



April 9, 2012

The Honorable Tom Harkin
Chairman
United States Senate
Senate Committee on Health, Education
Labor and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Mike Enzi
Ranking Member
United States Senate
Senate Committee on Health, Education
Labor and Pensions
835 Hart Senate Office Building
Washington, D.C. 20510

Member Organizations

*American Association
for Cancer Research*

*American Cancer Society
Cancer Action Network*

*American Childhood
Cancer Organization*

*American College
of Radiology*

*American Society for
Therapeutic Radiology
and Oncology*

*American Society of
Clinical Oncology*

*American Society
of Hematology*

*Association of American
Cancer Institutes*

*Coalition of Cancer
Cooperative Groups*

*CureSearch National
Childhood Cancer Foundation*

Friends of Cancer Research

*International Cancer
Advocacy Network*

International Myeloma Foundation

Kidney Cancer Association

*The Leukemia and
Lymphoma Society*

*The Lustgarten Foundation for
Pancreatic Cancer Research*

Melanoma Research Alliance

*Pancreatic Cancer Action Network
PanCAN*

Prevent Cancer Foundation

Prostate Cancer Foundation

*The Society of
Gynecologic Oncology*

*The V Foundation for
Cancer Research*

Dear Chairman Harkin and Ranking Member Enzi:

The National Coalition for Cancer Research (NCCR) is a nonprofit alliance of 23 national cancer research, cancer care and patient organizations representing cancer patients and survivors; children with cancer and their families; cancer researchers, nurses and physicians; and cancer hospitals, centers, clinics and specialized research institutions. The organization directs its efforts at making widely known the value of cancer research and the major contributions the National Cancer Program has made to the biomedical sciences and related fields to contribute to the reduction of cancer incidence, morbidity and death, and issues faced by cancer survivors.

We commend the Working Group of the Senate Committee on Health, Education, Labor and Pensions for its development of draft bipartisan legislation designed to address shortages of drugs that are critical for cancer research and treatment. We strongly believe a system of early notification regarding a drug discontinuance, or the interruption of a drug manufacturing process that could lead to a shortage of that drug, would be extremely beneficial in order for federal Agencies to take action to eliminate or mitigate current and future drug shortages. The Discussion Draft provides a meaningful and thoughtful approach to implementing such a system. Furthermore, we are supportive of the establishment of a Task Force to recommend strategies to mitigate drug shortages and to develop a strategic plan to ensure that drug shortages are taken into account when the Secretary initiates a regulatory action that could precipitate or exacerbate an existing drug shortage.

As noted in the testimony NCCR provided to the committee for its December 15, 2011 hearing, "Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions," the shortage of certain cancer drugs is not just affecting patients currently undergoing treatment, but it is also having a significant negative impact on current and future cancer clinical trials. These drug shortages have resulted in important cancer clinical trials being delayed, suspended and/or halting the accrual of new patients into them. Halting or delaying a cancer clinical trial wastes the investment made in the development of a treatment, data management and the time investment by patients and clinical scientists participating in the study and causes the loss of valuable information. We believe it is imperative the legislation address the critical research aspect of drug shortages.

Recommendations

After careful review of the Discussion Draft provided by the committee, NCCR is pleased to respectfully provide the following recommendations which we believe could strengthen the draft legislation.

Reduction in Notification Period – We respectfully suggest the elimination of subsection (D) – “Continuation of the manufacturing for the 6-month period would cause substantial economic hardship for the manufacturer.” The term “economic hardship” is vague and could be interpreted differently by different manufacturers. Furthermore, this reduction in the notification period would be extremely harmful if a manufacturer is the sole-source manufacturer of a life-supporting or life-sustaining drug.

Expedited Inspections and Reviews – NCCR commends the Working Group for the inclusion of provisions which provide for expedited review of a supplement to a new or abbreviated drug application when doing so could help mitigate or prevent a drug shortage. We also support efforts to expedite the inspection by the US Food and Drug Administration of an establishment when doing so could mitigate or prevent drug shortages.

Enforcement - Given the importance and magnitude of drug shortages on cancer research and treatment, we believe a strong enforcement provision is warranted. We respectfully request that language be included in the final legislation that instructs the Secretary to promulgate regulations establishing a schedule of civil monetary penalties for failure to submit a required notification.

Task Force – We commend the Working Group for the establishment of a Task Force to mitigate current and future drug shortages. We respectfully request the Task Force be required to carefully consider, as part of its mission, the impact of drug shortages on clinical trials.

Under the provisions of the Discussion Draft, the Secretary of Health and Human Services has sole discretion to appoint the members of the Task Force. As you know, oncology drugs are among the drugs most frequently in short supply. Therefore, NCCR respectfully requests that the Secretary be required to include a Hematologist/Oncologist, and/or a Certified Oncology Pharmacotherapist, as voting members of the Task Force. It is further recommended that consumer advocates also be included as voting members of the Task Force established by the legislation. We believe their combined experiences of addressing drug shortages on a daily basis would be of substantial benefit to the Task Force.

Furthermore, the potential impact on clinical trials also should be a criterion taken into consideration in the Strategic Plan developed by the Task Force that will ensure drug shortages are considered when the Secretary initiates regulatory or enforcement actions that could precipitate a drug shortage or exacerbate an existing drug shortage.

Recordkeeping – NCCR commends the Working Group for requiring the Secretary to maintain records related to drug shortages. We respectfully request that the recordkeeping requirements include a list of cancer clinical trials that were delayed, interrupted, modified or halted due to drug shortages as well as strategies that have been, or could be, undertaken to avoid the disruption of these important studies.

Definitions - NCCR is concerned the definition of the term “meaningful disruption” in the Discussion Draft includes vague terms such as “highly likely” and “more than negligible” that could be open to wide interpretation. We prefer the definition of the term “interruption” contained in H.R. 2245, the “Preserving Access to Life-Saving Medications Act of 2011,” and request the following definition be used in the Working Group legislation:

The term `interruption' means a change that--

`(A) may result in the total supply of a drug manufactured by the individual manufacturer not meeting average historic demand; and

`(B) consists of--

`(i) a change in the supply of one or more raw materials, including active pharmaceutical ingredients;

`(ii) an unplanned interruption in ability to produce the drug;

`(iii) a business decision affecting the manufacture of the drug, such as a merger or a change in production output; or

`(iv) any other type change that could have the result described in subparagraph (A), as determined by the Secretary.

We commend the Working Group for ensuring the term “meaningful disruption” does not include disruptions in manufacturing due to matters that would be resolved quickly, and enable the resumption of manufacturing in a short period of time.

Distribution of Drug Shortage Information – NCCR believes the timely dissemination of information on drug shortages and discontinuations is of paramount importance to provider and patient organizations. Therefore, we recommend the word “may” be changed to “shall” in this provision to ensure medical professionals can adequately plan for potential disruptions in patient care due to a drug shortage.

Confidentiality of Information – We note the absence of language to ensure the confidentiality of proprietary information submitted in a notification of a potential discontinuation, disruption or shortage of a drug. We encourage the Working Group to include this protection in the final legislation.

Conclusion

The National Coalition for Cancer Research understands and appreciates the complexity and numerous causes of drug shortages. We are working with our colleagues in the biomedical research and provider communities to identify potential regulatory and legislative solutions to address this ever-growing problem. However, we cannot overemphasize the urgent need for continued bipartisan efforts to act thoughtfully and expeditiously in order to resolve this critical issue. The bipartisan efforts of the Working Group are an important and meaningful effort to address this urgent matter. The National Coalition for Cancer Research looks forward to working with the members the Working Group and the Committee on Health, Education, Labor and Pensions on this important legislation.

As requested, by this letter we are respectfully requesting the opportunity for representatives of NCCR member organizations to meet with you and your staff to further discuss these recommendations.

We thank you for the opportunity to provide these comments for your consideration.

American Association for Cancer Research
American Cancer Society Cancer Action Network
American Childhood Cancer Organization
American College of Radiology
American Society of Clinical Oncology
American Society of Hematology
American Society for Radiation Oncology
Association of American Cancer Institutes
Gateway for Cancer Research
Coalition of Cancer Cooperative Groups
CureSearch Childhood Cancer Foundation
Friends of Cancer Research
International Cancer Advocacy Network
International Myeloma Foundation
Kidney Cancer Association
Leukemia and Lymphoma Society
The Lustgarten Foundation
Melanoma Research Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Prostate Cancer Foundation
Society of Gynecologic Oncology
V Foundation for Cancer Research

April 6, 2012

Dear Chairman Harkin and Ranking Member Enzi:

The organizations listed below are pleased to provide comments to the Senate bipartisan working group's discussion draft that addresses drug shortages. Our organizations represent patients, clinicians, and hospitals, all of whom have been impacted by the worst shortages of generic drugs in our nation's history. Given that patient harm has already occurred, we applaud your efforts to address the problem in a swift yet thoughtful manner. We believe this is a tremendous first step toward ensuring that patients have access to the medications they need while not compromising the safety and quality of those medications. However, we also believe the draft can be improved to ensure that the true goal of eliminating generic drug shortages can be accomplished.

In General

Within the early notification section, we support notification based upon broad parameters of drugs that are life-supporting, life-sustaining or intended for use in prevention of a debilitating disease or condition. Earlier drafts based this upon a list of critical drugs in short supply. It has been widely noted that basing the reporting upon a list is difficult as it must be constantly updated and may create some confusion among manufacturers about when they must report. We thank the working group for taking the approach of using criteria over a list, however, we urge the working group to ensure that emergency medicine drugs, anesthetics, and drugs used in the management of a debilitating disease are included as well.

We are strong supporters of the early notification requirement and note that it has a track record of successfully avoiding drug shortages as evidenced by the 195 shortages avoided in 2011, as reported by the Food and Drug Administration (FDA). We thank the working group for including this requirement in the draft. However, one concern we have is whether this reporting is mandatory. Without any redress such as civil monetary penalties, how is the FDA going to enforce this requirement? Typical Agency enforcement actions available for current use include injunctions or halting production, however, these types of enforcement actions would have no impact on drug shortages, and, in fact, could make them worse. We are concerned that a requirement lacking enforcement isn't really a requirement. Simply listing the names of manufacturers who fail to comply in an annual report to Congress will not serve as an effective enforcement mechanism. We ask the working group to consider including civil monetary penalties or some other type of enforcement mechanism to ensure compliance with this section.

Reduction in the Notification Period

The draft outlines a number of exceptions to the early notification system based upon a manufacturer certifying to the FDA that good cause exists. We are pleased to see that any exceptions would be at the discretion of FDA; however, we would ask that the working group receive input from the Agency on the potential that this would add another layer of bureaucracy. Many of the groups signed on to this letter have noted the added burden drug shortages has created by taking time away from clinicians caring for patients in order to track down medications. In other words, time spent tracking medications is time

not spent caring for patients. Our concern here is that by creating more bureaucracy, it would limit FDA's ability to address drug shortages. Again, we would defer to Agency input on whether this section would create significant paperwork burdens on the Agency due to increased requests for exceptions to the notification requirements.

Furthermore, the exception listed under (D), economic hardship, would be troublesome if it were a sole source manufacturer of a life-saving product that did not have to report to FDA under the guise of "economic hardship." We do not believe that the economic hardship suffered by a manufacturer outweighs the hardship of an untimely death due to a medication in short supply. We ask that the working group reconsider this exception, especially since (E) notes the exception for a bankruptcy filing.

Coordination

(1) Task Force

In general, we are pleased to see the creation of a task force to promote both inter- and intra-agency coordination, communication, planning and decision making. We would simply ask that consideration be given to either inclusion in the task force, or a requirement that stakeholders regularly participate in task force meetings or communications. We believe it is essential for FDA and other agencies to regularly hear from clinicians, patients and supply chain members, as their participation and input would be extremely valuable.

Recordkeeping and Reporting

We are pleased to see that within the recordkeeping and reporting section, FDA would also collect the names of manufacturers who did not comply with the early notification requirement. We believe, however, that with the absence of civil monetary penalties this provision should go further to require the list of non-compliant manufacturers to be publicly available. Furthermore, Congress could help ensure compliance with early notification by specifying that upon receipt of the list, leadership of the committees of jurisdiction will request justification from those manufacturers who fail to report.

Definitions

Under (3), meaningful disruption, we urge the working group to consider the following alternative to this definition. Within H.R. 2245, the term "interruption" is defined as:

A change that--

`(A) may result in the total supply of a drug manufactured by the individual manufacturer not meeting average historic demand; and

`(B) consists of--

`(i) a change in the supply of one or more raw materials, including active pharmaceutical ingredients;

`(ii) an unplanned interruption in ability to produce the drug;

`(iii) a business decision affecting the manufacture of the drug, such as a merger or a change in production output; or

(iv) any other type change that could have the result described in subparagraph (A), as determined by the Secretary.

We believe this definition provides a better framework for manufacturers to report and is based upon average historic demand, rather than highly subjective terms such as “highly likely” and “negligible.” These may be subject to interpretation. It may be worth noting that the above definition was developed with significant input from a manufacturer.

Distribution

We strongly urge the working group to amend this section by replacing “may” with “shall.” We believe that public notification is essential so that caregivers can adequately plan for potential disruptions in patient care caused by a drug shortage. Furthermore, we ask that the group consider adding some additional criteria in the distribution. For example, the name of the drug in shortage, the name of each manufacturer, reason for the shortage, and anticipated duration of the shortage as determined by the Secretary. These criteria are listed in the distribution section of the discussion draft developed by the House Energy and Commerce Committee (pages 195 and 196). We realize that all of this information may not be available to distribute but, to the extent that it’s practicable, we ask that it be included.

Inclusion of Biological Products

We strongly support the inclusion of both biologics and biosimilar products within the discussion draft. This will become increasingly critical in the future as the development and approval of biosimilar products for use in the United States become more prevalent. We commend the working group’s efforts to include biological products.

Items Not Included in the Draft

While we realize the boundaries of the HELP committee’s jurisdiction regarding DEA issues, we do believe that this policy option should be explored jointly with the committee of jurisdiction. Given the severity and scope of drug shortages, it is difficult to fathom that significant opposition from members of another committee would be a barrier to at least requiring FDA and DEA to work collaboratively and provide flexibility where needed in the development of quotas for manufacturers producing controlled drugs. We ask that consideration be given to addressing this issue.

Finally, given the additional authority and requirements of FDA to promulgate rules, develop guidance, strategic planning, and convene a task force, we ask that consideration be given to the resource constraints of the Agency. We fully understand that you, as authorizers, are not appropriators and are not in a position to direct additional resources to FDA, but we ask that consideration be given to include language that expresses the sense of the Congress that additional resources be allocated to FDA to address drug shortages.

Conclusion

Thank you for hard work and commitment to this issue. All of us hear not only from our constituencies but also from patients who are struggling to find medications that in some cases, are essential to their survival. As you well know, this problem has become a national crisis and we must take steps to address

it now. Your hard work and dedication is making this possible. Again, we appreciate your efforts and look forward to working with you to address this problem.



**American Academy of Emergency Medicine
Resident and Students Association**



