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The Progress of Plain Language in the US: A federal perspective

Joanne Locke
Food & Drug Administration

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It's wonderful to be back to speak to this great group of Plain Language enthusiasts. I know a lot of you didn't make it to Houston in 2000, but it's nice to see a few familiar faces. And I'm very pleased that Avi Arditti, senior news editor at the VOA and long time member of the Inter-government Plain Language working group, has agreed to join me. I'll be talking about what's been going on with Plain Language in the US Federal Government in the past 2 years.

It's especially gratifying for me as one of the US Government's PL representatives to be able to tell you that, despite the many skeptics in the government who initially thought this was just another one of those programs that would go away if they ignored it long enough - that PL is still alive and well in the US.

However, we still have a bit of work to do. Just last week, I was given these 2 memos. Yes, one's a joke, but the other is real!

QUIZ – Which is from a real memo?

Excerpt from Memo A
Each Agency is required to establish a COOP plan and assign a POC whose highest priority is to coordinate the Agency's Plan with the Departmental COOP/COG program. The Agency POC's will be required to have COOP as their highest priority and provide input in developing plans, policies, and procedures for use by OASPHEP in furtherance of the Departments' COOP/COG mission. By COB Sept. 19, please forward the name of your Agency's COOP POC to the Department's COOP Coordinator, in OASPHEP.

Excerpt from Memo B
Ten patients on IgA have filed an FOI request with FDA, requesting all documents, including copies of the demurrers, subpoenas duces tecum, and writs of mandamus, in a case involving ADRs in which USP had filed an amicus curae brief. In a recent MMWR article, scientists explained that the ANDAs, BLAs, PLAs, 510(k)s, and PMAs that plaintiffs had sought were covered by the exceptions covered in 21 CFR 331.10(2)(c)(III) Subpart E. The article cited the FD&C Act, including the reauthorization provisions of PDUFA and FDAMA.

2 years ago, I reported that the Administration strongly supported the use of Plain Language in Federal documents. In 1998, former President Clinton signed a memo directing the use of Plain Language in rulemaking documents published in the Federal Register and in documents for the public that explain how to obtain a benefit or service or how to comply with a requirement. Then, Vice President Gore put Plain Language under the umbrella of the National Partnership for Reinventing Government, where he personally presented No Gobbledygook

Awards every month to Federal employees who produced excellent, plainly written documents.

Since then, as you know, we have a new Administration. As a result, we in the Federal Plain Language community have tweaked a few things, such as changing the name of the Interagency Workgroup from the Plain English Network (PEN) to the Plain Language Action and Information Network (PLAIN).

But the commitment and the goal remain the same. The group still meets every month at the White House Conference Center, under the tireless leadership of Annetta Cheek (who sends her best wishes from Spain, where she is celebrating her 35th Anniversary.) The name doesn't matter -- PEN or PLAIN – the Plain Language work goes on. In fact, some Departments, like Education, report that it's even stronger under their Republican agency heads. And some Feds – but not enough - go so far as to state that PL has become "part of their agency's culture."

I work for the Food and Drug Administration, which is part of the Department of Health & Human Services. The Secretary of HHS, former Wisconsin Gov. Tommy Thompson, has long been known for his ability "to translate government-speak into plain English." Since he took the job of Secretary, he has made it clear that he strongly recommends clear communication, and he's insistent that all HHS agencies use plain language and avoid both jargon and highly technical language in all documents.

So, in looking for a spokesperson for Plain Language from the Bush Administration, he seemed like a natural choice. Early this year, we approached Sec. Thompson and he agreed to champion Plain Language. I understand he will be sending a letter to all the other Cabinet Secretaries "challenging them" to join him in asking their Departments and Agencies to use Plain Language, especially in documents intended for the public because, as Sec. Thompson says, "…by presenting crucial information and services to the public in an understandable way, we will help ensure a safe and healthy America."

Since we are confident he will soon become more active in the Federal PL initiative, the PLAIN Working Group is planning a Plain Language Forum in Washington D.C. this November, and we are inviting Sec. Thompson to be the keynote speaker.

Now let me spend a few minutes on what I know best - my agency, FDA. We have an enormous impact on consumers, in fact U.S. consumers spend more than 20 cents of every dollar on products regulated by FDA – including all food (except meat and poultry), drugs, medical devices, biologics such as blood and tissues, animal drugs…even cosmetics and x-rays machines. So you can see why it's so important that the information FDA writes about these products is

understandable to industry, health professionals, policymakers, and especially to consumers.

Since the Plain Language initiative gained prominence in the US in 1998, all 3 FDA Commissioners (or Acting Commissioners) have strongly supported it. This, of course, is one of the reasons we have been successful. This holds true for all the agencies I will talk about. Without the vocal support of leadership, it's an impossible uphill battle to begin to change behavior.

Like most Federal agencies, we started by focusing on improving our regulations and guidance documents – clearly a huge challenge. While it's not the norm yet, we do have a few excellent examples including a proposed rule on bioengineered food, which was published in Jan. 2001. Our new Director of the Office of Regulations at our Center for Food has included plain language in her training plan for reg writers, and the author of the plainly written Genetically Modified Food regulation is the teacher. This gives reg writers a respected colleague to learn from, and the training has much more credibility.

We find Plain Language champions in pockets through the agency and I tend to "go where the energy is " and support them, rather than nagging the resisters. I believe those who aren't on board yet will eventually "see the light" once they read the clear, plainly written documents written by their colleagues.

I found one enthusiastic champion in our Center for Devices, Ann Hawthorne, who held a series of Brown Bag lunches for her Center's reg writers, where she covered several different PL techniques. She developed this checklist for her writers.

Plain English Checklist for Guidance Documents

___ written for the average regulatory, scientific, or clinical reader

___ organized to serve the reader's needs, not the writer's

___ uses no more than 3 subordinate levels, for example, I. A. 1.

___ uses "you" and "we"

___ uses active voice

___ uses short sections and sentences

___ contains no deadwood, e.g., redundancy, extraneous facts or details

___ written to one person, not a group

___ written with nouns in the singular, e.g., a device, a submission

___ uses the simplest tense possible

___ avoids "would" and "could"

___ uses "must" only for things required by regulation or statute

___ places words carefully (e.g., subjects and verbs are together)

___ organizes topics carefully, general to specific, things of a kind

___ uses lists instead of sentences to list three or more items

___ avoids confusing sentence constructions

As a result of these training sessions, we have seen real improvement in their documents. But I'll admit that agency-wide, the biggest improvement is often not with our regs, but with our Guidance Documents – which is OK, since they are probably read more often that the regs are, by people who need to comply with FDA rules.

Our public affairs writers nearly always do a good job, so that's not where I put my efforts. Rather, I decided to preach the benefits of being *kind to each other* with-in the FDA, and encourage folks to improve our internal documents. As Edie Schwager of the American Medical Writers Association says, "Clarity begins a t home."

In the past year or so, our Reports to Congress, our Budget documents (including responses to the Appropriations Committee – the folks who fund our agency), even our Personnel Directives are noticeably better. In fact, not only are they better, some of the directions for preparing them clearly state, "Write this in Plain English." Talk about a government fad not going away! We are doing just fine.

<u>What else is new at FDA?</u> As we move from Plain Language awareness to motivation, we've begun to use new slogans targeted to specific staff members. I've got copies for you.

- Scientists: Be clear, be quick, and make the point stick!

- Attorneys: Plain Language makes a winning case.
- Budget Analysts: Jargon is no bargain; use Plain Language.
- IT Professionals: Plain Language: Keeping the information highway clear.
- Reg Writers: Before we can regulate, let's clearly communicate. Write in Plain Language
- Public Affairs Specialists: Writing clear with less is just good press.

We have also incorporated Plain Language awards into our regular annual FDA Awards programs –so not just other writers, but all FDA staff get a chance to see plain, clear writing recognized by the Commissioner and the Center Directors.

And, since I work in FDA's Executive Secretariat, I am very pleased about our progress in making letters easier to understand and more to the point. No more 4-page scientific treatises to consumers who ask a simple question.

Other successes? Well, what has made a real difference to virtually all consumers is our new and improved food and drug labels. I'm not sure that the developers of these labels were thinking, "This is Plain Language" but the results could not have been more in keeping with Plain Language goals. You are all familiar with the food labels. Well, information on OTC drug labels has a similar look & the information is now much easier for the "intended audience" to understand.

But food labels still need to be improved – the nutrition info is fine, but allergy info is not. Some firms are still using obscure terms like *caseinate* and *whey*, which doesn't help folks who have milk allergies know what to avoid. The same is true for firms who use terms like *semolina* instead of wheat. So, this year, one of FDA's stated goals is to "develop a strategy to improve the labeling of the most common allergens…using plain English labeling."

And a recent study has pointed to the need for FDA to become more involved in Prescription drug labeling, so that's next. A recent survey, reported last month in the *Washington Post*, showed that while more than 75% of the prescription drugs that consumers receive contain some kind of information, the quality of the information is quite uneven. The report stated, "Pamphlets provided by pharmacies are often poorly written, and may be virtually illegible due to type size and format."

What's next? Once we felt we had passed the Plain Language baton from FDA Headquarters to the Centers as far as regulations, guidances, and information for the public was concerned, we decided to take on a new challenge – scientists. Think about some of the science articles you may have read over the years – or some of the journals you might have thumbed thru. For those of you who are not experts in a particular scientific discipline, how many of these articles looked intriguing enough to read? Probably not a lot. We know that scientists want to be respected by their peers and that is most often their target audience. In fact, I

heard that a scientist once bragged, “There’s not more than a dozen people in the world who can understand this article I just had published.” …and he was proud of this!

But we believe scientists, especially those funded by the government, have an obligation to broaden their audience and -- at a minimum – be sure that scientists in other disciplines, and policymakers who control their funding, understand the work being done.

We have begun to work with scientists and science writers internally and externally. We began by encouraging better science posters, rather than science articles.

Judging of poster – criteria for a winner

First and foremost, a good poster must be **clear**, **concise**, **important**, **relevant, and eye-catching**

Clear --

- The "bottom line" should be unambiguous. The Title and the conclusion should say something such as "Chemical A kills people at three times the normal dosage", as opposed to "The effects of chemical A on human subjects".
- I’ve also seen postered titled as " the effects of …", when in fact the poster dealt with the "Lack of effects" or "no effects".
- Have no more than 3 major conclusions. The fewer the better.
- Leave out extraneous information. Lengthy details on "methods and materials" can be obtained later from the authors, if needed.

Concise --

- A poster may be the most important scientific work in a decade, but if the presentation is not concise, the judges can not evaluate it properly.
- The most common mistake is to present too much information, too much data, and too many words. A poster is not a written scientific article. A judge, or a fellow scientist, does not have an hour or two to read a lengthy dissertation.
- The message should be delivered in large type. Use pictures, bullets, arrows and other devices to deliver the message easily.

Important --

- Give a short, very clear statement of the importance of your work
- Examples:
- This is the <u>first</u> time that this "effect’ has been seen
- This method is <u>ten times faster</u> than the previous method
- This "effect" shows that consumers are in danger of …

- This method uses far fewer test animals than…

Relevant --

- Show relevance to FDA's mission.
- Don't belabor the relevance, but do show it.
- If appropriate, show usefulness to industry submissions, to field testing, to standards development, etc.
- Relevance and importance are closely related, so don't "beat your brains out" trying to decide the difference between the two criteria.

Eye-catching --

- Yes, the pretty poster often wins.
- You must attract the judges. A pretty poster does that.
- Posters don't have to be hi-tech. A simple, clean, attractive poster can accomplish the same mission of getting someone's attention.
- The most important "eye catcher" is the title. If you can get your "bottom line" across in the title, you're half way toward winning.
- The second most important "eye catcher" is the conclusion.
- If I've read the title and the conclusion and I'm still lost, then your poster is in serious trouble, at least from my perspective as a judge.

We developed these guidelines and every month we display a new, understandable poster in the prestigious Commissioner's Conference room.

We have also worked with our fundamental scientists at National Center for Toxicological Research – and they now submit understandable reports weekly – much improved from the techno-babble of years past. Recently, I made a concession to our scientists and call it "clear communication" instead of Plain Language - since they are still disdainful of the term "Plain Language." As a result, I have made progress getting *clear communication* incorporated into the 2003 FDA Science Forum.

And just last month, I was asked to give a Plain Language look to FDA's draft White Paper on Proteomics – a new and promising field in genetic research based on what we have learned since the human genome has been mapped & which could lead to huge advances in diagnosing and treating disease (including personalized medicine). It's the "I was asked" part that is so important. It shows that FDA scientists are beginning to realize the need to communicate new and important breakthroughs to non-scientific audiences. We are spreading the message I first heard from Julie Ann Miller, editor of ScienceNews:

Don't underestimate your readers' intelligence, but don't overestimate their knowledge of a particular field. When writing about science, don't simplify the science, simplify the writing.

Outside the government, my colleague Lily Whiteman and I have spoken to several scientific audiences over the past 2 years, including AAAS and the Council of Science Editors, to encourage editors to insist on clear science articles. And the American Medical Writers Assoc. has just accepted an article describing the need for clear science writing, which will publish no later than next March.

Now, I want to switch gears a bit and talk about Sept. 11**.** Like many of you, all of us in the US, especially in the Federal government, have a story about how the events of 9/11 changed our lives. As some of you know, FDA headquarters is located in the Washington DC suburbs. We felt up-close-and-personal to the events of that day. In fact, the mother of an FDA employee was on the plane that crashed into the Pentagon.

One thing that we learned again in the days following the terrorist attacks is the overwhelming need people have for clear information, especially in times like this.

As you might imagine, FDA was also very involved in the aftermath (along with other HHS agencies - NIH & CDC) especially in dealing with the anthrax situation. As the anthrax threat unfolded last fall, some of our colleagues were in the unenviable situation of having to work with and share information that later turned out to be out-of-date, incomplete, or less than accurate. So, first we need good, reliable information—then we need to ensure that it's clear and understandable.

FDA was directly involved with anthrax threats last October, when 5 of FDA's buildings in the DC-area tested *presumptive positive* for anthrax in the mailrooms. Now, we have a lot of smart people at FDA – including scientists, attorneys, and health professionals. But even after All Hands e-mails were sent to staff from the acting Commissioner explaining what was found and the test results, there was still wide-spread confusion and anxiety over the meaning of *presumptive positive*. The written word wasn't clear enough, so we ended up having a 2-hour video-conference where the Acting Commissioner and the Director of FDA's Office of Counter-terrorism explained in great detail exactly what it meant and what the risks were. We got lucky – all confirmatory tests came back negative –but it was a long week waiting for those results, and anxiety levels were probably higher than they needed to be.

So, Plain Language – Could we have done a better job in communicating this information from the beginning to better allay employee concerns? Probably. I think too often it's human nature to want to "Get it out fast" before we "Get it out

right." But no one cleared these All Hands e-mails on anthrax with the "Plain Language police."

Many days I think I need to hand out my favorite PL quote as a bumper sticker (or a mouse pad) "One should aim not at being possible to understand, but at being impossible to misunderstand."

The good news is that we learned. This past 4th of July, there were many threats to the Nation's capital – what a perfect opportunity for another terrorist strike. One concern was the fear of a "dirty bomb" that could release radioactive iodine into the atmosphere. If this happened, FDA wanted consumers to know how to protect their children. Many consumers were aware that potassium iodide can protect people against radiation poisoning – but at that time the only form of that drug approved was a tablet in a dosage for adults, NOT for children.

So, FDA scientists looked at various food and drinks that might disguise the unpleasant taste of potassium iodide well enough for children & infants to accept it, in the event the adult pills had to be broken down for them in an emergency. On July 2, FDA was ready to make this information available on the FDA website. But, while the information was all very accurate, it wasn't very easy to understand – especially if you were a frantic parent whose child had been exposed to a harmful substance. So, we did a quick PL rewrite – getting rid of acronyms, adding white space and bullets, and developing an "If-then" table. In less that a few hours, the scientists accepted our changes and even made a few more themselves as new information became available. The resulting website page was up on July 4, and WAS easy to understand. Here is an excerpt:

Home Preparation Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Small Children

PREPARATION FOR 130 MG POTASSIUM IODIDE TABLET

1. Grinding the potassium iodide tablet into powder

- Put **one** 130mg potassium iodide tablet into a small bowl and grind it into a fine powder using the back of the metal teaspoon against the inside of the bowl. The powder should not have any large pieces.

2. Mixing potassium iodide powder into a drink

- Add four teaspoonfuls of water to the potassium iodide powder in the small bowl. Use a spoon to mix them together until the potassium iodide powder is dissolved in the water.

3. Mix drink of choice with potassium iodide powder and water solution

- Add four teaspoonfuls of drink to the potassium iodide powder and water mixture described in Step 2.

If your child is:	Give your child this amount of Potassium Iodide (KI) *	Which is
An adolescent between 12 and 18 years old**	4 **teaspoonfuls** (NOT tablespoonfuls)	65 mg of potassium iodide (KI)
Between 4 and 12 years old	4 **teaspoonfuls** (NOT tablespoonfuls)	65 mg of potassium iodide (KI)
Over 1 month through 3 years	2 **teaspoonfuls** (NOT tablespoonfuls)	32.5 mg of potassium iodide (KI)
An infant from birth through 1 month	1 **teaspoonful** (NOT a tablespoonful)	16.25 mg of potassium iodide (KI)

* This is the amount to give your child for **one** dose. You should give your child one dose each day.

Fortunately, so far, we haven't needed to send folks there. Even better news is that a child's dosage (age 4-18) has been approved and will be available in a few weeks.

National Institutes of Health – FDA's sister-agency, NIH, is another strong force in making sure that the public receives plain & clear health-related information. Both former Acting NIH Director, Ruth Kirschstein, who launched NIH's active Plain Language program, and the new Director, Elias Zerhouni, enthusiastically support this initiative. NIH is so large, they convened a formal Plain Language Coordinating Committee with a representative from every Institute, Center and Office within NIH.

The Coordinating Committee does a great job spreading the Plain Language message to all of NIH's thousands of employees. They decided to have a separate Plain Language award ceremony every year to recognize the authors of easy-to-understand NIH pubs.

The first year, they had 100 submissions, and last year over 150. These ceremonies feature local media personalities. The first year, Michael Dirda, well-known *Washington Post* book critic gave the keynote speech. This year, Susan Dentzer from the NewsHour with Jim Lehrer did. Taking a page from the governments Homeland Security Alert system, she proposed a color-coded Plain Language Alert System for judging clear writing. Let me share it with you:

- Blue Alert Hifalutin' language ahead
  Soaring over everybody's heads, like the sky
- **Black** Alert Stultifying prose – can't see your way thru to the end of the tunnel
- Brown Alert – Obfuscatory: lots of you-know-what to wade through
- Purple Alert – Too many ruffles & flourishes, as in purple prose
- All Clear Language Alert – Clear…as a bell. Utterly transparent, like a cool mountain stream. Really beautiful!

In conclusion -- While some Plan Language champions are disappointed that there is no longer an official U.S. Government-wide push for plain language, the agencies that took the initiative to heart a few years ago are gratified to realize that we don't necessarily need a Call to Action to come from the very highest levels.

Once we published a number of plainly written documents, others in the Federal government recognized that we were doing a good job in getting information to our audiences. The Plain Language style is truly taking on a life of its own. And while we'd welcome more official support, we are making progress in the meantime.

I hope you'll join me tomorrow for the Plenary Session on Plain Language Around the World, where you'll hear about Plain Language progress in other U.S. agencies.

Thank you.

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Joanne Locke has been Plain Language Coordinator of the U.S. Food and Drug Administration (FDA) since 1998. This conference is a return engagement for Joanne, who represented the US government's Plain English Network at the 2000 Plain Language in Progress Conference. Since then, she has spoken about plain language in science writing at the annual meetings of the Council of Science Editors (2001) and the American Association for the Advancement of Science (2002).