serious influenza pandemic, we focused primarily on disasters causing numerous medically critically ill victims. The composition of our group was deliberately conceived to bring medicine, ethics, and public health experts together to collaboratively develop pragmatic, optimal clinical guidance. We knew that future work on critical care surge capability and triage for pediatric and trauma issues would be necessary, and work by Subbarao and colleagues7 has advanced additional, essential elements of triage planning.

The challenges of optimal triage across the entire health-care system spectrum are many. Even the goals of triage, such as mortality vs life-years saved or other outcomes, have not received sufficient professional consideration or input from community members. Furthermore, health system situational awareness (ie, patient needs and resource availability) needs much more real-time and detailed clinical information to optimally inform centralized triage recommendations. The capability to rapidly understand the course of a disease, identify prognostic variables, and determine treatment effectiveness across the entire health-care system remains elusive for most communities. This information will be essential for sustained-response events such as epidemics, when data-driven revisions of triage guidance would be expected to ensure that our community members get the best possible care in resource-limited circumstances. Finally, regional coordination of health-care system triage will require input from many different clinical specialties and professions as well as from nonclinical community members, such as elected officials, community advocates, and at-large community members, among whom are many of the same people who must provide consultation during responses. The majority of communities will still further develop their regional health-care system coordination infrastructure to assure such clinical expert involvement.

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Reflections From the Field Regarding the Clinical Commentary for Augmentation Therapy in the MZ Phenotype

To the Editor:

We read with interest and great anticipation the clinical commentary in a recent issue of CHEST (October 2008)1 regarding α1-augmentation therapy for PI MZ heterozygotes, but disagree with the conclusions reached by the Medical and Scientific Advisory Committee of the Alpha-1 Foundation in the strongest terms.

The authors acknowledged, although their evidence is somewhat anecdotal, the existence of patients with MZ phenotype who have severe obstructive disease despite being nonsmokers. They also acknowledged the difficulties involved in enlisting a subset of rapidly declining MZ phenotype patients in a trial to be “daunting.” There are also no data available that have looked at the quantity of Z or M α1-antitrypsin (AAT) within a given patient and the protectiveiveness of the level of each subtype in preventing disease.

The authors reiterated the fact that physicians legally enjoy the privilege of prescribing medications that have not been approved by the US Food and Drug Administration. They failed to realize that the physician is the greatest advocate for their patients, and that the doctor-patient relationship is an ethical one that is above any legal obligations and goes beyond any approval by a third party. We have for centuries advocated for our patients and have not placed an economic value on each individual’s life, though it is common knowledge that third-party payers have done so.

Given this background and the bleak prospects for any new knowledge being imminently available in a randomized prospective trial, we believe that the interim recommendation to clinicians by Sandhaus et al1 to avoid prescribing augmentation therapy for MZ heterozygotes is a disservice to patients and physicians alike. Patients who in today’s economy can hardly afford to reach the office (due to gasoline prices and increasing rates of copays) will never be able to reach specialists with experience in treating AAT deficiency (whatever the definition of an AAT deficiency specialist might be), and it is fair to say that deserving patients will be denied treatment based on this article.1

To ask the insurance industry to closely evaluate reimbursements for such a scenario is at the least an irresponsible recommendation after a doctor-patient relationship has been set up and a decision to treat has been made based on the best available knowledge. To our knowledge, this is the first time in a

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prestigious journal such as CHEST that a third party has been asked to police medical professionals and interfere in the doctor-patient relationship. This sets a dangerous precedent in which a document does not just give us the science about a somewhat controversial scenario but is asking the insurance industry and the US Food and Drug Administration to trump physician judgment in an area that is not black and white.

In conclusion, we believe that this clinical commentary only creates more problems for the practicing clinician who is in the trenches and has only muddied up the trench for those of us who are in the field.

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Dr. Reddy has participated in an advisory board for CSL Behring and dinners (in Philadelphia, PA, at the CHEST conference), and in a Champions for Alpha-1 Testing (CAT) study sponsored by CSL Behring. Ms. Zaremba has participated in a round table discussion for the University of Michigan and dinners (one in Detroit, MI, with Dr. D. Kyle Hogarth, of the University of Chicago; and one in Philadelphia, PA, at the CHEST conference), and in a CAT study sponsored by CSL Behring.

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REFERENCE


Response

To the Editor:

We appreciate the opportunity to respond to the comments of Dr. Reddy and Ms. Zaremba criticizing the perception of our “trumping” physician judgment.1 By way of clarity, we wish to emphasize that our intent is in no way to undermine physician judgment (which we believe we are also exercising in drafting this commentary), but to point out that the cornerstone of good judgment, namely evidence, is lacking with regard to the justification of augmentation therapy for individuals with PI*MZ α1-antitrypsin deficiency.

We lack clarity from reading Dr. Reddy’s letter as to how our clinical commentary1 undermines patients’ access to specialists any more than the current economic adversity may, but appreciate and agree that access to the best medical information and clinicians is essential for the optimal care of individuals with α1-antitrypsin deficiency. We suspect that in our current economic climate, patients’ precious dollars should be spent first on a visit to a well-informed physician before prescribing for them a treatment the efficacy of which in the specific setting of PI*MZ α1-antitrypsin deficiency lacks support and could contribute significant expense to the frail health-care system funding in our country. We contend that, in summarizing existing knowledge and its important gaps, our position in the clinical commentary1 facilitates informed judgment, and we applaud the leadership of CHEST for its careful and critical review of the material.

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All authors are or have been members of the Alpha-1 Foundation Medical and Scientific Advisory Committee. Dr. Silverman is also a member of the Alpha-1 Foundation Board of Director. Dr. Sandhaus serves as the clinical director of the Alpha-1 Foundation. Dr. Sandhaus has presented talks relating to α1-antitrypsin deficiency (AAT) deficiency at events sponsored by Talecris Biotherapeutics, CSL Behring, Baxter Healthcare, and Dey Pharmaceuticals, and has been a principal investigator for therapeutic clinical trials in AAT deficiency sponsored by Talecris Biotherapeutics, CSL Behring, and Kamada Pharmaceuticals. Ms. Everett has severe AAT deficiency, receives augmentation therapy, and has been a member of the voluntary leadership of the Alpha-1 Foundation for the past 12 years. Dr. Turino has no conflicts of interest to disclose. Dr. Trapnell has no conflicts of interest to disclose. Dr. Silverman received an honorarium for a talk on COPD genetics in 2006, grant support and consulting fees from GlaxoSmithKline for two studies of COPD genetics, an honorarium from Bayer Biologicals for a symposium at the 2005 European Respiratory Society Meeting, an honorarium for a talk at the Lund Symposium in 2007, and consulting fees from AstraZeneca. Dr. Stoller has served as a consultant to Talecris Biotherapeutics; has given lectures that have been supported by Talecris Biotherapeutics, Baxter Healthcare, and CSL Behring; and has served as a member of a data monitoring and safety committee for Kamada Pharmaceuticals. In addition to individual disclosures, the authors wish to disclose the following potential conflicts of interest: the Alpha-1 Foundation relies entirely on donations for its operating budget. Included among the major donors to the Alpha-1 Foundation are all the companies that produce the augmentation therapy products mentioned in this commentary.

Excerpt:

In discussing the diffusing capacity of the lung for carbon monoxide (DLco), Dr. Plummer1 points out the difficulty in...