Review of the FDA Office of Regulatory Affairs (ORA): Report by the ORA Subcommittee to the FDA Science Board

May, 2008

Executive Summary

An optimally-functioning ORA is critical if the FDA is to carry out its public health mission. The subcommittee's findings with respect to ORA mirror and support those issues identified by the Science Board subcommittee on science and technology in their December report, with additional, unique aspects related to (i) the particularly broad mission of ORA with its consequent need to collaborate with a wide and complicated range of stakeholders (ii) ORA's compliance and enforcement activities, which have hindered rapid implementation of technological change, and (iii) the extraordinary increased regulatory surveillance load which has developed in recent years.

As a result of a recent revitalization activity involving a wide representation of internal staff and other FDA stakeholders, ORA has generated a blueprint for organizational change; the subcommittee believes that this blueprint, if supported by further planning and prioritization along with adequate resourcing and FDA leadership support, could transform the organization and allow it to more successfully carry out its mission. Beyond resource-related issues affecting ORA are those related to ability to introduce change into the organization and its processes; the subcommittee notes that a major organizational change proposed by ORA within the last calendar year was blocked. Without commenting on the merits or otherwise of that proposal, the subcommittee believes that the current revitalization proposal for organizational change is based on realistic assessments of ORA's needs, and represents broad input. The subcommittee believes that the FDA would be well-served by providing resources and support for ORA to successfully implement the prioritized activities as outlined in the ORA Revitalization report.

In this report we have linked our own observations and recommendations with the general observations on FDA Science made in the Science Board Report, and with internal observations made by ORA in its Revitalization document along with ORA implementation plans as outlined in the document submitted to the FDA Commissioner.

Background:

In March, 2006 the FDA Commissioner charged the Science Board to review and report on the broad categories of scientific and technologic capacities that the FDA needs to support its mission. The subcommittee on science and technology presented its findings and recommendations to the Science Board Advisory Committee at the December, 2007 Science Board Advisory Committee meeting. At that time it was decided to add additional reviews of areas of the FDA not examined in the December report, including a review of the Office of Regulatory Affairs, and to provide a summary of this review as supplemental to the original report.

A workplan was created for the ORA review which included face to face meeting in Rockville, Maryland between the subcommittee and senior ORA staff, and subcommittee review of a mutually agreed series

of documents reflecting ORA structure, resourcing, and function, as well as summary documents of recent ORA change initiatives. In addition, the subcommittee visited ORA regional laboratories and district offices for individual discussions with senior regional and district staff.

Although the time for subcommittee activity was compressed, the subcommittee's review was greatly facilitated by the recent completion of a detailed internal review by ORA staff and other FDA stakeholders of ORA activities, strengths, weaknesses, and challenges, together with a broad set of prioritized business cases as a basis for ORA change initiatives. In addition, senior headquarters ORA staff, including the Associate Commissioner herself, provided very helpful input into the review; similar candor and cooperation was received from the district office and regional laboratory managers interviewed.

The review was conducted from the perspective provided by the findings in the parent Science Board report, but with particular attention to the unique aspects and challenges provided by the ORA mission.

The participants in the ORA Subcommittee Review included:

David R. Parkinson, Nodality Inc. (subcommittee Chairman, member FDA Science Board)

Lonnie J. King, CDC (subcommittee member, FDA Science Board)

Cato T. Laurencin, University of Virginia (subject matter expert, former member FDA Science Board)

John A. Thomas, Indiana School of Medicine (subject matter expert, former member FDA Science Board)

The ORA Subcommittee review process included the following activities:

(i) a face to face meeting by the subcommittee in Rockville, Maryland on February 15, 2008, which included presentations from ORA staff:

-general background: M. O'K. Glavin, Associate Commissioner

- "Applied Regulatory Science in Compliance Operations "(D. K. Elder)

-ORA Regulatory Science – Laboratories (C. Sciacchitano)

-"ORA's Mission and Use of Science in Carrying Out that Mission" (D.K. Elder, C. Sciacchitano, S. Solomon)

(ii) teleconferences

(iii) visits to ORA regional offices and laboratories:

-Los Angeles District Office & Pacific Regional Laboratory Southwest (D. Parkinson on April 3, 2008; C. Laurencin on April 4, 2008)

-Cincinnati District Office & Forensic Chemistry Center (J. Thomas on April 10, 2008)

(iv) review of FDA-provided information:

-Revitalizing ORA: Protecting the Public Health Together In a Changing World. Report to the FDA Commissioner, January 2008

-Action Plan for Import Safety. Report to the President, Interagency Working Group on Import Safety, November 2007

-FDA Strategic Plan

- Food Protection Plan

-ORA Prioritization Report Business Cases

-Task 2: Identify Limitations of Today's Regulatory Science Mapped to Regulatory Functions

-Map handout of US ORA Laboratories

General Findings and Recommendations of the Science Board Report, December 2007

The Science Board Subcommittee found that the Agency suffered from serious scientific deficiencies which compromised its ability to meet current or emerging regulatory responsibilities. The deficiencies were attributed to the increased demands on the FDA related to the increasing pace and complexity of scientific discoveries, the emergence of challenging safety problems, and the globalization of the industries regulated by the FDA. Resourcing was found to have not been increased in proportion to this increased demand, thereby compromising FDA's ability to fulfill its mission. Findings by the subcommittee included an erosion of the FDA science base as well as weak scientific organizational structure, with a scientific workforce lacking in both sufficient capacity and capability. Furthermore, the information technology infrastructure was deemed inadequate for the size, complexity, and geographical diversity of the mission.

While the Science Board report identified resource-related issues as critical to the ability of the FDA to carry out its scientific-driven mission, it also identified organization and management of scientific endeavors as critical, and called for a "phased approach based on a well thought-out plan". The subcommittee believes that in the context of ORA, the Revitalization proposals represent such an approach.

The Unique Characteristics of ORA

As the inspection and enforcement arm of the FDA, ORA activities span a remarkable range of activities, ranging from conducting inspections of both domestic and foreign firms producing FDA-regulated

products; collecting and analyzing samples of FDA-regulated commodities; initiating investigations in response to consumer complaints, food borne outbreaks, adverse events or public health emergencies; overseeing recalls and enforcement actions; and monitoring the nation's borders to mitigate the risks posed by FDA-regulated products that pass through them. As many of these activities are in support of the missions of the other FDA Centers, ORA therefore faces unique challenges with respect to scope in mission, geographical diversity, and the need for broad cooperation with many FDA as well as other federal and state collaborators. The resultant significant challenges of management and communication exist in the context of the remarkable increase in quantity and complexity of workload accompanying the increasingly global economy and the sourcing of increasingly complex products from foreign manufacturers.

In many respects the general challenges are similar in nature to those documented in the parent Science Board report: dramatically increasing quantity and complexity of workload, increasing legislative-mandated responsibilities, increasing expectations concerning product safety from the public, and until very recently static or decreasing human and budgetary resources with which to address these challenges. One representative case in point is the challenge of regulating imported goods, with more than a ten-fold increase in "import lines" over the period from 1991 to 2007 while only a relatively small increase in import and foreign inspection FTEs was allocated over that time.

The authority for the agency and ORA continues to be the many regulations and statutes that are their foundation; this authority is closely scrutinized by Congress as part of the appropriation process. Public trust and confidence are important components of a well functioning agency; recently as a result of well-publicized events this trust and confidence have eroded.

ORA Self-Assessment: the Findings and Recommendations of the ORA Internal Process "Revitalizing ORA" January, 2008

The subcommittee reviewed and discussed the FDA-provided materials; particularly relevant was the ORA document "Revitalizing ORA: Protecting the Public Health Together in a Changing World" submitted to the FDA Commissioner in January 2008. This document represented the distillation of an intense three month process of ORA review by a broad representation of more than one hundred internal ORA staff and external FDA stakeholders, with additional opportunity for input from the entire ORA community. The subcommittee found this document and the series of associated business cases to be a comprehensive analysis of the current state of ORA, with a clear prioritization process and outline of action steps which could be taken towards implementation. Making this document and the underlying process which led to it particularly useful was the linkage with important mandates affecting ORA, including the recent FDA-developed Food Protection Plan, the Action Plan for Import Safety developed by the Interagency Working Group on Import Safety, and the Food and Drug Amendments Act of 2007 (FDAAA).

The ORA analysis in this revitalization process characterized changes in three areas challenging ORA:

(I)environment changes, principally the increasing globalization of ORA's working environment

(II) workforce issues, including the need to develop a geographically-dispersed workforce skilled in a range of new technologies

(III) tool-related issues, including improved information technology and communications infrastructure

This ORA Revitalization document analyzed in detail the implications for ORA of the new mandates, of the changing external environment in which ORA operates, and provides a strategy for implementation of changes which the committee believes if implemented would lead to major improvements in the conduct of ORA's mission. The themes for revitalization were developed in a Future Search Conference in November of 2007; these themes were subsequently developed into a series of business cases which were proposed by the more than 100 individuals who participated in the Revitalization process; these cases were prioritized relative to the new mandates on ORA. Thirteen proposals were identified for initial analysis, development, and implementation, with 15 other proposals to be further analyzed. The process for further development of these prioritized proposals and for implementation is outlined in the Revitalization document.

ORA's self assessment included the recognition of the primary challenges as outlined above and analyses of the internal ORA environment as well as the external environments affecting ORA. Current strengths and areas for improvement were related to current and future opportunities; all of this work led to the development of the specific business cases. Cumulatively, the business cases cover a wide range of ORA activities, and outline a range of specific approaches to introduce new processes and capabilities to ORA. The Revitalization document was presented to the FDA Commissioner in January of 2008, with the thirteen business proposals and accompanying implementation plans.

District Office and Laboratory Visits

The district office and laboratory visits by subcommittee corroborated the themes outlined in the Science Board December, 2006 report. Findings included the following:

-human resource issues related to static laboratory FTE resources and lack of science-based career path advancement, particularly for those in regional laboratories

-lack of an enterprise software infrastructure for laboratory equipment and an overall approach to equipment IT support

-difficulty in procuring new equipment and incorporating new technology which might enable greater productivity

- inefficient or absent processes and inadequate resources to validate new technologies for more accurate and efficient product analysis which would be acceptable within the ORA's legal and forensic constraints

-difficulties (often budgetary) in engaging external scientific and technical consultants was described

-despite these issues, a number of very positive themes also emerged from subcommittee conversations with ORA district office and regional laboratory staff and management: pride in mission, recognition of the importance of broad collaboration with other federal, state, and foreign authorities, desire to innovate and to implement new technologies, and commitment to support the ORA Revitalization activity

-in addition, excellence in many of the training programs made available to staff was acknowledged, although FTE shortages made committing individuals to these programs problematic

Findings and Recommendations of the ORA Subcommittee

General Comments: Federal organizations can be viewed as three points of a triangle: mission, authority, and capacity. Within this context, they strive to create public value. In recent years while the mission of FDA and ORA has not changed, the scope, scale and implications of this mission have dramatically escalated along with public and congressional expectations. As was clear from the Science Board subcommittee report resources necessary to carry out this expanding mission have not increased commensurate with increased and more complex responsibilities. The review of materials and the discussions held by the committee found this resource limitation issue to be particularly true for ORA. The dramatic increase in work load, and the static availability of resources until very recently are well-documented in the materials supplied to the committee.

While this resource limitation has been a central focus of both the Science Board report and subsequent public discussion, the Committee's review of ORA also made clear that simple provision of additional inspectors and laboratory personnel will not automatically lead to greater ORA success in carrying out its mission. To this end, the committee finds the ORA Revitalization Report to be an objective and transparent review of the current state of ORA and the issues which affect ORA. Further it finds the document, together with associated business cases, to be a valid outline for organizational change.

Recommendations:

Support for the ORA Revitalization document and proposed process for organizational change:

The subcommittee applauds ORA's efforts in planning, futuring and visioning. Clearly ORA recognizes its need to change and is trying through a transparent and inclusive process to make and act on strategic choices that have far-reaching consequences. We wish to express our full support both for the vision

and for the initial outline of implementation plans. However, these choices represent today's assessment and are based on assumptions about a future that is more and more difficult to predict. This describes a "strategy paradox" that is a reality today as organizations plan forward. The subcommittee encourages ORA to include more external experts to help them continue to assess driving forces and assumptions as they move forward to implement the Revitalization business cases and beyond. The subcommittee also encourages ORA to recognize the need to develop greater flexibility and to recruit skillful people to address future uncertainty and ambiguity, which is both an important strategy in itself and a emerging core competency.

The Subcommittee Wishes to Identify the Importance of Unambiguous FDA Leadership Support for ORA Change, as Represented in the Revitalization Document

To a certain extent, ORA has conducted a self-examination and finds itself knowing that it needs to change; creating plans and strategies for change; yet, also caught up in an antiquated system/processes along with an unsympathetic public and congress that breeds a parochialism and stymies innovation, imagination, and change. ORA is taking on a leadership role in their efforts to become more strategic and contemporary but must have the support, internally and externally, to achieve revitalization.

Furthermore, the ORA Subcommittee believes that the ORA planning must not be fragmented or separate from the larger FDA efforts to change and build critical scientific foundation.

Support for the Discipline of Regulatory Science

The subcommittee also encourages ORA along with the entire FDA to further develop the discipline of regulatory science. The subcommittee meetings and discussions reinforced the uniqueness and importance of regulatory science as an intellectual field, and the subcommittee believes that ORA , together with the FDA Centers, must reinforce this regulatory science identity by championing risk-based programs, risk assessments, evidence-based policy and regulation, and knowledge management among other disciplines in order to successfully work in a world of greater uncertainty. These skills and activities need to be paralleled by the development of stronger analytical skills in decision-making. We understand that this discipline is still in a formative stage but encourage ORA to help lead the further maturation and use of regulatory science across FDA.

The Subcommittee Recognizes that Capacity is Important but Not Everything

The ORA review, like the larger FDA Science Board Review has especially focused on capacity and to some extent it is difficult to judge organizational efficiency in the context of the significant under-resourcing which exists. Yet it is clear from discussions with ORA management and staff that even if the resource gap were immediately addressed, ORA would not be performing optimally. ORA must be

enabled as well as resourced to develop further the requisite skills, experienced leadership and scientific foundation for success. To achieve these ORA must be allowed to incorporate the best technologies by which to accomplish its mission, and must be culturally receptive to the aggressive change management initiative that is called for in their Revitalization Report.

In addition, there is a special need to better quantify capacity. The subcommittee recommends that ORA evaluate capacity index systems that can better quantify personnel needs to build their scientific capacity. These systems are based on logic models that define critical outcomes and results, then uses these end points to inform strategic hires.

The subcommittee wishes to recognize that a number of the findings and recommendations made by the Science Board in the December 2007 report relate directly to observations made concerning ORA:

Support for Science Board Recommendation 3.1.1 and Science Board Recommendation 4.1.1:

"Rebuild CFSAN, CVM scientific base and their related inspection and enforcement functions to a level that is commensurate with their regulatory responsibilities"

and, "The FDA resource gap must be corrected to enable the Agency to fulfill its regulatory mandate"

The need for enhanced ORA inspection capability is obvious from the recently increased workload alone, and a major focus of the ORA Revitalization document, ORA business cases, the general Science Board findings, and the popular press. As pointed out elsewhere, increased inspection resources are required both domestically and in foreign venues; this increase in inspection resources needs to be accompanied by a host of other advancements, including certification programs for foreign manufacturers, greater inspection by foreign regulatory authorities, improved risk-managed inspection procedures, as well as in some situations more efficient and newer technology assay procedures which will stand up to legal challenge because they have been validated by the Agency.

One area identified by the Science Board followed from the recognition that FDA will not be able effectively to recruit and retain all the scientific expertise it needs in house. It was noted in discussions with ORA staff that budgets have been limited for consultative interactions with external academic and other scientific experts; provision for greater use of external expertise would rapidly expand ORA capability.

The subcommittee was pleased and impressed that ORA was committed to organizational transformation. While the organization's planning and thinking is laudable, its real test will be based on its ability to implement and execute strategy. Execution is also a key managerial skill and a discipline that must be embedded in the culture and reward system of ORA. Desired results will only be achieved through specific actions that link people and operations with strategy. The subcommittee stresses the need to maintain a sense of urgency, develop a guiding coalition, ensure champions and advocates and acknowledges that strong leadership that will be necessary to overcome natural organizational inertia and a resistance to change.

A number of the ORA Revitalization document recommendations relate directly to this recommendation; needed elements beyond these recommendations are significant additional inspection resources and relevant FDA leadership support: (Proposal 1, "ORA Deploys its Resources Efficiently and Effectively Using a Scientific Risk-based Approach", Proposal 2, "ORA Deploys its Highly Skilled Foreign Inspection Workforce", Proposal 4, "Enhance ORA's Risk Management Capability and Capacity", Proposal 6, "Obtain Additional Information from Untapped Sources to Make Risk-based Regulatory Decisions", Proposal 7, "FDA Foreign Presence", and Proposal 5, "Acceptance of Inspection, Investigation and Surveillance Information from Other Sources").

Support for Science Board Recommendation 3.1.2:

"The FDA must develop a program to manage "new science" that will provide a standardized approach to enable the FDA to address all emerging sciences and technologies".

ORA Revitalization Proposal 3, "Strengthen the Scientific Support of ORA Laboratories', represents ORA initial plans which address some of the issues around improving science capability in this area.

Support for Science Board Finding 3.1.4

"The FDA should institute a new scientific organization". The Science Board subcommittee recommended the creation of a central science infrastructure for developing, implementing and ensuring the execution of an effective science program at FDA. There was general support for this concept in discussion with ORA regional lab officials. Furthermore the Science Board recommendation that a Board of External Scientific Counselors be created for each Center should be extended to ORA, to deal with its particular challenges, including the particular one of linking its own scientific studies with forensic applications. It is quite clear though that ORA would benefit from and could potentially contribute to critical cross-Center areas of scientific and technical expertise within FDA e.g. genomics, or proteomics.

Support for Science Board Finding 3.2.1:

"The FDA should create a distinctive research culture, take concrete steps to hire more high-quality scientific talent, and create better career ladders."

The lack of defined career paths for scientists was a focus of several conversations with ORA staff and management; a strong perception is that it is not possible to remain in a technical capacity, particularly in a regional laboratory, without limiting career advancement. This lack of a career path for advancement for those in technical roles, and the relatively few higher level positions associated with regional laboratory roles, has led to the loss of excellent regional ORA scientists to academia or industry.

The ORA Subcommittee was impressed with ORA's dedicated and competent workforce and with its focus on improvement, strategic thinking and recommendations to create a more effective organization to protect public health in a changing world.

ORA Revitalization document Proposal 12, "Highly Skilled Workforce" outlines an implementation plan to improve the recruitment and retention, training, and other issues necessary to attract and maintain a highly qualified scientific workforce at ORA.

Support for the Science Board IT-Related Findings 3.3.1-5:

Consistent with respect to Science Board findings concerning IT infrastructure across the FDA Centers, ORA in its own Revitalization activity and in discussion with the subcommittee noted that its IT capacity is lacking in several important areas. The subcommittee concurs and stresses the need for interoperability of systems, both within ORA and across FDA. This is especially relevant to ORA because of its need for real time information and need for greater connectivity of its many employees, functions and activities. With greater interoperability, ORA could greatly increase its productivity and the quality and timeliness of its decision-making.

Revitalization document Proposals 9, "IT/Operations and Administrative System for Import Support (OASIS)" and 10, "Modernize ORA's Regulatory Software Applications" address many of the general issues raised in the Science Board report, and represent an outline of an approach to upgrade this area.

Support for Science Board Finding 3.2.4.:

"The FDA should strengthen its collaboration across centers and with other government agencies…."

By the nature of its mission ORA's work is increasingly more reliant on partners and collaborations, including various stakeholders within and outside of the FDA. The extensive collaboration among federal, state inspection and increasingly foreign regulatory agencies is already impressive. The subcommittee encourages ORA to continue expend the time, energy, and resources necessary to build and secure greater collaboration locally, statewide, across other federal agencies outside FDA and globally.

ORA is an excellent candidate for an FDA demonstration project on "governing by network". With great geographic diversity and its multisectoral relationships, ORA is truly a complex web of components and partners. It is being pushed to solve more problems and expand its regulatory influence yet pulled by the need for new tools to better connect people, facilitating communication, information sharing, and improved collaboration.

Conclusions

The committee recognizes the scope and importance of the work conducted by ORA, and the importance of scientific excellence and capacity in the process of fulfilling the ORA mission. ORA has conducted an internal process to outline its reorganizational vision, the outcome of which is summarized in the "Revitalizing ORA" report submitted recently to the FDA Commissioner. The current strengths and weaknesses relative to this vision are well outlined in the report, as is a path towards implementation of the specific proposals to close the resource and skills gaps of ORA. The subcommittee has reviewed the provided information and interviewed ORA staff and management concerning the ORA mandate, ORA's current situation and its proposals to move forward, and finds merit to these proposals. FDA leadership is encouraged to resource and support the implementation of these proposals, and ORA is encouraged to report back regularly to the Science Board on the status of progress with this implementation.

Respectfully submitted:

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