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October 17, 2007

David Catania, Chair
Committee on Health
1350 Pennsylvania Avenue, NW
Washington, DC 20004

Dear Mr. Catania:

I am writing on behalf of the American Society of Clinical Oncology (ASCO) to express serious concerns about several elements of your SafeRx Act of 2007. With more than 24,000 members worldwide, ASCO is the leading medical society for physicians engaged in cancer treatment and clinical research. We believe that these provisions will needlessly burden both patient care and cancer clinical research, and in some cases will create real obstacles to efficient, timely and optimal treatment for cancer patients.

Cancer chemotherapy is unusually dependent on off-label uses of drugs. Just last year, ASCO published in its peer-reviewed journal a Special Article detailing the importance of off-label uses in cancer chemotherapy and the necessity of reimbursement policies covering such uses.¹ Among other facts reported in the attached Special Article are the following:

- Approximately half of the uses of anticancer chemotherapy drugs are for indications other than those referenced in the labeling approved by the Food and Drug Administration (FDA)—i.e., “off-label uses,” as defined in your bill.
- Both FDA and the National Cancer Institute have expressly recognized the legitimacy of such off-label uses, particularly in the treatment of cancer.
- Medicare Parts B and D, as well as Medicaid, feature specific statutory protections ensuring the coverage of medically appropriate off-label uses of cancer drugs, as determined by their listing in certain medical compendia.
- The majority of states have provided safeguards requiring reimbursement of off-label uses of cancer drugs based on the compendia.

Clearly off-label uses of anticancer drugs represent, in many instances, the standard of care for cancer patients, and any system that unreasonably burdens such uses will undermine patient access to appropriate care and will likely be detrimental to patient outcomes.

Title II of the SafeRx Act of 2007 imposes on physicians a requirement of “informed consent” before prescribing drugs for off-label uses. The physician must not only disclose that the drug being administered is not approved for the relevant indication, but also “[p]rovide the patient with information commonly known by the medical profession regarding potential risks and side effects associated with using the prescription for an off-label purpose” and “[o]btain the written informed consent of [the] patient.”

¹ ASCO Special Article, “Reimbursement for Cancer Treatment: Coverage of Off-Label Indications,” *Journal of Clinical Oncology*, vol.24, p.3206

2008 Annual Meeting
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As clinical researchers, we are quite familiar with the time and effort involved in providing “informed consent,” since investigators are required to do so in connection with every clinical trial. In the context of clinical research, the informed consent process involves very specific regulatory requirements, including a detailed written document with specific elements and a thorough discussion with the potential trial participant. The document undergoes extensive review by institutional review boards. Although this document and process are necessary in the research context, there is no question that it adds substantially to the expense of the trial and to delays in trial accrual.

A sound ethical reason for informed consent exists where patients are receiving experimental therapy because the full risks and benefits of the therapy are unknown, but these detailed informed consent documents and process are not appropriate for patients who are receiving standard cancer chemotherapy that may include medically appropriate off-label uses. Because of the significant toxicities typical with many cancer treatments, it is routine for oncologists to discuss those toxicities with patients prior to administration of chemotherapy. The formality of the process set forth in your bill is duplicative and unnecessary. We fear that use of the detailed informed consent procedures for off-label drugs will be confusing to patients.

We are also concerned about the bill’s establishment of a “SafeRx Registry” administered by the District of Columbia government. You may be aware that the United States Congress has recently enacted, and the President has signed into law, the Food and Drug Administration Amendments Act of 2007, which in Title VIII creates clinical trials data bases, including requirements for reporting of trial results. The requirements of your bill are not entirely consistent with those of the new federal law, and such inconsistencies may lead to confusion among patients and physicians alike. Moreover, if every state chooses to devise its own clinical trial reporting system without taking into account the federal effort, there will be a great deal of unnecessary expense and unjustified burden on the clinical research enterprise. At some point, the accumulation of such burdens may act as a deterrent to the clinical trials that are going to be necessary for future advances against cancer and other life-threatening diseases.

ASCO appreciates the motivation of your bill to provide patients with necessary information and protections against abuse, but, at least in the two provisions we have mentioned, the effect of the SafeRx Act would not be positive for patients and would likely be negative for cancer treatment and research.

We would be happy to meet with you to discuss this issue further. Please call Shelagh Foster at 703-299-1050 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, MD
Chair, Government Relations Council