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Food and Drug Administration senior scientist Dr. Kathryn Aikin Undergraduate Class Visit on Direct-to-consumer Pharmaceutical Advertising

February 8, 2024

Abstract[1]

This transcript captures Dr. Kathryn Aikin's visit to the "Evidence" course at the University of Pittsburgh, an advanced undergraduate communication class that investigates evidence-based medicine. Dr. Aikin, from the FDA's Office of Prescription Drug Promotion (OPDP), presents to students as part of their curriculum, offering a real-world application of their studies on the psychological impact and regulatory considerations of direct-to-consumer drug advertising. She provides an overview of the OPDP's pivotal role in safeguarding public health by ensuring truthful and balanced communication of drug information. Dr. Aikin details the Paperwork Reduction Act's (PRA) influence on public feedback collection for a proposed FDA study, highlighting the criticality of the public's role in shaping research and policy through a structured comment process involving both the FDA and the Office of Management and Budget (OMB). The transcript includes a student-led Q&A, exploring the FDA's strategies for achieving diverse and inclusive participant recruitment for studies, factoring in variables such as health literacy and internet access. Dr. Aikin underscores the FDA's commitment to representing diverse populations through methodological adjustments like over-recruitment and data weighting. A student's suggestion for an FDA-endorsed informational website leads to a discussion on enhancing consumer engagement and the utility of centralized resources. Dr. Aikin's interaction with the class enriches their understanding of evidence-based communication within the context of public health and regulatory practices. It also supports students opting into an adjacent curriculum assignment enabling them to generate, revise, and submit their own public comments to the FDA during its 60-day comment window (open until February 20, 2024, for this particular study).

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[1] Synthetic communication generated in part by a ChatGPT-4 closed domain prompt: "Summarize the transcript in a 250 word abstract that frames Dr. Aikin's visit as part of an adjacent curriculum assignment in Evidence, an upper-level undergraduate communication course at the University of Pittsburgh."

Packback Deep Dive Assignment

Deep Dive

FDA Public Comment Draft (midterm pre-write)

In Evidence

This optional assignment describes how students can engage FDA rulemaking by drafting and revising a public comment regarding the agency's pending psychological study on indirect claims in DCTA.

Overview | Rubric

Deep Dive Prompt

A few words from your instructor

Gordon Mitchell

Basic Details

This is a purely optional assignment. Students wishing to take the standard mid-term exam can pass on this option, with no grade penalty. However, students opting in to the adjacent curriculum can earn up to 20 points (40% of the midterm exam points - substituting for the conceptual mastery question) by submitting a draft of their US Federal Drug Administration (FDA) public comment on Packback Deep Dives by January 30, 10:00 p.m., then submitting a revised, final version of their FDA public comment on Packback Deep Dives by February 15, 2024, 10:00 p.m. Final comments will be graded according to an evaluation rubric published on Packback Deep Dives. After that, it will be purely up to students to decide whether to submit comments to the FDA (note the agency's public comment window closes on Feb 20).

FDA and DTCA

With authority over direct-to-consumer advertising (DTCA), the FDA is responsible for ensuring that pharmaceutical advertising "is **truthful, balanced, and accurately communicated**" (US FDA 2015; Parekh & Shrank 2018) and not "**false or misleading**" (US FDA 2023b). The FDA's **Fair Balance Rule** requires that DTCA communicate drug benefits and risks information with relatively similar and comparable prominence (FDA, 2019, 2020). The FDA (2023a) recently adopted a Final Rule on DTCA holding that for "human prescription drug ads presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a **clear, conspicuous, and neutral manner**" (Phengsitthy 2023).

FDA Psychology Study on Indirect Claims

Following up this line of rulemaking, The FDA also recently announced draft plans to conduct a psychological study on indirect claims in FDCA (US FDA 2023c), soliciting public comment on design, rationale, and trajectory of the proposed study, asking in particular:

· Whether the proposed study is necessary for the proper performance of FDA's functions, including whether results will have practical utility;

· Ways to enhance the quality, utility, and clarity of the information to be collected.

Prompts and Assignment Logistics

Students can earn up to 40% of the midterm exam points (substituting for the conceptual mastery section) by writing public comments that address one or both of the following prompts:

· Does the FDA's proposed psychological study on indirect claims have practical utility as a potential source of information on DCTA?

· What should the US FDA do to enhance the quality, utility, and clarity of information generated by its proposed psychological study on indirect claims in DCTA?

Comments should be 500 words minimum, no maximum. To earn full credit, comments should deploy and cite at least two theoretical concepts from course readings. Provide citations for all source references, consistently applying APA citation style.

Frequently Asked Questions

- *If I opt-in to this assignment, how will my grade be included into my midterm?* Simply write "see FDA public comment assignment" as your answer to the conceptual mastery question (20 points).
- *If I opt-in to this assignment, can I also write the conceptual mastery section of the midterm?* Yes - your best score (out of 20 points) will be used.
- *Do I have to cite course materials for theoretical concepts?* Yes. Consult the syllabus for citations.
- *Where do I submit my draft and final comment?* Two places: 1) Here, via Packback for grading; and 2) On a designated Canvas Discussion Board so other students can read the comment.
- *Do I have to actually submit my final comment to FDA in order to earn credit?* No. Your comment will be graded using the assignment rubric, independently of whether you ultimately decide to submit it to the FDA.
- *When does the FDA public comment window close?* February 20, 2024, so you have five days between the due date for submitting your public comment for grading here and the deadline for FDA public comment submissions.
- *Why does the draft comment grading rubric only add up to 18/20 points?* 2/20 points are allocated for the next assignment, how your final submission addresses peer review suggestions.

References

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ChatGPT-4 Transcript Takeaways Analysis

Visit by Food and Drug Administration senior scientist Dr. Kathryn Aikin to Evidence University of Pittsburgh Undergraduate Course

February 8, 2024

Transcript Takeaways Analysis (FDA public comment prompt)
(synthetic communication generated with closed domain human prompt to ChatGPT-4)[2]

Based on the transcript of Dr. Aikin's class visit, the top five takeaways that could be useful for those revising draft public comments on the FDA's pending study of implicit claims in direct-to-consumer pharmaceutical advertising are:

1. **Public Comment Importance**: Dr. Aikin emphasizes the significance of the public commenting period as mandated by the Paperwork Reduction Act (PRA). This underscores the value and impact that well-considered public comments can have on the FDA's research directions and policy development. Commenters should ensure their feedback is constructive and addresses the PRA's four key questions regarding necessity, burden estimate accuracy, ways to enhance utility and clarity, and minimizing the burden of collection.
2. **Recruitment and Diversity**: The FDA is aware of the challenges in recruiting a diverse set of participants for studies. Comments could address the importance of representative sampling and suggest methods to include underrepresented groups, such as individuals with low health literacy or limited internet access, to ensure the study's findings are applicable to the broader population.
3. **Compensation and Incentives**: Compensation mechanisms are in place for study participants through research panels. Public comments might provide insights or concerns about the ethical considerations of incentivizing participation and whether the proposed compensation could influence participation or results.
4. **Role of Healthcare Providers**: Understanding the influence of direct-to-consumer advertising on the patient-provider relationship is a key aspect of the study. Comments could focus on the necessity of considering physicians' perspectives on prescription practices influenced by advertising and how implicit claims might affect clinical decisions.
5. **Potential for Misinformation**: The discussion of implicit claims and their potential to mislead consumers underscores the FDA's concern about accurate information in advertisements. Comments could address the need for clear guidelines and robust methods to identify and mitigate the impact of implicit claims to protect consumer health and ensure informed decision-making.

[2] ChatGPT-4 prompt: "What are the top five takeaways from Dr. Aikin's class visit that may be useful for those in the process of revising draft public comments responding the the FDA's request for public comments on its pending psychological study of implicit claims in direct-to-consumer pharmaceutical advertising?"

These takeaways provide a framework for public comments, ensuring they are relevant, focused on the FDA's research intentions, and constructive towards the study's goals of ensuring truthful and effective communication in direct-to-consumer pharmaceutical advertising.

Transcript Takeaways Analysis (Evidence Based Medicine prompt)
(synthetic communication generated with closed domain human prompt to ChatGPT-4)[3]

For those studying the role of evidence in evidence-based medicine, the following five takeaways from Dr. Aikin's class visit can provide valuable insights:

1. **Importance of Accurate Information**: Dr. Aikin's role in the OPDP highlights the FDA's commitment to ensuring that drug information is truthful, balanced, and accurately communicated. This aligns with the principles of evidence-based medicine, which relies on accurate and reliable information to inform clinical practice and patient care.
2. **Impact of Advertising on Patient Perceptions**: The FDA's interest in studying the psychological dimensions of implicit claims in direct-to-consumer advertising reflects a recognition that patient perceptions can be significantly influenced by such information. This influence must be understood and managed within the context of evidence-based medicine, where patient decisions should be informed by robust clinical evidence rather than persuasive marketing.
3. **Methodological Rigor in Research**: The detailed explanation of the recruitment process and the challenges of achieving a diverse study sample underscore the need for methodological rigor in research that informs evidence-based practices. The way participants are selected and the study is designed can have significant implications for the generalizability and applicability of research findings.
4. **Role of Public and Professional Input**: The PRA's requirement for public comment on FDA research projects, including those from healthcare providers, is a reminder of the value of diverse perspectives in shaping health policies and research agendas. It's a practical application of evidence-based medicine principles, which advocate for the integration of clinical expertise and patient values alongside the best available evidence.
5. **Continuous Monitoring and Evaluation**: Dr. Aikin's reference to previous studies on the effects of advertising on the doctor-patient relationship and the mention of longitudinal data point to the importance of ongoing evaluation. In evidence-based medicine, continuous monitoring of new evidence ensures that medical practices remain current and are based on the most up-to-date information.

These takeaways highlight the importance of rigorous, evidence-based approaches to evaluating the effects of pharmaceutical advertising and the broader implications for clinical practice and patient outcomes. They also suggest that the principles of evidence-based medicine should extend beyond clinical research to include the evaluation of how health-related information is communicated to the public.

[3] ChatGPT-4 prompt: "What are the top five takeaways from Dr. Aikin's class visit that may be useful for those studying the role of evidence in evidence-based medicine?"

Aikin Visit Transcript

Visit by Food and Drug Administration senior scientist Dr. Kathryn Aikin to Evidence University of Pittsburgh Undergraduate Course

February 8, 2024
Transcript generated automatically by Zoom recording, edited for accuracy and concision

Welcome and Introduction

Gordon Mitchell (GM): Dr. Aikin, can you hear us?

Kathryn Aikin (AD): Yes, I can.

GM: Wonderful. Thank you so much for joining our class. We are really honored and excited to have some time with you today. I think the students know a lot about you already. In fact, one of our students found your research before we found out that you were on this specific project. And the research both from that paper and the literature has been really useful for our class to study this issue of direct-to-consumer advertising, and specifically, the psychological dimensions of implicit claims which you, of course, are very well equipped to address given your background.

Dr. Aikin is working with the Food and Drug Administration, the senior social science analyst and research team lead there. Dr. Akin has degrees from Oberlin College, not far actually from Pittsburgh, just a little bit due west in Ohio, and also Penn State University. So, she brings the Nittany Lion mojo here to Panther territory. She's a frequent speaker at academic and professional conferences, member of the editorial board of the *Journal of Public Policy and Marketing*, and, of course, an extensive publication record. So, we thought, Dr. Akin, that a good plan for today is that we could just turn it over to you for some opening comments, and then, ask the students if they have some questions and go for for maybe a half an hour. Does that sound right?

KA: That sounds great. Well, thanks for the introduction, Dr. Mitchell, and good morning to everybody. Thank you so much for allowing me to come and speak with you today. It's a real pleasure and an honor to talk about OPDP and our research. Before I start, of course I have to give a disclaimer that anything I might say today are my views, and do not and should not be construed to represent the views or policies of FDA.

GM: I also should say we are recording this, so in case students that aren't able to see it live can come back and check it just to make sure that's on the record.

KA: That's fine, thanks for pointing that out. In my five minute introduction, I thought I would just give a brief introduction to OPDP, who we are, and then why we ask for public comment on our research, because this is sort of unique to the government. Why is it that we ask for public comment? So, as Dr. Mitchell said, I'm a member of the Office of Prescription Drug Promotion, which is in the Center for Drug Evaluation Research. Our super office is the Office of Medical Policy. As with many government institutions, there

are lots of layers, but we are the organization, the office that regulates prescription drug promotion both to consumers and to healthcare providers.

We do this, we protect the public health, by helping to ensure that prescription drug information and promotion is truthful, balanced, and accurately communicated. And we do this through comprehensive surveillance, compliance, and education programs, and by fostering better communication of labelling and promotional information to both health care providers and to consumers. Within OPDP there are two review divisions, and then there's a division of policy promotion operations. And the social science research team is organized within what we call DEPRO, and there are four of us, and I'm the lead. We all have Ph.d.s in social psychology, and our job is to provide scientific evidence and advice to help ensure that CDER's policies related to prescription drug promotion have the greatest benefit to public health.

We investigate issues relevant to healthcare, provider promotion and also patient and consumer usage of medical product information, in this case, drugs. We focus on drug products because we're in CDER. We consider the audience's perception and comprehension of medical product information, and we help to ensure the accuracy and effectiveness of the information and how it's conveyed. And that's where our background in social psychology comes into it, it's very useful.

So why do we ask for public comments on our research? This is due to the requirements of the Paperwork Reduction Act, and we refer to this shorthand as the PRA, which states that before requiring or requesting information from the public, federal agencies have to seek public comments on their proposed collections, and then submit their proposed collection requests to the Office of Management and Budget known as OMB, to obtain approval. Approvals are typically for no more than three years. The PRA statutory framework applies to information collection from 10 or more persons, and a person here could refer to an individual, a company, a state, territorial, tribal, or local governments. This counts as any information over a 12-month period and if you're collecting information from a substantial majority of an industry or a sector that's considered to constitute 10 or more persons. So, for instance, if there were 12 companies in a particular industry, and you wanted to survey 9 of them, because that's considered a substantial percentage of the entire industry, that would still fall under the PRA.

The PRA also ensures that the government collects only information that's necessary, that we minimize the burden on the public, and that we maximize the practical utility of the information that we collect. And since you've all read the *Federal Register* notice about this study, you can see that represented in the 4 questions that are in the beginning of the *Federal Register* notice, which is:

- Is the proposed information of collection necessary for the proper performance of FDA's functions, including whether the information will have practical utility?
- Is our burden estimate of the proposed information collection accurate, including the validity of the methodology and the assumptions used—did we get our numbers right?
- Are there ways that we could enhance the utility, clarity, and quality of the information that we plan to collect?
- Are there ways that we could minimize the burden of collection on respondents, including through the use of automated collection techniques when appropriate or other forms of information technology?

Those are the four PRA questions that are asked in the *Federal Register* notice. Now, what is information? Information is pretty broad, but it covers any statement or estimate of fact or opinion, regardless of form or format in numerical, graphic, or narrative form, whether it's oral, maintained on paper, electronic, or other media. For full PRA collections, there are two public comment periods. The first is a 60-day public comment period, and that is the one that we're in right now. Those comments come back to the agency originating the information collection. In this case, any comments we receive on this particular notice during the 60-day comment period will come back to FDA. FDA will then consider the public comments that are relevant to the PRA. Then we will write a 30-day public comment notice responding to all of the PRA-related comments. That notice is published for another 30-day comment period, and at the same time or shortly afterwards, we submit to the Office of Management and Budget our proposed information collection supporting materials.

It's important to note where the comments go during these two public comment periods differs. During the 60-day comment period, public comments come to FDA to be addressed. During the 30-day public comment period, comments go directly to OMB; they do not come to FDA. So, we don't see the comments in the 30-day public comment period to respond to. That in a nutshell is what we do and why we have public comment periods. I'm going to save a recitation of the actual study for the Q&A. So, Doctor Mitchell, if you wouldn't mind being sort of the gatekeeper, for who is in what order of questions that would be extremely helpful.

GM: Yes, we were just working on that prior to your arrival. So, I'm happy to do that. We have a leadoff question right here.

Student Q & A

Student: Hi, Dr. Akin, it's great to meet you. My question revolves around recruitment. I was just wondering, what does the recruitment process look like, especially in order to diversify the actual subjects and the people that participate in these surveys, in order to get the greatest conclusions possible?

KA: That is a really good question, and one that we are very cognizant of. In order to reduce costs and also increase the efficiency of our data collection, we recruit from existing research panels and those panels, of course, maintain lists of folks who are interested in participating in research studies, and also contain demographic information and what particular health conditions they might have. So, we recruit from existing panels. We know that certain groups are overrepresented in internet panels compared to others. So, for instance, there will not be as many folks who have low health literacy in internet panels. There will not be folks who don't have access to the internet in internet panels. And so, we have to be very careful about how we interpret the results from our studies, because there will be fairly predictable gaps in our population.

To try and account for this, if we're doing a survey that is looking at attitudes at a particular point in time, we will engage in weighting, to the greatest extent that we can, to try and balance out the opinions of folks that we're getting in this study. In this study we are doing an experiment, so we're not going to weight our data. But we are going to over

recruit certain populations we are using in this case both for educational attainment, and then we're also examining self reported health literacy and we're using those two as a fairly good approximation of health literacy, because we would very much like to have folks of lower health literacy in our studies, because they may have different interpretations of the information compared to people who are very high in health literacy, or high in educational attainment.

So, we're cognizant, and we do the best that we can to try and represent all the groups with the understanding that there are probably groups that were missing. With that in mind, we did actually do a study with folks who didn't have access to the internet. And in that particular study we went directly via either landline or mobile because folks without the internet do often still have access to a phone, and we specifically recruited those folks. So, it partly depends on the population we're looking at. But it is something that we try and pay attention to.

GM: Very nice. Thank you very much. Do you have a follow up question?

Student: I do have just a little bit of a follow up question. I was just wondering, you say, you guys are conscious about it. Do you have anything that is implemented in the studies in order to weigh different opinions in a different way?

KA: In an experimental study like this, we try and over recruit for folks that are lower health literacy, just to make sure that their opinions are represented. In a survey where we're actually trying to do something that's closer to representing a certain population of folks, then we will employ weighting. If we are, for instance, surveying healthcare providers, it's not possible to get a representative from every single healthcare provider group. But we might weight the responses of folks in very small categories higher than those who have a lot of people. I'm not prepared to give an entire lecture on weighting right now, but if you employ weighting, you can account for the size of the population relative to a larger population to ensure that both groups are getting equal weight in the sample.

GM: Thank you. Does another student want to jump in here with a follow up now?

Student: Hi Dr. Aikin, thank you for coming to our class, we really appreciate it. I was going to talk about compensation and the recruitment process and how that looks. Was this going to be a random sampling of just, you know, finding people with pre-existing melanoma? But you said subjects will be from existing research panels. So that kind of changes the way that I was going to ask that question, because if it's from pre-existing research panels, then, you guys, I'm assuming, approach it in a different way rather than say, just a randomized sampling from, you know this nation or community. So, I was wondering if that's what that looks like. Is there compensation for you know, how does that go about? How do we ensure that the people receiving these emails to conduct and help with experiments actually do it?

KA: Ah, those are two questions, but both very good ones. So, we do offer an incentive to folks who complete the study, and that incentive is set by the panel, and it's typically in the form of points. It depends on the panel, and they will get a certain number of points for completing the survey or study, and then those points will go into their account, and

the points have a certain dollar value. But it's done completely through the panel. And you had a second question, and I totally forgot it. Can you remind me what your second question was?

Student: How do we ensure that the people reaching out to in recruiting actually do the study? The goal, I think it was 1,300; how do we get to that number?

KA: You have to over recruit because a certain percentage of folks will not open the email. A certain percentage of folks will open the email and decide not to participate. A certain percentage of folks will open the email, decide to participate and not be eligible. So, you have to over recruit by a certain percentage and those percentages are typically calculated by the contractor who's doing the data collection based on their experience. For a very small population, for instance, if you're looking for someone who has a very rare condition, they're harder to get, because there are just fewer of them, and they're less represented in the panel. But we typically account for a certain percentage of response in our recruitment numbers. And if you look at the burden table in the *Federal Register* notice, it will say, "screener." That's how many people we expect to screen. And then the study number is how many people we expect from those we screened to actually complete the study.

GM: That's great. Thank you. Just a follow up there. I'm curious, does the FDA transfer resources to the studies to make up for the fact that each panel is going to be compensating their research participants through their own panel? Does that make sense?

KA: Our social science research studies are done under a blanket purchase agreement and on the blanket purchase agreement there are four contractors. When we write a research study task order, which is a request for help doing data collection, because we don't have the resources to do data collection ourselves—there are four of us—then those contractors, the one who wins the bid for the contract will subcontract with a panel, and they take care of that. So, we budget a certain amount for the study, and it is up to the contractor to do the tasks within that study within their budget. It's a fixed price task order.

GM: Gotcha. Okay, in the last exchange we heard a little bit about physicians. Now we have another student, who, I think, has a question specifically about that.

Student: Yes, hello. I know you said you're studying the audience perception for these ads and the drugs that are in the ads. So, I was just curious about the role that a physician or a healthcare provider would play in this exchange. We've done some research about how, in like this day and age, consumers are very involved in their health care and they come to doctors with ads they've seen or drugs they might want take. So, is it possible to broaden the scope of the study to also include healthcare professionals and physicians?

KA: Great question. When the guidance describing how companies could fulfill adequate provision on broadcast was first published in 1997, we did a study on the impact of direct-to-consumer advertising on the doctor-patient relationship, because we were concerned, and we had heard from various interested parties, that by advertising directly

to consumers, consumers were going to start pressuring physicians for particular products.

What we found in that particular study, and in a follow up study done in 2002, with both patients and healthcare providers, is that there is some pressure, but that physicians are pretty good at holding the line, and the percentage of consumers who are getting products for whom it is not indicated is quite small. And that's a real concern. You don't want patients to have drugs for conditions they don't have. So, if you go down from people seeing an ad, remembering an ad, going to see the doctor, talking about an ad in that interaction and then actually getting the product, that number is pretty small, at least based on the data that we have. That being said, this is promotion. This is promotion by a sponsor designed to drive attitudes and behavior. So, if you look at it from a straight return on investment standpoint, it probably wouldn't happen if it didn't work.

Student: Yeah.

KA: So, we are concerned both from the side of what is the physician's behavior, but also what is the consumer's behavior. Just taking one narrow part, if the point of the ad is to drive the patient in to see the doctor, that's one type of behaviour. The patient will make that decision based on what he or she or they see in the ad. If that information is inaccurate in some way then that patient is going to see a doctor, perhaps with the wrong impression. We want to prevent that, we want to prevent the wrong impression, but also we want the patient or the consumer to be able to make a correct decision. Sometimes the correct decision is not to go because you don't have that condition. We want to improve and ensure that the information is being communicated in a way that is accurate and non-misleading, and in a way that the viewer can make an informed and correct decision.

Student: Awesome. Thank you so much.

KA: You're welcome.

GM: Wonderful. I do have another thought about that which takes the question in the same direction but inflects it just a little bit to wonder about the case where there is a consumer who sees a direct-to-consumer ad that features an implicit claim that leaves an impression. They go to their physician, and they say, "I saw this ad, I want this drug, I think this could help me." The physician responds by saying, "Well, actually, that drug doesn't work. And the claim you thought you remembered in the ad was not even explicit. The drug company didn't even say that it worked. It's just that the ad left an impression on you." You said a lot of times physicians will "hold the line," so that means not necessarily prescribe the drug just because the patient is requesting it in response to something that they saw in a direct-to-consumer ad. So how does that affect the patient provider communication and relationship? Is that part of the 1997 study? Physicians "holding the line" sounds like a good thing, because it's making sure that prescriptions are accurate and that patients are getting the care that they need. But there does seem to be some kind of implication for the fabric, the trust, the quality of communication between the patient and the provider, when you inject this, especially via implicit claim, into the conversation. What about that?

KA: Well, whether consumers are actually remembering implicit claims as explicit claims in direct-to-consumer advertising is why we're doing this study, so that I'll just have to table for the moment, and I'll hopefully in a few years be able to give you an answer to that. The other question of whether these interactions are affecting the doctor-patient relationship, if you look at the results of the 2002 study, which is on our website, and I'm happy to give you that website at the end, it does affect some people.

We asked a variety of questions. If a doctor refused to prescribe a drug that you asked for, what would you do? Nothing? Would you switch doctors? We found a small percentage of respondents who said, yes, they would switch, but it wasn't very big. Same thing on the physician's side. How do you feel about direct-to-consumer advertising? We found that physicians were sort of split into three groups. Some thought it was good, some thought it was bad, and some were in the middle, so we didn't find huge negative effects. What we found is that it was sort of in the middle, and so with the caveat that was quite a while ago in 2002. I think it's still a useful question to ask, and something, because I'm a huge fan of longitudinal data to try and and test it every so often, and just take the temperature of what's going on, especially with the the the proliferation of direct-to-consumer advertising on TV, because it's much greater now than it was.

GM: Okay, so that I think is a good segue to our next question.

Student: Hi, Dr. Aikin, it's a pleasure to have you here this morning. My question sort of takes that into a different direction, because we know that the direct-to-consumer advertisements are just focusing on their level of persuasion. But I'm curious to think what you would think about the FDA or the OPDP creating a sort of public facing website that has, like a centralized place, for consumers or those being advertised to go after an advertisement. I guess this would make the most sense in a visual advertisement like maybe at the end of their ads, having a standard FDA screen like "visit the FDA's website."

Because of the semiotics of it all, I feel like it would help both the drug company, the consumers, and the FDA, because you know the FDA's image is trusted, and so that, paired with the drug being presented, would help them, and also give the consumers some agency to create their own place to go for their kind of questions. That opens up a whole other door about what the website could entail. But I was thinking, like accurate drug information information about the company presenting it, even like potential doctors, stances on the drug being presented, academic articles? And it could also open up a place for people to ask questions to the FDA like a little Q and A section, because there are so many people that don't want to spend the money going to the doctor and don't have that money. I feel like just an accessible platform that meets the needs of consumers would be potentially helpful.

KA: So, I love that you want to talk to the FDA. That is great. We love to talk to people. So, some of that's beyond our mandate as an agency. There are existing resources available now where you can go and look at information about what's in a direct-to-consumer ad. What are the things to look for? What might be false or misleading in an ad? And we've also published information about how good people are in recognizing things that are false or misleading in the ad. There is also what's called the "Bad Ad" program. That is a way for consumers and healthcare providers to report ads directly to FDA that they feel are

problematic. That email address, I think, is on our homepage. So, that's a way you can communicate directly with FDA. I think there's also what's called "Drug Information," I'll have to look up their exact email address, but you can communicate with them. We can't collect information from the public without a Paperwork Reduction Act information collection request. So that's that sort of stops us from reaching out. But there are existing resources that could be used, and I think it's fascinating to put those all together in one existing website. But I would just point point folks towards existing resources that are there.

Student: I guess I understand that there are those in place. And I feel sometimes I wanted to focus on the whole psychological aspect like when that's not necessarily available to people to see, it's not on or attached to the advertisement. People won't even think to reach out, it seems like such an extra step for them to make their own research and decisions, especially when they're just baseline consumers. And potentially, you know, partnering with the advertising companies to be like, "Hey, this would help you." The FDA would be attaching our image, not necessarily saying that we agree with your drug claims, but just like attaching the image to say, "Hey, we've reviewed this drug and we have more information on our website," which could potentially be an area where consumers would feel they have a place to go.

KA: We don't review the ads in advance, except in very specific, narrow circumstances. So, it sounds like a public service announcement almost to be attached to an end.

Student: Yeah, even if you couldn't attach it to the I just being like running something that's connected just solely to the FDA being like, hey? I know you're seeing all of these advertisements, and if you're, you know, suffering with any of these conditions, you're likely to want to explore them and giving like a trusted source. It's not, you know, interested in making money off of their drug, like the FDA is just like interested in consumer safety, I think would be something worthwhile.

KA: Yeah, that's that's a really great idea.

GM: Wonderful. Alright, so those were some excellent questions, and we really appreciated your responses, Dr. Akin, and your generous gift of time this morning. Rather than hanging around and keep adding more tasks to your modest 4-person shop, I think we're just going to stop at this point. Let's give Dr. Aikin a round of virtual applause. We can see some emojis? Come on, let's go students, send some emoji, you know, response. There we go. Look at those responses. We even have some exploding icons. Very nice. Alright. Thank you very much, Dr. Aikin, we really appreciate it. Keep up the good work and have a great day.

KA: Thanks so much for inviting me. And I've dropped some links in the chat. Bye, bye.