew Crawford

Policy Counsel | Privacy and Data Project

Center for Democracy & Technology | **cdt.org**

Check out CDT's **2020 Annual Report**, which highlights our most important work putting democracy and civil rights at the center of the digital revolution.

On Tue, Sep 14, 2021 at 1:20 PM OpenMeeting wrote:

Hello,

It is our understanding that you have requested a speaking slot for the FTC's September 15 Open Meeting that will take place **Wednesday, September 15, 2021 from 11:00am-1pm**. Since this event will be virtual, we are asking all participants to view the proceedings from our holding room **beginning at 10:45am**. When the official business concludes, we will join the holding room with the Commissioners meeting room. At that time, each registrant will be given 1 minute to address the Commissioners.

To ensure that the event runs smoothly on Wednesday, we ask that you click on the link below to run a test. Our goal is to ensure that everything is running smoothly.

This test must be completed by **7 AM September 15, 2021 (earlier is best)**. An operator will walk through testing your equipment and connection to ensure you can comfortably connect with the meeting platform. Afterward, please plan to use the same equipment and network that you will be using on the day of the event. The earlier this is done, the more time our team has to troubleshoot any issues.

******We ask that you click on the link below to run a test******

[redacted]

participant ID [redacted]

Please note an email reply to [redacted] is required before 7 AM September 15, 2021

to let us know you have completed the test (this impacts your addition to the list of speakers).

Here are some key pointers when conducting the test as well as for the actual day of Workshop:

1. **Have as much lighting from the front as possible. Avoid bright lights behind you.**

2. **Use an attached headset instead of the laptop microphone. Any GOOD set of smartphone earbuds with a mini-audio plug will work or use a larger headset with boom microphone. Some USB headsets may also work well. Bluetooth devices are not permitted with FTC laptops.**

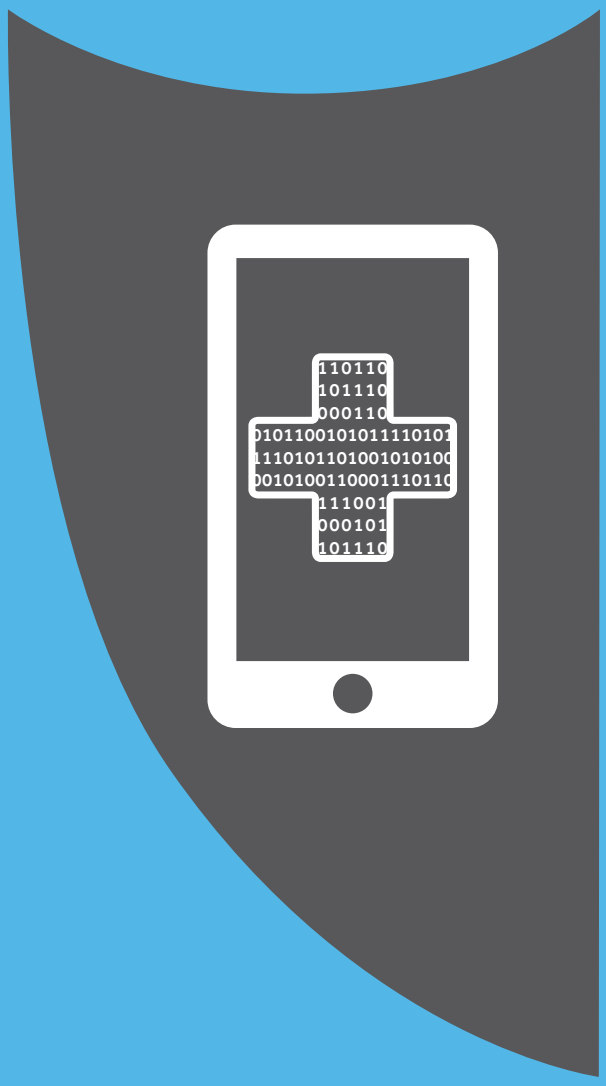
3. **Assure that your background is as simple as possible, and not too "busy."**

4. **Try to stay at least 18" from the camera to avoid distortion.**

Once your test is complete, please email us at [redacted] to let us know you have completed the test and if it was successful or you need assistance. We will share information on speaking order in a follow up email.

Thank you again for your cooperation,

Federal Trade Commission



Proposed Consumer Privacy FRAME-WORK for Health Data

FEBRUARY 2021

CENTER FOR DEMOCRACY & TECHNOLOGY

eHEALTH INITIATIVE

About Center for Democracy & Technology

The Center for Democracy & Technology is a 25 year old nonprofit, non partisan organization working to promote democratic values by shaping technology policy and architecture. For more information, visit cdt.org.

About eHealth Initiative & Foundation

eHealth Initiative & Foundation (eHI) convenes executives from every stakeholder group in healthcare to discuss, identify, and share best practices to transform the delivery of healthcare using technology and innovation. eHI, along with its coalition of members, focuses on education, research, and advocacy to promote the use and sharing of data to improve healthcare. Our vision is to harmonize new technology and care models in a way that improves population health and consumer experiences. eHI has become a go to resource for the industry through its eHealth Resource Center. For more information, visit ehidc.org.

Acknowledgements

This framework is made possible with the support of the Robert Wood Johnson Foundation, and with assistance from our Steering Committee.

Special thanks to members of our two work groups for their invaluable engagement help and for their guidance. A list of select Steering Committee members can be found in the Appendix.

Proposed Consumer Privacy Framework for Health Data

Table of Contents

Executive Summary

Introduction and Background

Health data—or data used for health-related purposes—is not regulated by a single national privacy framework. Since 1996, the Health Insurance Portability and Accountability Act (HIPAA) has governed the use and disclosure of certain health information held by certain entities such as doctors and insurance companies. However, with the rise of wearable devices, health and wellness apps, online services, and the Internet of Things, extraordinary amounts of information reflecting mental and physical well-being are created and held by entities that are not bound by HIPAA obligations. This issue has only gained importance, as new regulations finalized in the spring of 2020 will also ease and promote the movement of previously HIPAA-covered medical records into this commercially facing, non-HIPAA-covered and unregulated space.[1] The novel coronavirus has also thrust the issue of patient data privacy to the forefront, as efforts to trace and combat the spread of the virus have brought with them the relaxation of some federal privacy protections as well as increased data collection and use.

Project Goals and Process

With funding from the Robert Wood Johnson Foundation, the eHealth Initiative (eHI) and the Center for Democracy & Technology (CDT) collaborated on a Consumer Privacy Framework for Health Data, with invaluable engagement and help from a steering committee of leaders from healthcare entities, technology companies, academia, and organizations advocating for privacy, consumer, and civil rights.

This steering committee helped guide eHI and CDT during the development of this framework. Specifically, the framework consists of a set of detailed use, access, and disclosure principles and controls for health data that are designed to address the gaps in legal protections for health data outside HIPAA's coverage. The framework also includes a proposed self-regulatory program to hold companies accountable to such standards. Non-HIPAA-covered entities would voluntarily hold themselves to a set of standards and subject themselves to potential enforcement mechanisms beyond current Federal Trade Commission (FTC) processes. Even outside this program, the authors hope that the substantive standards will serve as a benchmark to shape industry conduct and influence companies' approaches to ensure users' health data is protected.

[1] 85 Fed. Reg. 25642 (May 1, 2020) and 85 Fed. Reg. 25510 (May 1, 2020). For a comprehensive review of the current legal landscape governing health data and the gaps in protection for the same, please see Belfort, R., Dworkowitz, A., Bernstein, William S., Pawlak, B. and Yi, P. *A Shared Responsibility: Protecting Health Data Privacy in an Increasingly Connected World*, June 2020, available at http://www.manatt.com/Manatt/media/Media/PDF/White%20Papers/Healthcare-Whitepaper-RWJF-Protecting-Consumer-Health-Data-Privacy-in-an-Increasingly-Connected-World_e.pdf (Manatt White Paper).

The standards emphasize transparency, accountability, and appropriate limitations on health data collection, disclosure, and use. Importantly, the standards:

1. Move beyond outdated models that place too much emphasis on notice and consent and fail to articulate data use limits;
2. Cover all information that can be used to make inferences or judgments about a person's physical or mental health; and
3. Cover all non-HIPAA-covered entities that collect, disclose, or use consumer health information, regardless of the size or business model of the covered entity.

With respect to the self-regulatory program, the framework seeks to balance the need for enforcement mechanisms that will effectively hold companies responsible and promote consumer trust, while ensuring the program is workable enough for potential participating entities to join. This is a challenging balance, which the authors know will rely on entities participating in good faith.

Importantly, this proposal is **not** designed to be a replacement for new and necessary comprehensive data privacy legislation. Indeed, we believe strongly in the need for such a law and support all efforts to date that have served to build momentum for one. Given that congressional action is likely some time away and would take additional time to go into effect, this effort is designed to build support for best practices and enable us to take what action we can now, in the interim, to shore up protections for non-HIPAA-covered health data. We hope that some of the tenets of our proposal can and will be helpful to federal lawmakers in their future efforts.

Value of This Proposal for Different Stakeholders

Consumers. This model raises the bar for consumer privacy. Some existing best practices and voluntary frameworks define health information quite narrowly and do not cover all the data that reflects mental or physical wellbeing or health. Many best practices are also often targeted at a specific type of app or service instead of all entities that collect and use health data. Our comprehensive proposal closes these gaps in coverage.

Substantively, our draft goes beyond outdated models that revolve primarily around notice and consent. While transparency and consent remain important elements within the framework, many of the core privacy-protecting provisions of this framework are focused on how consumer health information is collected, disclosed, and used. Although older laws or frameworks may have made sense in decades past, people can no longer make informed and timely decisions about all the different websites, apps, and devices they use every day given the proliferation in the number of available technologies and the length, details, and lack of clarity of their terms of service. By putting clear restrictions on the collection, disclosure, and use of data, the proposed framework shifts the burden of privacy risk off users and onto the companies.

Finally, because our model borrows the best concepts from Europe and California, users will benefit from the heightened protections developed in those regions even if their local laws have not been updated with more modern data privacy protections.

Non-HIPAA-covered technology companies that collect health information. Entities that elect to participate and adopt the framework will also benefit. First, they will stay ahead of the regulatory curve. By making pro-privacy decisions now, they will avoid having to make product changes that could be more expensive, time-consuming, or complicated in response to future regulation.

Second, while entities will be able to develop and offer the product a consumer requests, they will be deterred from collecting and using health data they do not actually need. This should reduce legal risks in a world where consumers and enforcement agencies expect more from companies that handle data. Participating entities may also see significant reputational and thus commercial benefit in an increasingly crowded market.

Finally, this model has the potential to provide some compliance certainty for participants. By adopting more forward-looking privacy practices, companies and organizations will avoid the gray or evolving areas of existing laws. Especially for smaller or newer companies having difficulty fully understanding their numerous federal and state legal obligations, which can often be unclear and/or conflicting, compliance with our framework's standards would provide some assurance that participants are staying ahead of various potential federal and state requirements.

Regulators and oversight bodies. Congress, the FTC and their state-level counterparts will benefit from companies committing to a common set of publicly available data practices. This commitment will allow these governmental bodies to enforce these practices, which will be more explicit than many existing company privacy policies. Instead of engaging in complicated investigations and balancing tests, these entities will be able to measure compliance more easily and better allocate their limited enforcement resources.

Traditional healthcare system entities. Finally, although this framework is geared toward companies that operate outside the traditional healthcare system and thus are not subject to the obligations and protections of HIPAA, our framework will benefit HIPAA-covered entities as well. The framework recognizes the importance of research and establishes clear standards for when research relying on consumer health information is permitted.

Moreover, the release of the Centers for Medicare & Medicaid Services and Office of the National Coordinator for Health Information Technology final rules regarding interoperability and information-blocking means that consumers will soon have greater access than ever to their own health data. By virtue of the framework, providers and consumers alike will have a far easier time choosing applications for this data transfer that adhere to meaningful and robust privacy practices.

Substantive Standards and Policy Rationale

For any follow-up questions, kindly contact Andrew Crawford at CDT (acrawford@cdt.org).

In addition to the text of the framework, throughout this section we include blue fields containing summaries of the feedback we received, policy rationale, and explanations for each section.

Definitions

1. **Affirmative Express Consent**
    a. In general - The term "affirmative express consent" means an affirmative act by a consumer that clearly communicates the consumer's authorization for an act or practice, in response to a specific request that:
        i. Is provided to the consumer in a clear and conspicuous disclosure that is separate from other options or acceptance of general terms; and
        ii. Includes a description of each act or practice for which the consumer's consent is sought that:
            (A) Is written concisely and in an easy-to-understand manner that is accessible to all consumers; and
            (B) Includes clear headings that would enable a reasonable consumer to identify and understand the act or practice.
    b. Express consent required - Affirmative express consent shall not be inferred from the inaction of a consumer or the consumer's continued use of a service or product.
    c. Voluntary - Affirmative express consent shall be freely given and nonconditioned.

Much of the data covered by this framework is inherently sensitive on its own or when used in certain ways. When the collection, use, or sharing of certain data is conditioned on consent, it is crucial that consent be meaningful. It has been repeatedly documented that terms that appear in lengthy privacy policies do not meet this standard. To that end, this definition requires the clear and thorough presentation of information to users and clarifies that consent cannot be inferred from consumer inaction. Moreover, consumer consent must be voluntary and cannot be conditioned (for example, with a condition that unnecessary data be collected as part of a sale). This approach is also consistent with the FTC's approach, other frameworks, and bipartisan constructions of affirmative express consent introduced during the 116th Congress, including comprehensive privacy legislation and legislation that would cover consumer health information.

2. **Aggregated Health Data** - The term "aggregated health data" means health data that relates to a group or category of individuals but cannot reasonably be used to infer information about, or otherwise be linked to, an individual, a household, or a device used by an individual or a household.

   A participating entity in possession of aggregated health data shall:

   a. Take reasonable measures to safeguard the aggregated health data from reidentification, including the adoption of technical and organizational measures to ensure that the information is not linked to any individual, household, or device used by an individual or a household;

   b. Publicly commit in a conspicuous manner not to attempt to reidentify or associate the aggregated health data with any individual, household, or device used by an individual or a household; and

   c. Contractually require the same commitments from recipients of all transfers of aggregated health data.

This framework recognizes that properly aggregated data may pose fewer privacy risks to individuals, families, and communities. As a result of that reduced privacy risk and the offsetting public benefit of some uses of aggregated data, this framework permits certain uses of aggregated data for research purposes or internal analysis (see Section V). Importantly, aggregation is not a silver bullet in protecting individual privacy. This framework requires covered entities to safeguard aggregated health data from reidentification and to contractually require the same commitment from any entity that receives the aggregated data.

We received comments asking for greater clarification around the definitions of both aggregated and de-identified data. It is critical for these definitions to be clear because aggregated and de-identified data sets are subject to different use limitations under the framework. To address these comments, the definitions of aggregated and de-identified health information have been modified to make clear that they are not subsets of consumer health information. Additional clerical edits have also been made to these definitions to ensure consistency of terms and approach.

3. **Consumer** - The term "consumer" means an individual, including minors.

Comments received about this section asked whether minors are included within the definition of consumer. Minors face the same potential harms when their health data is misused or used in unintended ways and should have the same protections as everyone else under the framework. To address this feedback, we have now included a reference to minors within the definition to clearly indicate that they are included.

4. **Consumer Health Information** - The term "consumer health information" means:
    a. Any information, recorded in any form or medium, that is created or received by an entity and:
        i. Relates to or is used to determine, predict, or estimate the past, present, or future physical or mental health condition of an individual; or
        ii. Relates to the provision of healthcare to an individual.
    b. The following data sets regardless of the purpose or outcome of the collection, disclosure, or use:
        i. Genetic data;
        ii. Data that reflects a particular disease or condition;
        iii. Data that reflects any substance use disorder;
        iv. Data that reflects reproductive health; and
        v. Data that reflects disability.[2]
    c. Exclusions - Consumer health information does not include:
        i. Protected health information (PHI) held or maintained by a HIPAA-covered entity or business associates acting for the covered entity.

[2] As defined under the Americans with Disabilities Act of 1990, available at https://www.ada.gov/pubs/adastatute08.htm.

This definition intentionally rejects previous notions of "health data" that are limited to the direct provision of health services by a professional. It also avoids the approach taken by some other voluntary frameworks that create a list of health conditions that qualify for protection. This definition instead focuses on the nature of the information and how it is used. It recognizes that all data can be "health data" if it is used for those purposes, even if it appears unrelated on its face. To that end, subsection (a) covers all data that a participant collects, shares, or uses for health purposes. Examples of some of these data sets are as follows:

- Data that reflects racial and ethnic origin;
- Biometric data; and
- Data that reflects sexual orientation.

Subsection (b) declares that certain sensitive health information shall always be subject to the framework, regardless of the context of its use.

A purpose- and use-based approach to this definition has several benefits. First, it benefits consumers by raising the bar for all the data that is used to impact their health and wellness. Modern data use is complex, opaque, and instantaneous. Trying to delineate distinct data sets as worthy of coverage and others as not no longer makes sense for the people whose information is implicated. Second, it creates a tech-neutral standard that will stay relevant as technology evolves.

We received a number of thoughtful and detailed comments about this section. Several of the comments focused on the broad nature of the definition. We took this feedback seriously. To address these points, the definition has been refined to clarify when certain data sets, such as racial and biometric data, will be treated as consumer health information. These edits focus the framework's protections on data sets that are collected, disclosed, and used for health purposes while still recognizing that certain types of data are always consumer health information. Finally, the addition of the exclusion section is intended to make clear that this framework is focused on consumer health information that is not covered by HIPAA.

5. **De-identified Health Data** - The term "de-identified health data" means health data that cannot reasonably be used to infer information about, or otherwise be linked to, an individual, a household, or a device used by an individual or a household.

   A participating entity in possession of de-identified health data shall:

   a. Take reasonable measures to safeguard the de-identified health data from reidentification, including the adoption of technical and organizational measures to ensure that the information is not linked to any individual, household, or device used by an individual or a household;

   b. Publicly commit in a conspicuous manner not to attempt to reidentify or associate the de-identified health data with any individual, household, or device used by an individual or a household; and

   c. Contractually require the same commitments from recipients of all transfers of the de-identified health data.

Properly de-identified data may pose fewer privacy risks to individuals, families and communities. As a result of that reduced privacy risk and the offsetting public benefit of some uses of de-identified health data, this framework permits certain uses of this data for research purposes or internal analysis (see Section V). De-identification is not a silver bullet in protecting individual privacy. This framework requires covered entities to safeguard de-identified health data from reidentification and to contractually require the same commitment from any entity that receives the de-identified data.

We received a number of comments about this definition that are discussed under the definition of aggregated health data above. Additionally, we received comments specifically about de-identified data. Those comments focused on de-identified health data carrying a greater potential to be reidentified compared to aggregated health data. While it is not possible to completely eliminate the risk of reidentification, the definition requires participating entities to not reidentify this data.

6. **Participating Entity** - The term "participating entity" means an entity that collects, gathers, or uses consumer health information in any form or medium for nonpersonal purposes and that adopts this framework.

This has been drafted broadly in an effort to capture all entities that collect and/or use consumer health information. It no longer makes sense for consumers to have different rights depending on what entities hold their information.

We received some comments seeking greater clarification regarding how this framework would apply to entities that may have certain data sets that are covered by HIPAA while others are not. This framework is focused on non-HIPAA-covered data and is intended to increase privacy protections around data sets that currently fall outside HIPAA's coverage while not creating overlapping or conflicting requirements for participating entities.

7. **Privacy Review Board** - The term "privacy review board" means an independent board that:
    a. Is composed of at least three members;
    b. Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
    c. Includes at least two members who are not affiliated with the participating entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities;
    d. Includes at least one member who is a consumer representative with experience working in the consumer health context; and
    e. Does not have any member participating in a review of any project in which the member has a conflict of interest.

    For the purposes of this definition, an institutional review board (IRB) or a privacy board as contemplated under the HIPAA Privacy Rule shall satisfy this definition so long as the IRB or privacy board meets the composition requirements of this provision.

Review boards inject valuable, independent professional review for certain proposed uses of consumer health data. Large and consequential uses of consumer health information will benefit from this independent scrutiny. In an effort to stay consistent and not introduce a host of new terms or requirements, this definition is heavily influenced by similar provisions within HIPAA and its accompanying regulations.

We received comments regarding the composition of privacy review boards. Because the framework is focused on health information, any consumer representative must have experience working on consumer health issues to best protect consumers' rights. The definition also makes it clear that IRBs and privacy boards satisfy this requirement so long as they meet each element within the definition.

8. **Publicly Available Information** - The term "publicly available information" means any information that:

    a. Has been lawfully made available to the general public from federal, state, or local government records;

    b. Is published in a telephone book or an online directory that is widely available to the general public on an unrestricted basis;

    c. Is video, audio, or Internet content published in compliance with the host site's terms of use and available to the general public on an unrestricted basis; or

    d. Is published by a news media organization to the general public on an unrestricted basis.

    For the purposes of this definition, information is not restricted solely because there is a login requirement associated with accessing the information or a fee. When a user of a social media service creates or shares information on that service, such information is restricted unless it is freely accessible to anyone using the service.

Like many proposals, this framework recognizes that there is individual and societal value in the free flow of information and that even health data may receive reduced protections when it has legitimately been made public. We have tried to craft this definition to capture truly public information while not being overly broad. We also clarify that traditional sources of news, such as newspapers, whose digital presence may have a login and/or small cost associated with their service, are still considered well within the public sphere.

We received several comments regarding publicly available information. Specifically, to address comments about information that requires a fee for access, we eliminated a specific dollar amount in an effort to account for several services that have varying fee schedules.

9. **Research** - The term "research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

This definition is heavily influenced by similar provisions within HIPAA, the Common Rule regarding federal human subjects and their respective regulations. This definition permits public interest research to continue while avoiding a loophole that could be used to justify any type of commercial data research.

Collection and Processing of Consumer Health Information

I. Obligations for Participating Entities

Currently, the burden of ensuring sufficient privacy protections around health data disproportionately falls on consumers. This portion of the framework focuses on data collection and use practices that ensure data is used for limited purposes consistent with consumer requests and expectations. We have also included data security provisions.

A. Relation to Existing Federal, State, and Municipal Laws and Regulations

To the extent that any participating entity's collection, disclosure, or use of consumer health information is already governed by federal, state, and municipal laws and regulations, those legal obligations are not affected by this framework.

This section is intended to make clear that framework participants must follow all applicable laws and regulations in addition to offering consumers the higher level of protections included within the framework.

B. Privacy and Security Protections

A participating entity shall offer the same levels of privacy and security protections and data rights and controls to all consumers, regardless of whether the consumer is paying for services or receiving them for free.

C. Permissible Collection and Use Practices for Consumer Health Information

A participating entity:

1. Shall not collect, disclose, or use consumer health information for any purpose other than the purpose for which the data was originally collected, disclosed, or used;
2. Shall limit the amount of consumer health information collected, disclosed, or used to only what is necessary to provide the product or feature the consumer has requested; and
3. Shall take reasonable efforts to contractually obligate third parties and service providers with whom it discloses consumer health information to also meet the obligations of this framework.

This section is intended to categorically prohibit secondary uses of health data that do not fall under one of the clearly defined exceptions to this framework. If a participating entity would like to offer a new product or functionality or repurpose data for any reason, it must seek affirmative consent for that new use. In no instance should terms of service serve as justification for secondary uses of data. Data collection and use limits carry through to third parties. Consumers should be protected without having to take additional steps to monitor how their data is being used by third parties.

This section is likely to curb some current behavioral advertising and commercial product development activities that do not avail themselves of one of the other exceptions, such as the use of de-identified data. We understand this approach is more stringent than other voluntary frameworks and legal standards, but we believe health data warrants the protection.

To address comments regarding the obligations section, we have clarified that a covered entity shall take reasonable efforts to contractually obligate third parties and service providers. This approach better aligns the framework with similar privacy protections found in other proposals and industries, and provides participating entities and consumers with greater assurance that the framework's protections carry though to third parties.

D. Consumer Health Information Retention

A participating entity:

1. Shall maintain consumer health information for a period of time only as long as necessary to carry out the purpose(s) for which the consumer health information was collected; and
2. Shall delete all consumer health information once there is no longer a valid reason to retain it.

There should be clear and reasonable limits on the length of time consumer health information may be maintained by participating entities. Retention limits benefit both consumers and participants. Less data can lessen the impact of breaches and ensure that decisions are not made on stale, old, and incorrect data and produces lower storage and security costs. These limits are consistent with limits in other existing proposals and regulations.

E. Prohibitions on the Use of Consumer Health Information to Harm or Discriminate Against Consumers

1. A participating entity shall not collect, disclose, or use consumer health information to discriminate against consumers.
2. A participating entity shall not collect, disclose, or use consumer health information when making significant eligibility determinations, including housing, employment, healthcare, and other significant determinations.
3. A participating entity shall not draw inferences from a consumer's refusal to use or cessation of use of a platform, product, app, or digital health tool that could lead to discrimination, stigmatization, harmful profiling, or exploitation.

Consumer health information is inherently sensitive. It should not be collected, disclosed, or used in ways that harm or discriminate against consumers, or limit consumers' access to critical life services or opportunities.

To address comments regarding the use of consumer health information to harm consumers, we have included an additional provision within this section. Specifically, the additional section makes it clear that a consumer's decision to not use or to stop using a specific product or service shall not have any negative or harmful consequences.

F. Security

1. A participating entity shall establish and implement reasonable information security policies, practices, and procedures for the protection of consumer health information, taking into consideration:

    a. The nature, scope, and complexity of the activities engaged in by such participating entity;

    b. The sensitivity of any consumer health information at issue;

    c. The current state of the art in administrative, technical, and physical safeguards for protecting such information; and

    d. The cost of implementing such administrative, technical, and physical safeguards.

2. Requirements - The policies, practices, and procedures required in subpart (1) of this section must include the following:

    a. A written security policy with respect to the collection, retention, and use of such consumer health information;

    b. The identification of an officer or other individual as the point of contact with responsibility for the management of information security;

    c. A process for identifying and assessing reasonably foreseeable security vulnerabilities in any systems maintained by such participating entities that contain such consumer health information, which shall include regular monitoring for vulnerabilities and breaches of security of such systems;

    d. A process for taking action designed to mitigate against vulnerabilities identified in the process required by subparagraph (c)—which may include implementing any changes to security practices and the architecture, installation, or implementation of network or operating software—or for regularly testing or otherwise monitoring the effectiveness of the existing safeguards;

    e. A process for determining whether consumer health information is no longer needed and for disposing of consumer health information by shredding, permanently erasing, or otherwise modifying the personal information contained in such data to make such consumer health information permanently unreadable or indecipherable;

    f. A process for overseeing persons who have access to consumer health information, including through network-connected devices;

    g. A process for employee training and supervision for implementation of the policies, practices and procedures required by this subsection; and

h. A written plan or protocol for internal and public response in the event of a breach of security.

This section imposes a "reasonable" security requirement on participants that is consistent with FTC enforcement and the laws in many states. Because "reasonable" is scaled to the sensitivity of the data, the way it is used, and the state of technology, participants' obligations will be commensurate with the business and engineering decisions they make. The processes required here are also flexible and outcome-based, which is usable for participants of all sizes and sophistication.

II. Consumer Controls

A. Consumer Rights With Respect to Consumer Health Information

1. Consumers' Rights to Access, Correct, and Delete Consumer Health Information:

   a. A participating entity shall provide a consumer with a free, clear, and easy process for requesting personal consumer health information within the participating entity's possession.

   b. A participating entity shall provide a consumer with a free, clear, and easy process for requesting and receiving a list of all other affiliates, service providers, and third parties that have received, licensed, or purchased their consumer health information:

      i. If a participating entity has shared, licensed, or sold consumer health information to another entity that contracts with one or more individuals who act as independent contractors to provide a benefit (such as transportation, deliveries, or another immediate benefit) directly to a consumer, the participating entity must identify the other entity, but need not list or identify any end-service providers.

   c. A participating entity shall provide a consumer with a free, clear, and easy process for requesting corrections or deletions to any inaccurate information within the consumer health information in the participating entity's control.

   d. A participating entity shall make reasonable efforts to correct or delete a consumer's health information based on a consumer's request for correction or deletion.

   e. When correction or deletion cannot occur, a participating entity shall provide the requesting consumer with an explanation as to why the correction or deletion request cannot be carried out.

To address comments regarding consumers' ability to receive information about all other entities that have received, licensed, or purchased their consumer health information, this section now provides consumers with a clear mechanism to obtain this information. The additions to this section are also necessary because of modifications made to the transparency requirements above that now require that consumers receive information about the types of entities that will receive, license, or purchase their consumer health information. This addition strikes a balance between consumers' interests and the compliance obligations of participating entities.

Additionally, we received comments that raised concerns regarding how information that was at one time HIPAA-covered data (PHI) should be treated under this section. Specifically, commenters raised concerns that a consumer's medical records, records that were once covered by HIPAA and may well be shared in the future with HIPAA-covered entities, should only be annotated and not subject to broader correction and/or deletion requirements. While we recognize these concerns, this framework is designed to operate outside HIPAA and give consumers greater control over their health information. We encourage participating entities that collect, disclose, or use these types of records to ensure that these consumer rights are made clear to everyone via the framework's transparency requirements. Moreover, medical professionals who may receive this type of consumer health information should appreciate that the consumer, and not a HIPAA-covered entity, is deciding what information they are sharing and proceed accordingly.

2. Consumers' Portability Rights

    a. Where technically feasible, a participating entity shall make available a reasonable means for a consumer to download their health information that is retained by the participating entity in a structured, standardized, and machine-readable interoperable format for the consumer's own use.

3. The Use of Consumer Health Information to Train or Be the Subject of Automated Systems or Processes

    a. A participating entity shall not collect, disclose, or use consumer health information to train or be the subject of any automated, algorithmic, or artificial intelligence (AI) application unless that entity has first:

        i. Obtained affirmative express consent from a consumer for the use of their health information in such applications, or

ii. Subjected the consumer health information to be collected, disclosed, or used to a risk-based privacy assessment, any risks identified have been appropriately mitigated, and the use is consistent with a reasonable individual's expectations given the context in which the individual provided or authorized the collection, disclosure, or use of their consumer health information.

b. If the consumer health information served as an input for an automated system or process, any resulting data that is produced or results from that automated system or process shall be considered consumer health information if:

i. The resulting data relates to or is used to determine, predict, or estimate the past, present, or future physical or mental health condition of an individual;

ii. The resulting data relates to the provision of healthcare to an individual; or

iii. The resulting data includes:

(A) Genetic data;

(B) Data that reflects a particular disease or condition;

(C) Data that reflects any substance use disorder;

(D) Data that reflects reproductive health; or

(E) Data that reflects disability.

c. Automated, algorithmic, or AI applications, processes and systems must be designed and implemented by the participating entity to mitigate potential algorithmic bias, including through design processes that regularly interrogate the variables and training data used, measures that ensure transparency and explainability, and routine auditing.

We have drafted this section to include several consumer rights that are consistent with existing domestic and international regulations and proposals.

To address comments regarding the use of data sets produced by automated, algorithmic, or AI applications, processes, and systems that used consumer health information in the creation of those subsequent data sets, this section has been modified to align with the framework's definitions to clarify when those new data sets shall be treated as consumer health information.

III. Notice and Transparency

Section I establishes data collection and use practices that ensure consumer health data is used for limited purposes consistent with consumer requests and expectations. This section builds on those critical protections and is designed to empower consumers with the information they need.

Notice and transparency serve two complementary functions. First, timely and meaningful notice allows individuals to make informed decisions before they agree to have their health information collected, disclosed, or used. Second, ongoing transparency requirements allow individuals to revisit a participating entity's data policies at a time of their convenience or keep up to date with changing data uses. It also allows researchers, regulators, and advocates to track data use trends and better understand companies' practices. Because these purposes require different levels of detail, the framework requires participating entities to prepare two sets of information. This approach provides consumers with the information they need without overwhelming them, while simultaneously providing more thorough information to be used over time or in the public interest.

A. Notice

A participating entity shall not collect, disclose, or use consumer health information as permitted under Section I unless it first:

1. Clearly identifies the types of health information that will be collected;
2. Clearly states the purpose(s) that any health information is collected for;
3. Clearly states the data retention policies that will apply to the consumer's health information;
4. States whether any health information will be disclosed and, if so, provides the user clear information about the specific types of entities that will receive, license, or purchase the consumer health information;
5. States the reason(s) any health information is disclosed;
6. Commits to promptly notifying consumers when policies and practices surrounding how their health information will be collected, disclosed, or used have changed; and
7. Provides consumers with a description of their individual rights and a clear list of any consumer controls that a participating entity has made available.

To address comments regarding greater transparency around data retention, this section now contains a provision requiring participating entities to tell consumers how long they will retain the consumers' health information. Retention information can help consumers make informed choices when selecting services and also allow consumers to act should they wish to obtain a copy of their health information before it is no longer retained by an entity.

We also received several comments regarding the framework's notice provisions. Specifically, commenters noted that it may not be possible and/or may be overly burdensome to identify every entity that may receive a consumer's health information at the time they consent to using a product. To address this, the notice provision now requires participating entities to provide information about the types of entities that receive consumers' health information. This modification still permits consumers to make informed decisions when engaging a product for the first time. If a user wishes to know the names of all the entities that may collect, use, or share their information, they may find them in the transparency report required by the next section.

B. Transparency

A participating entity that collects, discloses, or uses consumer health information shall, with respect to each service or product provided by the participating entity, publish:

1. A consumer-facing policy that:
    a. Includes information regarding each element listed within the "Notice" section of this framework; and
    b. Is written in a manner that is succinct and easily understandable to a consumer.
2. A complete second and more detailed policy that includes:
    a. Each element listed within the "Notice" section of this framework;
    b. The manner in which consumer health information is collected; and
    c. A detailed list of all affiliates, service providers, and third parties with whom the participating entity has disclosed or plans to disclose consumer health information.

With regard to obligations of a participating entity to list other entities that will receive, license, or purchase consumer health information, if the other entity is one that contracts with one or more individuals who act as independent contractors to provide a benefit (such as transportation, delivery, or another immediate benefit) directly to a consumer, the participating entity must identify the other entity, but need not list or identify any end-service providers.

As a result of the comments we received, this section now includes additional clarity around situations where covered entities work with partners that use independent contractors to provide a benefit. For example, a participating entity need not list the names of individual independent contractor(s) (such as a delivery person); it need only provide the name of the service provider partner.

IV. Consent

Participating entities must obtain a consumer's affirmative express consent prior to any collection, disclosure, or use of consumer health information permitted under Section I. Consent adds an important layer of protection and consumer control within the framework by permitting the individual consumer to decide whether or how their health information will be collected, disclosed, or used.

These provisions are drafted to require consumer consent for specific collections and uses of consumer health information, as opposed to a simple blanket consent for a host of possible uses. It also includes important consumer rights to revoke consent later on.

It is important to note that nothing in this section allows "consent" to override any of the categorical prohibitions and obligations in Section I. For example, a person cannot consent to being discriminated against, to having their data used or shared for prohibited secondary purposes, or to being subjected to a pay-for-privacy scheme.

A. Elements of Consent

In addition to the obligations for participating entities in Section I, before a participating entity may collect, disclose, or use consumer health information:

1. A participating entity must obtain affirmative express consent from a consumer;
2. A participating entity must seek additional consent for any new collection, disclosure, or use of consumer health information outside the scope of any previous consumer consent;
3. A participating entity may seek to obtain affirmative express consent from a consumer for continued, ongoing, or periodic collection, disclosure or use of consumer health information when both the purpose and intended use of consumer health information is the same for every instance of collection, disclosure, or use; and
4. Affirmative express consent shall be freely given and nonconditioned.

B. Revocation of Consent

1. A participating entity collecting, disclosing, or using consumer health information must provide consumers with the ability to revoke consent.

2. A participating entity must stop the collection, disclosure, or use of health information once a consumer has revoked consent.

We received numerous comments regarding the framework's consent provision, and recognize that questions around consent and its continued applicability and utility are difficult. While this framework is designed to move beyond existing consent-centric regimes by placing real limits around the collection, disclosure, and use of consumer health information, there are instances where consumers' control of their data matters. Given the sensitivity of the covered health information protected by this framework, consumers must consent before their health data is collected, disclosed, or used.

Additionally, we received comments and questions regarding the frequency of consent required under this section. To address this, we added additional clarifications that make it clear that a single consent is sufficient for continued, ongoing, or periodic collection, disclosure, or use of consumer health information, so long as the purpose and intended use of consumer health information is the same for every instance. Consumers and participating entities should not be overburdened with redundant consent requests.

V. Exceptions

Nothing in this framework shall limit participating entities from:

1. Engaging in practices that use consumer health information when necessary for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes that adhere to commonly accepted ethical standards and laws:

    a. With affirmative express consent from a consumer;

    b. Provided that the research has been reviewed and received written approval by a privacy review board; or

    c. If the research uses aggregated health data, provided that:

        i. A participating entity may use aggregated health data for research without consumer consent only after it:

(A) Determines that the aggregated health data to be used only relates to a group or category of individuals or devices and does not identify and is not linked or reasonably linkable to any individual;

(B) Documents the methods and results of the analysis that justify such determination; and

(C) Produces a publicly available statement explaining the participating entity's practices regarding the general methods used for aggregating consumer health information;

d. If the research uses de-identified health data, provided that:

i. A participating entity may use de-identified health data for research without consumer consent only after it determines that the data is not individually identifiable. This determination shall be made by a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, who:

(A) Applying such principles and methods, determines that the risk is very small that the de-identified health data could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information;

(B) Documents the methods and results of the analysis that justify such determination; and

(C) Produces a publicly available statement explaining the participating entity's practices regarding the general methods used for rendering consumer health information not individually identifiable.

2. Engaging in commercial, academic, or research practices that use only publicly available consumer health information.

3. Using or disclosing consumer health information to a medical professional or healthcare provider without consent if that participating entity, in good faith:

a. Believes that an emergency involving danger of death or serious physical injury to any person requires use or disclosure relating to the emergency; and

b. Believes that the recipient of this information is in a position to address, rectify, or prevent the emergency; and

c. If a participating entity uses this emergency exception, it shall promptly notify the consumer whose health information was disclosed.

4. Engaging in practices that use consumer health information when necessary and solely for the purposes of:
    a. Detecting and preventing security incidents, identity theft or fraud, or protecting against malicious or deceptive activity;
    b. Performing system maintenance, diagnostics, debugging, or error repairs to ensure or update the functionality of a product or service;
    c. Complying with a federal, state, or local law, rule, or other applicable legal requirement, including disclosures pursuant to a court order, subpoena, summons, or other properly executed compulsory process; or
    d. Addressing health misinformation or moderating content or accounts to prevent harm to consumers.
5. Collecting, disclosing, or using data:
    a. About an individual in the course of the individual's employment or application for employment (including on a contract or temporary basis), provided that such data is retained or used by the participating entity or the participating entity's service provider solely for purposes necessary for the individual's employment or application for employment;
    b. That is emergency contact information for an individual who is an employee, contractor, or job applicant of the participating entity, provided that such data is retained or used by the participating entity or the participating entity's service provider solely for the purpose of having an emergency contact for such individual on file; or
    c. About an individual (or a relative of an individual) who is an employee or former employee of the participating entity for the purpose of administering benefits to which such individual or relative is entitled on the basis of the individual's employment with the participating entity, provided that such data is retained or used by the participating entity or the participating entity's service provider solely for the purpose of administering such benefits.
6. Engaging in limited commercial product development:
    a. With affirmative express consent from a consumer for this specific use, provided that it:
        i. Uses aggregated health data or de-identified health data;
        ii. Complies with the provisions of the "Prohibitions on the Use of Consumer Health Information to Harm or Discriminate Against Consumers" section of this framework;

iii. Meets the requirements of the "Notice" and "Transparency" sections of this framework for this specific and limited use; and

iv. Does not share any consumer health information, de-identified health data, or aggregated health data used in that development with a third party.

The framework should include very limited exceptions that permit the collection, use, and sharing of health data without consent or for secondary purposes. Mindful of how exceptions can undercut the effectiveness of a framework, these provisions borrow from long-standing laws that attempt to balance the equities between individual privacy, societal benefits from the use of this data, and participants' needs to process data to deliver the service or product requested by an individual.

To address comments regarding the use exceptions for aggregated and de-identified data, modifications were also made to this section to keep terms consistent throughout the framework. Additionally, to address comments regarding employee data, subsection 5 was added to clearly list limited exceptions for the use of employee data. These points reiterate the provisions of the newly added employee data definition so that employers are not overly burdened when using data about their employees for purely administrative functions.

We received several comments regarding how participating entities should handle employee data under the framework. In response, we have included a new exception that is designed to identify limited, specific instances where data may be collected, disclosed, or used outside the framework's general provisions for the limited employment-related purposes enumerated here. Data about employees that is collected, disclosed, or used for any other purpose falls outside this exception and is subject to the same protections as the covered data of any other person.

Finally, we received several comments surrounding the use of consumer health information for commercial product development. We recognize that consumer health information can help entities develop innovative new products and services. However, these commercial benefits must be properly balanced with consumers' rights.

In an effort to strike a balance and permit limited commercial use, we have added language designed to promote strong consumer privacy protections when consumer health information will be used by a participating entity solely for commercial purposes. Specifically, to best protect consumer privacy, this section limits commercial development to aggregated and de-identified data. It incorporates the framework's antidiscrimination and transparency provisions to ensure consumers will not be harmed and will know how their data will be used. Since this is a new exception, we look forward to continuing to work with our partners and the public on this important provision.

Proposed Self-Regulatory Program: Policy Rationale

For any follow-up questions, kindly contact Alice Leiter at eHI (alice@ehidc.org).

Numerous efforts in recent years have successfully developed comprehensive codes of conduct and terms of service to protect consumer privacy.[3] Rather than duplicate such efforts, we decided to pursue a more formal, tangible, and meaningful accountability structure: a self-regulatory program for non-HIPAA-covered entities that collect, use, and share health data. This proposal would establish a voluntary self-certification program led by an independent, third-party organization. This reduces the potential for bias and lax internal policing, increases the possibility for meaningful adherence to privacy practices, and ensures consequences for nonadherence.

Addressing Consumer Trust

While we grappled with options to protect consumer privacy, a self-regulatory model arose as the most effective option available in the current environment. Perhaps most relevant to this project, self-regulation can engender trust: "...[T]he most important goal of any self-regulatory system is building consumers' trust in its participants. Self-regulation often arises in response to erosion of trust.... Laws rarely achieve the goal of building trust, because they merely set a baseline for compliance."[4] Further, self-regulatory programs can be nimbler and more flexible than government regulation.[5]

Successful self-regulatory programs can create trusted environments by "setting standards that only responsible organizations can meet. Participants in the self-regulatory system obtain the benefit of differentiating themselves from others whose conduct, while it may be legal, is not exemplary."[6] Moreover, public reporting of compliance with the standards provides a level of transparency and accountability that further engenders trust.

Self-regulation incentivizes competitors to monitor each other for compliance with the agreed-to standards. It provides consumers with a clear and straightforward way to file complaints. Most important, self-regulatory programs are based on a neutral enforcement mechanism.

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[3] *See* Manatt White Paper at pp. 16–17. This paper provides an in-depth discussion on self-regulation, what models have been implemented and how they have worked in other industries, and how one might work in healthcare. We have pulled out key points for this policy rationale but encourage a full read of the paper for a more thorough look at the benefits and particulars of a self-regulatory model for non-HIPAA-covered entities.

[4] Boulding, M. "Self-Regulation: Who Needs It?," *Health Affairs*, Volume 19, Number 6 (2000), available at https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.19.6.132.

[5] *See* Manatt White Paper at pp. 17–27.

[6] Boulding, M. "Self-Regulation: Who Needs It?," Health Affairs, Volume 19, Number 6 (2000), available at https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.19.6.132.

Program Goals

The goal of the program envisioned by our framework is that compliance with the self-regulatory program would be viewed by consumers as a "Good Housekeeping Seal of Approval," i.e., the gold standard for privacy-protecting technology. Through widespread promotion and adoption, certification of technology products through the program would ultimately become the industry standard.

Key tenets of the proposal are strong accountability and enforcement mechanisms, including comprehensive audits, spot checks and annual assessments, all of which would complement existing government regulation through the FTC.[7] The program would act as a partner to FTC regulators and state attorneys general (AGs) in that it would offer its participants compliance resources that government authorities may not have, such as time, infrastructure, and industry expertise.[8] This program would offer widespread monitoring and, given the already stretched resources of the FTC in particular, allow the commission to focus its efforts against the most egregious violators.

Establishment of a New Self-Regulatory Program

Operationalizing a new self-regulatory program will take extensive planning. Discussions about who might house a program of this type have centered around how the program should function rather than who should manage it. Although no final recommendations about program ownership were determined, several related issues were identified as needing further exploration. These will be considered during the second phase of this work:

- Ideally, the program would be housed in an existing organization rather than stood up as a brand-new entity. Succeeding at the latter would require more resources and a significantly heavier lift in terms of establishing name recognition and figuring out program logistics and a management structure. A number of reputable organizations have experience running self-regulatory programs in other industries.
- An organization that has a road map in place with experienced personnel to implement the new program would also lend credibility to the entire program for both consumers and regulators. There may be a need for an advisory body as part of the governance structure, another area for determination at a later date.
- A funding mechanism. Although funding details are for a later phase of work, the intention is that participating entities would pay an annual fee, scaled based on their size in terms of gross revenue.
- A sound economic model is key to a successful program, and in the implementation phase of this work, significant time and attention would be devoted to related logistics and ensuring that there are no conflicts of interest, whether real or perceived.

[7] While the Office for Civil Rights within the Department of Health & Human Services is the compliance and enforcement body for HIPAA-covered entities, it is the FTC that has similar authority for businesses outside HIPAA, even if they collect and use health data.

[8] *See* Manatt White Paper at p. 22.

Consumer and Participant Benefits

An inherent tension exists between "carrots" and "sticks" for encouraging and driving participation in the proposed program. Shoring up protections for consumers, as well as providing accountability and enforcement mechanisms, were the key areas this proposal sought to address. Consumers are often skeptical of self-regulation in the healthcare space due to perceived bias among participating companies. The introduction of a third-party, independent monitoring entity, with the backstop of FTC enforcement, would help assuage those worries.

During the next phase of this work, we will devote significant time and effort to involving consumers and consumer advocacy groups in fleshing out how this program will be implemented. Addressing consumer skepticism head-on by engaging consumer groups in these discussions will be critical.

To ensure the success of this program, participating entities will need meaningful incentives to join. The program will provide participants a way to distinguish themselves in an increasingly competitive market marked by widespread consumer distrust. And this benefit is real: Cisco's 2020 Data Privacy Benchmark Study, drawing from data from 2,800 organizations in 13 countries, showed that 70 percent of organizations say they received significant business benefits from privacy beyond compliance—up from 40 percent in 2019.[9] Further, "82 percent of organizations see privacy certifications as a buying factor: Privacy certifications ... are becoming an important buying factor when selecting a third-party vendor."[10]

As noted in the Executive Summary above, this framework creates a potential road map for future data privacy legislation. Companies that join as participants thus have the potential to be "ahead of the curve" when adopting the framework's policies. The combination of this with reputational and commercial benefits should provide significant incentives for companies to join.

Incorporation of Feedback

We received a number of thoughtful and detailed comments from a variety of stakeholders on all aspects of this framework, including the proposed self-regulatory structure. The above strives to address the majority of these, as do the adjustments to the following proposal. The most significant change to the draft released in August is the explicit recommendation that this new program be housed in an existing entity rather than established as a brand-new, stand-alone organization. As articulated above, we believe this will put us in a much stronger position for eventual implementation as well as help address many of the logistical and reputational questions we received. Perhaps most important, a reputable umbrella organization would help our program achieve far greater stakeholder confidence and trust, ultimately making it more meaningful for consumers and more attractive to potential participants.

[9] "Cisco 2020 Data Privacy Benchmark Study Confirms Positive Financial Benefits of Strong Corporate Data Privacy Practices," available at https://newsroom.cisco.com/press-release-content?type=webcontent&articleId=2047256&utm_source=newsroom.cisco.com&utm_campaign=Release_2047256&utm_medium=RSS.

[10] *Id.*

Self-Regulatory Program for Non-HIPAA Healthcare Data

The proposed framework structure is a self-regulatory program focused on accountability: an independent, self-certification model designed to hold participating entities to a set of standards separately developed through a multistakeholder process. The program, housed in and run by an independent nonprofit organization, would accept individual companies as participants. Participating entities would submit their products for certification and individual products validated as compliant with the framework would be certified.[11]

Participating entities would undergo a thorough onboarding review at enrollment, be educated as to the self-regulatory framework and its obligations, publicly commit to complying with it, and submit to annual audits and assessments. Additionally, active spot-check monitoring would be done on a random sample of participants throughout each year. Participating entities could publicly market their participation and certification level as an "XXX Health Data Privacy Participant" (name TBD) and receive a recognizable visual certification symbol to mark them as such.

Participant fees would be collected from participating organizations to maintain the program. The amount of the fee would be on a sliding scale, based on the size of the company in terms of gross sales. Annual fees would also depend on the amount of seed money put forward to stand up the program at its origination.

Relevant components of this program would include:

- Rigorous onboarding, including the submission of a detailed questionnaire regarding business practices to ensure compliance with program standards;
- Annual audits and compliance assessments;
- Ongoing monitoring of participant companies, including random spot checks;
- Criteria to ensure that the reviews and assessments conducted by the program are independent of the program's administrative and financial functions;
- A public commitment by each company to follow the program's standards;
- Maintenance by the program of a dedicated, public-facing website describing the program's goals, requirements, and governance logistics; listing participating covered organizations; and providing a simple and straightforward method for consumers to ask questions and file complaints about any product and/or any participating covered organization;

[11] Included entities will be all companies that collect, use or process health-related personal data. These would include, among others: hardware manufacturers; app developers; website publishers; third-party data management, brokering, collection or use outfits; and, potentially, businesses/employers that rely on third-party health technology in order to maintain the health of their workers.

- A standardized set of privacy rules that includes:
  - A broad, use-based definition of consumer health information;
  - Articulated appropriate uses and obligations surrounding the collection and use of consumer health information;
  - Greater consumer access to and control of their health information; and
  - Clear notice and transparency requirements; and
- An annual report card by program staff, publicly released, detailing the program's activities and effectiveness during the preceding year in obtaining compliance by participating covered organizations and in taking meaningful disciplinary and corrective actions for noncompliance.

Accountability and potential enforcement mechanisms for participating entities would include:

- Independent monitoring by program staff or other authorized evaluators, including publicly announced corrective or disciplinary cases;
- An active complaint-gathering process, clearly articulated in all public-facing materials and websites;
- A dispute resolution mechanism for resolving consumer complaints or complaints by another company based on the program's standards, and potentially providing consumers with redress for violations;
- A requirement to develop a corrective action plan (CAP) in the event of noncompliance and a process to lose certification if the CAP fails;
- Public announcement of investigations into complaints and complaint resolution, ensuring no complaints are ignored;
- Penalties for persistent or willful noncompliance with the law and the program's standards, such as suspension or dismissal from the program and/or referral to the FTC and/or state AG; and
- Potential for FTC and/or state AG enforcement of violations of agreed-to standards.

This type of self-certification program would help level the playing field among businesses, fostering a unified set of privacy practices that are responsive to recent regulation. At the same time, it would raise the bar for consumer privacy in an area of great personal sensitivity.

The critical difference between this program and a more passive, pledge-style or "best practices" program is the inclusion of rigorous onboarding and ongoing accountability assessments, all of which are designed to elicit full compliance from well-intentioned actors and prevent bad actors from falsely shielding their inappropriate conduct behind a pledge. Significantly, such a program could easily be converted into a safe harbor-style accountability mechanism in future legislation, giving it lasting utility even should new laws be passed.

Appendix

Steering Committee Members

The following organizations and individuals are some of those who participated in the development of this framework by virtue of being part of our Steering Committee. This committee met twice, in February and July of 2020, and many members also participated in one of our workgroups and/or offered feedback on earlier drafts of these proposals. Participation in the Steering Committee does not signify an endorsement of this framework, either in whole or in part. Rather, our Steering Committee provided valuable counsel and constructive criticism over the course of the framework's development. This final product reflects the work of the Center for Democracy & Technology and the eHealth Initiative alone.

Joseph Ashkouti
Change Healthcare

Jacqueline Baratian
Ascension Health

Julie Barnes
Maverick Health Policy

Robert Belfort
Manatt

William Bernstein
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Melissa Bianchi
Hogan Lovells

Susan Bouregy
Yale University

David Brody
Lawyers' Committee for Civil Rights Under Law

Rebecca Cady
Children's National Hospital

Shawneequa Callier
George Washington University

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Corey Cutter
American Cancer Society

Paul Eddy
Wellmark

Mary Engle
BBB National Programs

Shari Erickson
American College of Physicians

Dani Gillespie
National Partnership for Women & Families

Tina Grande
Healthcare Leadership Council

Carlos Gutierrez
LGBT Technology Partnership & Institute

Rachele Hendricks-Sturrup
Future of Privacy Forum

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American Medical Association

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Meg McElroy
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Deven McGraw
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Dena Mendelsohn
Elektra Labs

Ben Moscovitch
The Pew Charitable Trusts

Brenda Pawlak
Manatt

Jules Polonetsky
Future of Privacy Forum

Jessica Rich
Institute for Technology Law and Policy at Georgetown University Law Center

Alejandro Roark
Hispanic Technology & Telecommunications Partnership

Rajeev Ronanki
Anthem, Inc.

Alaap Shaw
Epstein Becker Green

Ashley Thompson
American Hospital Association

Lee Tien
Electronic Frontier Foundation

Charlotte Tschider
Loyola University Chicago School of Law

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CENTER FOR DEMOCRACY & TECHNOLOGY

eHEALTH INITIATIVE

[redacted]

From: Carl M. Szabo [redacted]
Sent: Saturday, July 17, 2021 3:40 PM
To: JulyPublicComments
Cc: Steve DelBianco; Trace Mitchell; Chris Marchese; Robert Winterton; Kir Nuthi; Zach Lilly
Subject: Public Comment Submission for July 21, 2021 Open Commission Meeting
Attachments: NetChoice Comment for the Record_ FTC Open Meeting, July 21, 2021.pdf

Please find attached and add to the record the comments of NetChoice for the FTC July 21, 2021 Open Commission Meeting

Thank you

-Carl Szabo | NetChoice
Vice President and General Counsel
[redacted]

NetChoice Comment for the Record: FTC Open Meeting, September 15, 2021

NetChoice[1] is a trade association of leading internet businesses that promotes the value, convenience, and choice internet business models provide American consumers. Our mission is to make the internet safe for free enterprise and for free expression. We also work to promote the integrity and availability of the internet on a global stage, and are engaged on issues in the states, in Washington, D.C., and in international internet governance organizations.

Introduction

We welcome the opportunity to provide the Federal Trade Commission with feedback about the important issues it will consider at its open meeting on September 15, 2021.

As discussed below, we ask that the FTC:

- Work with Congress to pass a federal privacy law rather than take matters into its own hands based on vague or nonexistent statutory authority;
- Ensure any report on HSR's viability in the 21st Century study more than just digital markets already targeted by the Commission for disfavored treatment;
- Establish procedures for meaningful public input that are reasonable and consistent with the agency's statutory authority; and
- Vote **against** repealing the bipartisan Vertical Merger Guidelines.

We appreciate the Commission's consideration of our views, and welcome the opportunity to provide any additional information or answer any questions.

The Problems with Adopting Major Policy Changes without Providing Adequate Opportunity for Meaningful Public Comment

Before we discuss the issues at hand we must again[2] express our disappointment in the Commission's seeming lack of effort in soliciting public input. Previously public comment was allowed for as little as fifteen days -- again without providing the actual text of the underlying changes. For the Sept 15, 2021 open meeting this

[1] NetChoice is a trade association of e-Commerce and online businesses, at www.netchoice.org. The views expressed here do not necessarily represent the views of every NetChoice member.

[2] *See* NetChoice Comment for the Record: FTC Open Meeting, July 21, 2021

window for public comment was less than three business days and only five days total. Moreover, this notice and comment period fell during the Jewish Holy Week.

This continued diminution in public comment periods, whether intentional or otherwise, gives the impression that the Commission and it's new Chair are not seriously interested in comments from the public. This is especially confusion since, in May 2020, Chair Khan and Commissioner Chopra published a law review article themselves arguing that FTC rules should be established through:

> "[A] transparent and participatory process, ensuring that everyone who may be affected by a new rule has the opportunity to weigh in on it, granting the rule greater legitimacy"

and that the agency should

> "[C]onsider and address all submitted comments before issuing the final rule."[3]

We agree. Such opportunities for public input and opportunities for FTC staff to speak about proposed and past decisions with the public help to ensure public trust in the Commission. As an agency designated to protect consumers, it's critical to recognize that trust is a two-way street -- as Chair Khan and Commissioner Chopra suggested in their May 2020 article.

But it is hard to square these assertions with the Commission's recent behavior unless it is to be believed that public input is invaluable for the making of a rule, but not for decisions to fundamentally overhaul the rulemaking process itself. Public input is important not just for rulemaking, but for any major decision made by the FTC that substantially impacts its approach to regulation and enforcement.

This is the third open meeting at the FTC since Commissioner Khan was appointed with less than the standard 30 days for public comment and shows a continued effort to shorten that window for comments to now less than a week.

To describe this time period for public comment as inadequate would be an understatement and the FTC's consideration of the public comments was clearly not meaningful given the Commission quite literally took no time to actually read or contemplate the comments. Even more concerning, the proposals adopted at this meeting were some of the most significant proposals that the FTC has adopted in decades. They involved rescinding a policy statement that tied the FTC's enforcement principles to the lodestar of American antitrust analysis: consumer welfare. They also involved gutting the reasonable restrictions imposed on the FTC's

[3] Rohit Chopra and Lina M. Khan, *The case for "unfair methods of competition" rulemaking*, 87(2) University of Chicago Law Review 357, 368-69 (2020).

rulemaking procedures and removing requirements that ensured the public had a role to play in such a process.

These are major changes that the FTC should have wanted to make only after receiving meaningful input from the public. In fact, these are changes that make the need for public comment all the more necessary, as they remove reasonable restraints on the FTC's broad and potentially devastating power. As Commissioner Wilson and Commission Phillips argue in one of their dissents to these decisions, "What the changes – adopted without public input – in fact do is fast-track regulation at the expense of public input, objectivity, and a full evidentiary record."[4]

Unfortunately, rather than changing course, the Commission continued providing *less time for public comment* for its second open meeting -- fewer than 7 days for public comment, two of which are over the weekend, and *even less time for public comment* for its third open meeting -- fewer than 5 days for public comment, two of which are over the weekend.

While we are grateful that the FTC decided to include at least some period between when the comments are due and when the voting will actually take place this time around, we are skeptical that three days is sufficient to meaningfully consider the significant amount of public commentary it receives on these important issues.

Going forward, we ask that the Commission provide adequate time for public comments and meaningfully consider such comments before adopting major policy changes that will impact the entire United States economy.

Proposed Policy Statement on Privacy Breaches by Health Apps and Connected Devices

Since the term "privacy breach" is not a term of art used in data security or privacy discussions, and given the inability to view the proposed policy statements themselves, and due to the virtually unprecedented less than five-day opportunity for public comments, we presume in our following comments that when the FTC says "privacy breaches" it is referring to "data breaches."

Companies across the United States recognize that the protection of its customers' or users' data is vital to its long term success. NetChoice agrees in principle with the FTC's interest in focusing attention on this critical matter but remains confused as to the value of focusing specifically on "health apps and connected devices."[5]

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[4] Federal Trade Commission, Dissenting Statement of Commissioners Christine S. Wilson and Noah Joshua Phillips Regarding the Commission Statement On the Adoption of Revised Section 18 Rulemaking Procedures (Jul. 9, 2021), https://www.ftc.gov/public-statements/2021/07/dissenting-statement-commissioners-noah-joshua-phillips-christine-s-wilson.

[5] FTC Announces Tentative Agenda for September 15 Open Commission Meeting

Common sense and past FTC actions show that dividing attention up along narrowly conceived industry lines would lead to politicized enforcement and insufficient outcomes for consumers. Data breaches can come from anywhere, and affect every type of company - whether that is a technology company or retailer, traditionally understood. Instead of expending limited FTC resources ignoring the majority of the data breach problem, focus should be turned to Congressional efforts to pass a comprehensive privacy law that gives companies clear guidelines to follow and gives the FTC clearly delineated enforcement authority.

The Wyndham data breach case is an illustrative example for why the FTC should not get silo its attention to a particular industry or marketplace. When the FTC sued Wyndham Worldwide Corporation, it did so because it alleged that "data security failures led to three data breaches" in under two years resulting in the theft of millions of dollars and the violation of personal account information.[6] After years of litigation and costly proceedings bogged down with questions of FTC authority, Wyndham settled. Wyndham is not a technology company, nor is it a health app. Regardless, it collects and stores sensitive consumer data and has an obligation to protect it, as do the vast majority of other companies. Large retailers like Target have regularly been the subject of data breach controversy.[7] The desire to pursue a particular type of company for infringements in their data practices is a distinction without a difference.

LabMD's hollow victory over the FTC is perhaps more illuminating for the overall point. In that case, the FTC moved against LabMD, a company which tested samples for urologists, for failures in its data privacy regime.[8] After half a decade in litigation, the Eleventh Circuit unanimously held that the FTC complaint was unenforceable, charging that the FTC had attempted to overhaul LabMD with minimal specificity.[9] Along the way to that defeat, the Commission had regularly upheld as obvious its authority to pursue the case against LabMD, a claim that was summarily dismissed. Regardless, the legal proceedings against LabMD caused its collapse. While the FTC failed to make its case, LabMD suffered the consequences.

The Wyndham and LabMD cases build upon each other to make two critical points:

> First, that data breaches can come from any source.
>
> Second, that due to a lack of clarity from Congress, the FTC is often pursuing cases it may not have the authority to.

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[6] Wyndham Settles FTC Charges It Unfairly Placed Consumers' Payment Card Information At Risk, FTC Blog

[7] Target Settles 2013 Hacked Customer Data Breach For $18.5 Million, NBC story

[8] A Leak Wounded This Company. Fighting the Feds Finished It Off, Bloomberg story

[9] The Anatomy of an FTC Data Security Lawsuit, S&W Cybersecurity and Data Privacy Law Blog

This hyper focus on health apps and connected devices issues will ultimately not be solved by the Commission getting distracted by one disfavored industry or another and charging private companies to litigate the edges of its authority.

What businesses and consumers across this country need is a comprehensive federal privacy law that will bring clarity, uniformity, and transparency. That way businesses can better understand their obligations and consumers can be confident that the FTC is interested in their welfare, and not distracted with expanding the authority of the Commission.

Non-HSR Reported Acquisitions by Select Technology Platforms, 2010-2019: An FTC Study

Regarding the Commission's vote on the public release of the report on an FTC inquiry into the structure of unreported acquisitions by large technology platforms: by discussing only mergers within the technology sector, the Commission makes clear their intention to use merger guidelines as a tool to target politically disfavored businesses, rather than to protect consumers from truly anticompetitive conduct.

Not only does this reinforce the impression that the FTC is focused only on the technology industry, but any report which does not acknowledge trends in the economy more broadly is not valuable to identifying harmful anti competitive behavior. Instead, seeking to attack those which are politically disfavored.

The use of investigatory power to influence mergers and acquisitions because of a predisposed dislike of a given industry is a gross abuse of FTC power. By investigating mergers which have occured within the legal guidelines set by the FTC, the Commission is intimidating legal mergers and acquisitions which promote innovation and benefit consumer welfare. This, in tandem with the recent lack of transparency being displayed by the Commission, highlights the current trajectory towards politically motivated antitrust enforcement. So, prior to releasing this report, Chair Khan must rescind the gag order on Commission staff and restore Commissioner access to internal documents, ensuring transparency within the FTC.

Proposed Revisions to FTC Procedural Rules Concerning Petitions for Rulemaking

An enormous amount of effort and energy will not be expended here in this section to reiterate what NetChoice and others have raised already raised to the Commission[10] and what the Commission has repeatedly ignored: namely that the

[10] NetChoice Comment for the Record: FTC Open Meeting, July 1, 2021

FTC is sprinting down a dangerous road outside of the guardrails Congress has put in place to confine the authority of the FTC.

The FTC and its rulemaking authority are not bound by the imagination of the Commission. They are bound by Congress.

As we have written previously to the Commission, the FTC's rulemaking authority, derived from Section 18 ("Magnuson-Moss") of the FTC Act, differs fundamentally from other agency rulemaking under the Administrative Procedures Act. Section 18 carries with it additional statutory requirements that curb the FTC's discretion and that the Commission is obligated to abide by.[11] Congress again went out of its way to constrain the FTC's rulemaking overzealousness of the 1960s and 70s, passing the Magnuson-Moss Warranty of 1975 and the FTC Improvements Act of 1980. Congress was exceedingly clear as to its motivations for passing this legislation. In a series of hearings held in the late 1970s, "Congress publicly lambasted the Commission for its activist programs branding these as 'regulatory abuse' by a 'runaway, controllable bureaucracy.'"[12] The Commission's current efforts over the past few months, and contained within this Open Meeting's "Tentative" Agenda, fly in the face of Congressional intent.

If the FTC is dead set on exceeding its Congressionally mandated statutory authority, it must engage meaningfully with the public and with stakeholders, and allow for extensive feedback throughout the rulemaking process - not simply after votes have been taken. At minimum, the FTC should:

- Submit to the Federal Register a copy of proposed rules; at least 30 days in advanced - consistent with APA rulemaking requirements
- Allow for the submission of public comments with sufficient time given to prepare and submit those comments
- Require full consideration of those comments prior to any vote taken on the underlying subject matter
- Provide FTC feedback to those comments prior to any vote taken on the underlying subject matter

Much has been promised in the way of a more open, collaborative, and collegial FTC process.

What remains is largely an elaborate performance in transparency. Feedback from members of the public is still only welcome after votes have taken place, sitting Commissioners are denied access to important FTC documents and information,

[11] Ibid

[12] Mark J. Moran & Barry R. Weingast, Congress as the source of regulatory decisions: The case of the Federal Trade Commission, 72 American Economic Review 109 (1982).

and even this tentative agenda was released with such short notice as to only allow for two and a half days of the standard work week with which to file comments. At this stage, the Chair's promises of reform ring hollow, and the Commission is falling woefully short of its obligations to the public.

Proposed Withdrawal of 2020 Vertical Merger Guidelines

The Commission should vote against rescinding the Vertical Merger Guidelines adopted in June 2020 and the Commentary on Vertical Merger Enforcement issued in December 2020.

Overall, the Vertical Merger Guidelines reflect a well-considered, balanced approach that helps enforcement agencies identify anticompetitive mergers while maintaining the ability to identify and appreciate the many cases in which such mergers are likely to be procompetitive. It was adopted by both the FTC and DOJ, the United States' two primary antitrust enforcers, after extensive research and consideration.

As intended, it has helped provide market participants with a greater level of clarity regarding how federal enforcers will analyze vertical merger cases and when such mergers are likely to be challenged as anticompetitive. These guidelines serve to promote transparency, clarity, and consistency. Repealing these guidelines, particularly when they were issued such a short time ago, will throw the values out the window, preventing businesses from making informed decisions regarding high-cost transactions and undermining public trust in the FTC and the various other guidelines it has issued.

The Commission should continue to take into consideration both the anticompetitive and procompetitive potential of vertical mergers. There is no question vertical mergers can have anticompetitive effects that the FTC should meaningfully consider when making enforcement decisions. In fact, the very goal of the vertical merger guidelines is to identify various factors that the enforcers should identify and assess when analyzing the competitive effects of vertical mergers. The bulk of these guidelines is spent on providing the FTC and DOJ with an analytical framework for identifying anticompetitive mergers and the factors that make them more likely. However, vertical mergers have a great potential to produce procompetitive effects as well, and the FTC should also take this potential into account when making enforcement decisions.

The economy constantly finds new and better ways to serve the needs of consumers. A core component of this dynamism is the ability of businesses to merge with one another or acquire entities to provide innovative products and services that take advantage of each companies' comparative advantage in a way that could not be achieved in a premerger world. This innovation is possible only because of gained efficiencies and the development of capabilities that did not exist previously.

Acquisitions and mergers are about far more than just acquiring another business, they're about gaining infrastructure, talent, intellectual property, and a variety of other capabilities that can help both businesses provide better products and services to consumers going forward.

Take the Amazon-Whole Foods acquisition, for example. This partnership sparked incredible innovation, much of which has been particularly important during the ongoing COVID-19 pandemic. From at-home delivery to pick-up lockers that minimize the need for interpersonal contact, Whole Foods was able to develop and integrate several new services that would have been unthinkable just five years ago. In addition, many consumers have seen significant price decreases since the acquisition, because of continuous pricing cutting and Whole Food's post-merger Amazon Prime discounting program.

By imposing cumbersome prior approval requirements, the FTC risks deterring these kinds of consumer-welfare enhancing mergers and undermining the enormous potential for innovation that comes with them. Decisions regarding mergers and acquisitions are made on the margin and an increase in the cost of these transactions or the risk that they will not be approved even after the expense of significant administrative costs can have the effect of killing them before they ever even have the chance to be reviewed by the FTC.

So, many of these transactions that would spur innovation and promote economic growth will never see the light of day, regardless of whether the FTC would have ultimately approved them. By artificially deterring what would be procompetitive transactions, the FTC would risk not only undermining innovation but also weakening the United States' economic position in the global community.

Mergers and acquisitions do not just allow businesses to develop new and innovative products and services, they also provide businesses with the tools necessary to both improve and lower the prices of their currently existing products and services. The purchase of a company with superior data security capabilities allows an existing firm to improve their offerings by providing their customers greater privacy protections in the services they already supply. The purchase of a company with superior manufacturing capabilities allows an existing firm to make their production capabilities far more efficient, leading to lower prices for their customers. By raising the cost of these types of procompetitive transactions, the FTC risks harming consumers when it comes to innovation, price, and quality. All of this is particularly pronounced when it comes to vertical mergers. According to the research, "the evidence on the consequences of vertical mergers suggests that consumers mostly benefit . . ."[13]

[13] Francine Lafontaine & Margaret Slade, Vertical Integration and Firm Boundaries: The Evidence, 45 J. Econ. Literature 629, 663 (2007).

Moreover, the Vertical Merger Guidelines were adopted by both the FTC and DOJ after broad consensus and considerable opportunity for public input. They reflect a balanced approach that takes into account both the procompetitive and anticompetitive potential of vertical mergers.

Public comments were received well in advance of the guidelines being formally adopted. At the very least, the FTC should allow greater opportunity for public input before voting to rescind such guidelines. The Commission announced this meeting just a week before it is scheduled to take place and provided less than 5 days, two of which are over the weekend, for public comment. Considerable public input was taken into account when adopting these guidelines and it should be taken into account when deciding whether to rescind them.

Finally, the Vertical Merger Guidelines were adopted only a year ago in an effort to increase transparency, promote predictability, and encourage consistency in how these types of mergers will be treated by federal enforcers. Rescinding them so shortly after they were adopted would greatly undermine each of these laudable goals.

Conclusion

As always, we stand ready to work with the Commission to achieve beneficial outcomes that promote the interests of the United States and benefit American consumers and innovation. We appreciate your consideration of our views.

Sincerely,

Carl Szabo, Vice President & General Counsel

Chris Marchese, Counsel

Trace Mitchell, Policy Counsel

Zach Lilly, Policy Manager

NetChoice

From: Federal Trade Commission via Federal Trade Commission
Sent: Sunday, September 12, 2021 1:47 PM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Sunday, September 12, 2021 - 13:47 Submitted by anonymous user: [redacted] Submitted values are:

First Name: Chantal
Last Name: Roubachewsky
Affiliation: N/A
Full Email Address: [redacted]
Confirm Email Address: [redacted]
Telephone: [redacted]
FTC-Related Topic: Competition
Register to speak during meeting: Yes
Link to web video statement: MD
Submit written comment:
I personally experienced extreme and extended shortages in thermometers in the Washington DC area post COVID. For months, none of the pharmacies in the area had basic thermometers. Generally (outside of COVID) I (and other
mothers) have struggled with the consolidated nature of daycare options in the DC area. This has a very large impact on families, and the developmental/educational options for children at the preschool age.
The one overwhelming option we had was not a good one. It was very difficult to find an option outside of this particular vendor. As a result many families such as ours had to keep their children within a system/preschool supplier that essentially had all of the power. Needless to say, there are some pretty negative consequences not just for the customer but also for teachers/workers within this system. Since this is a major metropolitan area it is quite surprising how few our options are. with regards to these markets. Additionally we have seen supermarkets nearby like the Giant be replaced with Amazon Prime, so increasingly our options in this market are also consolidated (Whole Foods vs. Amazon Prime, which of course share the same ownership.) Thank you for taking our comments!

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/28

From: Charles Crain
Sent: Friday, September 10, 2021 5:43 PM
To: OpenMeeting
Subject: NAM Comments for 9/15/21 Open Meeting

Attached please find written comments from the National Association of Manufacturers in advance of the Commission's September 15 open meeting. Please see below for the information requested by the online comment form:

First Name: Chris
Last Name: Netram
Affiliation: National Association of Manufacturers
Full Email Address: [redacted]
Confirm Email Address: [redacted]
Telephone: [redacted]
FTC-Related Topic: Competition & Consumer Protection

Please let me know if you have any questions or need any additional information.

Thanks much,
Charles

Charles Crain
National Association of Manufacturers
Senior Director, Tax & Domestic Economic Policy

Chris Netram

Vice President,
Tax and Domestic Economic Policy

September 12, 2021

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW
Suite CC-5610 (Annex B)
Washington, DC 20580

Re: *Open Commission Meeting—September 15, 2021*

To whom it may concern:

The National Association of Manufacturers ("NAM") appreciates the opportunity to provide comment to the Federal Trade Commission ("FTC") in advance of the Commission's September 15 open meeting.

The NAM is the largest industrial trade association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs for the people who make things in America.

The NAM is concerned that the Commission plans to use its September 15 open meeting to withdraw the Vertical Merger Guidelines adopted by the FTC and the Department of Justice ("DOJ") in June 2020[1] and the Commentary on Vertical Merger Enforcement issued by the FTC in December 2020.[2] We understand that President Biden's July 9 executive order on "Promoting Competition in the American Economy" encouraged the FTC and the DOJ to review the Vertical Merger Guidelines and to consider whether to revise them;[3] however, as with many components of the EO, the NAM believes the vertical merger provision is a solution in search of a problem.[4] Further, the EO simply encourages the FTC to consider whether to *revise* the Vertical Merger Guidelines. Instead, the FTC will vote on whether to rescind the guidelines entirely—after just four days of public comment.

If the FTC adopts this significant and damaging policy change, it will inject substantial regulatory uncertainty into decisions about vertical merger transactions that are critical to job creation, research and development, and consumer choice at manufacturers across the country. The NAM respectfully encourages the FTC not to withdraw its Vertical Merger Guidelines and Commentary on Vertical Merger Enforcement at the upcoming open meeting.

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[1] *Vertical Merger Guidelines*. Federal Trade Commission and U.S. Department of Justice (30 June 2020). *Available at* https://www.ftc.gov/system/files/documents/reports/us-department-justice-federal-trade-commission-vertical-merger-guidelines/vertical_merger_guidelines_6-30-20.pdf.

[2] *Commentary on Vertical Merger Enforcement*. Federal Trade Commission (22 December 2020). *Available at* https://www.ftc.gov/system/files/documents/reports/federal-trade-commissions-commentary-vertical-merger-enforcement/p180101verticalmergercommentary_1.pdf.

[3] *Promoting Competition in the American Economy*. Exec. Order No. 14036, 86 Fed. Reg. 36987 (14 July 2021). *Available at* https://www.govinfo.gov/content/pkg/FR-2021-07-14/pdf/2021-15069.pdf.

[4] *Manufacturers on Biden EO: Some Actions Are Solutions in Search of a Problem That Doesn't Exist.* National Association of Manufacturers (9 July 2021). *Available at* https://www.nam.org/manufacturers-on-biden-eo-some-actions-are-solutions-in-search-of-a-problem-that-doesnt-exist-14545/.

I. Vertical mergers are critical to manufacturing growth and are overwhelmingly likely to result in pro-competitive effects.

The 2020 Vertical Merger Guidelines make clear that vertical mergers "combine complementary economic functions and eliminate contracting frictions," ultimately leading to "efficiencies that benefit competition and consumers."[5] In the manufacturing sector, vertical mergers often drive innovation, lower transactional expenses, and reduce supply chain costs, including the overhead costs of production and distribution. These outcomes lower consumer prices in several important ways.

For example, the 2020 guidelines highlight the fact that vertical mergers eliminate "double marginalization," resulting in merged businesses accessing materials and other inputs at cost rather than paying a markup—and ultimately passing those savings along to consumers.[6] The guidelines also note that vertical mergers can lead to significant pricing efficiencies, again benefitting consumers.[7] For manufacturers, the ability to anticipate and avoid supply chain disruption is another critical benefit of vertical mergers—especially during times of economic uncertainty such as the ongoing COVID-19 pandemic.

Vertical mergers also provide economic opportunities for small and medium-sized firms that may help justify initial investments into expensive capital equipment or innovative new technology. These transactions are also important "exit" opportunities for entrepreneurial founders and other early-stage investors that are critical to the innovation ecosystem. Indeed, antitrust scholars have noted that burdensome restrictions on vertical mergers could "dampen entrepreneurial investment and innovation" and "chill[ ] business formation."[8]

Vertical mergers allow companies of all sizes to evolve and grow, leading to downstream effects that benefit all Americans, including job creation, investment in research and development, and economies of scale and scope that produce lower prices and create greater choice for consumers. Rather than cast doubt on these important transactions, the NAM respectfully encourages the FTC to explicitly acknowledge that the vast majority of vertical mergers are rooted in pro-competitive strategies and to use the 2020 Vertical Merger Guidelines to focus its investigative efforts on the small minority of deals that raise anticompetitive concerns.

II. The FTC should not withdraw the June 2020 Vertical Merger Guidelines or the December 2020 Commentary on Vertical Merger Enforcement.

The Vertical Merger Guidelines were adopted after significant deliberation and public debate, with feedback from a variety of stakeholders, including the NAM.[9] The previous guidelines for non-horizontal mergers had been in place since 1984, and last February the NAM applauded the efforts of the FTC and the DOJ to update the guidelines and provide "[c]learly defined enforcement policies" designed to "help manufacturers better plan for potential vertical mergers by adding predictability about the scrutiny with which both agencies will evaluate proposed deals."[10]

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[5] Vertical Merger Guidelines, *supra* note 1, at 11.

[6] *Ibid.*

[7] *Id.* at 12.

[8] *See*, *e.g.*, D. Daniel Sokol, *Vertical Mergers and Entrepreneurial Exit*. 70 Fla. L. Rev. 1357 (October 2019). *Available at* https://scholarship.law.ufl.edu/flr/vol70/iss6/5.

[9] NAM Comments on Draft Vertical Merger Guidelines (25 February 2020). *Available at* http://documents.nam.org/llrp/FINAL_NAM_Vert_Merger_Comments_2.25.20.pdf.

[10] *Id.* at 1.

The FTC's consideration of updated guidelines for non-horizontal mergers dates back to at least 2018, when the Commission held a hearing titled *Vertical Merger Analysis and the Role of the Consumer Welfare Standard in U.S. Antitrust Law* as part of its *Competition and Consumer Protection Hearings for the 21st Century* series.[11] In conjunction with the hearing, the FTC invited public comment on a straightforward question: "Should the U.S. antitrust agencies publish Vertical Merger Guidelines?"[12] The FTC and the DOJ issued proposed guidelines in January 2020, again soliciting public comment.[13] The agencies' review of years of "well-informed public comments"[14] led to the updated guidelines in June 2020. The final guidelines "incorporate the agencies' accumulated knowledge from over 35 years of experience investigating and challenging anticompetitive non-horizontal mergers" and, importantly, "more accurately reflect the agencies' current enforcement practices and policy" than the 1984 guidelines.[15] Yet this week the FTC will vote on whether to rescind these guidelines just more than a year after they were adopted, following just four days of public comment in response to an open meeting notice.

This about-face will create significant regulatory uncertainty for businesses across the country. The 1984 guidelines were in place for nearly four decades; the 2020 guidelines were the result of substantial public feedback and were designed to provide the market with rules of the road that could be relied upon for years or decades to come. Recission would return the marketplace to a status quo based on outdated practices that no longer reflect the FTC's current approach to enforcement or, worse, leave the marketplace without any vertical merger guidance at all.

Businesses depend on transparency, reliability, and stability from the federal antitrust agencies in order to guide critical decisions about potential transactions that have far-reaching economic consequences. Withdrawing the 2020 guidelines for businesses considering vertical mergers—which, again, are overwhelmingly likely to *benefit* consumers—could undercut the FTC's ability to set appropriate antitrust standards and maintain effective antitrust enforcement. The NAM respectfully encourages the FTC to reconsider its interpretation of President Biden's directive to consider potential revisions to the guidelines for vertical mergers and, thus, not to withdraw the 2020 Vertical Merger Guidelines.

* * * *

[11] *FTC Hearing #5: Vertical Merger Analysis and the Role of the Consumer Welfare Standard in U.S. Antitrust Law*. Competition and Consumer Protection Hearings for the 21st Century: An FTC-Georgetown University Event (1 November 2018). *See* https://www.ftc.gov/news-events/events-calendar/ftc-hearing-5-competition-consumer-protection-21st-century.

[12] Docket No. FTC-2018-0091. *See* https://www.ftc.gov/policy/advocacy/public-comment-topics-process; *see also* https://www.ftc.gov/policy/public-comments/2018/10/initiative-778.

[13] *DOJ and FTC Announce Draft Vertical Merger Guidelines for Public Comment*. Federal Trade Commission and U.S. Department of Justice (10 January 2020). *Available at* https://www.justice.gov/opa/pr/doj-and-ftc-announce-draft-vertical-merger-guidelines-public-comment.

[14] Chairman Joseph Simons, Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson. *Statement Regarding Joint Department of Justice and Federal Trade Commission Vertical Merger Guidelines* (30 June 2020). *Available at* https://www.ftc.gov/system/files/documents/public_statements/1577507/vmgmajoritystatement.pdf.

[15] *Id.* at 1.

The NAM respectfully encourages the FTC to provide regulatory certainty to manufacturers considering vertical mergers and, in so doing, to promote a "fair, open, and competitive marketplace" that supports "broad and sustained prosperity."[16] We look forward to working with you to support clear standards for pro-competitive mergers by manufacturers across the country, which lead to job creation, investment in research and development, and economies of scale and scope that produce lower prices and create greater choice for consumers.

Sincerely,

Chris Netram
Vice President, Tax and Domestic Economic Policy

[16] Competition EO, *supra* note 3, at 36987.

From: Federal Trade Commission via Federal Trade Commission
Sent: Friday, September 10, 2021 12:28 PM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Friday, September 10, 2021 - 12:27 Submitted by anonymous user: [redacted]
Submitted values are:

First Name: Christopher
Last Name: gabriel
Affiliation: King4life
Full Email Address [redacted]
Telephone [redacted]
FTC-Related Topic: Competition
Register to speak during meeting: Yes
Link to web video statement: TX
Submit written comment: Claim comission.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/32

From: Federal Trade Commission via Federal Trade Commission
Sent: Sunday, September 12, 2021 9:45 AM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Sunday, September 12, 2021 - 09:45 Submitted by anonymous user: [redacted] Submitted values are:

First Name: Douglas
Last Name: Brooks
Affiliation: Law Offices of Douglas M. Brooks Full Email Address[redacted]
Telephone: +[redacted]
FTC-Related Topic: Consumer Protection
Register to speak during meeting: Yes
Link to web video statement:
Submit written comment:
I am an attorney in private practice for 39 years. I have substantial experience representing franchisees and distributors in traditional distribution systems. Since 1992 I have represented distributors in multi-level marketing (MLM) companies in a number of class actions, including Webster v. Omnitrition International, Inc., 79 F.3d 776 (9th Cir. 1996). I have also represented consumer advocates and critics of MLM companies who have been sued or threatened with lawsuits. Since 1995 I have been advocating that the Commission should use its rule-making authority to protect consumers from unfair and deceptive practices by MLM companies, and I submitted a number of comments to that effect in connection with the rule-making proceedings that led to the Commission's promulgation of the Business Opportunity Rule (BOR). Unfortunately, for reasons that to me seemed highly unsatisfactory, the Commission decided to exempt MLM offerings from the BOR.

I was heartened by Commissioner Chopra's statement Regarding the Business Opportunity Rule issued on June 14, 2021 (Commission File No. P924214), in which he questions the wisdom on the Commission's exemption of MLM from the BOR.

I understand that the Commission intends to undertake its periodic review of the BOR this Fall, and I would encourage the Commission to reconsider the MLM exemption, and to improve the BOR. Alternatively the Commission would certainly be justified in promulgating a new rule devoted to the MLM industry.

While I anticipate submitting more detailed comments when the BOR review process is underway, I would like to take this opportunity to outline some of the key features that an MLM Rule (or the BOR without the MLM exemption) would include.

First, like the BOR Rule, the MLM Rule should require pre-sale disclosures for prospective distributors and it should impose a cooling off period between the time a prospective distributor is provided with a disclosure statement and the time the distributor is required to sign a contract and make any payment. The seven days provided by the BOR would be appropriate for MLM offerings. Every existing MLM distributor should also be provided with an updated copy of the disclosure statement on at least an annual basis and prior to incurring any additional financial obligation resulting from advancing in the MLM plan.

Second, the MLM Rule should require the MLM company to provide clear and complete disclosures regarding earnings of MLM distributors, including the mean (i.e., average) and median incomes at each level of the plan, the number and percentages of distributors who achieve each level of the plan, the number of distributors who persisted at the same level from the prior year, the type and amounts of expenses incurred by distributors, and – crucially – the attrition rate of distributors at each level of the plan. These earnings disclosures should not be optional, as they are with the BOR, which permits business opportunity sellers to check a box on the disclosure form disclaiming that they make earnings claims. In my opinion, at least in the context of MLM offerings, such a disclaimer would be an invitation to commit fraud and deception. Deceptive earnings claims are endemic in the MLM industry and, in my experience, MLM offerings are never sold without either the company or the recruiting distributor or some higher level distributor making earnings claims, most of which are inevitably deceptive.

Third, in addition to earnings information, the MLM Rule should require the disclosure statement to provide information on the following topics:

- Names and trademarks of the MLM company both current and any prior names
- Business experience of the officers, directors and high level

distributors, including their participation in other MLM companies.

- Business experience of the MLM company
- Criminal convictions, civil actions and injunctions against the MLM company, its officers, directors and high level distributors
- Bankruptcy history of the MLM company, its officers, directors and high level distributors
- Description of the MLM compensation plan, including all payments required to commence or continue operations, to advance through each level of the MLM plan, and to maintain or qualify to earn commissions or other compensation from the MLM plan. This would include not only payments that are contractually required but also payments that are required as a matter of practical necessity in order to participate in the MLM plan.
- Whether or not the MLM imposes any limits on the numbers of distributors or the territories in which they may do business
- Key terms of the MLM distributor agreement, including in-term and post-term non-competition covenants, non-disparagement clauses, choice of venue, arbitration and class action waiver clauses
- The existence, content and cost of any optional or required training programs
- The terms of any relationships between the MLM company and any public figures who promote the MLM offerings of the company, as well as the terms of any relationships between the MLM company and its high level distributors that are not reflected in the MLM distributor agreement

Fourth, the MLM Rule should not be limited to pre-sale disclosure but should also impose some limitations and requirements on the terms of the MLM compensation plan and distributor agreement. At a minimum the MLM Rule should prohibit compensation plans which impose inventory purchase qualifications on distributors either for advancing in the ranks of the plan or for earning commissions or other compensation. The purpose of this requirement is to ensure that the only reason for a distributor to purchase a product or service is either because they expect to sell it at a profit or because they have a bona fide desire to use the product themselves. Commissions or compensation should not be payable on a distributors' purchase of products for personal use.

I appreciate the opportunity to provide this summary of my views to the Commission and I would be happy to provide further comment on any of these points, as well as any other issues concerning the regulation of MLM offerings.

I am authorized to say that Professor William Keep of the College of New Jersey School of Business joins me in these comments.

From: Pozza, Duane
Sent: Sunday, September 12, 2021 11:03 AM
To: OpenMeeting
Cc: Michael Petricone ; Rachel Nemeth
Subject: Comment of Consumer Technology Association regarding September 15, 2021 open meeting

Please see attached a comment submitted by Consumer Technology Association, regarding the September 15, 2021 open meeting.

Regards,

wiley

Duane C. Pozza
Attorney at Law

Download V-Card | wiley.law | Bio

Consumer Technology Association™

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

September 12, 2021

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Comment on Agenda Items at September 15 Open Meeting

Dear Chair Khan and Commissioners Chopra, Phillips, Slaughter, and Wilson:

The Consumer Technology Association (CTA) submits this comment in advance of the Commission's September 15, 2021 open meeting to address two agenda items.[1] CTA is North America's largest technology trade association. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most influential tech event in the world. CTA members operate in a competitive marketplace to produce innovative products that provide enormous benefits to consumers and power the economy.

CTA first addresses the September 15 open meeting agenda item regarding a vote to rescind the Vertical Merger Guidelines (the "Guidelines") adopted in June 2020[2] and the Commentary on Vertical Merger Enforcement ("Commentary") issued in December 2020.[3] The Guidelines were jointly adopted by the FTC and U.S. Department of Justice ("DOJ") after significant public input, including an extensive public comment period.[4] CTA opposes any move to rescind the Guidelines and Commentary and has serious concerns about the Commission doing so without meaningfully seeking public input on such a significant move.

[1] "FTC Announces Tentative Agenda for September 15 Open Commission Meeting," Sept. 8, 2021, https://www.ftc.gov/news-events/press-releases/2021/09/ftc-announces-tentative-agenda-september-15-open-commission

[2] "FTC and DOJ Issue Antitrust Guidelines for Evaluating Vertical Mergers," June 30, 2020, https://www.ftc.gov/news-events/press-releases/2020/06/ftc-doj-issue-antitrust-guidelines-evaluating-vertical-mergers

[3] "FTC Issues Commentary on Vertical Merger Enforcement," Dec. 20, 2020, https://www.ftc.gov/news-events/press-releases/2020/12/ftc-issues-commentary-vertical-merger-enforcement

[4] Draft Guidelines were released on January 10, 2020, and the public comment period was eventually extended to February 26. *See* "FTC and DOJ Extend Deadline for Public Comments on Draft Vertical Merger Guidelines, Announce Two Related Public Workshops," Feb. 3, 2020, https://www.ftc.gov/news-events/press-releases/2020/02/ftc-doj-extend-deadline-public-comments-draft-vertical-merger.

American businesses need and deserve to operate in an environment of legal certainty. Withdrawal of the Guidelines and Commentary would re-introduce uncertainty that was addressed by the adoption of the Guidelines in 2020. More, any move should be subject to public input, at least as rigorous as the process leading up to the adoption of the Guidelines in 2020.

CTA supported the adoption of the Guidelines in 2020, in order to help provide clear and transparent rules of the road for industry.[5] Prior to 2020, guidance on vertical mergers had become dated, and companies subject to antitrust merger review could not predict with certainty the analytical framework that government agencies would apply in the review process. CTA is concerned that withdrawing the Guidelines would return the market to this untenable situation and discourage competitively beneficial activity. Companies of all sizes benefit when reviewing agencies clearly and transparently communicate their approach, and legal certainty spurs innovation and investment that benefits consumers.

At the same time, any sudden shifts in direction in agency approaches to reviewing vertical mergers – including a shift away from the approach in the years leading up to the 2020 Guidelines and Commentary – would stifle companies' ability to plan, invest, and innovate. As CTA noted when the Guidelines were being developed, revisions to the agency guidance should not be a process to expand or develop new regulatory principles or priorities, or attempt to create a new framework that does not already exist. Threats of sizable departures from past approaches would create confusion in the marketplace, and could substantively impede innovation by adding costs and uncertainty to business planning.

Finally, CTA believes that all stakeholders would benefit with robust notice and public input as to any significant competition policy changes. As the public comment period in response to the draft Guidelines illustrated, affording greater opportunity and time for public input can only help the Commission's deliberations on matters that may have great impact across the economy. The Commission's announcement of the agenda item – with less than a week to submit a comment in advance – is no substitute for a meaningful notice and comment period.

The US tech sector in particular is powered by rapid, consumer-friendly innovation, and provides the products and services that help Americans safely navigate the pandemic. The agency should tread carefully and gather evidence on which to make important decisions, rather than take sudden actions that risk chilling innovation.

We urge the Commission to reject the vote to withdraw the Guidelines and Commentary, or in the alternative, to postpone the vote and provide notice and a reasonable comment period for public consideration and input.

The September 15 meeting agenda also notes that the Commission will vote on whether to issue a policy statement on "the importance of protecting the public from privacy breaches by health apps and other connected devices." CTA agrees on the importance of protecting sensitive health information, and to

[5] CTA's comment on the draft Guidelines can be found at https://www.ftc.gov/system/files/attachments/798-draft-vertical-merger-guidelines/cta_letter_on_ftc_doj_guidelines_2262020.pdf.

advance this goal, it has developed and released guiding principles for the privacy of personal health data.[6] These include: (1) be open and transparent about the personal health data collected and why; (2) be careful about use of personal health data; (3) make it easy for consumers to access and control the sharing of their personal health data and empower them to do so; (4) build strong security into technology; and (5) be accountable for practices and promises. CTA urges the Commission, in crafting any policy statement, to recognize the importance of voluntary industry engagement and leadership, given that companies must keep consumer trust top of mind when offering health-related services.

Sincerely,

CONSUMER TECHNOLOGY ASSOCIATION

/s/ Gary Shapiro
Gary Shapiro
President and CEO

/s/ Michael Petricone
Michael Petricone
Sr. VP, Government and Regulatory Affairs

/s/ Rachel S. Nemeth
Rachel S. Nemeth
Senior Director, Regulatory Affairs

[6] See CTA's *Guiding Principles for the Privacy of Personal Health Data* at https://cdn.cta.tech/cta/media/media/membership/pdfs/final-cta-guiding-principles-for-the-privacy-of-personal-health-and-wellness-information.pdf.

From: Emily Konstan
Sent: Wednesday, September 15, 2021 1:55 PM
To: OpenMeeting
Subject: anti-competitive practices of the National Certification Commission of Acupuncture and Oriental Medicine

Dear Federal Trade Commissioners,

My name is Emily Konstan. I have been a Licensed Acupuncturist in Massachusetts for 15 years.

My colleagues and I are writing to inform you about the anti-competitive practices of the National Certification Commission of Acupuncture and Oriental Medicine.

According to this link with CauseIQ, they are listed as a business and professional association (https://www.causeiq.com/organizations/national-certification-commission-for-acupuncture,112760706/?fbclid=IwAR03tKeiZuslfCAmKiW9BTtjKoUlNFwr9NyOJ6dLG76T9Mylia0-BT5PhJw) . However, they act as the acupuncture profession's gatekeeper by offering the only national certification exam for acupuncture and herbal medicine. From their website: "Established in 1982, NCCAOM is the only national organization that validates entry-level competency in the practice of acupuncture and Oriental medicine (AOM) through professional certification."

All but four US states use or require the NCCAOM Exams for initial licensure; roughly half of the state laws require ongoing credentialing from practitioners, which means that, in addition to state licensing fees, we must pay the NCCAOM to maintain current status every four years, long after we have passed their exams. Despite the fact that we are subject to an expensive national credentialing requirement, we do not enjoy license portability across state lines. Our relationship with the NCCAOM is all cost, no benefit, and absolutely mandatory if we wish to legally practice our profession.

NCCAOM functions with no oversight in terms of fees or their lobbying efforts in Washington, DC or at the state level. Over time, their lobbyists have expanded the NCCAOM's scope of influence to have more and more states: 1. Require their exams; 2. Require ongoing active diplomate status; 3. Require their Herbal Medicine exam in addition to the three others most states require. The only oversight provided by the NCCA, their accrediting body, relates to test content. While I believe that tests are necessary for public safety, the costs (and content) of the NCCAOM exams contribute to the high cost of entering the acupuncture profession and do very little to protect the public.

I would like to ask the FTC to review the practices at the NCCAOM and initiate changes that will reduce their power to create barriers to entering and continuing practice as a licensed acupuncturist.

Signed,
Emily Konstan

--
Emily Konstan, Licensed Acupuncturist
Down to Earth Acupuncture

From: Federal Trade Commission via Federal Trade Commission
Sent: Saturday, September 11, 2021 1:07 AM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Saturday, September 11, 2021 - 01:07 Submitted by anonymous user: [redacted] Submitted values are:

First Name: Jeanette
Last Name: DeCastro
Affiliation: Person whose life is held in the balance by trade Full Email Address: [redacted]
Telephone: [redacted]
FTC-Related Topic: Consumer Protection
Register to speak during meeting: No
Link to web video statement:
Submit written comment: Please investigate the major pharmaceutical manufacturers for price fixing insulin. I have had Type 1 for 28+ plus years. In my observation, the rising cost of insulin has outpaced inflation, and outpaced innovation. Of course, like all people, I require insulin to live. But mine comes in a vial. It is vital to stop this extortion.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/4

From: Federal Trade Commission via Federal Trade Commission
Sent: Sunday, September 12, 2021 9:05 AM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Sunday, September 12, 2021 - 09:04 Submitted by anonymous user[redacted]
Submitted values are:

First Name: Jon
Last Name: Wickizer
Affiliation: Fellow Human
Full Email Address[redacted]
Telephone: +[redacted]
FTC-Related Topic:
- Competition
- Consumer Protection
- FTC Operations

Register to speak during meeting: Yes
Link to web video statement:
Submit written comment: Idea origination and initial concepts by average people with limited resources. Is it possible for an individual to have an idea that they want to take to the world and actually achieve that? Or do the circumstances and process in place make it so, by the time they have worked tirelessly, leveraged it to compete against larger entities, established its proof of concept and viability to help the world, that the system designed to ensure and make "just" that process is so overly influenced by the even bigger competitors that no matter the effort, proof, value to our society, the "dream" from the initial idea creator will never be recognized? What is stopping that from happening? Or is that just "Trade?"

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/12

From: Josh Withrow
Sent: Sunday, September 12, 2021 8:51 PM
To: OpenMeeting
Subject: Comment on FTC September 15 Open Meeting from National Taxpayers Union Foundation

Hi,

On behalf of the National Taxpayers Union Foundation, I would like to submit the attached written comment on the process and items on the agenda for the upcoming September 15th FTC open meeting.

Thank you,

JOSH WITHROW | DIRECTOR OF TECHNOLOGY POLICY
National Taxpayers Union Foundation

NATIONAL TAXPAYERS UNION FOUNDATION

Sept. 10, 2021
Federal Trade Commission

Comment on proposed recension of the FTC's 2020 vertical merger guidelines ahead of the Sept. 15, 2021 open meeting of the Federal Trade Commission

National Taxpayers Union Foundation (NTUF) appreciates the opportunity to comment on the agenda for the upcoming open meeting of the Federal Trade Commission (FTC). Once again, however, we wish to raise significant concerns about the process with which major policy decisions are being made by the Commission, as well as about the policy changes proposed.

Though the date of this proposed meeting has been published for some time, the agenda was released only one week in advance of the meeting, on Sept. 8th, with a deadline for comments at midnight on Sunday the 12th. Two and a half business days' notice is clearly insufficient time for anything resembling thoughtful or detailed public input, particularly for a major decision like entirely withdrawing the FTC's revised 2020 vertical merger guidelines. This lack of any useful period of public comment has been a common flaw that renders these meetings more performative than an exercise in actual transparency.[1]

With a new Chair and a new majority on the Commission, Chair Lina Khan has previously stated her intent to have the FTC revisit and revise the current vertical merger guidelines, which were updated jointly with those of the Department of Justice (DoJ) Antitrust Division in June of 2020.[2] However, simply erasing the new guidelines and reverting to the 1984 vertical merger guidelines that were universally understood to be inadequate and outdated is neither good policy nor process.

The 2020 guidelines set to be discarded brought the Commission's standards for evaluating vertical mergers and acquisitions closer in line with how enforcement was already being conducted in the first place, in view of current economic and legal analysis of the competitive effects of these transactions. While the degree to which vertical mergers should be understood as generally harmless to competition is a matter of dispute between the majority and minority Commissioners, the preponderance of economic evidence continues to show that vertical integration tends to result in increased efficiency and corresponding benefits to consumers.[3]

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[1] See NTUF's similar comments in advance of the FTC's inaugural open meeting on July 1, 2021: https://www.ntu.org/foundation/detail/ntu-foundation-submits-comments-to-ftc-urging-no-sudden-partisan-changes-to-antitrust-enforcement

[2] https://www.ftc.gov/news-events/press-releases/2021/07/statement-ftc-chair-lina-m-khan-antitrust-division-acting

[3] Geoffrey A. Manne, Kristian Stout, and Eric Fruits, "The Fatal Economic Flaws of the Contemporary Campaign Against Vertical Integration," *Kansas Law Review,* Vol. 68, 2020. https://kuscholarworks.ku.edu/bitstream/handle/1808/30526/2%20-%20MSF.pdf?sequence=1&isAllowed=y

Causing further uncertainty about acquisitions by large firms is especially likely to harm tech startups, for whom acquisition is an important exit strategy option to have when securing venture capital.[4] Repeated studies have shown that a majority of tech startups expect to end up being acquired,[5] and one can expect to see investment in US startups to diminish if this option were made less certain to be viable for them.[6]

The majority on the Commission has indicated a desire to pursue a more aggressive approach to merger review and antitrust enforcement. Eliminating the present vertical merger guidelines, in addition to other recensions of prior FTC policies already made this year, increasingly leaves companies uncertain as to what transactions and conduct may subject them to review, whether immediately or *post hoc*. This increased uncertainty threatens to negatively impact the U.S. economy's recovery and growth as companies adopt a "wait and see" approach to mergers and acquisitions that may be beneficial to consumers.

We urge the Commission to provide better opportunities for public input regarding merger guidelines. The Commission and American taxpayers would be better served by a process that allows for more detailed analysis and feedback by stakeholders on all sides.

Respectfully,

Josh Withrow
Director of Technology Policy
National Taxpayers Union Foundation
jwithrow@ntu.org

[4] Gary Dushnitsky and D. Daniel Sokol, "Mergers, Antitrust, and the Interplay of Entrepreneurial Activity and the Investments That Fund It," *UCLA Law Legal Studies Paper No. 21 - 35.* Aug. 5, 2021 https://nvca.org/wp-content/uploads/2021/06/Mergers-Antitrust-and-the-Interplay-of-Entrepreneurial-Activity-and-the-Investments-That-Fund-It.pdf

[5] Martin Armstrong, "Exit Strategy: Most Startups Are Hoping for an Acquisition," *Statista.com*, Feb. 16, 2017. https://www.statista.com/chart/8122/exit-strategy_-most-startups-are-hoping-for-an-acquisition/

[6] "The State of the Startup Ecosystem," Engine, Charles Koch Institute, and Startup Genome report, Apr. 22, 2021. https://static1.squarespace.com/static/571681753c44d835a440c8b5/t/60819983b7f8be1a2a99972d/1619106194054/The+State+of+the+Startup+Ecosystem.pdf

From: Acupuncture Together
Sent: Thursday, September 9, 2021 11:26 AM
To: OpenMeeting
Subject: Please review NCCAOM for anti-competitive practices

Dear Federal Trade Commissioners,

My name is Justine Myers, and I have been a licensed acupuncturist in Massachusetts since 2007.

My colleagues and I are writing to inform you about the anti-competitive practices of the National Certification Commission of Acupuncture and Oriental Medicine (NCCAOM). According to this link with CauseIQ regarding the NCCAOM https://www.causeiq.com/organizations/national-certification-commission-for-acupuncture,112760706/?fbclid=IwAR2MsNbA2OVFP4rlOyYdKBmVciSHxrWqOs7ceLVbPW0nKAjv_n6OUpLeRcA
they are listed as a business and professional association. However, the NCCAOM acts as the acupuncture profession's gatekeeper by offering the only national certification exam for acupuncture and Chinese herbal medicine. From their website: "Established in 1982, NCCAOM is the only national organization that validates entry-level competency in the practice of acupuncture and Oriental medicine (AOM) through professional certification."

46 US states use or require the NCCAOM Exams for initial licensure; roughly half of the state laws require ongoing NCCAOM credentialing from practitioners, which means that, in addition to state licensing fees, we must pay the NCCAOM to maintain current status every four years, long after we have passed their exams. Despite the fact that we are subject to an expensive national credentialing requirement, we do not enjoy license portability across state lines. Our relationship with the NCCAOM is all cost, no benefit, and absolutely mandatory if we wish to legally practice our profession.

NCCAOM functions with no oversight in terms of fees or their lobbying efforts in Washington, DC or at the state level. Over time, their lobbyists have expanded the NCCAOM's scope of influence to have more and more states: 1. Require their exams; 2. Require ongoing active diplomate status; 3. Require their Herbal Medicine exam in addition to the three others most states require. The only oversight provided by the NCCA, their accrediting body, relates to test content. While I believe that tests are necessary for public safety, the costs (and content) of the NCCAOM exams contribute to the high cost of entering the acupuncture profession and do very little to protect the public.

I would like to ask the FTC to review the practices at the NCCAOM and initiate changes that will reduce their power to create barriers to entering and continuing practice as a licensed acupuncturist. If you have any further questions, please feel free to email me back.

Sincerely,
Justine Myers, Lic. Ac.

Justine Deutsch Myers, Lic. Ac. (she/her/hers)
Acupuncture Together LLC
https://acupuncturetogether.com

From: Kevin Picco
Sent: Sunday, September 12, 2021 5:33 PM
To: OpenMeeting
Subject: 09/15/21 Meeting

I submitted a complaint for the 09/15/21 open meeting. However, I have more data to share regarding Batteries Plus Corporate in Hartland Wisconsin.
Please see attached.

Kevin Picco

The spreadsheet attached illustrates actual royalties paid to Batteries Plus based on their definition of Net Revenue. I have recalculated the numbers deducting COGS from their definition of Net Revenue and recalculated the royalty charges, as you can see, I

September 1st, 2021

We officially shut down BPB #346 in Austin Texas on January 31st 2021 after 10 ½ years in business. The main reason for shutting down the business is the fact that we were slowly going broke by BPB Corporate's definition of Net Revenue in the FDD along with the fee's from Corporate for Marketing, computer support fee's, POS fee's, Gateway fee's and on and on. The only one making money in this agreement was Corporate. We actually had to work outside the store in order to make it work and we were getting tired and going broke from taking out loans to keep financially afloat.

I have compiled a word documents that I will attach to this email, the first is this Introduction letter, the second is an in-depth analysis of BPB Corporate's sketchy accounting practices. I have a third excel spreadsheet that illustrates BPB's definition of Net Revenue and actual sales data from my store and the royalty and marketing fee's deducted. Then I subtracted out Cost-of-Goods-Sold (COGS) from their definition of Net Revenue and recalculate royalty and marketing fee's, my spreadsheet shows that BPB would owe us $225k in overpayment if COGS were subtracted from their definition of Net Revenue. You will also notice on the spreadsheet that our Net Income was negative for six out of the 10 years in business. If you would like a copy of the spreadsheet, please write me in a separate email and I will send to you.

I have spoken to several other franchisee's across the Country, most seem to be in the same financial condition as us. We have had several franchisee's driven into bankruptcy by Batteries Plus's aggressive collection tactics, absolutely, no regard for the franchisee, always profits before people.

New Braunfels, TX – owner threatened bankruptcy and told BPB that they and the bank could fight over the crumbs. BPB Corporate finally purchased the store.

Northern Kentucky- owner bailed after five years, she wrote me an email and stated she had yet to take a paycheck from the store. Almost had the store sold when Corporate discouraged the potential new owner from procuring the store. She also stated that from the amount of emails she had received, that there are many BPB franchisee's in the same boat.

Conroe Texas – closed

Carrollton Texas – closed, Franchisee is saddled with debt.

San Diego – franchisee committed suicide.

BPB bought out the New Braunfels Texas store a year or so ago, also two of the Roten stores in Austin recently. I approached Corporate about procuring my store, they said No.

I had a little faith when one of our franchisee's tried to introduce the American Association of Franchisee's and Dealers (AAFD) last year, to work in conjunction with the FAC that we have today, that concept has seemed to fizzle out.

Also, on several occasions, when money was tight, we would call corporate to try to restructure or realign our debt in order to stay liquid, the answer was usually no, or we were told to get a personal loan In order to pay ABS, the exact opposite of our objective. We were also tired of being jack-booted by corporate, coerced into buying into new products that we did not want to invest in and frankly could not

afford. The old “Credit Hold” would be quickly implemented, putting a further financial strain by having to pay the current PO with cash or credit card and having to pay the PO from 30 days prior as well, again further hampering our financial well being – I am sure most of you have been through this scenario as well.

In a parting shot by Corporate, they sent us out a final summary of what we owed, detailing the money still owed. I calculated we owed approximately $3750.00 dollars. The AR specialist deducted $4350.00 from our account, I questioned the reasoning why they deducted $600.00 more than they had to, he reply via an email was:

“The remaining NA due you will be paid to you after we have been paid. The credits that are totaled will also be paid, but I am checking to make sure we have been paid first”.

You have got to love a Franchisor taking care of a Franchisee.

If you want to join me in the class-action suit against BPB Corporate, please let me know in a separate email.

Good luck to you all.

Penny Picco

Batteries Plus address and contacts:

Batteries Plus LLC

[redacted]

[redacted]

Linda Grota – Franchisee Director

Scott Williams - CEO

To Whom it may Concern: September 1st, 2021

Batteries Plus Bulbs lists $1,359,229 as the average net revenue for the top quarter of their stores.

Accounting terms can be tricky in meaning, BPB found an example of the term Net Revenue and utilized it to their benefit . Any first year accounting / finance student will advise that Net Revenue is derived by deducting COGS from Gross Revenue. Today's accounting / POS software automatically deduct's tax's from the Gross Revenue as tax is not considered revenue.

In theory, if you deducted COGS and had a product margin of 50%, this $1,359,229 would be reduced by 50% to Net Revenue of $679,614. You also have to remember that marketing fees and other monthly fee's are based on Batteries Plus's $1,359,229, which in essence could double these fee's.

This is an incorrect statement on their website to entice people to check on franchising. The FTC requires that these statements be in plain English, this Net Revenue definition is clearly misrepresented. I found out ten years ago when I questioned their definition of net revenue and that it should subtract Cost of Goods Sold (COGS). They immediately had their attorney's, Gray, Plant and Moody send a threatening letter and advised that I could be in violation of my agreement.

The Franchise agreement states "Net Revenue" means the *aggregate amount of all sales and services, whether for cash, or credit or otherwise, made or provided at or in connection with the store. Net Revenue does not include any federal, state, municipal or other sales tax, value and or discounts allowed to customers on sales, this is the definition of Gross Revenue.

To add salt to the wound, BPB Net revenue will not be adjusted for uncollected accounts. This has happened on several occasions, a customer will order a product 0n-line via Batteries Plus's sanctioned web site and one that we are REQUIRED to utilize. A customer picks up the product, goes home and disputes the charge with their bank, the bank will state CARD NOT PRESENT (CNP) and immediately dispute the charge and charge back our account for the full price of the product. Bank of America's card services manager's have stated that this is not an effective way to conduct business for a small business, but as you can see, BPB still collects their royalty on the sale of the product.

To illustrate my meaning, let's looks a three scenarios of BPB's Net Revenue:

1. Batteries plus gives me a product for FREE, I sell it for $100.00, my Net Revenue is $100.00.
2. Batteries plus sells me a product for $50.00, I sell it for $100.00, my Net Revenue is $100.00.
3. Batteries Plus sells me a product for $100.00, I sell it for $100.00, my Net Revenue is $100.00.

Traditionally, this would work by deducting the cost of the product (COGS) in case #1, I made Gross Revenue of $100. Case # 2, Net Revenue $50.00, case # 3, Net Revenue $0.00.

To boot, BPB charges a royalty fee, so in scenario 3, I lose money. Additionally, allocation of funds for marketing and Royalty are based on the $100.00 revenue in all three scenarios.

In the real world, Net Revenue is calculated by subtracting (COGS) from Gross Revenue.

Example: Shoemaker – Net Revenue for a pair of shoes sold for $100.00, cost $40.00 to make, would be $60.00. From that $60.00 they would also deduct any other costs such as wages, rents, etc. from Gross Revenue resulting in Net Revenue.

Net Revenue: common term for profit, the difference between total revenue and total cost (COGS, Overhead, Marketing, etc.) Net Revenue or Net Sales computes what's left on the "bottom Line", calculated by subtracting COGS from Gross Revenue.. This is the Generally Accepted Accounting Practice (GAAP) definition of Net Revenue.

Several franchisee's have stated "Well that's how Batteries Plus defines Net Revenue in the FDD", I agree with that statement, however Batteries Plus can state that 2+2 = 5 in the FDD, that does not make it correct, the State of Texas and the FTC agree with me.

Net Sales – gross sales minus sales returns, sales allowances and sale discounts.

I have also compiled an Excel worksheet that explains the difference in paying royalties and advertising based on BPB definition of Net Revenue as Net Sales and my definition of Net Revenue and deducting COGS. As you can see, I propose that BPB owes us approximately $225,000 in overcharges from 2010 to 2019.

I have used actual data from our P&L for the past 10 ½ years to calculate the numbers in the spreadsheet. If you are interested in reviewing the spreadsheet, please contact me individually via your personal email and I will send a copy.

I am proposing a Class Action suit against Batteries Plus Corporate for utilizing deceptive accounting practices and enforcing these practices through coercion. I require several franchisee's to join us in this suit. I have already retained an attorney, have conversed with the Federal Trade Commission (FTC) and the Small Business Association (SBA) as well as the Attorney General for the State of Texas, I believe you should follow suit with your State.

I firmly believe that if we can take this to trial, any jury with common sense would agree with my analysis.

Penny Picco

Batteries Plus Bulbs

[redacted]

I have been conversing with fellow franchisee's at the AAFD (American Association of Franchisee's and Dealers), was advised by Robert Purvin and Keith Miller (Subway Owners) in California that Subway utilizes Gross sales to determine royalty.

Robert Purvin - [redacted]

Keith Miller [redacted]

Gross sales – all the revenue generated from selling your products or services.

Investopia – Net Revenue

Net Revenue or Net Sales computes what's left on the bottom line, calculated by subtracting COGS from Gross Revenue / Gross sales.

Typical Royalty by several USA franchise organizations. Note that Royalty fee is an ongoing fee that the franchisee pays to the franchisor, typically calculated as a % of gross sales, the most common calculation, there is no confusion. Gross Sales does not include sales Tax, as sales tax is not considered revenue.

McDonalds – 4% of Gross Sales

Burger King – 4.5% of Gross Sales

Wendy's – 4.0% of Gross sales.

From: Federal Trade Commission via Federal Trade Commission
Sent: Saturday, September 11, 2021 5:00 PM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Saturday, September 11, 2021 - 16:59 Submitted by anonymous user: [redacted] Submitted values are:

First Name: Kevin
Last Name: Picco
Affiliation: Batteries Plus LLC
Full Email Address: [redacted]
Confirm Email Address [redacted]
Telephone: [redacted]
FTC-Related Topic: Consumer Protection
Register to speak during meeting: No
Link to web video statement:
Submit written comment:
Batteries Plus defines Net Revenue as total sales minus tax's, which is Gross Revenue. They tout $1.3 million in net revenue for top tier stores, if you assume 50% margins, which they do, your actual revenue is 1/2 of that
$1.3 million given that COGS is not deducted. Therefore if I am given a battery and sell for $100, my net revenue is $100. If I buy a battery for $50 and sell for $100, my Net revenue is $100. If I buy a battery for $100 and sell for $100, my net revenue is $100.
This coupled with very aggressive collections has caused many to go broke or bankrupt.
Batteries Plus offered a $10k discount to veterans, which is nothing in the total dollars required to start a store.
I have written to the FTC, SBA, Wisconsin DFI and several franchise associations with little result. Batteries Plus operates with impunity,, have franchisee's terrified and locked into a mediation and arbitration clause that they know we will never win. They have deeper pockets and will resort to any practice to silence or squash a franchisee.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/16

From: Laura Marston
Sent: Wednesday, September 15, 2021 11:50 AM
To: OpenMeeting
Subject: Public Comment on Insulin Price Fixing

Hi! My public comment on insulin price fixing and request for the FTC to investigate this unlawful conspiracy is attached hereto.

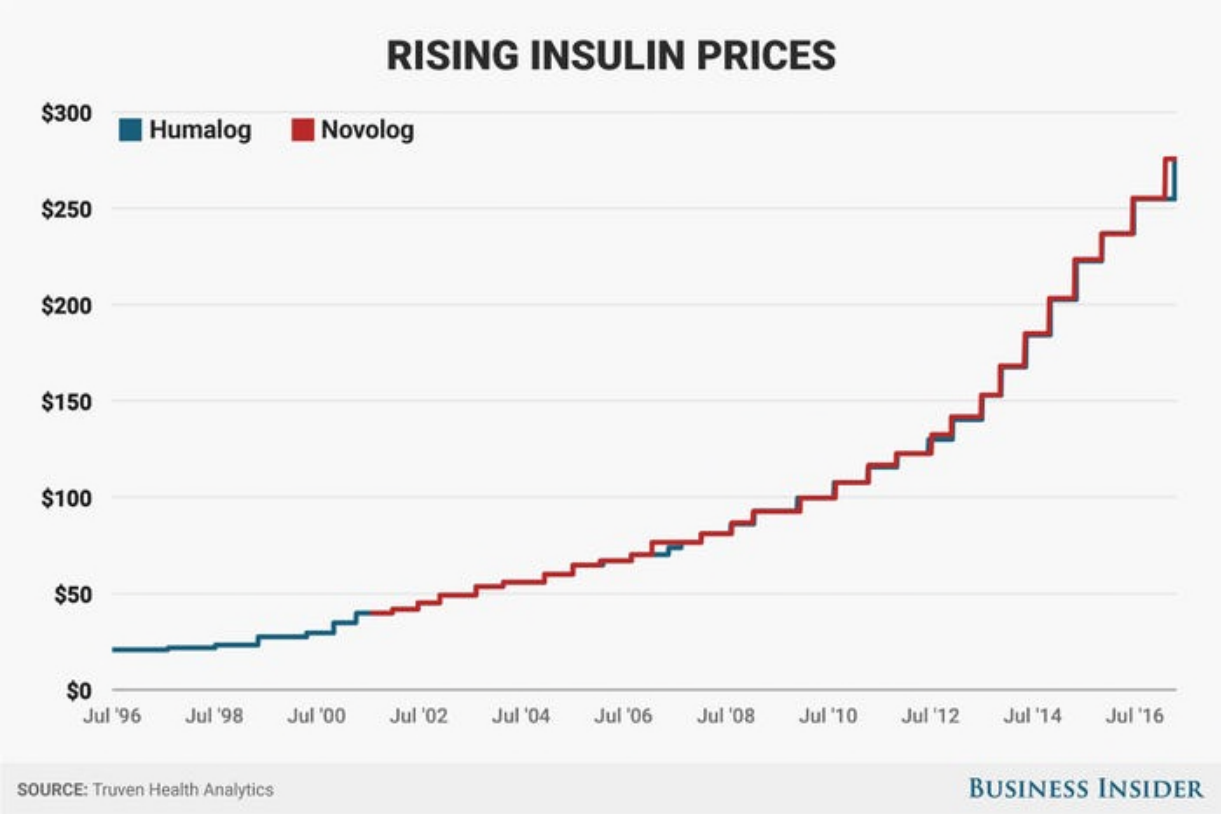
Thank you!

Laura

I am Laura Marston, a 39-year old DC resident with Type 1 diabetes. I was diagnosed as Type 1 diabetic 25 years ago, in 1996, at 14 years old Since that time, I've used Humalog insulin by Eli Lilly. The price of a vial of my insulin has gone from $21 to $300 during the past 25 years. The insulin itself is wholly unchanged.

The competing insulin by Novo Nordisk, Novolog, is priced identically to Humalog. Between 2001 and 2016, 22 of 28 price increases on Humalog and Novolog insulin were by the exact same percentage on the same day and at the same time, leading to the 1200% increase on Humalog since 1996.

Please, on behalf of 7 million Americans who need insulin to survive, investigate this insulin price-fixing – subpoena Eli Lilly, Novo Nordisk, and Sanofi for their unlawful conspiracy to raise the price of insulin to the point where 1 in 4 American diabetics now ration insulin to survive.



From: Federal Trade Commission via Federal Trade Commission
Sent: Friday, September 10, 2021 1:21 PM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Friday, September 10, 2021 - 13:21 Submitted by anonymous user: [redacted]
Submitted values are:

First Name: Mark
Last Name: Preston
Affiliation: Citizen of the USA
Full Email Address: [redacted]
Telephone: [redacted]
FTC-Related Topic:
- Competition
- Consumer Protection

Register to speak during meeting: No
Link to web video statement:
Submit written comment: Honorable Commissioners: The desire by large corporations to impose monopolistic practices on those who purchase products from such corporations, should be regulated in a way to promote the ability of the consumer, who by consideration of their purchase is now the owner of the product, to make repairs to it. These corporations will argue that safety is involved, but better engineering for repairability contradicts those averments. If flashlights can have replaceable batteries, without safety concerns, so can all electronic consumer products using batteries, such as cell phone, et cetera. The notion by these large businesses, that making something difficult to repair will spur the hapless consumer to buy anew, instead of repair is selfish. And these corporations, knowing this, discourage and prevent a whole class of industry, called the repair shop, from operating. These corporations should not limit or distort the free enterprise system. Thank you for your time.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/36

From: Federal Trade Commission via Federal Trade Commission >
Sent: Monday, September 13, 2021 11:25 AM
To: OpenMeeting >
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Monday, September 13, 2021 - 11:24 Submitted by anonymous user: [redacted]
Submitted values are:

First Name: Maureen
Last Name: Tkacik
Affiliation: Protect Our Restaurants Coalition Full Email Address[redacted]
Telephone: [redacted]
FTC-Related Topic: Consumer Protection
Register to speak during meeting: Yes
Link to web video statement:
Submit written comment: Want to make a verbal comment about deceptive and predatory behavior by Uber Eats.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/16

From: Federal Trade Commission via Federal Trade Commission
Sent: Friday, September 10, 2021 10:07 AM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Friday, September 10, 2021 - 10:07 Submitted by anonymous user: [redacted] Submitted values are:

First Name: MICHAEL
Last Name: RATRIE
Affiliation: Diabetes Patient Advocacy Coalition Full Email Address [redacted]
Telephone: [redacted]
FTC-Related Topic:
- Competition
- Consumer Protection

Register to speak during meeting: Yes
Link to web video statement:
Submit written comment:
I have lost count on the number of times I have driven away from the pharmacy because my prescription coat was too high. Recently, I went to pick up a prescription for Advair - I was expecting the cost to be $105 for a three month supply, but NO!, the price was $398.

At another pharmacy, I went to pick up my prescription for Humalog insulin, where I was expecting to make a copayment of $25 for a three month supply.
The bill was for over $1300. Why? Because unknown to me, my PBM had changed the preferred drug to Novolog without any notification. I had to make an appointment with my endocrinologist to have a new prescription written and then have that filled.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/24

From: Federal Trade Commission via Federal Trade Commission
Sent: Thursday, September 9, 2021 10:54 PM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Thursday, September 9, 2021 - 22:53 Submitted by anonymous user: [redacted] Submitted values are:

First Name: Naresh
Last Name: Patel
Affiliation: 360 Hospitality
Full Email Address: [redacted] Confirm Email Address[redacted]
Telephone: [redacted]
FTC-Related Topic: Competition
Register to speak during meeting: Yes
Link to web video statement:
Submit written comment: Franchisors have various segments which does not protect perimeter and does involve indirect marketing with additional fees which is unfair, if Franchisors are not self-sufficient they shouldn't solicitor relatio n s for locations.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/32

From: Federal Trade Commission via Federal Trade Commission
Sent: Thursday, September 9, 2021 10:15 PM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Thursday, September 9, 2021 - 22:14 Submitted by anonymous user[redacted] Submitted values are:

First Name: Robert
Last Name: Lande
Affiliation: University of Baltimore School of Law Full Email Address[redacted] Confirm Email Address: [redacted]
Telephone[redacted]
FTC-Related Topic: Competition
Register to speak during meeting: No
Link to web video statement:
Submit written comment: The Commission should bring a no-fault monopolization test case, as a violation of Section 2 of the Sherman Act or as a violation of Section 5 of the FTC Act. For an article that uses textualist analysis to show this should be possible see Robert H. Lande, "The No-Fault Approach to
Monopolization: Terrific, Terrible, or Textualism?", available at https://www.americanbar.org/content/dam/aba/publishing/antitrust-magazine-online/august-2021/atonline-lande.pdf

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/28

From: Federal Trade Commission via Federal Trade Commission
Sent: Sunday, September 12, 2021 5:21 AM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Sunday, September 12, 2021 - 05:21 Submitted by anonymous user: [redacted] Submitted values are:

First Name: Rubina
Last Name: Halwani
Affiliation: Many
Full Email Address: [redacted]
Telephone: +[redacted]
FTC-Related Topic: Consumer Protection
Register to speak during meeting: No
Link to web video statement:
Submit written comment: Is there any way to influence businesses to instill masks, distancing, and sanitization practices in stores?

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/4

From: Rooted Community Acupuncture & Holistic Care
Sent: Monday, September 13, 2021 2:31 PM
To: OpenMeeting
Subject: Investigate the NCCAOM for anti-competitive practices

Dear Federal Trade Commissioners,

My name is Saja Lynn, I am a licenced acupuncturist in Arizona. My colleagues and I are writing to inform you about the anti-competitive practices of the National Certification Commission of Acupuncture and Oriental Medicine. According to this link with CauseIQ (https://www.causeiq.com/organizations/national-certification-commission-for-acupuncture,112760706/) they are listed as a business and professional association. However, they act as the acupuncture profession's gatekeeper by offering the only national certification exam for acupuncture and herbal medicine. From their website: "Established in 1982, NCCAOM is the only national organization that validates entry-level competency in the practice of acupuncture and Oriental medicine (AOM) through professional certification."

All but four US states use or require the NCCAOM Exams for initial licensure; roughly half of the state laws require ongoing credentialing from practitioners, which means that, in addition to state licensing fees, we must pay the NCCAOM to maintain current status every four years, long after we have passed their exams. Despite the fact that we are subject to an expensive national credentialing requirement, we do not enjoy license portability across state lines. Our relationship with the NCCAOM is all cost, no benefit, and absolutely mandatory if we wish to legally practice our profession.

NCCAOM functions with no oversight in terms of fees or their lobbying efforts in Washington, DC or at the state level. Over time, their lobbyists have expanded the NCCAOM's scope of influence to have more and more states: 1. Require their exams; 2. Require ongoing active diplomate status; 3. Require their Herbal Medicine exam in addition to the three others most states require. The only oversight provided by the NCCA, their accrediting body, relates to test content. While I believe that tests are necessary for public safety, the costs (and content) of the NCCAOM exams contribute to the high cost of entering the acupuncture profession and do very little to protect the public.

I would like to ask the FTC to review the practices at the NCCAOM and initiate changes that will reduce their power to create barriers to entering and continuing practice as a licensed acupuncturist.

yours in wellness,

Saja Lynn, L.Ac.

From: Scott Johnson [redacted]
Sent: Sunday, September 12, 2021 6:48 PM
To: OpenMeeting [redacted]
Subject: September 15, 2021 Open Meeting Comment

First Name *
Last Name *
Affiliation *
Full Email Address * [ ]
Confirm Email Address * [ ]
Telephone *
Do not include parentheses ()
FTC-Related Topic *
[ ] Competition
[ ] Consumer Protection
[ ] FTC Operations
Register to speak during meeting
( ) Yes
( ) No
Link to web video statement
Submit written comment
One of the Republican FTC Commissioners (by the way, I'm a conservative Republican) bragged at a recent FTC public meeting how their team of lawyers did such a terrific job with the clothing care labeling issue. One could almost hear the back-slapping on the audio. Only in the bureaucratic federal government would a decade-long process that yielded no change be celebrated. In the private business real world, such an announcement would be met with scorn and derisive laughter. Taking a decade to do absolutely nothing is NOT something to brag about. The decision to reject the proposal to do away with clothing care labels should NOT have taken 10 years, it should have taken less than 10 seconds. This country crawls with lawyers, it is quite simple to consider doing away with clothing care labels would have resulted in a flurry of lawsuits, also known as lawyer lifestyle enhancements, regarding who is to blame for damaged clothing. Was it the manufacturer who stopped using the labels, the detergent company, or the dry cleaner/laundromat doing the cleaning? It was a no-brainer that this was a VERY bad idea. On top of that, during the decade of "work" on this issue, the FTC Commissioner also announced that no new guidance was provided for the new fabrics developed during this time period, although in my opinion this guidance should be left to private industry, not the FTC. The FTC should require labels and the clothing manufacturers should determine the content of the labels. In the private business world, whoever was in charge of and involved in such an "effort" would rightly be fired on the spot, if not several years earlier. It's one thing to take a decade to do nothing, it is quite another to brag about it. This was NOT responsible use of MY tax dollars.

But I digress, the topic of this comment is the similar lack of action the FTC has taken with MLM scams. Going back to the 1979 Amway decision, where the FTC apparently did not challenge Amway's claim that they enforced their 10 customer rule by requesting Amway produce sales receipts, the FTC has failed to hold MLM scams accountable, with very few exceptions. There are about 666 MLM scams in the U.S., and although every single one of them that I've looked at have similar traits, namely overpriced products that cannot be sold to customers outside the network to any significant extent, which is the exact definition of an illegal pyramid according to the FTC website, the FTC only shoots a fish in the barrel using a bb gun, once every few years on average. The FTC should be blasting the fish in the barrel with a shot gun. In the meantime, several new MLM scams are created and some go out of business, never to be held accountable for their illegal activity.

My theory (the meaning of theory in this case is the scientific/mathematical meaning, a well-tested and proven set of ideas that goes FAR beyond a mere hypothesis or conjecture) of MLM scams having hybrid legitimate sales and a pure-play (no products) illegal pyramid, which can be refuted ONLY by significant retail sales outside the distributors' consumption, and the FTC has drawn the minimum line at a minimum of at least half the revenue coming from outside customers. Instead of applying this simple concept, the FTC has offered the false excuse that MLMs are very complicated, and only their expertise over a typical three-year period of investigation can determine which ones are legitimate MLMs and which ones are illegal pyramids, yet the FTC expects an uninformed citizen to somehow determine whether a given MLM is legitimate or not by reading the FTC website, and most people don't have a clue the FTC even exists, let alone what the FTC does or whether it provides MLM guidance on the FTC website. The FTC has also offered the lame excuse that they don't want to mandate at least 50% of an MLM's revenue come from retail sales to outside customers, as this would somehow restrict the FTC's "flexibility" and prefers to keep the much more generic "unfair and deceptive" language as the sole public basis of their [in]action against MLM scams. The FTC can have it both ways in this instance. I earned an engineering degree and was trained in root cause analysis in the nuclear power industry, and I can assure the FTC lack of retail sales to outside customers is the root cause of MLM scams. The 50% criteria is a joke, only 50% of sales being

made to outside customers would put any other non-MLM business out of business, yet most MLMs would go out of business if held to this ridiculously low criteria.

To make matters even worse, MLM scams such as Amway have tool scams, which is the source for most of the profit for the upper level distributors (Amway calls their distributors IBOs, or Independent Business Owners, which is another fantasy story for another time). Tools consist of highly profitable (to the tune of several times more profit than they "earn" from the Amway illegal product pyramid) meetings, books, recordings, phone apps, website access, voice mail, etc., and both Amway and the upper level distributors pretend this massive profit does not exist, which means Amway and other MLM scams with tool scams are not only illegal pyramids but RICO/business frauds as well. When a material fact is left out of a business deal, it is business fraud. When only a small number of individuals know about such fraud, it is RICO fraud, in my layman's opinion. I am 62 years old. I described the Amway (then Quixtar) tool scam to the FTC in detail literally a decade and half ago in 2006 when I was 47 years old during the comment period for the Business Opportunity Rule revision. The only result was a footnote in the Federal Register. Numerous contacts with FTC lawyers since then have resulted in less than a footnote, I can feel the blank stares and lack of concern over the telephone, as literally millions of U.S. citizens have been scammed by Amway since then, and 10s of millions, if all MLMs are considered. In addition to the lost money, lost time and damaged relationships have resulted. Will I have to wait another decade and a half for the FTC to take action, when I'll be 77 years old?

There is a small group of so-called experts who, for some unknown reason, perhaps because they are on the rolodex of every media company in the country when an MLM article is written, get contacted and their erroneous views are placed in the story. These false MLM "experts" usually include:

1. Robert FitzPatrick, who still promotes the legally rejected and logically false "saturation" idea. One only has to google "Ger-Ro-Mar" along with "FTC" to find a judge's humorous rejection of this false theory, or ask anyone who has been in an MLM (FitzPatrick has never been in an MLM) whether saturation could ever occur, and the mathematical formula would be similarly rejected. In fact, I'm not aware of a single court of law that has accepted the saturation idea;

2. Doug Brooks (also believed never to have been in an MLM), a lawyer who has made a lot of money suing MLM scams but getting no to little benefit to the former and current distributors he has represented over the decades; and

3. Bill Keep (also never in an MLM), a business college professor who somehow is an expert because he comes from academia and has letters behind his name.

The above individuals, and most of the numerous "anti-MLM" people on social media, don't have a clue what they are talking about and are actually causing more confusion, not less. This confusion creates opportunities for MLM scams, as they can easily explain away the falsehoods the anti-MLM “experts” promote. Even worse, these anti-MLM “experts” don't even WANT to be educated regarding the issues the FTC should be concerned about, illegal behaviors. Instead, they wrap themselves into emotional knots with describing immoral and unethical behaviors, most of which are not illegal and therefore they should not expect the FTC to take action on.

On the other hand, I have personal experience as an Amway distributor/IBO from 1993-2005, when I found out about Amway's tool scam and unsuccessfully attempted to develop a legitimate Amway business, as Amway frustrated every move I made, until I decided to "act up" in 2009 to get myself terminated, and Amway obliged. However, I collected a large amount of inside information during the 2005-2009 "undercover" period (which continues to this day), including Amway providing Amway IBOs a template to fill out and modify as desired to keep MLMs out of the Business Opportunity Rule revision. Since 2005 I have documented my first-hand experience and extensive research on a number of websites, on three of my own blogs, a YouTube channel, and a currently running, six-year weekly podcast.

In 2016, after the Vemma and Herbalife settlements, then Chair Edith Ramirez made comments regarding strong future actions, which mostly fizzled out. More recent comments by Republican and Democrat FTC commissioners offer another glimmer of hope, but it reminds me of the Peanuts characters Lucy and Charlie Brown, where Lucy insists she will hold the football for Charlie Brown to kick, only to pull it away at the last second, with him landing on his backside. Is the FTC serious this time around or is this another Lucy/Charlie Brown moment, with the FTC playing the role of Lucy and giving hope that the FTC will finally do the right thing and lay down the law against the entire MLM industry, and the U.S. citizens playing the role of Charlie Brown, and finally getting a chance to kick the football? The FTC has my phone number and my email, websites, YouTube channel, and link to my over 300 podcasts are available on my Facebook page, [redacted]. I'm ready to kick the ball, what will YOU do, FTC?

As Tom Brady, longtime NFL quarterback is well known for exhorting to his teammates says: Do. Your. Job.

From: Shelby Smith
Sent: Monday, September 13, 2021 2:12 PM
To: OpenMeeting
Subject: NCCAOM

Dear Federal Trade Commissioners,

have been in practice since 2019.

My colleagues and I are writing to inform you about the anti-competitive practices of the National Certification Commission of Acupuncture and Oriental Medicine. According to this link

the acupuncture profession's gatekeeper by offering the only national certification exam for acupuncture and herbal medicine. From their website: “Established in 1982, NCCAOM is the only national organization that validates entry-level competency in the practice of acupuncture

All but four US states use or require the NCCAOM Exams for initial licensure; roughly half of the

state licensing fees, we must pay the NCCAOM to maintain current status every four years, long

credentialing requirement, we do not enjoy license portability across state lines. Our

legally practice our profession.

NCCAOM functions with no oversight in terms of fees or their lobbying efforts in Washington,

Over time, their lobbyists have expanded the NCCAOM’s scope of influence to have more and

their Herbal Medicine exam in addition to the three others most states require. The only oversight provided by the NCCA, their accrediting body, relates to test content. While I believe

contribute to the high cost of entering the acupuncture profession and do very little to protect the public.

I would like to ask the FTC to review the practices at the NCCAOM and initiate changes that will

Signed,
Shelby Smith, L.Ac.

From: Susie Sabunciyan
Sent: Friday, September 10, 2021 12:57 PM
To: OpenMeeting
Subject: NCCAOM

Dear Federal Trade Commissioners,

My name is Susie Sabunciyan and I have been practicing acupuncture in Seattle, Washington since 2009. I have long been frustrated with the National Certification Commission of Acupuncture and Oriental Medicine, or NCCAOM, for what I consider the taking advantage of people who wish to practice the medicine. Compared to other professions their exams are expensive, as are their requirements of membership and continuing education.

Fellow acupuncturists wrote it best in their letter to you and I am fully behind this statement:

My colleagues and I are writing to inform you about the anti-competitive practices of the National Certification Commission of Acupuncture and Oriental Medicine. According to this link with CauseIQ, they are listed as a business and professional association. However, they act as the acupuncture profession's gatekeeper by offering the only national certification exam for acupuncture and herbal medicine. From their website: “Established in 1982, NCCAOM is the only national organization that validates entry-level competency in the practice of acupuncture and Oriental medicine (AOM) through professional certification.”

All but four US states use or require the NCCAOM Exams for initial licensure; roughly half of the state laws require ongoing credentialing from practitioners, which means that, in addition to state licensing fees, we must pay the NCCAOM to maintain current status every four years, long after we have passed their exams. Despite the fact that we are subject to an expensive national credentialing requirement, we do not enjoy license portability across state lines. Our relationship with the NCCAOM is all cost, no benefit, and absolutely mandatory if we wish to legally practice our profession.

NCCAOM functions with no oversight in terms of fees or their lobbying efforts in Washington, DC or at the state level. Over time, their lobbyists have expanded the NCCAOM’s scope of influence to have more and more states: 1. Require their exams; 2. Require ongoing active diplomate status; 3. Require their Herbal Medicine exam in addition to the three others most states require. The only oversight provided by the NCCA, their accrediting body, relates to test content. While I believe that tests are necessary for public safety, the costs (and content) of the NCCAOM exams contribute to the high cost of entering the acupuncture profession and do very little to protect the public.

I would like to ask the FTC to review the practices at the NCCAOM and initiate changes that will reduce their power to create barriers to entering and continuing practice as a licensed acupuncturist.

Signed,
Susie Sabunciyan, EAMP

From: Federal Trade Commission via Federal Trade Commission
Sent: Thursday, September 9, 2021 12:30 PM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Thursday, September 9, 2021 - 12:30 Submitted by anonymous user: [redacted]
Submitted values are:

First Name: Vimal
Last Name: Patel
Affiliation: Q Hotels
Full Email Address: [redacted]
Confirm Email Address: [redacted]
Telephone: [redacted]
FTC-Related Topic:
- Competition
- Consumer Protection

Register to speak during meeting: Yes
Link to web video statement:
Submit written comment: I want to request to speak at this event. I want to bring attention to the one-sided playing field between franchisees and Franchisors. Small business franchisees owners are losing their equity due to the one-sided contracts and forceful tactics the franchisors use. I have already communicated some of the challenges that I am facing and have shared the lawsuit I filed against IHG, the largest hotel chain in the world. Rohit Chopra's office has a copy of the lawsuit and my communication with his advisor.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/20

From: Federal Trade Commission via Federal Trade Commission
Sent: Sunday, September 12, 2021 8:48 PM
To: OpenMeeting
Subject: Form submission from: Speaker Registration and Public Comment Submission Form for September 15, 2021 Open Commission Meeting

Submitted on Sunday, September 12, 2021 - 20:47 Submitted by anonymous user: [redacted] Submitted values are:

First Name: Zhi
Last Name: Liu
Affiliation: None
Full Email Address: [redacted]
Telephone: [redacted]
FTC-Related Topic: Consumer Protection
Register to speak during meeting: No
Link to web video statement:
Submit written comment:
Dear Federal Trade Commission

Since 2020, I have been a consumer advocate who has sought to inform consumers from the unfair and deceptive practices of multilevel marketing (MLM) companies.

As I learned more about these types of companies, I discovered MLMs were exempt from the Business Opportunity Rule (BOR)

It pleased me to hear Commissioner Chopra's statement Regarding the Business Opportunity Rule issued on June 14, 2021 (Commission File No. P924214), in which he questioned the wisdom on the Commission's exemption of MLM from the BOR.

I understand that the Commission intends to undertake its periodic review of the BOR this Fall, and I would encourage the Commission to reconsider the MLM exemption, and to improve the BOR. Alternatively, the Commission would certainly be justified in promulgating a new rule devoted to the MLM industry.

I would like to take this opportunity to outline some of the key features that an MLM Rule (or the BOR without the MLM exemption) would include.

First, like the BOR Rule, the MLM Rule should require pre-sale disclosures for prospective distributors, and it should impose a cooling off period, for instance seven to ten days, between the time a prospective distributor is provided with an income disclosure statement and the time the distributor is required to sign a contract and make any payment. The seven days provided by the BOR would be appropriate for MLM offerings. Every existing MLM distributor should also be provided with an updated copy of the income disclosure statement on an annual basis and prior to incurring any additional financial obligations resulting from rank advancing in the MLM plan.

Second, the MLM Rule should require the MLM company to provide clear and complete income disclosures regarding earnings of MLM distributors, including average incomes at each level of the plan, the number and percentages of distributors who achieve each level of the plan, the average length of time it takes distributors to advance to each rank, the average length of time distributors maintain each rank, the type, such as personal development books, travel to and from events, accommodations when attending events, and – crucially – the attrition rate of distributors at each level of the plan. These earnings disclosures should not be optional, as they are with the BOR, which permits business opportunity sellers to check a box on the disclosure form disclaiming that they make earnings claims. In my opinion, at least in the context of MLM offerings, such a disclaimer would be an invitation to commit fraud and deception. Deceptive earnings claims are endemic in the MLM industry and, in my experience, MLM offerings are never sold without either the company or the recruiting distributor or some higher-level distributor making earnings claims, most of which are inevitably deceptive.

Third, in addition to earnings information, the MLM Rule should require the disclosure statement to provide information on the following topics:

• Names and trademarks of the MLM company both current and any prior names • Business experience of the officers, directors and high-level distributors, including their participation in other MLM companies.
• Business experience of the MLM company • Criminal convictions, civil actions and injunctions against the MLM company, its officers, directors and high-level distributors • Bankruptcy history of the MLM company, its officers, directors and high-level distributors • Description of the MLM compensation plan, including all payments required to commence or continue operations, to advance through each level of the MLM plan, and to maintain or qualify to earn commissions or other compensation from the MLM plan. This would include not only payments that are contractually required but also payments that are required as a matter of practical necessity in order to participate in the MLM plan.
• Whether or not the MLM imposes any limits on the numbers of distributors or the territories in which they may do business • Key terms of the MLM distributor agreement, including in-term and post-term non-competition covenants, non-disparagement clauses, choice of venue, arbitration and class action waiver clauses • The existence, content and cost of any optional or required training programs • The terms of any relationships between the MLM company and any public figures who promote the MLM offerings of the company, as well as the terms of any relationships between the MLM company and its high-level distributors that are not reflected in the MLM distributor agreement

Fourth, the MLM Rule should not be limited to pre-sale disclosure but should also impose some limitations and requirements on the terms of the MLM compensation plan and distributor agreement. At a minimum the MLM Rule should prohibit compensation plans which impose inventory purchase qualifications on distributors either for advancing in the ranks of the plan or for earning commissions or other compensation. The purpose of this requirement is to ensure that the only reason for a distributor to purchase a product or service is either because they expect to sell it for a profit or because they have a bona fide desire to use the product themselves. Commissions or compensation should not be payable on a distributors' purchase of products for personal use and including omitting the earning "volume points" in order to qualify to be paid a commission.

I appreciate the opportunity to provide this summary of my views to the Commission and I would be happy to provide further comment on any of these points, as well as any other issues concerning the regulation of MLM offerings.

The results of this submission may be viewed at:
https://www.ftc.gov/node/1591350/submission/44