Desk Officer for the Administration for Children and Families.

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Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Evaluation Policy; Cooperative Research or Demonstration Projects

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: Administration for Children and Families (ACF) is announcing its evaluation policy for research or demonstration projects as authorized by 42 U.S.C. 1310.

SUPPLEMENTARY INFORMATION: This evaluation policy builds on ACF's strong history of evaluation by outlining key principles to govern our planning, conduct, and use of evaluation. The evaluation policy reconfirms our commitment to conducting rigorous, relevant evaluations and to using evidence from evaluations to inform policy and practice. ACF seeks to promote rigor, relevance, transparency, independence, and ethics in the conduct of evaluations. This policy addresses each of these principles.

The mission of ACF is to foster health and well-being by providing Federal leadership, partnership, and resources for the compassionate and effective delivery of human services. Our vision is children, youth, families, individuals, and communities who are resilient, safe, healthy, and economically secure. The importance of these goals demands that we continually innovate and improve, and that we evaluate our activities and those of our partners. Through evaluation, ACF and our partners can learn systematically so that we can make our services as effective as possible.

Evaluation produces one type of evidence. A learning organization with a culture of continual improvement requires many types of evidence, including not only evaluation but also descriptive research studies, performance measures, financial and cost data, survey statistics, and program administrative data. Further, continual improvement requires systematic approaches to using information, such as regular data-driven reviews of performance and progress. Although this policy focuses on evaluation, the principles and many of the specifics apply to the development and use of other types of information as well.

This policy applies to all ACF-sponsored evaluations. While much of ACF's evaluation activity is overseen by OPRE, ACF program offices also sponsor evaluations through dedicated contracts or as part of their grant-making. In order to promote quality, coordination, and usefulness in ACF's evaluation activities, ACF program offices will consult with OPRE in developing evaluation activities. Program offices will discuss evaluation projects with OPRE in early stages to clarify evaluation questions and methodological options for addressing them, and as activities progress, OPRE will review designs, plans, and reports. Program offices may also ask OPRE to design and oversee evaluation projects on their behalf or in collaboration with program office staff.

Rigor: ACF is committed to using the most rigorous methods that are appropriate to the evaluation questions and feasible within budget and other constraints. Rigor is not restricted to impact evaluations, but is also necessary in implementation or process evaluations, descriptive studies, outcome evaluations, and formative evaluations; and in both qualitative and quantitative approaches. Rigor requires ensuring that inferences about cause and effect are well founded (internal validity); requires clarity about the populations, settings, or circumstances to which results can be generalized (external validity); and requires the use of measures that accurately capture the intended information (measurement reliability and validity).

In assessing the effects of programs or services, ACF evaluations will use methods that isolate to the greatest extent possible the impacts of the programs or services from other influences such as trends over time, geographic variation, or pre-existing differences between participants and non-participants. For such causal questions, experimental approaches are preferred. When experimental approaches are not feasible, high-quality quasi-experiments offer an alternative.

ACF will recruit and maintain an evaluation workforce with training and experience appropriate for planning and overseeing a rigorous evaluation portfolio. To accomplish this, ACF will recruit staff with advanced degrees and experience in a range of relevant disciplines such as program evaluation, policy analysis, economics, sociology, child development, etc. ACF will provide professional development opportunities so that staff can keep their skills current.

ACF will ensure that contractors and grantees conducting evaluations have appropriate expertise through emphasizing the capacity for rigor in requests for proposal and funding opportunity announcements. This emphasis entails specifying expectations in criteria for the selection of grantees and contractors, and engaging reviewers with evaluation expertise. It also requires allocating sufficient resources for evaluation activities. ACF will generally require evaluation contractors to consult with external advisors who are leaders in relevant fields through the formation of technical work groups or other means.

Relevance: Evaluation priorities should take into account legislative requirements and Congressional interests and should reflect the interests and needs of ACF, HHS, and Administration leadership; program office staff and leadership; ACF partners such as states, territories, tribes, and local grantees; the populations served; researchers; and other stakeholders. Evaluations should be designed to represent the diverse populations that ACF programs serve, and ACF should encourage diversity among those carrying out the work, through building awareness of opportunities and building evaluation capacity among under-represented groups.

There must be strong partnerships among evaluation staff, program staff, policy-makers, and service providers. Policy-makers and practitioners should have the opportunity to influence evaluation priorities to meet their interests and needs. Further, for new initiatives and demonstrations in particular, evaluations will be more feasible and useful when planned in concert with the planning of the initiative or demonstration, rather than as an afterthought. Given Federal requirements related to procurement and information collection, it can take many months to award a grant or contract and begin collecting data. Thus, it is critical that planning for research and evaluation be integrated with planning for new initiatives.

It is important for evaluators to disseminate findings in ways that are accessible and useful to policy-makers and practitioners. OPRE and program offices will work in partnership to inform potential applicants, program providers, administrators, policy-makers, and funders through disseminating evidence from ACF-sponsored and other good quality evaluations.

It is ACF's policy to integrate both use of existing evidence and opportunities for further learning into all of our activities. Where an evidence base is lacking, we will build evidence through strong evaluations. Where evidence exists, we will use it. Discretionary funding opportunity announcements will require that successful applicants cooperate with any Federal evaluations if selected to participate. As legally allowed, programs with waiver authorities should require rigorous evaluations as a condition of waivers. As appropriate, ACF will encourage, incentivize, or require grantees to use existing evidence of effective strategies in designing or selecting service approaches. The emphasis on evidence is meant to support, not inhibit, innovation, improvement, and learning.

Transparency: ACF will make information about planned and ongoing evaluations easily accessible, typically through posting on the web information about the contractor or grantee conducting the work and descriptions of the evaluation questions, methods to be used, and expected timeline for reporting results. ACF will present information about study designs, implementation, and findings at professional conferences.

Study plans will be published in advance. ACF will release evaluation results regardless of the findings. Evaluation reports will describe the methods used, including strengths and weaknesses, and discuss the generalizability of the findings. Evaluation reports will present comprehensive results, including favorable, unfavorable, and null findings. ACF will release evaluation results timely—usually within 2 months of a report's completion.

ACF will archive evaluation data for secondary use by interested researchers, typically through building requirements into contracts to prepare data sets for secondary use.

Independence: Independence and objectivity are core principles of evaluation.[1] Agency and program leadership, program staff, service providers, and others should participate actively in setting evaluation priorities, identifying evaluation questions, and assessing the implications of findings. However, it is important to insulate evaluation functions from undue influence and from both the appearance and the reality of bias. To promote objectivity, ACF protects independence in the design, conduct, and analysis of evaluations. To this end:

- ACF will conduct evaluations through the competitive award of grants and contracts to external experts who are free from conflicts of interest.
- The director of OPRE reports directly to the Assistant Secretary for Children and Families; has authority to approve the design of evaluation projects and analysis plans; and has authority to approve, release, and disseminate evaluation reports.

Ethics: ACF-sponsored evaluations will be conducted in an ethical manner and safeguard the dignity, rights, safety, and privacy of participants. ACF-sponsored evaluations will comply with both the spirit and the letter of relevant requirements such as regulations governing research involving human subjects.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

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[1] American Evaluation Association, ''An Evaluation Roadmap for a More Effective Government'', November 2013, *http://www.eval.org/d/do/472,* accessed 16 December 2013, and Government Accountability Office, ''Employment and Training Administration: Increased Authority and Accountability Could Improve Research Program'', GAO–10- 243, January 2010, *http://www.gao.gov/products/GAO-10-243,* accessed 18 June 2012.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0886]

Determination That JADELLE (Levonorgestrel) Implant, 75 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) has determined that JADELLE (levonorgestrel) implant, 75 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for JADELLE (levonorgestrel) implant, 75 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–4455.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

JADELLE (levonorgestrel) implant, 75 mg, is the subject of NDA 20–544, held by Population Council, and initially approved on November 1, 1996. JADELLE (levonorgestrel) implants, 75 mg, are indicated for the prevention of pregnancy and are a long-term (up to 5 years) reversible method of contraception.

Population Council has never marketed JADELLE (levonorgestrel) implant, 75 mg. Therefore, as in previous instances (see e.g., 72 FR 9763, 61 FR 25497), the Agency has determined, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Arnall Golden Gregory, LLP submitted a citizen petition dated July