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FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology	)))	Docket No. 2007N-0489

COMMENTS OF THE SENIOR CITIZENS LEAGUE
(February 4, 2008)

The Senior Citizens League ("TSCL"), through its undersigned counsel, submits the following comments pursuant to 21 CFR 14.35 and 73 Fed. Reg. 869-70 (January 4, 2008), regarding the following documents in Docket No. 2007N-0489:

1. "FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology," (November, 2007). http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf.

2. FDA Notice, "Request for Comments on the Science and Technology Report; Establishment of Docket; Request for Comments," 73 Fed. Reg. 869-70, (January 4, 2008) (providing public notice of the solicitation of public comment on the subcommittee report to be forwarded to the FDA Science Board for its review). http://edocket.access.gpo.gov/2008/pdf/E7-25607.pdf.

I. TSCL, AS WELL AS ITS MEMBERS AND SUPPORTERS, HAS GREAT INTEREST IN THE FDA SCIENCE BOARD'S REPORT AND HAS, IN THE PAST, COMMENTED TO THE FDA ON OTHER, RELATED MATTERS.

A. TSCL Seniors' Health Initiative

The Senior Citizens League is the d/b/a of TREA Senior Citizens League, which is a non-partisan social welfare organization incorporated under the laws of Colorado, and is exempt from federal income taxation under Section 501(c)(4) of the Internal Revenue Code of 1986. TSCL, headquartered in Alexandria, Virginia, is known as one of the largest U.S. seniors groups, engaging in education and advocacy on behalf of senior citizens. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens,

to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned.

TSCL has more than three quarters of a million senior citizen members and supporters. Its activities include monitoring developments in the United States with respect to the interests of senior citizens and defending those interests before government, developing educational materials designed to explain to senior citizens their various rights as U.S. citizens, raising the level of public awareness of senior citizens' rights by conducting surveys and polls, and publishing and distributing informational newsletters to members, supporters, and the public.

In 2007, TSCL launched the **TSCL Seniors' Health Initiative**. TSCL has previously demonstrated its interest in the activities of the Food and Drug Administration (FDA) relating to seniors in the following prior filings of comments with the FDA:

- May 29, 2007, TSCL comments regarding FDA "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration" in Docket No. 2006D-0480; and

- September 7, 2007, TSCL comments regarding FDA "Draft Guidance for Industry on Evidence-Based Review System for the Scientific Evaluation of Health Claims" in Docket No. 2007D-0125.

Additionally, TSCL has demonstrated interest in FDA policy and practices by filing a brief *amicus curiae* in the U.S. Supreme Court in support of a petition for review of a decision of the U.S. Court of Appeals for the District of Columbia upholding the FDA's generalized and impersonal administrative process that excludes access to developmental drugs by a terminally-ill person who has exhausted all other available drug treatment programs in an effort to prolong his life.[1]

B. FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology

TSCL's members and supporters have a vital interest in the Food and Drug Administration Science Board's report entitled "**FDA Science and Mission at Risk: Report**

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[1] *See* Brief *Amicus Curiae* of The Senior Citizens League in Support of Petitioners in Abigail Alliance for Better Access to Developmental Drugs v. Andrew Von Eschenbach, Commissioner, Supreme Court Docket No. 07-444 (December 13, 2007). http://www.seniorsleague.org//index.php?option=com_content&task=view&id=2718&Itemid=183.

of the Subcommittee on Science and Technology" (hereinafter abbreviated as "Rep."). They are especially concerned about many of the Report's findings that apparently underlie its conclusion that the FDA "is not positioned to meet current or emerging regulatory responsibilities." Rep., p. 2.

If the Report's findings are true, then the health of TSCL's members and supporters are being adversely affected by the FDA's inability to perform its gatekeeping role in the pre-market review of new drugs for "safety and efficacy," and in the regulation of "80 percent of the food consumed in this country." *See* Rep., p. 1. Unfortunately, the Report seems to conclude that the only real solution to problems at the FDA is to appropriate twice the money it now receives so that it actually can do in the future what the people thought it had been doing in the past. The press has taken on the role of lobbying for more money for the FDA as a result of this report.[2] In this regard, the Report is not unlike many other government reports which are designed to seek additional funding for an agency or department. *See* Rep., pp. 6, 53-56.

However, if the Report's findings and recommendations are flawed, then steps other than throwing money at the problem as proposed by the Report should be explored in order to protect the individual health needs of the American people, and especially of the more vulnerable of the populace, such as senior citizens. Among those other steps would be a reorientation of the FDA's mission, certainly including an immediate end to the FDA's efforts to restrict seniors' access to Complimentary and Alternative Medicine (CAM), and imposing new restrictions on seniors' access to vitamins and minerals. *See* TSCL comments filed with the FDA, *supra.*

II. THE REPORT OF THE SCIENCE BOARD SUBCOMMITTEE IGNORED ITS MANDATE AND GENERATED A POLITICIZED REPORT DESIGNED TO OBTAIN GREATER APPROPRIATIONS.

On March 31, 2006, the "FDA [Commissioner] charged the **Science Board** to conduct a broad review of FDA scientific capacities, processes and infrastructure which support FDA's

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[2] *See* Julie Schmit, "Report: FDA So Underfunded, Consumers are Put at Risk," USA Today. http://www.usatoday.com/news/washington/2007-12-02-fda_N.htm. *See also* "FDA Advisors Declare 'FDA Science and Mission at Risk:' Broad-Ranging Report Concludes That Increased Resources Are an Essential First Step," http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=/www/story/01-29-2008/0004744999&EDATE=. *See also* Letter of Chairman Waxman, House Committee on Oversight and Government Reform to Commissioner Von Eschenbach, December 3, 2007, requesting a plan to ensure adequate budget requests, http://oversight.house.gov/documents/20071203134857.pdf.

core regulatory functions" of pre-market review, product quality oversight, and post-market safety surveillance. 73 Fed. Reg. 870 (Jan. 4, 2008) (emphasis added).

The Science Board, in turn, created a **Subcommittee on Science and Technology**, instructing it to:

> (1) uncover "any important gaps in current scientific capacities";
>
> (2) identify "areas of science" where the FDA should "maintain [,] strengthen [, or] refocus [] its efforts";
>
> (3) explore "opportunities ... to enhance [] overall effectiveness, [including] priority setting"; and
>
> (4) identify opportunities for "collaboration" to enhance FDA's scientific and technological capacities. *Id.*

A. The Report Ignored Its Charter In Order to Focus on Obtaining Greater FDA Appropriations

The Report makes clear that the Subcommittee was "not [asked] to assess available resources," yet it nevertheless focused on the inadequacy of current funding, asserting that the "gaps in scientific expertise and technology" that it had found "were so intertwined with two decades of inadequate funding that it was impossible to assess technology without also assessing resources." Rep., p. 6.

Unilaterally rejecting its assignment as "impossible" without an assessment of resources, the Subcommittee cast aside the fiscal constraints under which the FDA must operate, ignoring the discipline that decision-makers are under to craft wise programs and processes within available resources, and thus producing a report driven almost entirely by recommendations of a dramatic increase in resources with the conclusion that, "without a significant increase in resources, its recommendations will be superfluous." Rep., p. 53.

Because the Subcommittee chose this all-or-nothing approach, its Report is flawed having, in light of real world limitations, (a) failed to set meaningful priorities, (b) drawn suspect conclusions, and (c) overstated the FDA's need for additional resources.

B. The Report Fails to Meet its Mandate to Address the Setting of Priorities.

Included in the March 30, 2006 charge, the Science Board was instructed to explore "[w]hat opportunities exist to enhance the overall effectiveness of FDA's scientific and technological capacity through coordination of scientific activities and **priority setting** across FDA components." *Id.* (emphasis added). Yet, the Report treats all of the FDA's responsibilities and needs as critical and immediate on the **assumption** that, if the FDA does not **completely fulfill every aspect of its mission**, then the adverse impact on the nation's health, economy, and security would be "incalculable." Rep., p. 1.

In both its overall narrative and its specific findings and recommendations, the Report repeatedly assumes that all functions assigned to it by Congress **must** be undertaken to the fullest, notwithstanding the fact, as the Report acknowledges, that:

> [d]uring the past two decades Congress has enacted 125 statutes that directly impact FDA's regulatory responsibilities — an average of more than six each year — in addition to the **core** provisions of the 1938 Act itself and its amendments from 1939 to 1987. Each of these statutes **require** some type of FDA action.... Yet none of these statutes has been accompanied by an appropriation of the new personnel and increased funding necessary to enable adequate implementation. [Rep., p. 9 (emphasis added).]

In its discussion of this "growing disparity between responsibilities and resources," the Report makes no effort to assess the scientific and technological needs of the FDA's priority role mandated by its "core" responsibilities — such as the pre-market review of new drugs — with, for example, its less important role concerning the regulation of dietary supplements. *Compare* Rep., pp. 9-10 *with* Rep., p. 24. Nor has the Report taken into account that the FDA has presumed to extend its powers even beyond its statutory mandate, most recently issuing its Draft Guidance for Industry on [CAM] Products. *See* Comments of TREA Senior Citizens League, pp. 9-10 (FDA Docket No. 2006D-0480: May 29, 2007).

Remarkably, the FDA has taken this step to add CAM to its regulatory jurisdiction even though, as the Report points out, the "dietary supplement" and "cosmetic" industries over which it has statutory jurisdiction have gone "essentially unregulated." *See* Rep., p. 24. But the Report does not provide any evidence that this regulatory shortfall poses any health threat. Indeed, as TSCL has previously submitted in its September 6, 2007 Comments to the FDA Draft Guidance for Industry on Evidence-Based Review System for the Scientific Evaluation of Health Claims (Docket No. 2007D-0125), the FDA's regulatory approach to dietary supplements is statutorily, constitutionally, and scientifically defective

Equally lacking in priority perspective is the Report's finding that the FDA "does not have the capacity to ensure the safety of food for the nation" (Rep., p. 21):

> The Subcommittee found that FDA's ability to provide its basic food system inspection, enforcement and rulemaking functions is severely eroded.... During the past 35 years, the decrease in FDA funding for inspection of our food supply has forced FDA to impose a 78 percent reduction in food inspections, at a time when the food industry has been rapidly expanding and food importation has exponentially increased. [*Id.*]

Yet, the Report makes no distinction between the primary role that the FDA should play in the inspection and monitoring of "imported products," in contrast to its role in the inspection and monitoring of domestic "retail food establishments or of food-producing farms." *Id.*

Moreover, the alleged FDA shortcoming in the latter case is hardly attributable to any rapid advance in science and technology, but the Report uses it as a springboard for yet another proposal to enlarge the FDA's scientific staff and enhancing its informational technology capacities. Missing from its analysis and recommendation is any attempt whatsoever to ascertain whether there are **state and local government agencies** to "inspect" retail food markets and farms, or to "ensur[e] the safety of milk, meat and eggs." This omission is remarkable in light of the **federal system** established by the United States Constitution wherein there is no delegation to the government of the United States of a general police power[3] over the health, safety and welfare of the people of the several states. *See, e.g.*, United States v. Lopez, 514 U.S. 549, 584-85, 594 (Thomas, J., concurring).

Also missing in the Report's calculus for increasing the scientific and technological capacity of the FDA is any assessment of the scientific and technological needs of the FDA, after taking into account the role that **other federal agencies** might play. For example, the Report examined the action that the FDA had taken in the "development and testing of West Nile Virus standards ... to safeguard the nation's blood supply," without examining whether the FDA should continue in that role in light of the functions and expertise of the **Centers for Disease Control**, the **National Institutes of Health**, or other appropriate public or private entities. *See* Rep., p. 13.

In short, instead of assessing the scientific and technological needs of the FDA in a context of setting priorities, the Report is premised upon the assumption that if the FDA does not act, then no one will, leading it to recommend dramatic increases in funding without regard to the tax burden that such an approach might impose upon the people, and without regard to the political and economic realities of the Congressional appropriation process.[4]

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[3] *See* United States v. Morrison, 529 U.S. 598, 618 (2000).

[4] *See, e.g.*, Rep., Appendix B-1 ("Congress must commit to a two-year appropriations program to increase the FDA employees by 50 percent and to **double the FDA funding**, and then at least to maintain a fully burdened yearly cost-of living increase of 5.8 percent across all segments of the agency.") (Emphasis added.) *See also* Rep., Appendix B-6: "The entire [FOIA] system is clearly broken. It cannot be fixed by admonitions that the agency should 'do better.' It can only be fixed by congressional appropriation of adequate resources devoted to implementing the FOI Act and providing this information to the public." *See also* Rep., Appendix B-24: "Congress must commit to **doubling the current FDA funds**, together with a 50 percent increase in authorized personnel, within the next two years." (Emphasis added.)

C. The FDA Commissioner Disagrees with Important Portions of the Report.

On Tuesday, January 29, 2008, FDA Commissioner **Andrew Von Eschenbach** appeared before the Oversight Subcommittee of the House Committee on Energy and Commerce to give testimony and answer questions concerning the role of the FDA to protect the nation's food supply. Under questioning by Subcommittee Chairman Bart Stupak (D-MI), the Commissioner was **asked if he agreed** with the Report's finding 3.1.1 that the **"FDA does not have the capacity to ensure the safety of food for the nation."** *See* Rep., p. 21 (emphasis added). After he was pressed for a clear yes-or-no answer, the Commissioner finally stated that he **disagreed** with the finding.

In an ensuing exchange between the Commissioner and another subcommittee member from the other side of the aisle, the Commissioner was afforded an opportunity to characterize the Report's finding as equivalent to a finding that, like a contending athletic team, the FDA team was a good one, but with more money and more skilled personnel it could be made better. Such an analogy is **directly contradicted** by the Report's unabashed critical assessments of FDA's scientific and technological capacity:

> The Subcommittee concluded that science at the FDA is in a **precarious** position: the Agency suffers from **serious** scientific **deficiencies** and is **not** positioned to meet current or emerging regulatory responsibilities. [Rep., p. 2 (emphasis added).]
>
> The Subcommittee found **substantial weaknesses** across the Agency. [Rep., p. 3 (emphasis added).]
>
> Today, not only can the Agency **not** lead, it **cannot** even keep up with the advances of science. [Rep., p. 3 (emphasis added).]
>
> The FDA **cannot** fulfill its **surveillance mission** because of inadequate staff and IT resources.... [Rep., p. 4 (emphasis added).]
>
> FDA [Information Technology] infrastructure is **obsolete**, **unstable** and **lacks** controls to execute effective disaster recovery protocols that ensure continuity of operations when systems are compromised. [Rep., p. 5 (emphasis added).]

Additionally, the Report contains numerous findings of scientific and technological inadequacies and insufficiencies, as illustrated by its three major findings:

1.2.1 The FDA **cannot fulfill its mission** because its scientific base has eroded and its scientific organizational structure is weak. [Rep., p. 3 (emphasis added)].

1.2.2 The FDA **cannot fulfill its mission** because its scientific workforce does not have sufficient capacity and capability. [Rep., p. 4 (emphasis added)].

1.2.3. The FDA **cannot fulfill its mission** because its information technology (IT) infrastructure is inadequate. [Rep., p. 5 (emphasis added)].

The fact that the Commissioner is on record disagreeing with the Report's finding that the "**FDA does not have the capacity to ensure the safety of food for the nation**" causes one to wonder whether the Commissioner might disagree with one of more of these and other formal findings in the Report. In any event, there is a discrepancy between the **public perception of the FDA** and the **perception that is conveyed by the Report**.

As a representative of over 750,000 senior citizens and supporters, TSCL has a significant interest in knowing whether the Commissioner disagrees with any other of the Report's findings and conclusions about the FDA's scientific and technological capacity to protect the American people from unsafe drugs and food and, if so, to receive an elaboration on the reasons for those disagreements.

D. The Report Appears To Reflect Primarily the Views of Former Government Officials Responsible for FDA Oversight, and FDA Regulated Businesses.

In a transparent effort to downplay the fiscal impact of the Report's "conclu[sion] that FDA can no longer fulfill its mission without substantial and sustained additional appropriations,"[5] the Report states that it would cost each American only "three cents daily," up from "about a penny and a half." Rep., p. 8. Disguised by this parabolic expression is the fact that the Report calls for a **doubling** of FDA funding, via a "15 percent increase in appropriations during the next five years." *Id.*

In support of this proposal, the Report cites the **Coalition for a Stronger FDA**, co-chaired by the last three Secretaries of the Department of Health and Human Services. What the report fails to mention, however, is the obvious relationship between the Coalition and the Subcommittee which produced the report, which includes as "members and advisors" persons who have or have had relationships with, among others, such FDA regulated entities as Eli

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[5] Rep., p. 7.

Lilly and Company, GlaxoSmithKline, and Pfizer, Inc., **all of which also belong to the Coalition for a Stronger FDA**.

In a further effort to justify an increase in the FDA appropriations by $450 million over the next five years just to "ensure safety of the food supply," the Report relies on the **Grocery Manufacturers / Food Products Association.** But this association is also part of Coalition for a Stronger FDA .[6] Rep., pp. 7-8.

In short, the Report's plea for more money is not supported by any outside independent assessment of needs and costs, but instead by businesses, and business trade associations, and individuals associated with them, that have a proprietary interest in the FDA's funding levels.

III. THE REPORT IS BASED ON A MISUNDERSTANDING OF THE ROLE OF THE FDA, AND IGNORES BOTH THE TREND TO PERSONALIZED REMEDIES AND THE PEOPLE'S DEMAND FOR PRIVACY.

According to the Report, the FDA scientific and technological shortcomings are wholly attributable to "two decades of inadequate funding." Rep., p. 6. In reaching this conclusion, the Report fails to consider three major factors, each of which militates against the enhanced scientific and technological capacity that would result if the Report's recommended increases in funding would be adopted.

First, while the Report acknowledges the "disconnect between the promises of cutting edge science and the reality of clinical benefit" (Rep., p. 19), it ignores the intractable fact that the Agency's need for a "mission driven" (Rep., p. 6) science, designed to further its regulatory function, **will always lag behind** the "cutting edge science" (Rep., p. 19) of the academy and industry which is motivated by competition to develop new ideas and products. *See* Rep., pp. 27-30.

Second, the Report ignores the equally obstinate truth that the **administrative regulatory model is ill-suited** to deal with the coming "paradigm shift ... that medicine will move progressively from the assessment of drug efficacy and safety based on large average effects detected in clinical trials" into a new "era of the **personalization of medicine**." Rep., pp. 14, 17, 26-27 (emphasis added).

Third, the Report fails to come to grips with the dangers posed to the **privacy** of individual medical records by an increasing **centralization of government power** in a single federal agency.

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[6] http://fdacoalition.org/about.php

A. Regulatory Science Need Not Be Cutting Edge Science.

The Report asserts that FDA science needs to be "mission driven," *i.e.*, shaped by the threefold FDA mission statement:

(a) "assuring the safety, efficacy, and security" of foods, drugs, and cosmetics;

(b) "advancing the public health" by making such foods, drugs and cosmetics "more effective, safer and more affordable;" and

(c) ensuring availability to the public of "accurate science-based information" needed "to improve their health." [Rep., p. iii, 6.]

To be sure, the FDA's mission statement includes "helping to speed innovations," but that goal is subordinate to its overarching mission to ensure safe, effective and affordable foods and medicines. Necessarily, then, the FDA will always be a step behind cutting edge science in light of its primary regulatory and informational mission.

Indeed, as the Report states, "[t]he bulk of the Agency's activities involve **reviewing** new drugs, biologics, medical devices and additives." Rep., p. 13 (emphasis added). By definition, then, the FDA as a regulatory body does **not initiate** the development of new products, but **responds** to the initiative of the private highly competitive market sector. Yet, the Report paradoxically calls for a "scientific competency within FDA [that] matches or exceeds an **applicant's** knowledge." Rep., p. 12. (emphasis added).

Optimistically, the Report cites the **FDA's Critical Path Initiative** as evidence of the FDA's embryonic effort to "catch up with the new knowledge and technology available today," but that "for lack of funds, has only begun to be implemented." Rep., p. 18. On closer look, however, the Critical Path Initiative, if implemented, would "'transform the FDA from an organization of rule-based regulators to a public health Agency staffed with 21st Century science-based standard setters.'" *Id.* If such a transformation of the FDA's regulatory role were achieved, it would exchange dramatically the FDA's congressionally authorized mission for a wholly unauthorized foray into the development of "new life-saving products."

Such a transformation would not only be unauthorized, but also illegitimate, putting the FDA into competition with private companies and endangering the competitive market forces that spur research and development of new medical treatments, including CAM, in which TSCL members and supporters have a vital interest.

B. Present Administrative Processes Are Ill-Suited to the New Paradigm of "Personalization of Medicine."

The Report makes cryptic references to a coming "era of the **personalization** of medicine" and "the progressive **personalization** of medicine," indicating in the first instances that this new era will impact both the "risk analysis paradigm" and the "assess[ment] [of the] efficacy" of new drugs. Rep., pp. 14, 16. (Emphasis added.) Then, the Report opens the door a little wider, asserting that "[t]he promise of the [coming] **paradigm shift** is that medicine will move progressively from the assessment of drug efficacy and safety based on **large average effects detected in clinical trials** to a more personal paradigm." *Id.*, p. 17 (emphasis added). Later, the Report intimates that this new paradigm is coming into existence by means of "[s]afety pharmocogenetics using genetic technologies [that] can, and have, defined 'diagnostic profiles that can predict which patients should not risk an adverse event before they take the drug." *Id.*, pp. 26-27 From this observation, the Report concludes that "[t]his is not simply 'new science,' but represents the coming wave of 'new medicine' and the need for 'new regulatory scientists.'" *Id.*, p. 27.

Apparently, this new "paradigm" is being spurred into existence by the development of "genomic technologies" which already are "impacting critical regulatory issues, such as the evaluation of benefit/risk, drug and vaccine safety, and new drug target identification." *Id.*, p. 26. Further, "the use of genetics and genome-wide association analyses may separate and identify patients with genetic profiles who are more likely to experience an **intended effect** of the drug candidate (efficacy pharmacogenetics, **personalized medicine).**" *Id.* In response to these existent programs, the Report observed that "[t]he mission of getting safe and effective drugs to patients in a timely manner is currently **threatened by inadequate expertise and capabilities.**" *Id.* (emphasis added).

Missing from this response is any assessment through a wider lense which would illuminate the procedural inadequacy on a fundamental level of the present clinical trial system of assessing the safety and efficacy of a new drug measured by "large average effects," without regard to a "more personal" assessment based upon pharmocogenetics. While the Report recommends the creation of a **Task Force for Ethnic Minority Health** to "evaluat[e] and understand[] the differential effects/responses of patients to drugs, biologics and devices on the basis of ethnic minority status,"[7] the Report recommends no comparable task force to explore such differential effects that have been discovered through genomic technologies.

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[7] Rep., p. 37. The recommendation for a **Task Force for Ethnic Minority Health** to explore drug responses of patients based on "ethnic minority status" may have political appeal, but fails to acknowledge views that ethnic and racial differences have not been established, and may be unnecessary or even counterproductive to the cause of determining adverse reactions to drugs based on genetics. *See generally* http://www.fda.gov/cder/reports/race_ethnicity/race_ethnicity_report.htm.

Nor has the Report addressed the question whether the existence of such technologies should open a wider door to developmental drugs according to "genome-wide association," or to individuals outside normal clinical trials based upon "efficacy pharmocogenetics." Otherwise, scientifically identified individual candidates (especially the terminally-ill) needing experimental drug treatment will be denied access to such treatment based upon a generalized assessment of patient needs balanced against an outdated scientific assessment of efficacy and safety.[8]

Finally, the Report omits altogether any concern that the administrative process, by which the FDA currently approves new drugs before marketing, may very well be outmoded in the near future. As safety and efficacy of drug treatment modalities become more individualized, the FDA clinical trial methodologies testing new drugs for safety and efficacy "based on large average effects" (Rep., p. 17) would appear to be ill-adapted. Indeed, the continuation of such an administrative process screening new drugs for their "effective[ness] for public use," as the Drug Amendments of 1962 prescribes,[9] would appear to be a perverse **barrier to the availability of a developmental drug treatment**, if access to such treatment would be based upon "a more personal paradigm," as anticipated by the Report. *See* Rep., p. 27. Because this paradigm shift "is well underway and is gathering speed," marked by an "increased marketing of ... testing directly to the consumer,"[10] it would appear to call for a return to the common law system **placing medical decisions in the hands of an individual patient and his or her doctor**, unencumbered by current or similar preventive administrative approval processes. *See* Brief *Amicus Curiae* of the Senior Citizens League, pp. 15-20 in Abigail Alliance v. Von Eschenbach (U.S. Supreme Court, Docket No. 07-444).[11]

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[8] In the last several years, there have been a numerous reports and articles indicating that the future of medicine is not just in personalizing medicine for groups of people with similar genetics, but the creation of a uniquely tailored drug (or combinations of drugs) designed for a single individual. "Genentech (DNA) has prospered by creating cancer drugs that target ever-smaller patient groups, such as women diagnosed with HER2-positive breast cancer, an especially deadly form of the disease. That kind of research is 'going to change medicine fundamentally from one-size-fits-all down to an individual view,' says Kleiner Perkins partner Brook Byers, a venture-capital investor since 1972." Jim Hopkins, "Personalized Drugs Draw Biotech Dollars," *USA Today*, October 19, 2005, http://www.usatoday.com/tech/news/biotech/2005-10-19-biotech-drugs_x.htm.

[9] *See* Abigail Alliance for Better Access to Developmental Drugs v. Andrew Von Eschenbach, 2007 U.S. App. LEXIS 18688, * 28 (C.A.C.D).

[10] Rep., p. 17.

[11] http://www.seniorsleague.org//index.php?option=com_content&task=view&id=2718&Itemid=183.

C. An Expanded Health Information Database is a Threat to Privacy.

In a concerted effort to "hasten the progressive personalization of medicine," the Report encourages the FDA to improve its Information Technology (IT) infrastructure for ready access to "individual genome information" in order to enhance its ability to "predict[] drug efficacy and safety." Rep., p. 16. To that end, the FDA Subcommittee on Science and Technology has proposed that the FDA develop appropriate "workforce and collaborations necessary to exploit," among other things, "**access to population-wide phenotypic and genotypic databases.**" *Id.*, p. 17 (emphasis added).

To that end, the Report's recommends the development of:

> (a) "[n]ew statistical approaches ... to address the **deluge of data** on product safety that will become available electronically from **networks of care providers**"[12];
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> (b) "improved database ... access ... in support of safety assessment, including access to **health** and public health **databases**"[13];
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> (c) advanced **data mining** and analytical methodologies for signal detection in **large health care databases**;"[14] and
>
> (d) "access to **existing data bases** with relevant information to FDA reviewers."[15]

Emphasizing the importance of increased access to such individual medical identification data, the Report also urges the FDA to:

> (a) "**aggressively** pursue access to health and public health databases for adverse-event identification and surveillance for risk identification"[16];
>
> (b) **"work closely** with the legislative branch to develop the **mandates** to drive adoption of data sharing standards, ... includ[ing] all aspects of data and information exchange"[17]; and

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[12] Rep., p. 31 (emphasis added).

[13] *Id.*, p. 32 (emphasis added).

[14] *Id.* (emphasis added).

[15] *Id.*, p. 33 (emphasis added).

[16] *Id.*, p. 47 (emphasis added).

[17] *Id.*, p. 49.

(c) "**accelerate** the development of **health information exchanges** [with] entities ... **owned by health care providers and payers.**" [Rep., p. 54 (emphasis added).]

Although the Report justifies these recommendations and urgencies as necessary measures to obtain accurate and complete data, it completely omits any concerns for the **privacy** of health care and medical information to be gathered and placed in the FDA's IT infrastructure. Yet, the apparent scope of data sought is breathtakingly broad, ultimately extending to the entire population of the country. Further, the data sought would be significantly invasive, potentially including "the entire genome of each [American] for some 500,000 to 1 million subtle genetic variations."[18]

While the FDA, itself, currently conducts a **Voluntary Genomics Data Submission** (VGDS) program,[19] the Report's call for accurate and complete individualized data seems as if it could lead to something of an Orwellian nightmare — a mandatory submission if the future of medicine gives rise to personalized prescriptions based upon a person's DNA or genetic code.

The Report, like the VGDS, reflects a **total insensitivity to the legitimate privacy concerns of the people**. Consequently, the Report contains no assessment weighing the putative benefits of marshaling such personal data against the real costs of a program that could result in an universal genomic profile of each and every American.

IV. THE REPORT RECOMMENDS INCREASING FDA'S CONNECTIONS TO THE FOOD, PHARMACEUTICAL AND OTHER INDUSTRIES, JEOPARDIZING ITS INDEPENDENCE AS A REGULATOR.

The Report's expanded vision for the FDA's regulatory role with respect to drugs spills over into the Agency's "responsibility for food safety." *See* Rep., p. 20. Deploring "the absence of an Agency-wide vision for the role of science" (*id.*, p. 21) the Report urges the FDA "to significantly build a 21st Century science-based regulatory science that could anticipate future food safety issues and develop a cadre of professionals capable of applying the new biology, chemistry and bioinformatics to the regulation of foods that exist in ... today's global marketplace." Rep., p. 23. To accomplish this goal, the Report candidly concedes that "a **culture must be created** [inside the FDA] in which [certain employees would] have the freedom and support to pursue the regulatory science needed **to keep pace**

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[18] *See* National Human Genome Research Institute (NHGRI), Office of Population Genomics, http://www.genome.gov/PopulationGenomics/

[19] *See* http://www.fda.gov/cder/genomics/VGDS.htm.

with a global economy." *Id.* (emphasis added). But the Report offers no plan whereby the FDA could, inside the agency, replicate the culture of innovation that naturally exists in the competitive global food economy.

To the contrary, the Report's section on "Workforce: Securing Critical Scientific Capability and Capacity" demonstrates that the current civil service hiring and retention system is inadequate to "build[] a high-quality workforce [and to] retain them." Rep., p. 40. In short, the incentives and opportunities in academia and business outstrip those available in career government service. Rep., pp. 40-43. While the Report "recommends that the FDA create a distinctive and exciting regulatory science culture," it nevertheless acknowledges that the FDA "workforce is mandated to pursue much important public service, but routine, work." Rep., p. 40.

To redress this inevitable routinization, the Report recommends the establishment of "**meaningful partnerships with other agencies, academia and industry**." Rep., p. 44 (emphasis added). By this means, the Report hopes that "more extensive and regular involvement of external scientists" would enable the FDA science personnel to better assess "the emergence of new scientific issues." *Id.* Specifically, the Report urges the FDA "actively to establish ties with extramural scientists with expertise in **drug mechanisms** and pharmocogenomics to better integrate such knowledge into pre- and post-market safety assessments, surveillance activities and assessment of product quality." *Id.* (Emphasis added.)

How such interrelationships are to be developed and nurtured without compromise of the FDA regulatory mission surprisingly is not addressed, much less explained, in the Report. *See* Rep., pp. 43-45. While contacts with other scientists in other government agencies may not create conflicts of interests, certainly such contacts with scientists in the regulated pharmaceutical industry would give added credence to the general observation that, with respect to the FDA, like other federal administrative agencies, **the "'public interest' is equated more and more with the interest of [the] regulated,"**[20] rather than in the interest of the American people.

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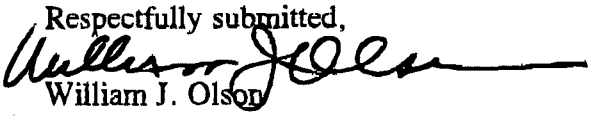
[20] B. Schwartz, Administrative Law, Section 1.11, p. 26 (Little, Brown: 1984) (emphasis added).

CONCLUSION

The Report of the Subcommittee on Science and Technology in no way justifies a doubling of the budget of the FDA, but it does support a rethinking of the mission of the FDA. Certainly, if its resources are as limited as the Report implies, the FDA should focus on independent regulation of dangerous pharmaceuticals, and immediately drop its plans to divert its resources by extending its jurisdiction to Complementary and Alternative Medicine, and vitamins and minerals.

Respectfully submitted,



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