AMERICAN HOMEPATIENT

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Via FedEx
October 13, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1484
Safety Reporting Requirements for Human Drug and Biological Products

Dear Sir or Madam:

American HomePatient (AHOM) provides the following comments as they relate to the proposed rule, "Safety Reporting Requirements for Human Drug and Biological Products", Docket 00N-1484, appearing in the Federal Register on March 14, 2003 on pages 12406 through 12497.

American HomePatient applauds and commends the Agency for the focus on regulations seeking global harmony as it relates to the purposed safety rule.

American HomePatient, is one of thousands of health care providers, manufacturers and suppliers who furnish home health services, rehab and assistive technologies, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to thousands of Medicare and other government and private payors' beneficiaries. A significant percentage of our locations manufacture (fill) and distribute medical gases for respiratory care patients at their residences. American HomePatient, therefore, limits its comments to the impact this rule has on us as a Home Health Care Provider that is also a manufacturer of medical gases classified as drugs, primarily Oxygen, USP and specifically the changes proposed to 21 CFR §310.305.

Today 1.2 million people receive medical oxygen in the home care setting. Annually, greater than 600,000 patient deaths occur as a result of the patient's primary disease. As discussed in this letter, if the rule remains as proposed, we as a home care medical gas manufacturer would be required to generate a report on each patient death where medical oxygen is supplied. This would result in an insurmountable negative financial impact on us as a medical gas manufacturer.

Including medical oxygen in this ruling would be of no benefit to the medical community and home medical oxygen users. Nor would it fulfill

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the intended safety rule objective of reporting noxious and unintended responses to drug therapy. From our review of the studies cited in this Federal Register notice (pages 12470 through 12471, and others throughout the document), it is evident that medical gas manufacturers, in general, were not included in the primary financial data estimates provided. Ensuring that we and other medical gas manufacturers are exempt from certain aspects of this ruling is paramount to the industry. This rule, as proposed, would potentially create a financial burden and hardship, resulting in an unsustainable company and industry.

American HomePatient strongly supports the following proposals and comments of AAHomecare to the Agency: (all of the following are from the AAHomecare letter dated October 13, 2003, related to Docket No. 00N-1484 Safety Reporting Requirements for Human Drug and Biological Products).

1. Exempt cases where medical oxygen is ***'unlikely related'*** to the SADR or SAR, from the clarification of the definition of a SADR
2. Exempt medical oxygen from the expedited report (15-day alert) requirement specified in the proposed rule, if the agency does not agree with modifying its guidance toward 'unlikely related' incidents in number 1 above.
3. Expand the definition of a 'contact person' to include other medical healthcare professionals; and to allow them to be responsible for the content of post-marketing safety reports submitted to the FDA.
4. Exempt DMEPOS companies, who fill medical oxygen containers, from using MedDRA to code safety reports even when medical oxygen usage may be indicated as a SADR or SAR.

    1. Regarding our request to "Exempt cases where medical oxygen is *'unlikely related'* to the SADR or SAR, from the clarification of the definition of a SADR"

On page 12417 of the Federal Register Notice, guidance is provided as to what would be a SADR. Including those incidents where "the relationship cannot be ruled out" may cause extensive reporting when persons do not have a SADR that is "caused" by medical oxygen. Patients prescribed supplemental medical oxygen have some significant disease process or abnormality. Medical oxygen therapy is typically and extensively used as an adjunct to the primary prescribed drug therapy.

Including supplemental medical oxygen therapy in the agency's required SADR reporting will be non-productive, non-informational, and create enormous amounts of paper flow with no benefit. In addition, if an individual expires or experiences a medical deterioration requiring medical intervention from underlying disease processes, while using medical

oxygen, this will result in increased and unnecessary submissions of complex reports.

2. Regarding our request to "Exempt medical oxygen from the expedited report (the current 15-day alert) requirement specified in the proposed rule, if the agency does not agree with modifying its guidance toward 'unlikely related' incidents in request 1 above."

We request the agency exempt medical oxygen from the 15-day alert requirement where incidents of acute respiratory failure have occurred, as well as all the other listed conditions. This request would only be required if the agency does not agree with modifying its guidance in regards to 'unlikely related' incidents previously discussed in item 1 above.

For example, if a patient should experience acute respiratory failure while using medical oxygen, this occurrence would result in the need for our industry to perform Expedited Reporting (15-day alert). Because the guidance currently states that the "relationship cannot be ruled out", the medical oxygen filler may need to complete the 15-day expedited report. Although a SADR associated with "acute respiratory failure" may be the most obvious example, when the adjunct use of medical oxygen is employed, most conditions listed in the Federal Register notice would also include the use of medical oxygen. Hence, all SADRs would cause unnecessary (upwards of 600,000) expedited reports for the use of medical oxygen.

This ruling will be extremely difficult, if not impossible, to comply with in any timeframe, let alone within 15 days. As medical gas manufacturers/fillers, we would need to have access to each patient's medical records from the healthcare facility, the patient's physician, and/or other entities (healthcare provider, coroner, Department of Health, etc.). Access to the record would not be permitted without written consent from the patient or his/her power of attorney.

3. Regarding our request to "Expand the definition of a 'contact person' to include other medical healthcare professionals; and to allow them to be responsible for the content of post-marketing safety reports submitted to the FDA."

Medical gas manufacturers/fillers, including many home healthcare companies filling medical gas (medical oxygen) containers, do not typically have licensed physicians on staff, or on contract. Most of these firms have healthcare professionals (e.g., Nurses, Respiratory Therapists, etc.) on staff or on contract. The process of manufacturing and distributing

medical oxygen does not require the oversight of a physician. We propose that the agency permit a company representative (a healthcare professional) to be responsible for the content of post-marketing safety reports submitted to the FDA. To require firms to hire a physician for the sole purpose of meeting the requirements of this proposed rule, if it is even possible to find a physician to accept such a position, will cause undue financial hardship on medical gas firms with no increased patient safety.

4. Regarding our request to "Exempt DMEPOS companies, who fill medical oxygen containers, from using MedDRA to code safety reports even when medical oxygen usage may be indicated as a SADR or SAR."

We propose that the agency exempt all home healthcare providers who fill medical oxygen containers from the use of MedDRA. In the unlikely event that medical oxygen is determined to be the cause of a SADR or SAR, the use of MedDRA in the DMEPOS arena would not be economically feasible.

Based on discussions with agency personnel, our understanding is that over fifty percent of all drug manufacturers registered with the agency are medical gas firms, and many of those would be classified as small business. The financial impact of this rule on these firms, as well as larger regional and nationwide firms, would be very significant if our exemption requests are not granted. Contrary to the overall goal of trying to stem the increased cost of healthcare in the United States, this rule will significantly add cost to the manufacture and distribution of Oxygen, USP. Users (healthcare institutions and patients) of Oxygen, USP would receive little or no benefit from unnecessary reporting processes.

In conclusion, our review of the studies cited in the Federal Register notice makes it evident that medical gas fillers, especially those that manufacture medical oxygen used to treat patients in their residence, were not included in the primary data estimates provided in this document. We do not believe it was the agency's intention to include medical gas manufacturers, as the rule does not address the uniqueness of our industry. Perhaps it is for this reason that the financial data did not include medical gases. We have documented our issues in the above response with the understanding that the agency's intention was not to include medical gas manufacturers. Ensuring that medical gas manufacturers are not included in this ruling is paramount to the industry, as the financial burden and hardship it would create would make the industry financially unsustainable.

If the agency does not concur with our arguments requesting exemption from the cited sections of the proposed rule (changes to 21 CFR §310.305), we strongly plead that the agency meet with the American Association for

Homecare prior to issuing a final rule. The purpose of this meeting would be to discuss the degree this regulation would impact this industry and, more importantly, further discuss the minimal potential health benefit to the patient, if any, that this regulation would have on the safe administration of medical gases.

American HomePatient firmly believe that the arguments made by AA Homecare provide adequate rationale to support the need for the Agency to change some of the language of the proposed safety rule and exempt cases where oxygen is 'unlikely related' to the SADR or SAR, or exempt medical oxygen from the expedited report (15-day alert) if the Agency does not modify the guidance toward 'unlikely related' incidents. We would want to see the definition of the 'contact person' to be expanded and we would want to see an exemption for the DMEPOS companies from using MedRA to code safety reports even when medical oxygen may be indicated as a SADR or SAR. If the agency does not concur with our request and the proposals of AAHomecare, we strongly recommend that, prior to publishing this as a final rule, the agency meet with the American Association for Homecare. The purpose of this meeting would be to discuss the degree this regulation will impact our industry and to further discuss the minimal potential health benefit, if any, that this regulation will have to the medical community and the home medical oxygen users.

American HomePatient appreciates the opportunity to comment on this proposed rule. If there are any questions regarding this request, please do not hesitate to contact me at 1.800.890.7270, ext. 8525.

Thank you for your consideration.

Sincerely,

Tom Mills, Chief Operating Officer
American HomePatient

CC: Joe Furlong, President and Chief Executive Officer
Len Serafino, VP of Purchasing and Support Services
Deborah Stewart, Corporate Director of Clinical and Regulatory Compliance