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ALAN M. KIRSCHENBAUM

February 4, 2008

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Docket No. 2007N-0489: Request for Comments on the Science and Technology Report; Establishment of Docket; Request for Comments**

Dear Sir or Madam:

On behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR) and the Medical Imaging Contrast Agent Association (MICAA), I am pleased to provide these comments on the report of the Science and Technology Subcommittee (the "Subcommittee") of the FDA Science Board entitled, "FDA Science and Mission at Risk" (the "Report"). CORAR is an association of companies that manufacture and distribute radiopharmaceuticals and radionuclides for use in medicine and in life science research. MICAA is an association of companies involved in the research, development, manufacturing and distribution of medical imaging contrast agents in the U.S. Our comments relate to the Subcommittee's findings concerning medical imaging.

The Report accurately described in vivo medical imaging technologies as one of the forces revolutionizing medicine. Personalized medicine, where pharmaceutical therapy is tailored to the particular characteristics of the individual patient, is being realized through procedures and agents that permit greatly enhanced targeting (e.g., targeted ultrasound, targeted MR using nanoparticles, and nuclear scans using highly targeted antibodies and peptides) and paired use of a procedure/agent for diagnostic and therapeutic purposes in the same patient. In addition, high accuracy in anatomical and biological function imaging is being made possible through new technologies (e.g., optical imaging), new combinations of existing technologies (e.g., CT in combination with PET or SPECT), and new agents (e.g., new PET agents beyond FDG-18). In addition, medical imaging biomarkers have become an increasingly important tool in therapeutic drug development to characterize a disease or predict response to therapy.

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The Subcommittee explained that “[a]dvances in medical imaging offer the potential to understand drug, receptor, disease and patient relationships in promising ways.”<sup>1</sup> Unfortunately, the Subcommittee also identified medical imaging as one of the eight emerging science and technologies that are most challenging the FDA.<sup>2</sup> In particular, the Subcommittee identified innovative approaches to imaging drug response as a high priority.<sup>3</sup> The Report also stated that FDA must make investments in putting an IT infrastructure in place so that it can regulate medical imaging and other “new science” fields.<sup>4</sup>

As a means to ensure that FDA can effectively address emerging sciences and technologies such as medical imaging, the Report recommended the establishment of an “Incubator for Innovation in Regulatory and Information Science” (IIRIS), which would consist of at least 20 scientists whose function would be to identify the tools and approaches necessary for FDA to understand and regulate emerging science and technologies. They would do this by interacting with and harnessing the expertise of academia, and also by leveraging partnerships with industry.<sup>5</sup>

CORAR and MICAA would be firmly supportive of the IIRIS concept. However, in today’s fiscal environment at FDA, a project of this size requiring a nucleus of scientists at FDA overseeing at least 20 research scientists with support staff is very unlikely to be implemented without additional Congressional appropriations for this purpose. Indeed, absent such appropriations, an IIRIS could actually be damaging to the Agency because it could draw necessary resources away from FDA’s core regulatory functions. As explained at length by Peter Barton Hutt in Appendix B to the Report, in terms of both personnel and the money to support them, FDA is already “barely hanging on by its fingertips.”<sup>6</sup>

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<sup>1</sup> Report at 17.

<sup>2</sup> Id. at 4 and 26.

<sup>3</sup> Id. at 30.

<sup>4</sup> Id. at 55.

<sup>5</sup> Id. at 27-30.

<sup>6</sup> Id., Appendix B, at B-1.

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Unless and until Congress appropriates funding for IIRIS, CORAR and MICAA believe that there is another way for FDA to avail itself of outside expertise on emerging sciences which, though more modest, is more consistent with FDA's existing structure and budget: advisory committees. With respect to the Center for Devices and Radiological Health, the Report explicitly recognizes the value of advisory committees in harnessing the expertise of outside scientists and recommends greater efforts in this area.<sup>7</sup> Similarly, in the area of surveillance and statistics, the Report recognizes that FDA will not effectively be able to maintain the expertise it needs within realistic budget expectations, and that, in order to harness the enormous potential source of expertise in the academic community, FDA should make "increased use of advisory committees in areas where in-house expertise is limited."<sup>8</sup> Similarly, until an IIRIS can be funded and implemented, it behooves FDA to make greater use of advisory committees to achieve the same goal: to learn about and understand new sciences.

In the area of emerging medical imaging technologies, a medical imaging advisory committee would be the ideal vehicle for FDA to obtain information and expert opinions on new developments. FDA had a standing medical imaging advisory committee from 1967 until 2002, when it was terminated as part of an Agency effort to reduce the number of standing advisory committees. The Agency explained at the time that medical imaging drugs could be adequately reviewed by existing, disease-specific standing advisory committees.<sup>9</sup> However, as the Subcommittee recognized, medical imaging has been developing at an exponential rate,<sup>10</sup> and the years since 2002 have seen new advances that have the potential to revolutionize medicine and drug development.

Today, a medical imaging drugs advisory committee would have value going well beyond its traditional role of reviewing medical imaging drugs seeking approval for diagnostic indications. Such a panel could also advise FDA on new medical imaging technologies, their applications, their potential benefits and risks, and strategies for regulating them. The panel could advise FDA on what IT and technological infrastructure FDA needs to evaluate such products across a variety of disease states. It could address, not only the utility of new imaging modalities for diagnostic use, but also their use as biomarkers for safety or effectiveness in therapeutic drug clinical studies, and

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<sup>7</sup> Id., Appendix H, at H-14-15.

<sup>8</sup> Id., Appendix J, at J-1 and J-3.

<sup>9</sup> 67 Fed. Reg. 70227 (Nov. 21, 2002).

<sup>10</sup> Report at 17, 26.

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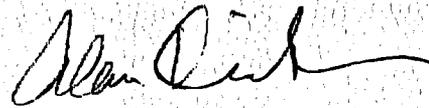
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their use in conjunction with therapeutic drugs to identify patients most at risk of adverse responses, or patients for whom the therapeutic drug promises to be most effective.

CORAR and MICAA strongly encourages FDA to reconstitute a standing medical imaging advisory committee. Such a committee would serve functions that could immediately help to remedy the deficit in emerging science expertise at FDA identified by the Subcommittee, and that are not available from any current standing committee.

Sincerely,



Alan M. Kirschenbaum

AMK/vam