PUBLICCITIZEN
1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

March 11, 2015

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: The Food and Drug Administration's draft Guidance for Industry: Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices

Dear Secretary Burwell:

Nearly 1,800 people or organizations — including individual consumers, doctors and other health professionals, academics, people working in the drug industry, pharmaceutical companies and other organizations — have responded to the Food and Drug Administration's (FDA's) June 2014 proposed Guidance referenced above concerning information about the safety of prescription drugs.[1] The response, by over 99 percent, was strong opposition.

The contentious issue at the heart of this Guidance was the FDA proposal to give drug companies free rein (the FDA "will not object") to tell doctors that a medication is less dangerous than the FDA has concluded and is stated on the approved labeling. The Guidance was proposed by the agency on June 6, 2014, and was open for public comment through August 25, 2014. If finalized, the Guidance would allow pharmaceutical companies to inform health care providers that the FDA-approved labeling overstates a medication's risks, by distributing peer-reviewed articles and by having discussions with doctors.

Because the FDA inexplicably had posted only one comment on www.regulations.gov as of October 15, Public Citizen sought and eventually obtained, through a Freedom of Information Act request, and has now reviewed all 1,782 comments. Only 11 commenters (less than 1 percent) supported the proposed FDA Guidance. (As of March 6, 2015, more than six months since the comment period closed, only 79 of the 1,782 comments have been posted by the FDA on www.regulations.gov.)

[1] Food and Drug Administration. Draft Guidance for Industry: Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices. June 2014. http://www.regulations.gov/#!documentDetail;D=FDA-2014-D-0758-0002. Accessed March 9, 2015.

In the largest category of commenters, there were 1,217 **individual consumers,** none of whom supported the Guidance. The second-largest category, **drug industry**, included 322 commenters, of which 316 opposed the Guidance and only six — all pharmaceutical companies or a law firm representing 13 pharmaceutical companies — favored the Guidance. In the third-largest group, among 73 **health professionals**, primarily comprising physicians but also including nurses and pharmacists, zero were in favor. Similarly, none of the 67 comments from **consumer groups**, the fourth-largest category, favored the Guidance. In the fifth-largest group, 30 individuals in **academia** commented, and 29 opposed the Guidance. All **16 government employees** opposed the Guidance.

Four other supportive comments — of the 11 supporting the Guidance — were from industry associations, including drug associations and one association representing researchers doing studies for the pharmaceutical industry.

An appendix at the end of this letter includes representative comments from 42 commenters, including a summary of the stated basis for pharmaceutical industry support of the Guidance.

Two striking and frequent themes emerge from the 1,771 comments opposing the Guidance:

(1) About one-third of the commenters explicitly referred to "**my doctor**," with statements such as "I oppose the FDA proposal to let Big Pharma push information on my doctor that contradicts government-approved warning labels" or "If drug companies can tell my doctor that a medication is safer than the FDA says it is, what is the FDA for?" Some of these commenters viewed the proposal as FDA-encouraged drug industry interference with the doctor-patient relationship.

(2) A related theme was a **widespread and increasing distrust of the FDA** for proposing the Guidance. Comments included the following:

- A physician wrote that "I am beginning to wonder about the FDA. I always thought the purpose of the FDA was to put out reliable information - 100% trustworthy, at least so far as current scientific knowledge is concerned. This proposal has shaken my confidence in the FDA. The FDA is not supposed to be working for the pharmaceutical industries!"

- Another comment stated, "It seems ridiculous to me that the FDA would promote the sharing of misinformation by the beneficiaries of that misinformation in direct conflict with research the FDA has conducted. This is not free speech by some voiceless minority, but the reckless misuse of information to promote sales and profits. This is political correctness run amok and is just plain wrong!"

- Another comment was, "The Food and Drug Administration is in place for a reason. Incidents like this weaken the public's trust in the purpose and intent of the FDA. Please do what is best for the public."

Since the FDA is legally the government shield against drug industry efforts to market products that may not have a favorable ratio of benefits to risks, many commenters recognized that giving companies a green light to persuade doctors that risks are lower than the FDA-approved labeling could distort the benefit-risk balance established through the new drug application review process in a manner favorable to drug companies, but possibly dangerous to patients.

Public Citizen wrote to you on October 22, 2014, asking that the proposal be withdrawn, and I attached an article that I had published in *JAMA Internal Medicine*, alerting physicians to the proposed Guidance and urging them to respond. As I wrote in the article: "When evidence supports a reduction in the risk associated with the use of a prescription drug or biological product, the manufacturer should send the evidence to the FDA, state the basis for the reduction in risk, and request a labeling change. … The fact that such promotion, if incorporated into either the labeling or the advertising for a drug, might violate FDA laws and regulations highlights the substantial, risky change in drug promotion that the draft Guidance would allow."[2]

Predictably, the only supporters of the proposal in the 1,782 comments I reviewed were pharmaceutical companies and their trade associations, along with a single academic.

Public Citizen again urges you to immediately withdraw this reckless and justifiably embarrassing proposed Guidance, because it seriously undermines FDA authority. Its main supporters are drug companies and their associations, all of which would benefit from being allowed and encouraged to sell more drugs by making them seem safer than FDA has judged them to be. Ninety-nine percent of commenters strongly disagreed with the FDA's proposed Guidance — and only 1 percent supported it.

Sincerely,

Sidney M. Wolfe, M.D.
Founder, Senior Adviser
Public Citizen's Health Research Group

[2] Wolfe SM. Proposed US Food and Drug Administration Guidance for industry on distributing medical publications about the risks of prescription drugs and biological products: A misguided approach.
JAMA Intern Med. 2014 Oct;174(10):1543-1544.

Appendix

Comments from categories of responders are preceded by the four-digit number in the order in which they responded to the docket (0001 through 1782).

Individual Consumers

0956 Carol Hudson

When being prescribed drugs by my physician, I need to hear scientific reasons why the drugs will help me and I also need to know all the side effects and risks of the drug. What I DON'T need is to have pharmaceutical corporations push merchandising on my doctor and on me, withholding warnings that could save my life and my health.

1016 Anonymous

I don't think the FDA should allow drug companies to tell my doctor that a medication is safer than the FDA says it is. If drug companies had their way the only "warning" their drugs would carry would be "by taking this drug you waive all right to sue the manufacturer"…….. The public will NEVER get objective information about the dangers of these drugs from the companies that make them. That is why it is vital for the FDA to refuse to let these companies to have any control over the final information that is released to doctors and the public.

0177 Glen Shue

As an old retired FDA'er I'm really insulted if you are actually considering allowing the Drug Industry to provide information of safety INSTEAD of your information. I saw the Industries attempts to influence regulations to their benefit while I was there nearly 30 years and I know you know better than I so why in the world would you ease your regulations in their favor? Please, stop any political influence in the essential work you have to do enforcing your/our Food and Drug regulations.

0743 Anonymous

Before my retirement I worked for over thirty years in the pharmaceutical industry and medical education and advertising agencies so I am very familiar with FDA regulations concerning promotion of approved prescription drugs.
Pharmaceutical companies try to communicate the benefits of their products and minimize the risks. Limiting promotional claims to those supported by the approved label is one way to safeguard patients. I am opposed to the industry being permitted to distribute literature that makes safety claims not supported by the approved label.

0877 Nancy Champion

Based on pharmaceutical companies' documented aggregate history of deception, hiding crucial information from the FDA and the public, and their complete dedication to their profit margin and shareholders regardless of public health consequences, I am utterly against allowing the companies this freedom to misrepresent their products to physicians. The public is entitled to full knowledge about medications and physicians MUST HAVE full information in order to prescribe properly... the for-profit bias of industry reps censoring out the bad in order to sell more product would be an unmitigated health disaster.

1211 Bill C

It seems ridiculous to me that the FDA would promote the sharing of misinformation by the beneficiaries of that misinformation in direct conflict with research the FDA has conducted. This is not free speech by some voiceless minority, but the reckless misuse of information to promote sales and profits. This is political correctness run amok and is just plain wrong!

1674 Alan Alpert

It is the responsibility of the FDA to safeguard the health of the American people.
It is the responsibility of the pharmaceutical companies to safeguard the dividends and stock prices of their shareholders.
It is not in the interest of the American people for the FDA to allow drug companies to tell the medical community and the public that their drugs are safer and have lesser risks than the FDA says. If they have evidence that the risks are less, then let them submit that information to the FDA and let the FDA decide if the drug has been found to be safer than previously thought.
If the drug companies have the final say about how safe their products are, then, just what is the function of the FDA?
Don't let this become the heyday of the multi-national, corporate Snake-Oil salesman!

1749 Patrick Vingo

This is such a fundamental issue that it cannot be ignored. The pharmaceutical companies cannot objectively separate themselves from the fact that they are engaged in a profit making business. To allow them to contradict the findings of the FDA undermines the public charge and trust of this government agency.

Drug Industry

0009 David Dittman

This is a misguided FDA proposal that could result in physicians relying not on approved warning labels but on information provided by drug companies that may be more concerned with profits than patients.

Please call on the Food and Drug Administration to withdraw its proposal to allow pharmaceutical companies to undermine FDA-approved information about pharmaceutical risks. Allowing drug salespeople to hand doctors information that makes drugs look safer than they are is potentially dangerous for patients who are subsequently prescribed these drugs. Laws and regulations requiring FDA approval of drug labels would have little meaning if a company, without prior FDA review and approval of supporting data, can distribute to physicians information about purportedly lower risks.

0020 Anonymous

This is the most ludicrous proposal I've heard in a very long time. Drug companies are interested in their bottom line - period - end of story. I do not want them telling my Doctor how safe their drugs are. That is your job. It's what you get paid for - or have you forgotten???

0145 Anonymous

Industry sales reps delivering claims of purportedly lower risks about their products?! WHY would the FDA allow that? It would undermine the FDA-approved warning labels, circumvent the approval process and distort the full picture of potential risks. The FDA has a process for reviewing new information and updating labels. If companies have new information about the risks of their products, they should share it with the FDA and ask that the approved warnings be revised. What is the point of an FDA that does not protect the people? ! Taxpayers should no longer fund an FDA that puts Big Pharm's priorities before the citizens' !

0154 Barbara Coulson

I am really appalled that any regulatory organization would allow any corporation to tell the American people that drugs are 'not as bad' as studies have shown. We are swiftly being sold down the river by being lulled into thinking that certain drugs, that the pharmaceutical industry wants to push in order to sell even more, are safer than previously thought. ……..Now we have the FDA considering relaxing regulations that are there to protect us. The drug industry has been pumping dangerous drugs into the marketplace, then pays some professors of prestigious colleges to develop 'findings' that are contrary to good scientific findings. Please do not allow

this relaxation of recommended practices to become the standard. We deserve better from our regulatory agencies.

0305 P. Ross

It is unbelievable that consumers have to ask the FDA to prohibit pharmaceutical companies from telling my physician that drugs are safer than the FDA says they are. Do I as a taxpayer pay the FDA or have the drug companies taken over the entire system. This is unbelievable.

0358 Connie Williams

The food and drug administration is in place for a reason. Incidents like this weaken the public's trust in the purpose and intent of the FDA. Please do what is best for the public.

0425 Anonymous

I can't even begin to think why you would consider letting drug companies tell my doctor drugs are safer than the FDA says they are. This a true no-brainer. If you allow this to happen, you can't even pretend that you are not wholly captured by big pharma.

0660 Anonymous

As a primary care physician approaching 25 years in practice, I have been painfully and perpetually aware of the corrupting influence of "Big Pharma" on the practice of medicine in this country. Restraints of such influence are sorely needed if we truly wish to achieve better and more efficient health care in the US.

0673 Daniel Hatch

It is hard to imagine why the FDA would allow drug companies to assure doctors that their product is safer than the FDA says it is. You are supposed to be an independent agency, working on behalf of, and trying to protect, the American people. Giving the drug companies your okay to contradict the findings of your agency's scientists seems absurd on the face of it, and hints at corruption. Your job is not to make sure the drug companies are doing okay, but rather to be sure that the ever more complicated drugs and drug combinations that these companies are pushing are safe for the public to use. Please take your responsibilities seriously.

1292 Bonnie Logan

Seriously, does anyone have to explain to you WHY it's a bad idea to allow drug companies to tell doctors a medication is safer than the FDA says it is??? Are you guys kidding? Does anyone in government ever do the right thing any more---or is money the only thing that matters in our so-called democracy?

1479 Denise Flynn-Webb

If this isn't the very definition of "Conflict of Interest", then strike the term from the dictionary. The history and evidence is beyond overwhelming that when industries are left to research and police themselves it never ends well for the consumer. Again, consumers have to send comments to government agencies to convince them to put our best interest ahead of greedy corporations and politicians who always have a monetary interest they want to protect. Really??? I pay my taxes, unlike most, if not all, of the previously mentioned yet here I am having to defend and convince an agency that works for us to not make policies that are NOT in the best interest of Americans. The evidence is there, why is this even a consideration. Money over rights of consumers!! Enough. PLEASE do your job and put Americans health and well-being before anything. Period!!!!!!!

1766 Charles Connolly

My doctor never mentions side effects. Thank god I've got a pharmacist that does. Allowing drug companies to tell my doctor or pharmacist that a medication is safer than the FDA says it is, is sort of like allowing the fox to say who goes in the chicken coop, don't you think?. It's a BAD idea folks, don't do it. Thanks for your time

---

Physicians

0001 Kenneth Logan MD

I am a Family Physician in Chico, California - I am wishing to make a comment on an FDA draft proposal relative to pharmaceutical industry Guidance relative to distribution of scientific/medical publications relating to already approved prescription medications. My opinion, as a practicing physician, is "no". This is not a good idea - does not assure adequate safety, into the future, for my patients, and other patients in the country. I say "no" to this proposal.

0018 Frank Kline MD

Relaxing the process for approving new medications and giving less information to the public and healthcare providers does not seem wise or in the best interest of the public. Drug reps stretch the truth more than enough. It isn't a good idea to give the drug companies even more latitude or to buy their way to head of the line.

0113 Jan Crean MD

As a practicing physician, I rely on factual information to safeguard my patients and my own reputation. We need strong and independent FDA performing honest and well-designed evaluations of pharmaceuticals. Please do not short-circuit this crucial function and service.

0445 Robert Lawrence MD

As a physician and as a patient I am appalled at the prospect of allowing drug companies to tell me that a drug is safer than what FDA's assessment and expert committee analysis determines. It's bad enough that we are barraged by direct drug company to patient advertising. To allow the drug companies to misrepresent the true safety issues of their product would be unconscionable.

0537 Walt Maack MD

Please do not allow any more corporate influence on drug info .there's already too much! i see the problems, & wreckage, on most of my shifts as an emergency physician.

0997 Anne C. Courtright MD
Doctors intent is to "do no harm". Giving them misleading information is absolutely the wrong way to go. It has been my impression that drugs are being released with inadequate testing already, but to encourage drug salesmen to give misleading information is criminal.

1108 Sara L. Hoyt MD
As a retired pediatrician I know how important it is for physicians to have accurate information about drugs.

1338 Wayne Spiggle MD
From experience as a primary care internist, I believe drug companies find ways to mislead U.S. pharmaceutical prescribers. The FDA should tighten rules to prevent this.

1506 Ricardo Bartelme MD
I don't think the FDA should allow drug companies to tell my doctor that a medication is safer than the FDA says it is. It will be too easy for drug companies to cherry pick the articles that are positive for their product and ignore contrary evidence.

1596 Robert M Cohen MD

As a physician, I rely on the scientifically determined information put out by the FDA for my information. I really don't understand the purpose of allowing the pharm company which makes a given drug to put out its own information on that drug or of allowing that company to in any way affect or effect the information given physicians and the public about that drug. Quite frankly, I am dead set against this proposal. In fact, I am beginning to wonder about the FDA. I

always thought the purpose of the FDA was to put out reliable information - 100% trustworthy, at least so far as current scientific knowledge is concerned. This proposal has shaken my confidence in the FDA. The FDA is not supposed to be working for the pharmaceutical industries!

Nurses

1509 Nancy Schmidt

I have been a nurse for 40 years, noticing how big pharma manipulates doctors and patients with advertising and unscientific pressures to buy their products, leaving many patients unable to afford even the most basic drugs. Big pharma exists to make money, to be responsible to shareholders, not sick people. Do not give them even more leeway to influence the treatment that sick persons receive. Restrict their actions as much as possible. Money must not continue to control the care of the sick.

1615 Nancy Wilcox RN

This proposed regulation appears to be protecting the pharmaceuticals interests and reducing the protection for patients from risks of prescription drugs and biological products.
More and more drugs are showing negative effects with longer usage. More reporting of risks over time are needed, not less. I am very concerned about the proposed relaxation of regulations that relax the pharmaceutical companies to self-promote off-label uses without proper peer review. Peer review is essential for protections of consumers.

0986 Barbara Baird RN

The FDA should NOT allow drug companies to tell my doctor that a medication is safer than the FDA says it is. Prescriptions provided by the attending physician include information about risks, side effects, and adverse effects. No drug company should ever supersede the advice of a physician for the purpose of increasing profit. The oath of physicians is “to do no harm.” And certainly drug companies should be prohibited from causing harm to patients by actions that are not truthful. Stand up for health and safety of all our citizens. Prohibit drug companies from giving misinformation to anyone. Our life depends on the FDA to protect us from the unscrupulous practice by drug companies.

Pharmacists

1720 Carol Timm PharmD

It is Time for the FDA to step up and do its job. I am a retired pharmacist at the age of 74. I retired mainly because I no longer trust Pharmaceutical Companies to give me accurate information on drugs or the FDA to guarantee a proper drug.

0137 Moira Bue

This is totally unacceptable. There are problems enough as it is.
1/ Serious warnings and mandated insert data are not currently required in samples. Overworked doctors are unaware of this. 2/ Pharmaceutical companies appear to consider fines for non compliance with FDA regulations as the cost of doing business as their profits outweigh their fines. 3/ I do not want to end up having the same level of trust for the FDA as I currently have for the pharmaceutical industry.
As a retired pharmacist I am alarmed by the current trends.

Academia

1691 Barbara Mintzes PhD

Companies have a fiduciary responsibility to shareholders to increase sales of their products. This creates a conflict when it comes to medication safety, as information on harmful effects and required restrictions on use lead to limits on sales.

Allowing manufacturers to disseminate information dismissing or minimizing risks in approved product information, whether or not that information is based on a peer-reviewed publication, can only be expected to lead to less cautious and judicious prescribing and increased harm to patients from adverse events of medicines. There is already a problem of inadequate information on harm reaching physicians through biases exaggerating benefit and minimizing harm in the medical literature and in information disseminated directly by manufacturers through their sales force. The changes proposed in this Guidance would only worsen the problem.

1725 Debra DeBruin

It is a very fundamental conflict of interest for pharmaceutical companies to be allowed to try to influence providers by providing them with information that is not consistent with FDA approved messaging such as warning labels. The FDA has a moral obligation to prevent this type of practice, and protect consumers from such industry conflicts of interest. I am a professor of bioethics, and feel strongly that the bioethics issues here are not complicated.

Government Employees

0321 James Lin MD

As a physician, I strongly oppose letting pharmaceutical companies directly give information to doctors that may contradict the information published in scientific studies. There is already ample information the pharmaceutical companies in the past have pushed drugs where the scientific data was weak or even absent. The last thing the FDA should do is encourage this sort of unethical behavior**.**

1649 David McCullough

I wish to register a comment to the FDA urging the agency not to let pharmaceutical companies undermine objective, scientific evidence about pharmaceutical risks. As a public health professional I seek to make accurate and objective information available in as wide an arena as possible. A primary tenet we follow is to NOT permit bias to enter the discussion and allowing pharmaceutical companies to insert their own positions biased or not as fact is BAD policy.

Miscellaneous

0053 Harry Geyer

As a former reviewer at the FDA, I know the twist that industry puts on the scientific findings of their drugs. It comes very close to lying and I know their drug reps are even worse ---- There is no way the busy physicians could get an unbiased review of drug data by the drug reps,,,,,,, This must not be allowed!!!

0524 Herman Hardy

I worked in the HMO industry for thirty (30) years and I've seen first hand how big Pharma works. They need more regulations.

****

Drug Industry: Supporting the Guidance

[Excerpted from the August 25, 2014 submission, on behalf of the Medical Information Working Group(MIWG) by the Ropes & Gray/Sidley Austin law firms, representing many of the largest

pharmaceutical companies. The members of the MIWG are: Allergan, Inc.; Amgen Inc.; Bayer Healthcare Pharmaceuticals Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Eli Lilly and Company; Genentech, Inc.; GlaxoSmithKline LLC; Johnson & Johnson; Novartis Pharmaceutical Corporation; Novo Nordisk, Inc.; Pfizer, Inc.; Purdue Pharma L.P.; and Sanofi US.]

1678

The main thrust of the MIWG comments is that the First Amendment protections for commercial speech allegedly allow the FDA to encourage companies to provide doctors with information demonstrating that drugs are safer than indicated in the FDA-approved labeling. What follow are verbatim comments from the submission referred to above followed by the page number on which the comment appears. Included are complaints that the Guidance does not go far enough.

The free flow of speech "has great relevance in the fields of medicine and public health, where information can save lives." In recent years, courts have made it increasingly clear that FDA's regulatory authority over the sale of medical products does not permit it to broadly prohibit truthful, non- misleading communications regarding such products (page 2).

"Vagueness in FDA's speech restrictions is problematic because it chills manufacturers from communicating information that is both highly valuable and protected by the First Amendment" (page 3).

For the first time, FDA has in the *Draft Guidance* explicitly permitted manufacturers to communicate proactively with payers, prescribers, and other stakeholders about emerging risk information that is related to, but not set forth verbatim in, the approved product labeling; moreover, the *Draft Guidance* appropriately permits company representatives to discuss the information with recipients rather than simply provide a copy of the underlying study or analysis (page 4).

… the *Draft Guidance* outlines a number of stringent criteria that must be satisfied regarding the source of the information and the manner of distribution before manufacturers can avail themselves of the safe harbor. The First Amendment will not abide such content- and speaker-based distinctions (page 4).

Finally, it is unlikely that many peer-reviewed articles are written in a way that satisfies the requirement that the publication be a "fair characterization of all relevant information in the safety database, including contrary or otherwise inconsistent findings" (page 7).

> (The comment below refers to the overly restrictive safe harbor requirements referred to above.)

Rather than prohibiting the dissemination of publications that fail to satisfy these safe harbor requirements, the Agency should instead affirmatively permit manufacturers to distribute a

broader range of studies and analyses so long as the design and limitations are clearly disclosed (page 8).