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November 19, 2003

Dr. Mark McClellan
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No. 2003P-0274/CP1 – Response to submission of Sept. 9, 2003, from Ms. Fran Visco regarding "Tier 1 Initial Approval"

Dear Commissioner McClellan:

The purpose of this letter is to respond to a recent submission to the docket from Ms. Fran Visco, President of the National Breast Cancer Coalition ("the NBCC"), referred to herein as "the Visco letter." Please consider this response a submittal to the docket for the referenced Citizen's Petition.

The Visco letter presents a number of arguments in opposition to the petition. We submit that the positions in the Visco letter do not serve the best interests of most Americans suffering from life-threatening diseases with unmet needs.

The letter states that NBCC is "now more than 600 organizations and 60,000 individual members strong;" but it gives no indication of how many of those organizations or individuals support the positions in the letter. The only signature on the letter is Ms. Visco's, and it may be that the positions and arguments in the letter represent those of Ms. Visco alone. With regard to the sweeping positions in the letter – for example, its apparent opposition to compassionate use programs in general, including already-existing ones – it seems very unlikely that the letter represents the views of any significant number of individuals or organizations.

A general flaw in the Visco letter – and in other such submissions opposing the Citizen Petition – is its assumption that nothing is known about the safety and efficacy of an investigational drug until the day it receives FDA approval. In truth, as you are aware, evidence of safety and effectiveness for an investigational drug are often known to patients, physicians and others long before the FDA completes its process and makes a decision. For example, two drugs that appear headed for approval right now – but that are

legally "investigational" and therefore largely unavailable in the United States – are Avastin and Erbitux, both for colon cancer. Erbitux was recently approved in Switzerland, making it yet another safe and effective drug for colon cancer made available to patients elsewhere in the world before in the United States. The effect of the FDA's hardwired delays in issuing approval of drugs for which testing is complete is devastating to those that run out of time waiting for the process to run its course. Colon cancer patients in the United States are losing an average of more than eight months of life expectancy right now as they wait for and are denied access to Avastin and Erbitux.

Excerpts from the Visco letter are presented below in italics followed by our detailed responses.

Excerpt No. 1
Since NBCC'S beginning, the concept of evidence-based medicine has been fundamental to the Coalition. We need to know what works for women with and at risk for breast cancer, and we want all women to have access to what works. Women with breast cancer should not be given false hope by treatments that are unproven. Interventions must be based on the best possible science available, and the best way to achieve that is through well-designed clinical trials. We continue to help develop policies to increase the number of quality clinical trials, and bring the perspective of breast cancer advocates to the design of trials.

Response
The Visco letter is unequivocal in stating that the positions in the letter are intended to serve the best interests of "women with breast cancer," implying that women with breast cancer are a monolithic group of patients that uniformly agree with Ms. Visco's general opposition to investigational drug access outside clinical trials – an unsupportable position. The Visco letter makes no distinction, for example, between women with curable breast cancer and those with incurable forms of the disease, implying that all members of her organization would agree with and support her letter – again an inherently insupportable assumption.

The Abigail Alliance clearly does not agree with the statement that allowing patients access to investigational drugs creates "false hope" when it is an undeniable fact that a significant number of patients do benefit from access to investigational drugs both inside and outside of clinical trials. Congress and the FDA also support the concept of allowing patient access to investigational drugs and have created several mechanisms that can be used by sponsors to implement access programs.

We applaud Ms. Visco's and NBCC's support of good science and well-designed clinical trials. The Abigail Alliance and its counsel, the Washington Legal Foundation (WLF), share these precepts and have included strong measures (in fact stronger than those included in current regulations) to ensure that good science and well-designed clinical

trials will remain the focus of our nation's efforts to discover and develop better treatments.

Excerpt No. 2
The Citizen Petition essentially requests that the FDA relax its regulatory standards for evidence of drug efficacy. The Abigail Alliance seeks to amend the Food, Drug and Cosmetic Act (21 C.F.R. 312) so that patients with life threatening diseases and unmet treatment needs would gain access to investigational drugs at an earlier stage in the drug development process than ever before: after a new "Tier 1 Initial Approval." This amendment would effectively allow access to unapproved new drugs outside of a clinical trial, commonly known as "compassionate use," before Phase II. Currently, compassionate use is allowed by the FDA in certain circumstances during Phase III trials, or at the earliest, in certain cases of immediately life-threatening diseases, during Phase II. However, compassionate use is never allowed before Phase II.

Response
The petition does not seek changes to the Food, Drug and Cosmetic Act ("the FD&C Act"). The petition does include a detailed legal analysis concluding that no amendments to the FD&C Act are needed to implement Tier 1 Initial Approval. The petition proposes changes to the Code of Federal Regulations (CFR) that can be made administratively by the FDA.

The Visco letter also incorrectly identifies the earliest point in the drug development process when Tier 1 approval would be an option. Tier 1 Initial approval could not be granted during Phase I as implied in the Visco letter. It is very clearly explained in the petition and the original Tier 1 Initial Approval concept document that a sponsor could not apply for Tier 1 Initial Approval until after completion of a Phase I trial resulting in a defined level of evidence for safety and effectiveness that is, among other requirements, sufficient to support conduct of a Phase II clinical trial. In fact, the earliest possible point in the process for issuance of a Tier 1 approval would be during Phase II. In this regard, Tier 1 is not materially different from the existing regulations governing access to investigational drugs.

Excerpt No. 3
The Abigail Alliance also seeks an exception for sponsors of drugs under Tier 1 Approval that would allow them to charge a price higher than cost. Most concerning, is the Abigail Alliance's call for an amendment that would allow limited marketing based on "evidence of efficacy from case history data on a modest number of patients," where [s]tatistically significant support will not be required." The Abigail Alliance's rationale for these changes is that they will meet the needs of patients with life-threatening disease who are without treatment options. Their legal basis for these changes is that the concepts of different phases in a trial, the use of double-blind studies, and particular levels of

statistical power are not mandated by statute. NBCC believes that all these amendments would severely weaken the integrity of the FDA as a scientific body that bases its approval on evidence, and be detrimental to patients.

Response
It appears that Ms. Visco does not dispute the legal opinions advanced in the petition. Instead, NBCC advances "beliefs" that implementing the limited marketing and approval standards incorporated into Tier 1 would somehow weaken the integrity of the FDA and cause detriment to patients, but offers no logical or factual support for these beliefs. Tier 1 Initial Approval would in fact strengthen the FDA as a regulatory agency, allowing it to respond to the needs of thousands of Americans the agency is not now empowered to serve. The real detriment to patients stems from the FDA's inability to respond to their legitimate needs.

Excerpt No. 4
Public policy should discourage access to investigational drugs outside of clinical trials. Investigational treatments made outside of clinical trials have the potential to undermine the clinical trials system. There is little incentive for a patient to participate in a clinical trial if she can obtain the investigational drug outside of the trial. This makes trial accrual difficult, and may significantly undermine the ability of the investigators to determine the efficacy and safety of the intervention. That was certainly the case with bone marrow transplant for breast cancer – because it was so widely available outside of clinical trials it was extremely difficult to accrue patients to trials, and it took many years longer than it should have to learn that the high-risk and expensive procedure provides no benefit to women with breast cancer.

Response
This across-the-board opposition to compassionate use and similar programs is reactionary and inconsistent with existing consensus, regulations, and policy. The FDA's regulations and policy already allow access to investigational drugs outside of clinical trials. Congress passed legislation creating the authorities that allow it, many patient advocacy groups actively encourage sponsors to provide their drugs to patients outside clinical trials, some sponsors do it on a relatively small scale, and some patients clearly benefit. The practice has not undermined the clinical trials system, and the FDA has clearly signaled its support of the concept by developing and implementing regulations and policy to implement Congress' direction. The FDA has routinely approved access to investigational drugs when requested, but its policies have served to disincentivize sponsors from participating at a level that would adequately serve the legitimate needs of patients.

The belief that Tier 1 will undermine the clinical trials system is unfounded and is addressed in detail in our response to the "Mayer letter," already submitted to the docket. The petition proposes language to support continued enrollment in clinical trials and will

likely result in faster and more efficient enrollment of trials. Tier 1 programs also could be administered by sponsors in a manner that guarantees all patients receiving a Tier 1 drug are first considered for enrollment in a trial.

The comment regarding bone marrow transplants is an incomplete summary of a problem that emerged as a result of clinical trial designs that were apparently perceived by patients and their physicians as less desirable options when compared to high-dose chemotherapy and a bone marrow transplant that was available outside randomized clinical trials. Eventually, clinical trials showed that the high-dose chemotherapy, which necessitated a bone marrow transplant as a result of the chemotherapy, was not more effective than standard chemotherapy, but was significantly more dangerous. There is no connection at all between our Tier 1 proposal and the cited example. No sponsor would have applied for a Tier 1 or other form of approval to market the high dose chemotherapy regimen because no approval was needed. Some patients apparently abandoned or avoided some clinical trials in favor of an available treatment that they perceived (at the time) to be a better option than a randomized trial in which they might not get the treatment of their choice. The situation was the result of the very real world of inadequate cancer treatments and the challenges associated with enrolling randomized, blinded trials.

The scenario described in the excerpt is far less likely to occur with a Tier 1 drug than with drugs that have received accelerated or full approval because of the controls built into the Tier 1 restricted marketing provisions. If a patient qualifies for a trial, they would not be eligible for the drug through Tier 1 marketing until they are taken off study (i.e., no longer eligible for the trial). If a patient chooses to avoid or leave a trial of their own accord to pursue some other treatment, that must remain their choice.

Excerpt No. 5
Investigational drugs are by definition unproven; even the most promising data in earlier stages of trials do not hold up. Further, there may be significant safety issues that do not emerge until well into a Phase II trial. For example, the cardiotoxicity of Herceptin was not apparent in the phase II data, but emerged in the much larger phase III trials.

Response
Investigational drugs are "investigational" by regulatory definition, not according to the level of evidence available regarding the scientifically-proven safety and effectiveness of a drug or device. A drug is "investigational" one day and "approved" the next when the FDA issues an approval letter. The data used to support the approval decision existed in every case for many months while the sponsor assembled its application and the FDA conducted its review. In most cases at least some of the data existed for years prior to the change in regulatory status of the drug.

In fact, the FDA is by virtue of its own regulations and policies almost always the last entity to learn about the performance an "investigational" drug. The regulations require (and the agency insists) that all the data be organized into an application, or segments of

an application, before the agency will even begin to look at it. The FDA does not pro-actively pursue updates on promising investigational drugs and never makes decisions on approval without a complete application on its desk. The physicians administering the investigational drug, the patients, and the sponsors know a great deal about the safety and efficacy of an investigational drug long before the FDA agrees to "learn" the same things.

If recent rejections of drugs by the FDA in a given year were adjusted to reflect the fact that the rejected drugs were later approved, a calculation of the success rate of new drugs would be higher and more accurate.

Herceptin is an excellent example of a drug that has benefited thousands of cancer patients even though a relatively small number of patients suffer cardiotoxicity effects from the drug. Discovery of the cardiotoxicity problem prompted appropriate screening of patients prior to treatment, and monitoring during treatment, to minimize the risk. The FDA correctly did not decide to withhold or withdraw approval of the drug. As is the case with almost all approved cancer drugs, Herceptin can cause serious side effects in some patients, but the potential for benefit outweighs the risk when compared to the high risk of death posed by the disease.

Excerpt No. 6.
Any access to investigational drugs outside of a clinical trial should be in the context of expanded access protocols only, in which distribution of the investigational therapy is fair and data is captured that will add to the scientific base of knowledge about the intervention. Expanded access should not be the norm, rather a protocol may be allowed in particular circumstances only for individuals that do not meet the eligibility requirements of a clinical trial. If an expanded access program is allowed, access to the drug must be fairly and blindly allocated and all individuals who apply to the program must be followed, and their data reported to the trial sponsor. Expanded access should not be allowed until there is safety data available from a completed Phase II trial of the drug, including data that provides some basis for determining that the drug may be efficacious.

Response
The intent of "expanded access" is to make the drug available to more people than can get it in clinical trials. While collecting more safety data or even more evidence of efficacy to supplement data from clinical trials should be an option for sponsors, it should not be a requirement for sponsors to provide access to investigational drugs outside of a trial. The FDA has indicated their concurrence with this model by approving expanded access protocols, Single-Patient INDs, and open label trials that generally require only adverse event reporting. Converting "expanded access" into "expanded clinical trials" is economically impracticable, unnecessary from a regulatory standpoint, and would have the effect of "killing" sponsor interest in providing any access to their drugs outside trials. Sponsors already attempt to design their clinical trials, often in consultation with

the FDA, to produce a data set sufficient for the FDA's decision-making process. The cost of clinical trials can reach hundreds of millions of dollars before an application can be successfully submitted for accelerated or full approval. An expectation that sponsors should be asked to incur even greater costs to collect data not required by the FDA to make decisions is inherently unworkable and if forced on sponsors, will simply serve as a further disincentive to provide their investigational drugs to anyone outside clinical trials. The effect on patients would be decidedly negative.

Tier 1 creates incentives for the sponsors to manufacture and provide their investigational drugs to patients that are not eligible for clinical trials, and will actually create a better environment for achieving what the Visco letter purports to seek - more safety data collection in the form of adverse event reports from a larger patient population. The concept that investigational drugs must be provided "fairly and blindly" has arisen from the reality that supplies of drugs in existing expanded access programs have been less than needed to respond to the demand. One of the benefits of Tier 1 Initial Approval is that sufficient supplies of drugs would be made available to meet the demand, thus eliminating the need for controversial practices like lotteries that serve only to extend the wait and increase the stress level of already stressed patients and their families. Finally, Tier 1 approval would be available only for drugs with clinical trial data that meets the defined standard of safety and efficacy specified for the approval, which can emerge from a Phase I trial or before completion of a Phase II trial.

Excerpt No. 7
It seems compassionate to argue that investigational therapies should be available to seriously ill individuals for whom there is no known effective treatment. An individual may support early access to unproven drugs based on a tragic and emotional personal experience, but policy should not be based on emotion alone. There are significant negative consequences for all patients. The potential risk and harm involved in exposing patients to therapies that have no evidence to support their efficacy is far greater than any perceived benefit.

Response
It is compassionate **and reasonable** to argue that investigational therapies should be available to seriously ill individuals for whom there is no **approved** effective treatment, but for which there are "investigational" drugs that have been shown to be safe and potentially effective for some patients when compared to the certain risk of death posed by their disease. This is an inherently correct policy decision that was made by Congress and the FDA years ago, and affirmed in the FDA Modernization Act in 1997. Unfortunately the programs put in place by the FDA to implement the laws and intent of Congress have fallen far short of meeting the legitimate need of patients.

The implication that the Abigail Alliance is acting "based on a tragic and emotional personal experience" is unfortunate not only because it is condescending and insulting, but because it is uninformed.

First, the people that are best informed with regard to the shortcomings of our system are those who have directly experienced the negative effects of those shortcomings. Their observations and ideas should not be dismissed because the experience has been frustrating, or because the death of a loved one is an inherently emotional experience. We completely reject the concept that those who are failed by our system are somehow intellectually incapacitated by their experiences. Excluding the views and ideas of people who have directly observed the failures of our system is a recipe for continuing those failures and their inexorable cost in terms of lives lost.

Second, we know that the time for change has come because many supporters of the Abigail Alliance (consisting of patients with many different types of cancer and other life-threatening diseases, their caregivers, and surviving family members) have directly experienced the benefits of gaining access to investigational drugs in the form of longer, better lives. They also are experiencing the tragedies that invariably occur when access is denied or unreasonably delayed, an outcome that is now far too common and a direct result of failed regulatory policies.

The risks from investigational drugs that have demonstrated some evidence of safety and efficacy are not somehow automatically greater than the risks posed by a terminal disease, and the potential for benefit often outweighs the risk posed by an investigational drug. No one objects if a patient facing certain death elects to be retreated with an approved drug he/she has already failed with little chance of benefit, even given the risks associated with taking that drug. Most physicians and informed patients agree that trying an investigational drug is a better option under those circumstances, and many attempt to do so by trying to get the drug they seek in clinical trials, or outside of a clinical trial. The argument advanced in the Visco letter that the risk posed by investigational drugs outweighs the potential for benefit is simply wrong, and in any case is not a decision for a "patient advocate" to make on behalf of the patients themselves. Investigational drugs are not available to most patients that seek them for reasons that have little to do with risk, evidence of safety and effectiveness, or potential detirmental effects to clinical research. The patients are simply being abandoned to die as a result of ineffective FDA policy.

Excerpt No. 8

There are all too few truly effective treatments for most types of cancer. While the public is inundated with information about cancer "breakthroughs" and news of promising new drugs, the reality is that most drugs result in incremental improvement. The research process seems agonizingly slow for those who have run out of treatment options. Pharmaceutical companies, scientists and the media each bear a responsibility for creating unreasonable expectations about unproven drugs. This has created a climate

where many patients mistakenly believe that access to an investigational drug is their last hope, when most often it is a false hope.

Response

We agree that there are too few effective treatments for most types of cancer, a clear argument for earlier and wider access to new treatments. The rest of the excerpt is a selective denial of reality as we know it in the United States. The public is inundated with information about everything, including cancer, and when that information is provided in the responsible lay and scientific press, their sole responsibility is to report that information accurately. It is not their responsibility to control "expectations." The public has a right to information that allows them to judge whether their regulatory agencies are doing a good job, and ill Americans and their physicians should have access to accurate information regarding how and where they might best obtain potentially effective treatments.

Similarly, the pharmaceutical companies and scientists bear a responsibility only to report the information accurately. Accurate information, even if it is preliminary, should not be withheld from those who need it for the purpose of controlling "expectations." If the information is accurate, even though preliminary, then an expectation that a new treatment might provide benefit is reasonable, and is precisely the kind of information used by sponsors and the FDA to move to the next phase of testing in which a larger group of living human beings will be asked to accept the risk of being given the drug (or not being given the drug).

The repeated use of the term "false hope" in the Visco letter is a meaningless and unsupported "buzz word," especially given the fact that some investigational drugs do work and are eventually approved. There is nothing "false" about gaining benefit from an investigational drug. The position presented twice in the Visco letter that investigational drugs offer only "false hope" is inherently wrong. If access to investigational drugs presented only "false hope" there would never be another approved drug because none would work, and there would no reason at all for patients to enroll in clinical trials because they would represent only "false hope" for them and all future patients. The FDA should reject the "false hope" argument as it is presented in the Visco letter as being completely without merit.

The research process is sometimes slow, but the true scientific research happens mostly in laboratories before the start of clinical trials, and after approval when a drug is more widely available to scientists for conducting research. The drug development and approval process, which consists primarily of human clinical trials is as much compliance with regulatory requirements as it is "research." Although it is a type of research, it is generally termed "translation" because it is a regulated set of steps mandated by the FDA for approval; and it really is agonizingly **and unnecessarily** slow. It is a fact that many Americans die while they wait for the process to run its course, denied access to the only drugs with any potential to help them. The Commissioner of the FDA, the Director of the

National Institutes of Health, and the Director of the National Cancer Institute have all been informing the public in recent months that our system for translating drugs from the laboratories to the clinics is in need of a major overhaul to speed up the process. Unfortunately, the overhaul they are descibing is going to take many years and may yield little in the way of real results for patients. Now is not the time for patient advocates or the FDA to dig in and defend the status quo. This is a time of tremendous opportunity that can only be realized through effective change, and delaying that change will have very real and deadly effects on thousands of people.

The accelerating success of our medical research has created a "climate" where many patients with no approved options correctly believe that access to an investigational drug poses a real chance to extend, improve, or even save their lives. The improvements in treatment are in most cases incremental when looked at statistically, but for the relatively few patients that gained access to Herceptin, Gleevec, Iressa, Velcade, or Eloxatin in expanded access programs or clinical trials before they were approved, the improvements for some were much more than incremental; they lived longer, better lives. The same is true for the small number of patients who are now gaining access to "investigational" drugs like Avastin, Erbitux and Revamid; some are realizing real benefit in the form of longer, better lives. Some will, as a result, live long enough to gain access to yet another new drug, and will succeed in extending their lives even more.

Excerpt No. 9

It is compelling to argue that there is little harm in making an investigational therapy available to a seriously ill individual for whom there is no effective therapy, if someone is willing to pay for it. This argument does not hold upon scrutiny. To follow this to its logical conclusion completely undermines research and the concept of evidence based care. Where would the line be drawn? It would mean that any individual should have access to any drug, as long as she is willing to pay for it.

Response

It is indeed compelling to argue for greater access to new drugs with some evidence of safety and efficacy for terminal diseases because it is reasonable, and an inherently personal judgment that should rightfully be left to a patient and his/her physician. Ms. Visco and the FDA should be aware based on a careful reading of the petition that Tier 1 would make a drug that has received restricted approval available to a patient with no **approved** options and no reasonable access to the drug by other means. Furthermore, the drug will have been approved for such use only after a defined and appropriate standard of safety and efficacy for that patient (taking in to consideration the risk posed by the disease) has been demonstrated. The claim that Tier 1 would undermine clinical research has been extensively addressed in this and earlier submittals and is simply unfounded. Finally, Tier 1 is clearly not an uncontrolled program with no FDA input or control, as suggested in the excerpt, and would not result in the stated conclusion which is neither logical nor likely under the provisions of Tier 1. Where the lines are drawn, the

requirements for Tier 1 approval, and the conditions for gaining access to Tier 1 drugs are clearly explained in the petition.

Excerpt No. 10

Single patient INDs or INDs with small numbers of patients under Tier 1 approval raise serious issues of fairness. Granting access to investigational drugs with Tier 1 approval to patients who can pay for them at a price higher than cost makes this proposed system highly inequitable. Patients with access to them would likely be very knowledgable, well-connected, and financially privileged. They would have access to physicians who have the ability to develop a protocol for them, and are willing and able to implement it. This is not the case for most cancer patients. Resources devoted to fighting cancer should be based on the best evidence available. The off-trial process involves a great deal of time and expense for clinicians, regulators and investigators, with very little likelihood of benefit to the patient, or to accumulation of knowledge about the intervention in question, that would benefit all.

Response

The comments in the above excerpt are based on a fundamental misunderstanding of the Tier 1 Initial Approval concept. Tier 1 is an approval, not a Single-Patient IND, or Treatment IND, and would not require separate applications from physicians to the FDA. The concept that patients or physicians would need "connections" or "special knowledge" would certainly not apply to gaining access to a Tier 1 approved drug. Physicians would not have to develop separate protocols for their patients, but would have to fill out a few forms at the beginning of treatment, and probably from time to time during treatment. The only comments in the excerpt that would apply to Tier 1 are that some patients would have to bear some or all of the cost of the drug, and physicians would have to be willing to report adverse events to the sponsor and/or the FDA. Tier 1 drugs would not require major investments in time or expense for clinicians, regulators or investigators because Tier 1 is a restricted approval, not a clinical trial or compassionate use IND.

Closing Comment

The Visco letter suggests that its author is interested only in rolling back the status quo rather than attempting to fully understand the problems with our system and participating in the search for solutions. The Abigail Alliance and WLF have focused considerable efforts on understanding the problems with our system **and proposing solutions**. The staunch positions in the Visco letter against compassionate use in general are outside the mainstream of current thinking and regulatory practice. The concept that nothing can or should be done to better serve patients facing certain death from their diseases, or that they should be systematically denied access to potentially effective therapies as a direct result of the ineffective policies of their own government, are indefensible positions.

We also respectfuly submit that the content of the Visco letter is based on an incomplete and incorrect understanding of the Tier 1 Initial Approval concept and the petition. Ms. Visco has presented no information relevant to the FDA's consideration of the petition.

The Abigail Alliance and WLF have repeatedly requested a dialogue on the Tier 1 Initial Approval concept and the petition, and have clearly stated as part of those requests that our goal is to work with the agency, patient advocates on both sides of the issue, and other stakeholders to build a consensus on how to implement new and more effective policies governing access to investigational drugs. We have repeatedly informed the agency that we are willing to consider our Tier 1 Initial Approval concept a framework for discussion in a such a forum. It remains the only comprehensive and workable proposal that we are aware of for addressing the abandonment of hundreds of thousands of sick Americans by our system each year. The FDA's continuing failure to act in any material manner to address the massive and deadly problem described in our petition represents an abdication of the FDA's mission to protect and promote the public health.

Sincerely,

Abigail Alliance for Better Access to Developmental Drugs

Steven Walker
Advisor on Regulatory and FDA Issues

Frank Burroughs
President

cc: Ms. Fran Visco, NBCC